

Recovery Incentives Program: California's Contingency Management Benefit Program Manual

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Common Terms and Abbreviations

Member (Medi-Cal member)*

California Department of Health Care Services (DHCS)

Client*

Cognitive Behavioral Therapy (CBT)

Community Reinforcement Approach (CRA)

Contingency Management (CM)

Contingency Management Coordinator (CM Coordinator; the primary CM Team Member)

Contingency Management Supervisor (CM Supervisor)

Drug Medi-Cal Organized Delivery System (DMC-ODS)

Incentive Manager (IM)

Methamphetamine (Meth)

Motivational Incentives

Motivational Interviewing (MI)

Recovery Incentives

Serious Mental Illness (SMI)

Substance Use Disorder (SUD)

Stimulant Use Disorder (StimUD)

Urinalysis (UA)

Urine Drug Test (UDT)

**Throughout this Manual, the terms member and client are used somewhat interchangeably. When discussing contingency management in general, we use the term client. When discussing the specific protocol and procedures associated with the Recovery Incentives Program, we use the term member.*

Chapter 1. Overview of Contingency Management

Contingency management (CM) is one of the most powerful ways to help people stop using stimulant drugs and is associated with increased abstinence for up to one year after treatment.^{1,2} CM is a behavioral intervention for SUD where tangible reinforcers (e.g., gift cards, prizes) are provided when an individual meets a goal for reduction of or abstinence from one or more target substances. CM has also been applied to other treatment-related behaviors such as attendance. In the Recovery Incentives Program, CM is used to reinforce negative urine tests for stimulant drugs (i.e., cocaine, amphetamine, and methamphetamine). In this Program Manual, we provide information on how to implement a specific research-based CM intervention that is associated with reduced stimulant drug use.

Positive Reinforcement in Contingency Management

CM is based on the learning theory of operant conditioning. In operant conditioning, a behavior increases or decreases when something in the environment (a stimulus) is either added or taken away. Three methods of changing behavior exist in operant conditioning: (1) positive reinforcement, (2) negative reinforcement, and (3) punishment. CM relies on the use of **positive reinforcement** to reinforce drug abstinence.

Psychologists have studied positive reinforcement for nearly 70 years and understand the important ways in which it influences individual behavior. Positive reinforcement occurs when a behavior (e.g., a child completes their homework) is followed by a desirable result (e.g., the parent lets them watch TV) and because of that result that behavior increases (e.g., the child completes their homework more often in the future). While all forms of operant conditioning change behavior, we know that positive reinforcement is the best way to change behavior because it does not have the negative side effects (e.g., shame, discomfort) that come with other types of operant learning such as punishment.

Positive reinforcement occurs all the time in our daily lives, from a compliment you receive from your boss for completing a project on time, to a smile from a stranger when you hold the door for them. The key aspects of positive reinforcement are that a specific behavior increases because someone learns that the behavior is followed by a desirable result. Positive reinforcement may happen without us being consciously aware of it, though there are substantial changes taking place in the brain in response to these activities.

Long-term use of alcohol and drugs causes damage to several areas of the human brain. One area of the brain that is highly susceptible to the effects of psychoactive substances is the reward pathways that release dopamine whenever we experience something pleasurable. Another affected area is the prefrontal cortex, where conscious thinking, reasoning, and decision-making occur. Because of this damage, it becomes much more difficult for a person using drugs to make healthy choices. CM helps rewire the neural pathways so that the person begins to make healthier choices (like not using drugs) in the future.

In CM, positive reinforcement is used to help people choose abstinence over continued substance use. A tangible reward like a gift card is given when a person submits evidence that they have not used one or more drugs. This is particularly exciting because many people living with a substance use disorder are not used to being recognized and encouraged for choosing to reduce or stop their drug use. It is also refreshing for the clinician to emphasize the benefits of negative drug test results rather than negative consequences of positive drug test results.

Questions People Ask about CM

Here are some common questions people ask about CM when they are first introduced to the intervention.

“You pay people to stop using drugs?”

Many people ask this question when first introduced to the concept of CM. While many people stop using drugs on their own, it is far more difficult to achieve abstinence without effective treatment interventions, such as CM. It is important to recognize that stimulant drugs can take over the natural reward pathways in the brain. CM helps bring the reward pathways back into balance by offering people non-drug rewards in exchange for achieving specific goals for substance use-related behaviors. This is especially important when people are just starting treatment or are new to recovery. In the Recovery Incentives Program, small incentives are provided to help encourage people to choose abstinence over continued stimulant use. This effect is amplified by the feelings of reward from personal changes that they begin to make in their lives. ^{1,3-5}

“Wait, what happens if someone slips or lapses and uses drugs, do they still get rewards?”

While CM does not use punishment, it does emphasize accountability. A person who submits a urine sample that is positive for stimulant drugs will not receive a reward during that visit. They can, however, receive a reward the next time they submit a stimulant-free urine sample. In CM, people are encouraged to keep trying and they are offered many opportunities to succeed.

“Can CM be added onto existing treatment?”

Definitely! CM was created to be an adjunct to traditional intensive outpatient and outpatient SUD treatment and to treat co-occurring stimulant drug use in people receiving methadone in a narcotic/opioid treatment program (NTP/OTP).⁷ The Recovery Incentives Program is offered in outpatient, non-residential treatment. Because CM visits typically occur at least twice a week, CM is ideal to add to outpatient treatment models that require multiple visits per week.

“Can CM be delivered without other treatments?”

While it is ideal that CM be added to ongoing outpatient treatment, research has found that it is associated with large reductions in substance use in people who are not involved in other SUD treatment.⁸⁻¹¹ In fact, many individuals report that while they are not interested in “treatment,” they are interested in CM. Therefore, CM is an important tool for engaging people in care. Once engaged in CM, individuals may become interested in other available SUD treatments and ancillary services. We can also encourage individuals who are struggling to achieve abstinence to participate in other available services.

Chapter 2. Key Elements of CM

Several key elements are necessary to consider when implementing an effective CM program.

The behavior selected for reinforcement (e.g., stimulant drug abstinence) should be:

- **Objective, observable, and easily measurable** by the staff member/CM Coordinator.
 - The most commonly available objective, observable measurement for stimulant abstinence is a negative urine drug test (UDT).
 - Self-report of stimulant abstinence is ***not*** an appropriate marker for monitoring behavior because it is not objective, observable, or measurable by both the clinician and client.
- **Clear and unambiguous** for the client and CM Team Member.
 - It should be communicated at the beginning of the CM program that the results of the UDT will be how stimulant abstinence is demonstrated, so that there is no opportunity for disagreement or confusion.
 - The Recovery Incentives Program utilizes point-of-care UDTs to assess recent cocaine, amphetamine, or methamphetamine use. Several UDT products that meet minimum standards for reliability and contain built-in validity assessments have been approved for this Program (see Chapter 4). Only tests from this list may be used for the Program unless otherwise approved by DHCS.
 - While other substances, such as opioids, may be identified in the UDT, this does not impact the member's receipt of an incentive; however, it should prompt a conversation about overdose prevention and general safety when using drugs.
- **Achievable** for the client.
 - The goal should be attainable early in the program. Because stimulant use can be detected by point-of-care urine drug tests for approximately 2 to 3 days after use, most individuals can stop using long enough to earn their first CM reward (i.e., they only need to have been abstinent from stimulants for a few days to earn their first incentive).

Monitoring of the behavior should be:

- **Frequent**.
 - CM works best when rewards are delivered regularly (at least once a week). Less often than that is too infrequent to counteract the immediate reinforcing effects of drug use.
 - The Recovery Incentives Program requires UDTs twice per week for the first 12 weeks and once per week for weeks 13-24.

- **Feasible.**
 - CM must be administered consistently over time. Longer treatment periods are associated with better outcomes. The standard active intervention period for CM is 12 weeks. In the Recovery incentives Program, participating sites administer an escalating CM schedule (this will be explained in Chapter 4) for 12 weeks, followed by a stabilization period of an additional 12 weeks (for 24 total weeks).
 - Fitting CM into your clinic workflow will require advance preparation. CM is administered in each site by the CM Coordinator, a Back-up CM Coordinator, and/or a CM Supervisor. Prior to launching CM services, it is important to determine specific protocols for your agency regarding where UDTs will be collected and interpreted, where CM rewards will be discussed and delivered, when CM visits will be scheduled, and how members will be linked with other needed services. These are important factors to consider as they affect the overall flow through the clinic for both members and CM Team Members. You will be provided guidance on this during the 2-part Implementation Training and as part of the Readiness Assessment process. Ongoing technical assistance is also available, should you need additional support.

CM Rewards (reinforcers) should be:

- **Contingent.**
 - Rewards are only provided when the agreed-upon behavior occurs. For stimulant abstinence, this means a UDT that is negative for stimulant drugs (i.e., cocaine, amphetamine, and methamphetamine).
- **Tangible.**
 - Rewards should be tangible. In this Program, rewards are delivered in the form of an e-mail, text link, printed voucher, or other mechanism as approved by DHCS. While other approaches like community reinforcement approach (CRA) do emphasize social rewards, in CM, rewards should be given for the demonstration of a specific behavior.
- **Desirable.**
 - Rewards should be desirable and something that members want, while still promoting recovery and health. Rewards must also be large enough in magnitude that they are desirable to individuals. For instance, \$0.50 might not be a large enough reward to change behavior, whereas studies have shown that people will choose an incentive of \$2.00 over cocaine use.
- **Immediate.**
 - Delivered as soon as possible after the behavior has been achieved and verified.
- **Escalating.**
 - Rewards should increase over time when the behavior is consistently achieved. This increases the likelihood of long-term abstinence.

- **Closely Tracked.**

- It is critical to monitor the CM incentives your agency uses for two reasons: (1) to assure high fidelity to the CM program and positive member outcomes; and (2) to assure that your agency is compliant with federal regulations (more information on federal regulations will be presented in Chapter 6 and in Appendix F).

With CM for stimulant use, the **objective, observable, and measurable** behavior is stimulant drug abstinence as measured by a point-of-care UDT. We know that the point-of-care UDTs can detect most use if administered weekly. We use UDTs because they provide a measure of abstinence that is **clear and unambiguous**. Members only need to achieve a few days of abstinence to submit a negative UDT and receive a CM reward, an **achievable goal** for most members. The detection period of these tests means that we must conduct UDTs at least twice a week to accurately assess abstinence in the first 12 weeks of treatment, which also provides **frequent opportunities** for members to receive rewards.

Point-of-care UDTs are utilized in CM because it is important that reinforcers are provided **immediately** after the behavior is demonstrated. This allows the member to receive their reward right after they submit a stimulant-negative UDT. This kind of immediate gratification is essential to supporting people who are new to stimulant abstinence, since they are used to the instant “reward” they feel when they use drugs.

The **escalating nature** of the reward system is very important for maintaining stimulant abstinence and we will discuss that more in Chapter 4. The most important thing to remember when implementing CM is to make your system as **feasible** for you and your members as possible, while still maintaining the other key characteristics of CM that make it effective (i.e., observable, tangible, desirable, immediate, and escalating). Feasibility was carefully considered in the design of the Recovery Incentives Program and regular input was gathered from key stakeholders across the Drug Medi-Cal Organized Delivery System (DMC-ODS) Treatment System.

The Recovery Incentives Program protocol is implemented in a standard fashion across all participating sites. Your treatment **setting** will also have to consider all the Program requirements to determine how to best incorporate these into existing clinic policies and procedures and workflows. You are required to use a web-based Incentive Manager (IM), and you will enter information into the IM Portal during each member’s visit. The IM Portal calculates, tracks, and delivers the rewards. It is important to **closely track** the CM rewards for each member you serve to ensure you are conducting CM according to best practice standards and consistently across members. Fidelity is an important component of implementing any behavioral intervention; however, in CM, it is also critically important to ensure you are safeguarding the Program against fraud and abuse. Applicable laws and regulations are discussed in Chapter 6 and in Appendix F.

Incentives. When implementing CM, thought should be given to what types of rewards are made available. If the rewards are not desirable to the individual, the CM intervention may be less effective. For this Program, the protocol stipulates the use of gift cards delivered using an IM Portal. Training and consultation are provided on the use of the IM Portal during the 2-part Implementation Training and Readiness Assessment period. Ongoing technical assistance is also available should you need additional support.

Some clinicians worry that gift cards could be exchanged for drugs, or they could be used to buy alcohol. It is important to remember that if a member uses their gift card to purchase and use stimulants, they will test positive for that drug at their next CM visit and they will not receive a reward at that visit. Therefore, they will learn that this strategy really does not work for them if they want to continue earning incentives. In addition, individuals in the Program are asked to sign a consent form acknowledging that they will not make prohibited purchases. Importantly, the gift cards used in the Recovery Incentives Program are restricted to prohibit the purchase of alcohol, tobacco, cannabis, pornography, gambling products/lottery tickets, and in the case of Walmart, firearms and ammunition. While some CM projects have used other tangible prizes as rewards in CM, we do not use “prizes” in the Recovery Incentives Program and only provide rewards using gift cards.

How CM Builds Success: Escalation, Reset, and Recovery

Below we describe three important aspects of CM that help people stay motivated to achieve abstinence. Understanding and correctly calculating the appropriate incentive amounts is one of the most challenging aspects of CM to explain and may be the most challenging aspect of CM to implement. While CM Team Members need to understand these concepts, the IM will automatically perform the calculations when a UDT result is entered.

Three concepts, **escalation**, **reset**, and **recovery**, are essential to an effective CM intervention and are what makes CM different from other types of reward-based interventions. These concepts are based on many years of research, where investigators figured out exactly how to design a positive reinforcement intervention that maximized abstinence.^{8–12} Below we describe these concepts in general. However, more detailed information on escalation, reset, and recovery in the Recovery Incentives Program will be provided in Chapter 4.

Escalation. In CM, we want people to be invested in their goals and we want them to learn that the longer they stay stimulant-free, the more they can gain. To facilitate this learning, CM uses an **escalating schedule of reinforcement**.¹³ In other words, the amount of reward increases the longer a person remains abstinent from stimulants.

For example, a member starts CM and receives a \$10 gift card for their first stimulant-negative UDT. In CM, we increase the reward (e.g., by an extra \$1.50) for every week of abstinence a member achieves. That means that at their first two visits they would earn \$10/visit for their stimulant-negative UDT, and by their second week, they would earn \$11.50/visit if they submit another stimulant-negative UDT. This is because the two-consecutive stimulant-negative UDTs represent one week of stimulant abstinence, which earns them an even greater, escalated reward amount. If they submit two more stimulant-negative UDTs, their reward will increase again, for a total of \$13/visit, and so on. So, by the end of 12 weeks of abstinence, a member can receive up to \$26.50/visit for their final two stimulant-negative drug tests. The longer the member is abstinent, the bigger their rewards get with every week of continuous abstinence. This is further illustrated in Chapter 5.

Reset. Punishments are not used in CM, though we do emphasize accountability. In the Recovery Incentives Program, when a member has a drug test that indicates they used stimulants, the

member does not receive an incentive for that visit. The other consequence is that the IM Portal temporarily “resets” the reward level. This means that members who earned the escalated amount for one or more weeks of continuous stimulant abstinence temporarily lose the escalation. For example, when they submit their first stimulant-negative urine test after a stimulant-positive test, they reset to the original week 1 level of rewards (e.g., \$10). This can be a big consequence for someone who has worked their way up to a large incentive amount. It is important to explain the concept of the reset to members, especially as they build success, and their rewards escalate in value. When they are aware that they can lose their escalated amount, this can help members stay motivated to maintain their abstinence.

Slips, Lapses, and Resets are Common in Recovery. This can be disheartening, so when a reset occurs, the CM Coordinator should remain positive and encouraging. Remember, members are typically attempting to change longstanding behaviors. Change is challenging for everyone. Make sure to praise their efforts (e.g., attending their CM appointment) and remind them of upcoming appointments and opportunities for additional rewards. You can also remind them of the opportunity for ‘recovery’ of their escalated reward amounts, which we describe below.

Resets and Missed Appointments. In CM, a missed appointment is a missed opportunity to submit a UDT, which results in no reward and activates a reset. While we encourage you to be flexible (e.g., allow the member to come in later in the day if they miss a morning appointment, or allow them to reschedule for a contiguous day), we do want to emphasize accountability and we can only reward behaviors when we can objectively measure them. It is important to explain the consequences of a missed test to members.

Excused Absences. In some instances, a member may have a legitimate reason not to attend an appointment. If the member notifies the clinic or CM Coordinator *ahead of time* with a valid reason for missing an appointment, the CM Coordinator should attempt to reschedule the visit for an earlier or later time that same day or on a contiguous day, so that the visit is not missed. If the visit cannot be rescheduled, it is counted as an ‘excused absence’ instead of an ‘unexcused absence.’ Excused absences include a planned surgery or other medical procedure, illness, death in the family, or a court date, etc. The member must provide documentation of the reason for the absence at the next scheduled visit (e.g., note or receipt from a medical clinic, funeral announcement, or court document). Failure to provide documentation for an excused absence will result in that absence being coded as an unexcused/missed appointment and an incentive reset will occur. A member may have up to two consecutive excused absences; if the excused absence extends to three or more visits, it will activate an incentive reset.

Recovery. ‘Recovery’ refers to the return to previously achieved reward levels when a member returns to sustained abstinence (as defined by two consecutive stimulant-negative UDTs). This is possibly the most challenging aspect for the CM Coordinator to track, though the IM Portal will take the guess work out of things since it automatically calculates the correct reward amount at each CM visit. The idea of incentive recovery is that we do not want a single episode of stimulant use (one stimulant-positive test) to turn into continued use of stimulants use. Therefore, if a member has achieved an escalated reward amount, let’s say of \$16 per stimulant-negative UDT and then they submit a UDT that indicates use (or they have an unexcused absence) and the reset occurs, we want to give them motivation to return to abstinence as soon as possible. So, if the

member submits a stimulant-negative UDT after a reset, they receive the \$10 incentive for that UDT. If the next UDT is also negative for stimulants, they return to the place in the escalation schedule where they would have been, had the positive UDT or unexcused absence not occurred. For instance, if they had the positive UDT or unexcused absence at the second visit of week 5, when they would have earned \$16 for a stimulant-negative UDT, the next stimulant-negative UDT would result in a \$10 incentive, and if the next UDT after that is also negative for stimulants, they would earn \$17.50 (recovery of the \$16 escalation, plus the next escalation). They will then continue the incentive schedule from that reward amount. This will be demonstrated in more detail in Chapter 4. The 'recovery' helps people get back on track after a stimulant-using episode and gives them a reason to return to abstinence after use. We will put it all together later and show you how escalation, reset, and recovery work through an example member's CM program.

Chapter 3. Evidence that CM Works

Now that we have told you about CM in general, it's time to share with you the evidence that CM is an effective intervention for treating stimulant use disorder (StimUD).

Research Evidence. Multiple studies conducted over the past 30+ years demonstrate that CM is the most effective intervention for StimUD, including methamphetamine, amphetamine, and cocaine use disorders.^{1,3–5,7} It also works well for treating nicotine use disorder and opioid use disorder.^{7,17} Given the lack of medication-assisted treatment options for stimulant drugs, such as methamphetamine and cocaine (there are currently no FDA-approved medications for StimUD), CM is an important clinical tool in the treatment of StimUD.

More evidence supports the effectiveness of CM for StimUD than any other treatment.^{1,3,4,9,18} Multiple meta-analyses have been published on CM. A meta-analysis is a comprehensive review of research studies where all the studies done on a topic are combined and analyzed together.

Several meta-analyses collectively support the efficacy of CM as an intervention for stimulant use and other substance use disorders.^{1,7,16,19–21} One meta-analysis found that compared to all other cognitive and behavioral interventions for substance use disorders, CM was the most powerful way to assist clients to stop using drugs.¹

Research also finds that the effect of CM is lasting. In fact, one study found that the effects on abstinence rates of a treatment episode of CM at a 12-month follow-up assessment are comparable to the effects on abstinence rates of a treatment episode of cognitive behavioral therapy at a 12-month follow-up assessment.^{2,22} We also know that those individuals who stay in CM longer are more likely to continue to be abstinent after the CM intervention is completed.²²

CM also has important secondary positive benefits and impacts on health. It has been found that when one drug is targeted in CM (e.g., a stimulant such as methamphetamine) individuals not only stop using that drug, they stop using other substances, as well (e.g., alcohol).^{8–10,23} In another study, researchers found that people with co-occurring StimUD and serious mental illness (SMI) who received CM had fewer psychiatric symptoms and inpatient psychiatric hospitalizations than those who did not receive CM.⁹

In addition, multiple cost-effectiveness studies demonstrate that the cost savings of CM associated with reduced substance use and improved mental health outweigh the costs of rewards, UDTs, and staff time needed to implement the intervention.^{14,24} Therefore, CM reduces substance use and saves money too.

CM is also an effective intervention for diverse cultural groups. The CM team at Washington State University (WSU) partnered with five American Indian and Alaska Native communities to study whether CM was associated with reduced alcohol and drug use. They found that CM was associated with lower alcohol, stimulant drug, and cannabis use.^{10,11} Participants and clinicians also reported that the adapted CM intervention was consistent with their community values. WSU has developed a separate CM manual and training materials for American Indian and Alaska Native communities who are interested in this adapted CM model.

Clinician and Client Evidence. After implementing CM for a while, clinicians have seen the positive impact it has on their clients, their practice, and on their overall clinic or agency. In surveys, clients appreciate the more positive environment of their CM program and providers viewed CM more positively because their clients' treatment attendance increased.^{25–27} Clients affirmed that incentives enhanced their motivation to remain abstinent and the CM program provided accountability to do so.

While clients report that they like receiving prizes or gift cards, more often they emphasize that they really liked their CM providers and how CM helped them change their lives. Specifically, they report how positive their CM providers are, that CM holds them accountable in a positive way, and that CM providers are respectful. One of the WSU CM studies was called the HONOR project, in part because as CM providers we are honoring people when they choose to be abstinent.¹¹

Clinicians also like CM, with 77% of clinicians saying they would use it if given the opportunity to do so.²⁷ Many clinicians share concerns when the idea of CM is first introduced to them. These concerns relate to “paying” people to stop using drugs and the belief that people should be intrinsically motivated to change. Another concern is that CM only rewards abstinence, so it seems inconsistent with approaches that meet people where they are. CM was initially developed to help people who were receiving methadone to reduce or stop using stimulant drugs, like cocaine. So, CM was originally developed in the context of medications for addiction treatment (MAT) to reduce the harms associated with substance use. Overall, when it comes to clinicians' initial concerns about CM, it is very common that as soon as clinicians start seeing the successes their clients have in CM, their opinions change.

Currently, the biggest barrier to implementation of CM is financial. More specifically, there has not been an easy way to pay for CM rewards, despite the average cost per client (\$300–\$500) being relatively low²⁸. Increasingly, federal, state, and local governments, as well as treatment agencies and insurers are seeing the benefits of CM, particularly for StimUD. Some are now providing funding for CM incentives. The Recovery Incentives Program is funded as a Medi-Cal benefit. California is the first state in the nation to cover CM as a Medicaid benefit under CalAIM (California Advancing and Innovating Medi-Cal)^{29–30}.

Chapter 4. A CM Model for Stimulant Drugs

So far, we have reviewed CM, what it is, what makes it work, and how it is based on research evidence. Now it is time to talk about how to implement the Recovery Incentives Program protocol in your site. Below we describe an evidence-based CM model to reward stimulant drug abstinence. That means it is based on models used in CM studies that are associated with clinically significant reductions in drug use.

CM for Stimulants Overview

- **Identify Behavior for Reinforcement** – Stimulant abstinence as measured by point-of-care UDTs for amphetamine, methamphetamine, and cocaine.
- **Frequency of Monitoring and Reinforcement** – Twice-weekly on non-consecutive days, such as Mon/Thurs or Tues/Fri for the first 12 weeks and once weekly in weeks 13-24.
- **CM Intervention** – 12-weeks of CM starting at \$10 for each stimulant-abstinent sample, escalating by \$1.50 for each week of consecutive abstinence (assessed twice-weekly). This is followed by a 12-week stabilizing period in which UDTs are collected once per week and stimulant-free samples are rewarded with either a \$10 or \$15 gift card, with a final possible gift card worth \$21 in week 24.

Stimulant Urine Drug Testing in CM

UDTs as a Tool for Success. In CM, we use UDTs in a very different way than they are traditionally used in typical SUD treatment. In CM, we celebrate UDT results that demonstrate abstinence, and we value an individual's efforts to remain engaged in treatment even after recent drug use (i.e., UDT positive for stimulants). UDTs are a tool for facilitating rewards, not a tool for "catching" clients who have used drugs. In fact, you will notice that we never use the terms "clean" or "dirty" when we refer to UDT results. These terms are stigmatizing and judgmental, so we do not use them in CM. Instead, we use the terms recommended by the test manufacturers: positive (indicates recent use) and negative or stimulant-free (indicates no recent use).

It may take some time for members and treatment programs to get accustomed to this new way of using UDTs. In CM, UDTs are still used to keep people accountable, but the focus is on positive accountability that facilitates trust, self-efficacy, and pride. In fact, many CM members report that they really value urine testing because it helps them remember that they are accountable to themselves and their CM provider when they have urges to use.

To facilitate this new approach to urine testing, we do not require directly observed tests, though we do use tools like integrated thermometers to reduce the chances that someone is tempted to carry in someone else's urine or to dilute their own urine sample using water or other liquids or to contaminate the sample using bleach or other chemicals. Temperature strips ensure that the sample temperature is near normal body temperature, creatinine levels/specific gravity detect dilution, and pH levels detect contamination. All these safeguards are included in the UDTs

approved for the Recovery Incentives Program. It is important to include validity measures such as requiring the member to wash their hands before handling the testing supplies (to prevent members from putting bleach under their fingernails and urinating on them, which would contaminate the urine sample), applying bluing agent in the toilet the member will use, and turning off the hot water in the restroom that will be used for the UDTs. And if you do suspect an inaccurate test, it is important to have a conversation with the member and remind them that they will only earn rewards for valid samples.

Remember, many members are trying to unlearn a history where a positive UDT resulted in negative outcomes, like judgment from the treatment provider, shame, jail time, loss of custody, or being “fired” from a treatment program. So, having a nonjudgmental conversation often solves the problem of inaccurate or invalid tests. The bottom line is that if you emphasize the positive and nonjudgmental approach to urine testing that balances accountability and trust, and remind members that the results are confidential, and that the only negative consequence for this visit is not earning an incentive, they will be less likely to tamper with their urine samples.

What if the Results Seem Wrong? CM studies have conducted tens of thousands of UDTs over the last 30+ years. And if you are an SUD treatment provider, you probably have a lot of experience with UDTs, as well. Like us, you probably have at times obtained a UDT result from a client that just doesn’t seem to make sense. It might be a negative test from a person you knew was arrested for possession over the weekend or a test that indicates use from someone who has been in recovery for months.

UDTs are not perfect and understanding the detection periods of each test is important to using them appropriately. At the same time, we know that UDTs are more accurate than self-report, when they are used frequently enough to detect use. They also take self-report off the table, so clients are not tempted to provide inaccurate information about their use. In CM, rewards are based on the UDT result and it is important that clients are informed of this right from the start.

In all the thousands of UDTs that have been conducted, it is almost always the case that after the dust settles, it is the person’s self-report that was inaccurate, not the UDT (when the test is used properly). Additionally, there are prescription and over-the-counter medications/drugs containing amphetamine, pseudoephedrine, or their metabolites that can cause a false positive test. Members are provided with a list of medications that may cause a false positive test (see the Recovery Incentives Sample Consent Form in Appendix A) and informed that they should not use these during their participation in the Recovery Incentives Program. Rewards are based solely on the results of the UDTs, and all positive tests are treated the same, even if they result from the use of one of these medications.

Note: when there is a voiced dispute from a member who insists that there must be a problem with the test being performed, you may offer to re-test the member to either confirm the original test or to overturn it. This should be done with a new point-of-care UDT. The member should be informed that the results of the second test are binding. A second test should be used **very sparingly** and primarily as a way to preserve the clinical relationship with a member who is very upset. Clinical judgment must be used, so we encourage you to consult the CM Supervisor if this situation occurs. Also remember that reimbursement rates are based on a single test per visit, so additional tests would be an expense incurred by the site. We also encourage you to seek

consultation from an expert on the UCLA Training and Implementation Team if you are confused by a test result. You can request individualized expert consultation through the [Recovery Incentives Program Warm Line](#).

Frequency of UDTs. In the first 12 weeks of the Program, we monitor stimulant drug use twice per week, on two non-consecutive days. This fits well within the standard of an outpatient or intensive outpatient treatment setting, where clients attend group sessions multiple times a week. Testing shall be separated by at least 48 hours, and ideally, 72 hours (e.g., Monday and Thursday OR Tuesday and Friday) to minimize the chance that drug metabolites from the same drug use episode shall be detected in more than one UDT.

The Recovery Incentives Program may only be implemented in DMC-ODS outpatient, intensive outpatient, partial hospitalization, and NTP/OTP treatment clinics/programs. CM implemented in these settings consists of twice-weekly visits for the first 12 weeks of the program and once weekly visits for the second 12 weeks of the program (i.e., weeks 13-24).

Stimulant-Specific UDTs. Point-of-care UDTs are available for stimulants, including amphetamine, methamphetamine, and cocaine. A selection of UDT kits are approved for use in the Recovery Incentives Program. Each cup includes tests for amphetamine, methamphetamine, cocaine, cannabis, oxycodone, and opiates; some (not all) of the approved UDT kits also test for fentanyl/fentanyl metabolites. They also test for benzodiazepines, MDMA, PCP, and several other substances depending on the specific test kit. The purpose of testing for oxycodone and opiates is to assess the relative risk of exposure to fentanyl or other synthetic opioids; this is based on the concept that a person who uses in a polysubstance pattern has a greater potential to accidentally ingest fentanyl than a person who uses a single substance due to the likelihood of additional drug sources. Please note that reimbursement for covered CM services in the Recovery Incentives Program does not include independent urine testing to detect the presence of fentanyl in a specimen, nor does it include reimbursement for fentanyl test strips. However, DMC-ODS providers are not prohibited by DHCS from independently testing for fentanyl as part of urine drug testing. Please refer to the [Frequently Asked Questions](#) document for additional information regarding safety strategies, the use of drug test strips, approved CLIA waived UDTs that test for fentanyl, and reimbursable costs.

The opiate-, oxycodone, or fentanyl-related results, even if positive, shall not impact the member's ability to receive an incentive; however, counseling should be provided, and an assessment should be completed for the clinical need for induction of an evidence-based medical treatment for opioid use disorder. If the CM Coordinator is an LPHA or certified/registered SUD counselor, they can complete the assessment. If the CM Coordinator is not an LPHA or certified/registered SUD counselor (i.e., a Peer Support Specialist), the CM Coordinator shall refer the member to an LPHA or SUD counselor for the assessment. In addition, the CM Coordinator shall discuss the risks associated with fentanyl, safety strategies including the use of fentanyl test strips, and ensure the member has access to naloxone and knows how it is used. If the member is positive for any of the substances tested in the UDT cup, this shall not impact their ability to receive incentives related to their stimulant test results. However, inquiring if the use of other substances is impacting their stimulant use and assessing for the need for referral to other

behavioral treatments to address these substances may be warranted, particularly if the member is having difficulty attaining consecutive stimulant-negative UDTs.

The cocaine UDT detects only the use of cocaine; it will not detect amphetamine or methamphetamine use. The Recovery Incentives Program requires UDTs that test for all three substances. The amphetamine test is designed to detect prescription drugs, like methylphenidate (Ritalin®, Concerta®) or other amphetamines (i.e., Adderall®). It is likely that a person who uses methamphetamine will test positive for amphetamines too. The methamphetamine UDT will identify methamphetamine, though not other amphetamines. As mentioned above, it is possible that a member could test positive for amphetamine or methamphetamine if they take a cold medicine that contains amphetamines, pseudoephedrine, or similar compounds. All positive tests are handled the same (i.e., no reward) even if they result from the use of an over-the-counter or prescription medication. Therefore, it is very important to discuss this with members as they enroll in the Recovery Incentives Program.

The amphetamine, methamphetamine, and cocaine tests approved for use in the Program have the following metabolite detection thresholds:

	Metabolite	Threshold	Min Detection	Max Detection
Amphetamine	d-Amphetamine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine	D(+)-Methamphetamine	500 ng/mL	2-7 hours	2-4 days
Cocaine	Benzoylcegonine	150 ng/mL	1-4 hours	2-4 days

*Minimum and maximum detection periods as listed in package insert for [CLIAwaived, Inc. Instant Drug Test Cup](#).

Remember the detection periods described above are provided for overall guidance. However, detection periods of UDTs for any given person will vary depending on the amount of drug used and individual-level factors. Also, the detection period for methamphetamine and cocaine urine tests is up to four (4) days. Therefore, if you are conducting CM visits twice a week, it may take up to two (2) UDTs before a member tests negative for these drugs after they stop using. Reminding the member of this can help maintain motivation as they are working toward their first stimulant-negative UDT. If you ever have questions about a potential “false” positive or negative test you can always request consultation.

It is also important to remember that point-of-care UDTs have an expiration date. Therefore, it is important that you do not order more tests than you can use over a given period and that you ask for the expiration date of the tests you purchase before you place your order if your volume of urine drug testing is relatively low.

CLIA-Waived Certification. To participate in the Recovery Incentives Program and receive Medi-Cal reimbursement for CM services, DMC-ODS providers must attain a Clinical Laboratory Improvement Amendments (CLIA) “waived test” certification and be registered with the California Department of Public Health (CDPH) (or be



accredited by an approved accreditation body). Laboratory Field Services, which is part of the California Department of Public Health, has an online application process through which providers can apply for both the CLIA Waiver and State Lab Registration. Sites should choose certificate type “Registration” and be prepared to upload three forms: the [CMS 116](#), [LAB 182](#), and [LAB 183](#). Sites that already have a CLIA Waiver and State Lab Registration in place can use these certificates for the Recovery Incentives Program, even if their original application was for another test. It may take up to six months for CDPH to process applications once they are correctly submitted. It is therefore essential that sites submit applications as soon as possible, if needed. The user manual for submitting CLIA waiver applications can be found [here](#).

Each UDT must be performed in accordance with the manufacturer’s instructions for the test (see Appendix B), and the identified Site Lab Director must ensure that waived testing personnel meet facility-defined minimum requirements and have records of training and competency assessment.

Importance of Point-of-Care Tests. Several commercially available UDT cups make onsite, immediate testing feasible without the need for specialized laboratory equipment or training. Refer to the DHCS CM Website for a [table](#) of approved cups that meet minimal standards for validity testing, cutoff values, and coverage of necessary substances (amphetamines, methamphetamine, and cocaine).

If you would like to use a different UDT device that you think meets Recovery Incentives Program UDT requirements, you can request a review of the product for potential addition to the approved product list. If you would like for your existing UDT product to be evaluated for use in the Recovery Incentives Program, please email the following information to RecoveryIncentives@dhcs.ca.gov:

- Package insert
- Cut-off values for amphetamine, cocaine, methamphetamine, opiates, oxycodone, and fentanyl, if applicable
- Cross-reactivity list for amphetamine, cocaine, methamphetamine, opiates, oxycodone, and fentanyl, if applicable
- Information on specimen validity measures (whether the cup includes these):
 - Temperature strip
 - pH
 - Creatinine/specific gravity
- Certification: CLIA-waived and/or FDA approved

DHCS will review each request submitted by a provider for an alternative UDT and either approve or deny the request for an alternative UDT. The site cannot receive reimbursement for CM unless the test has been approved by DHCS.

UDT kits are purchased directly by each participating site or through their County according to their usual procurement process. Check with your County Recovery Incentives Program staff to determine how to obtain the UDT kits. As a standard practice, sites should routinely inspect all UDT kit shipments to ensure that the correct kit was received, and that the kit is one of the approved UDT products.

Tracking UDT Results and Rewards. Tracking and monitoring of members is done electronically through the Incentive Manager (IM) Portal (see Chapter 5). Carefully tracking and documenting UDT results and incentives earned and disbursed is essential to making sure your site is compliant with specific rules pertaining to providing CM as a Medi-Cal benefit (see Chapter 6, Federal Law and Incentive Payments). Entering data into the IM Portal accurately helps ensure that the Recovery Incentives Program is compliant with state and federal laws, regulations, and DHCS program requirements.

Specific Program Elements of the Recovery Incentives Program: California's Contingency Management Benefit

Below is a step-by-step process for implementing the Recovery Incentives Program.

Reinforce Behavior. Stimulant abstinence is objectively measured by point-of-care urine drug testing. The point-of-care UDTs measure cocaine, methamphetamine, and amphetamine. They will also assess for opiates and oxycodone, and, if applicable, fentanyl. A test that is positive for opiates, oxycodone, or fentanyl but negative for stimulants will lead to the member earning an incentive for that visit, because stimulant use is the focus of the Program. Because of the presence of synthetic opioids in much of the stimulant drug supply in California, the following steps shall be taken for a member who tests positive for opiates, oxycodone, and/or fentanyl.

Recovery Incentives Program sites shall:

- Establish and implement a protocol to prescribe FDA-approved Opioid Overdose Reversal Medications (e.g., naloxone, nalmefene) to all members with an opioid, sedative and/or stimulant use disorder as outlined below.
- Establish and implement an opioid overdose reversal medication distribution protocol for members who do not obtain a prescription for an opioid overdose reversal medication.
- Provide education to each CM member regarding:
 - The risks associated with fentanyl and its presence in the illicit drug supply. Safety strategies, such as the use of fentanyl test strips (e.g., fentanyl, xylazine) and programs that distribute test strips for home use, based on information from the [California Department of Public Health Overdose Prevention Initiative](#) webpage.

Specific education regarding the use of naloxone to reverse an opioid overdose.

Whenever a member needs an additional naloxone dose, due to the naloxone expiring, or due to use in the community, CM Teams shall either replace the naloxone or remind a member to obtain a new dose through a pharmacy or local organization. DMC-ODS providers are able to dispense naloxone onsite to members by leveraging the Medi-Cal pharmacy benefit. As a best practice overdose prevention measure, sites can prescribe naloxone to all DMC-ODS members who are participating in the Recovery Incentives Program and arrange for staff to routinely fill these naloxone prescriptions at a pharmacy on behalf of the members. The community pharmacy should bill these naloxone prescriptions to the Medi-Cal pharmacy benefit. Pharmacists can also directly dispense naloxone and bill to Medi-Cal. The CM Team could then bring the dispensed naloxone back to the provider site for furnishing directly to members. This method would enable Recovery Incentive Program sites to better facilitate onsite access to naloxone reimbursed through the Medi-Cal pharmacy benefit.

Monitoring and Reward Schedule. Twice-weekly during the initial 12 weeks, either 1) Mondays and Thursdays or 2) Tuesday and Friday, if possible. If this is not possible, for instance in the event of an excused absence being rescheduled to a different day, then twice-weekly on non-consecutive days as long as there are at least 48 hours between UDTs.

Duration of Intervention. 12-weeks of CM treatment, which serves as the escalation/reset/recovery period, plus 12 weeks of a stabilizing period. During the initial 12 weeks of CM treatment, participating members visit the treatment program twice per week for CM services as stated above, and during the stabilizing period in weeks 13-24, participating members visit the treatment program once per week for CM services.

Many CM interventions conducted as part of research studies have ended after 12 weeks and have not included a stabilizing period after the active intervention period. In the Recovery Incentives Program, weeks 13-24 serve to help members stabilize and maintain the progress they made in weeks 1-12. This period is also important in terms of treatment retention. For members who have taken advantage of other clinical interventions offered by sites implementing the CM benefit, such as group or individual counseling, the continuing incentives that can be earned during the stabilizing period will be a tool to encourage members to remain fully engaged in those interventions.

Reinforcement Amount, Escalation, Reset, and Recovery. The gift card values for each qualifying urine sample are at least \$10. For each week the member achieves/maintains abstinence (i.e., two consecutive stimulant-abstinent UDTs), the gift card value increases by \$1.50. Therefore, the maximum a member could earn if they attend every CM visit and are abstinent for the entire 12 weeks is \$438. During weeks 13-18, members test once per week and earn \$15 for each negative test. Weekly testing continues in weeks 19-23 with each negative test earning \$10. In week 24, a negative test earns the member \$21. Thus, a member can earn a maximum of \$161 for weeks 12-24, for a total of \$599 across the entire 24-week period if they attend every visit and submit a stimulant-negative UDT every visit.

Although the total reward per member may be as high as \$599, it is unlikely that everyone will achieve this level of success in CM. Due to missed appointments and periodic stimulant use, the

No Reward



average cost of incentives in your implementation of the Recovery Incentives Program will be approximately half of the maximum amount possible (\$599), or approximately \$300 per member.

A **reset** occurs when a member submits a stimulant-positive UDT or has an unexcused absence. The next time they submit a stimulant-negative UDT, their reward level “resets” to the initial incentive value (e.g., \$10).

A **recovery** occurs after two consecutive stimulant-negative urine tests. At that time, the member “recovers” their previously earned incentive level plus the next escalation of \$1.50. See Table 2 below for an example of how this process works.

Gift Cards. The IM Portal manages incentives and dispenses gift cards, because they are both desirable and feasible. The full list of available gift card vendors is available in the IM Portal.

UDT and Incentive Tracking

The IM Portal automatically calculates the appropriate incentive amount based on the UDT results with adjustments for the escalating value, reset, and recovery features described above. At each visit, the CM Team Member enters the results of the UDT into the IM Portal, and the IM Portal indicates the appropriate incentive amount, per the protocol. A positive UDT for stimulants results in the member receiving no incentive, along with encouraging coaching from the CM Team Member. A negative test for stimulants results in an incentive amount as indicated by the IM Portal, considering escalations and resets.

After the incentive amount is determined, the IM Portal either disburses the incentive for that visit in the form of an e-mail, text link, printed voucher, or “bank” the incentive amount for future use by the member. It also tracks all incentives awarded to all participating members. Additional data in the IM Portal includes the CM Team Member who conducted the visit (e.g., CM Coordinator, Back-up CM Coordinator, or CM Supervisor), the format of the incentive provided to the member (i.e., text, email, or printed voucher), the date the incentive was distributed, and the amount of the incentive.

Participating members receive incentives in the form of gift cards to which the IM makes a deposit upon entry of stimulant-negative UDT results. Restrictions are placed on the incentives so they cannot be used to purchase alcohol, tobacco, cannabis, lottery tickets or other gambling services, firearms, or ammunition.

Table 1 depicts an example of a CM gift card tracking table demonstrating reset and recovery with a stimulant-positive UDT, a missed appointment (unexcused absence), and an excused absence. For the purposes of easy tracking and clear communication, we use the following terms: **positive** (urine test was positive for at least one stimulant drug), **negative** (urine test was negative for all stimulants), **missed** (unexcused absence), and **excused** (approved absence). An example table of incentives when all of a member’s UDTs are stimulant-negative appears in Chapter 5. Remember that although you need to understand how incentives are calculated in order to explain to members, the IM Portal calculates the value of the incentives for you.

Table 1. Missed Sample and Positive UDT (Demonstrating Reset and Recovery)

Starting Incentive = \$10, incentives escalate by \$1.50 for each week of continuous abstinence

Week #	Visit #	UDT Result	Incentive Earned (\$)	Week #	Visit #	UD Result	Incentive Earned (\$)
1	1	Negative	10.00	7	13	Missed	0
1	2	Negative	10.00	7	14	Positive	0
2	3	Negative	11.50	8	15	Negative	10.00
2	4	Negative	11.50	8	16	Negative	19.00
3	5	Negative	13.00	9	17	Negative	19.00
3	6	Negative	13.00	9	18	Negative	20.50
4	7	Negative	14.50	10	19	Negative	20.50
4	8	Positive	0.00	10	20	Negative	22.00
5	9	Negative	10.00	11	21	Excused	0.00
5	10	Negative	16.00	11	22	Negative	22.00
6	11	Negative	16.00	12	23	Negative	23.50
6	12	Negative	17.50	12	24	Negative	23.50
				Total			\$323.00

- **At visit 8**, the member submitted a stimulant-**positive** UDT. They **did not receive an incentive** that day.
- **At visit 9**, the member submitted a negative UDT, and their gift card amount was **reset** to the base amount, \$10.
- **At visit 10**, the member again submitted a negative UDT, which represents another consecutive negative UDT. So, they **recovered** the previous escalation they had earned (\$14.50) from visits 1-7. They also earned an additional escalation for another week of abstinence (visits 9 and 10), for a total of \$16 earned that day.
- A similar cycle of reset and recovery is triggered on **visits 13-14** after the member **missed a visit** and **submitted a positive UDT**.

- At **visit 15**, their gift card amount **reset** to \$10, when they returned and submitted a stimulant negative UDT.
- At **visit 16**, they demonstrated another consecutive stimulant-negative UDT, so they again **recovered** their previously earned escalations much like they did above, this time totaling \$19.
- At **visit 21**, they missed their CM session due to advance notice of an excused absence. A **reset** and **recovery** does not occur because it was an excused absence.
- At **visit 22**, their gift card amount continued at \$23, again because visit 21 was an excused absence.

Program Readmission. A member is considered a readmission if they leave the Recovery Incentives Program for more than 30 days. At readmission, the member must have a new ASAM multidimensional assessment that indicates they can appropriately be treated in an outpatient treatment setting (i.e., ASAM levels 1.0–2.5) and confirm that the member meets the medical necessity criteria for CM. If the member has remained engaged in other services, such as residential treatment, during their absence from CM, an update to the most recent ASAM assessment is sufficient, and the member does not require a new diagnostic assessment. Based on the assessment, the site may offer other treatments *as alternatives to the CM program* if there is strong clinical evidence that CM is unlikely to produce the intended results. However, if the determination from the new assessment is that CM is an appropriate course of treatment for that member, the member may receive CM and the incentive structure would restart at Week 1. The maximum amount of incentives a member can earn is \$599 per calendar year.

A member who is readmitted to the Recovery Incentives Program earns incentives according to the schedule described above until they earn \$599 for all program participation during that calendar year. They would then be discontinued from the Recovery Incentives Program and encouraged to continue with other program services. In January of the next calendar year, the member could be reassessed and, if they meet all criteria, they can be readmitted to the Program, again with a maximum earning potential of \$599 for that calendar year.

If a member leaves the Program (for any reason) and returns to the program within 30 days, they return to the schedule of UDTs and incentives as if there was no break in service.

In rare circumstances, following completion of the CM treatment phase of the Program, a member may benefit from re-entering the CM treatment phase protocol instead of proceeding to CM continuing care services. Repeating the ASAM assessment and diagnostic assessment is not required for the member to re-enter the CM treatment phase of the Program. In these instances, the clinical documentation, completed (or reviewed) by an LPHA, must demonstrate that CM services are medically necessary and appropriate based on the standard of care. The documentation must clarify that outpatient treatment continues to be appropriate for the member and include the provider's reasoning for resuming CM services. In this scenario, the member still may not exceed the \$599 annual limit for earned incentives, and once that limit is reached the member would no longer be eligible for the Recovery Incentives Program and should be transitioned to continuing care services. Re-entry to the CM treatment phase following completion of the initial CM treatment phase of the Program should prompt providers to assess

whether a higher level of care than outpatient services (i.e., ASAM Level 3.1 or above) is medically necessary.

Establishing Member Eligibility for CM Services

The Recovery Incentives Program is only available to Medi-Cal members who meet the following conditions:

- Are enrolled in Medi-Cal and meet criteria for a comprehensive, individualized course of SUD treatment. Medi-Cal enrollment must be confirmed prior to initiating services through the Recovery Incentives Program.
- Reside in a participating DMC-ODS county that elects and is approved by DHCS to participate in the Recovery Incentives Program.
- Receive services in a non-residential level of care operated by a DMC-ODS provider participating in the Recovery Incentives Program and offering CM in accordance with DHCS policies and procedures.

CM services delivered under the Recovery Incentives Program are only covered when medically necessary and appropriate as determined by an initial SUD assessment consistent with DMC-ODS Intergovernmental Agreement (IA) showing (1) diagnosis of any of the related moderate or severe cocaine or stimulant use disorder diagnoses, including diagnoses in remission, as defined by the clinical criteria in the Diagnostic and Statistical Manual (DSM, current edition); (2) clinical determination that outpatient treatment is appropriate per the American Society of Addiction Medicine (ASAM) criteria; and (3) that the CM benefit is medically necessary and appropriate based on the fidelity of treatment to the evidence-based practice. The presence of additional substance use disorders and/or diagnoses does not disqualify an individual from receiving CM services.

Members may access CM when transitioning from residential care or carceral settings to outpatient treatment settings, including services initiated on the day of admission to the outpatient program and discharge or release from residential care or a carceral setting. Providing CM services on the date of admission to the outpatient program and the date of discharge from a DMC-ODS residential level of care is an acceptable circumstance justifying multiple service billing for both a residential treatment service and a CM service at a non-residential level of care.

CM should never be used in place of medications for addiction treatment (MAT). CM may be offered in addition to MAT for people with co-occurring stimulant and alcohol or opioid use disorders.

Eligible Medi-Cal members shall be referred to, and admitted into, treatment through a participating site's routine client admission process. Consistent with other DMC-ODS programs, there is no minimum age limit for an individual to receive CM services if they meet all eligibility criteria. In addition, pregnant and parenting people with StimUD are eligible to receive CM services. Medi-Cal members who are receiving care in residential treatment (e.g., ASAM levels 3.1–4.0) or institutional settings are ineligible for CM services until the day of discharge, when they are transitioned into outpatient care.

Members Under the Age of 21. Covered services provided under the Recovery Incentives Program shall include all medically necessary SUD services for individuals under 21 years of age as required pursuant to Section 1396d(r) of Title 42 of the United States Code. Federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) statutes and regulations require States to furnish all Medicaid-coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions, regardless of whether those services are covered in California's Medicaid State Plan. Consistent with federal guidance, services need not be curative or completely restorative to ameliorate a mental health condition, including substance misuse and SUDs. Services that sustain, support, improve, or make more tolerable substance misuse or a SUD are considered to ameliorate the condition and are thus covered as EPSDT services.

CM Visit Flow

Greet. Establish a positive relationship. Always keep the interaction pleasant and non-confrontational. The positive nature of CM allows for an opportunity to strengthen the therapeutic alliance. Your positive attention is also reinforcing to most members.

Assessment. Assessment consists of activities to evaluate or monitor the status of a member's behavioral health and determine the appropriate level of care and course of treatment for that member. Consistent with DMC-ODS policies described in [BHIN 24-001](#), members must have an ASAM multidimensional assessment completed by a Licensed Professional of the Healing Arts (LPHA) or registered/certified counselor that indicates the member can appropriately be treated in an outpatient treatment setting (i.e., ASAM levels 1.0–2.5). To ensure that members receive the right service, at the right time, and in the right place, providers shall use their clinical expertise to complete initial assessments and subsequent assessments as expeditiously as possible, in accordance with each member's clinical needs and generally accepted standards of practice. The initial clinical assessment shall confirm: (1) the individual has a diagnosis of any of the related moderate or severe cocaine or stimulant use disorder diagnoses, including diagnoses in remission, as defined in the DSM, current edition; (2) outpatient treatment is appropriate per the ASAM criteria; and (3) CM is medically necessary treatment.

Intake Visit. During a member's first visit, the CM Coordinator completes several steps to initiate the service, specifically:

- Conduct eligibility check as described above – The CM Coordinator or other designated CM Team Member (e.g., Back-up CM Coordinator, CM Supervisor) at the site confirms the member's current Medi-Cal eligibility, as well as their eligibility for the program before initiating the CM service. The eligibility check should be done via the Automated Eligibility Verification System (AEVS) for Medi-Cal.
- The member should also be asked whether they are currently enrolled in a residential SUD treatment program. Members may not be enrolled in the Recovery Incentives Program if they are attending residential treatment.
- Before beginning CM treatment, a member must complete a thorough orientation and consent to the conditions of the Recovery Incentives Program. The orientation addresses the following:

- The days/times that a member must visit the facility in order to be eligible for incentives (during weeks 1-12, twice-weekly visits; during weeks 13-24, once-weekly visits).
- The method of incentive delivery, as well as how and where incentives can be redeemed, including the prohibition of using incentives to purchase alcohol, cannabis, tobacco, firearms/ammunition, lottery tickets, or for any form of gambling.
- The availability of incentives and ongoing program participation when a member lapses or relapses and seeks readmission and the process for a member to seek readmission.
- The site's UDT procedures and an explanation and review of medications/substances that may result in false-positive UDTs.
- The rules governing when an incentive are provided, including:
 - An explanation that the incentives are contingent on the absence of evidence of stimulant (e.g., cocaine, amphetamine, methamphetamine) use on a UDT.
 - An explanation that opioid testing is done for the purpose of safety, due to association with overdose deaths, but does not impact the delivery of an incentive.
 - An explanation that all positive tests are treated the same even if they result from use of one of the medications/substances known to provide false positive UDT results.
- The amount of the initial incentive and how the value increases with consecutive stimulant-free UDTs and how the value is reset to the initial \$10 value in the case of a positive test or unexcused absence, and that increases are recovered upon the submission of two consecutive stimulant-negative UDTs.
- Program participation consent – The CM Team Member reviews with the member, and obtains their signature on, a consent form authorizing services and the secure sharing of data with DHCS and the program evaluation team, including all DHCS-required consent elements. See sample consent form available in Appendix A.
- Explain the CM process and reinforce the expectations set forth above.
- Enroll the member into the Incentive Manager (IM) Portal – The CM Team Member completes a member profile to enroll them into the web-based IM Portal that keeps track of UDT results and incentive gift cards distributed.

Ongoing CM Visits. Engage the member and initiate the visit – The CM Team Member greets the member, reviews their progress in the program (e.g., weeks completed out of 24), logs into the IM Portal and locates the member's record/profile.

- Conduct eligibility check – The CM Team Member checks member Medi-Cal eligibility at least monthly or more frequently if required by agency policy.

- At the same time as the monthly Medi-Cal eligibility check, the member should be asked whether they have enrolled in a residential SUD treatment program in the past month. If the member has been enrolled in a residential level of care, they must be immediately disenrolled from the Recovery Incentives Program. They may be readmitted to the Recovery Incentives Program when they are discharged from the residential treatment program, as detailed above.
- Administer UDT – The CM Team Member administers the UDT, including processing the results of the UDT in real time.
- Log results in IM Portal – The CM Team Member logs the results of the UDT for stimulants (i.e., positive or negative).
- Discuss results – The CM Team Member discusses the UDT results with the member and offer other services if/as appropriate, which could include brief encouragement, motivational interviewing, and/or education based on the CM Team Member’s scope of practice and training. The CM Team Member encourages the member to meet with their counselor or LPHA. If opiate, oxycodone, and/or fentanyl UDT results are positive, the CM Team Member will document these results in the clinical chart, reinforce the risk of overdose, ensure the member has naloxone, and offer other treatment services as appropriate, including referral for MAT if the member has a co-occurring alcohol or opioid use disorder.
- Disburse incentives consistent with the “Incentive Delivery” section in Chapter 5.
 - If the UDT result entered is negative for stimulants, the IM disburses the incentive generated by the IM consistent with the “Incentive Delivery” section in Chapter 5.
 - If the UDT result entered is positive for stimulants, the IM Portal does not disburse an incentive.
- Plan for next appointment – The CM Team Member reminds the member of their next scheduled appointment (date and time). The CM Team Member should offer to answer any questions before adjourning the visit.
- Documentation – The CM Team Member shall document the visit in the member’s medical record (or chart). The CM Team Member shall also document StimUD on the problem list (or treatment plan for Narcotic Treatment Providers, NTPs) within a member’s medical record. Consistent with best clinical documentation practices, the CM Team Member shall describe all interventions utilized with the member as part of their progress notes for each service to include CM in addition to any other outpatient services, such as motivational interviewing, cognitive behavioral therapy, or Community Reinforcement Approach. CM should not be offered to a member as a stand-alone treatment, but rather as one component of an individualized plan of care. However, if a member chooses to participate only in selected services (e.g., they only participate in CM and not in other aspects of treatment), they shall remain in outpatient treatment and shall not be penalized, chastised, criticized, or discharged from the program for declining to participate in any treatment or recovery service or for failure to participate in all recommended treatment services. Members needing or utilizing CM must be served and

cannot be denied CM or be required to participate in other aspects of a SUD treatment program as a condition of entering or remaining in the Recovery Incentives Program.

- If the member does not attend a scheduled visit, the CM Team Member should document the absence and any extenuating circumstances in the member's medical record and in the IM Portal.
- Billing – The CM Team Member shall complete claims documentation to bill the DMC-ODS county for the service, using as many units of the 15-minute code H0050 as appropriate, given the length of the visit, and using one of two required ICD-10 diagnoses (in addition to any other relevant codes for the visit; for example, the primary diagnostic code may be for stimulant use disorder, with the appropriate code below used as a secondary diagnosis):
 - R82.998: Positive urine test for stimulants
 - Z71.51: Negative urine test for stimulants
- Thank the member for coming to the clinic/program that day. Validate success as well as frustration, though always model a positive and hopeful attitude.

Chapter 5. Incentive Manager

Overview of Incentive Manager Portal

- CM Team Member enters UDT results.
- System automatically assesses member-specific circumstances.
- System automatically applies correct incentive amount.
- Incentive amount is “dispatched”, meaning the CM Team Member can select delivery method and incentive vendor in consultation with the member.
- Incentive transaction is logged.

Adding a New Member (see Figure 1)

- Open “dashboard pane”.
- Click “+” button to the left of “member” on the top of the data table.
- Input required patient information, including client identification number (CIN) and DOB.
- Input optional information for email and/or cell number (these fields support incentive delivery).
- The CM Team Member’s name should appear on the pane automatically.
- Confirm that your agency verified the member’s Medi-Cal eligibility in the AEVS and eligibility for CM.
- After clicking “Submit,” the CM Team Member may see an error stating that the member already exists in the system. This is a safeguard against members trying to enroll in multiple programs simultaneously. It may also occur because the member is seeking to transfer to your site from another program.
- Instances may occur when a member needs to transfer to another site and/or county temporarily or permanently. In the case of temporary travel, the CM Team Member at the member’s current site should engage in the following procedures.

Courtesy Services for Temporary Travel

In situations where a member receiving CM services from their DMC-ODS County of Responsibility temporarily travels to another DMC-ODS county that also participates in the Recovery Incentives Program, and the member is unable to attend scheduled CM service appointments during their travel, the DMC-ODS County of Responsibility shall reimburse CM services that an out-of-county DMC-ODS provider participating in the Recovery Incentives Program delivers to the member.

Prior to the member traveling out of county, the CM Team Member from their DMC-ODS County of Responsibility (Home CM Coordinator) shall identify and contact a participating Recovery Incentives Program provider located within the travel location’s DMC-ODS County (Travel Recovery Incentives Program provider) to notify them of the member’s travel plans and schedule

an appointment for the member based on their current UDT schedule. The Home CM Coordinator shall also contact the incentive manager call center and provide them with the same information, so the call center can change the member service location within the incentive manager program during the member's temporary travel. Prior to the member returning to their County of Responsibility, the CM Coordinator from the travel location's DMC-ODS County (Travel CM Coordinator) shall contact the County of Responsibility Recovery Incentives Program provider to notify them of the member's pending return and schedule an appointment for the member based on their current UDT schedule. The Travel CM coordinator shall also contact the incentive manager call center and provide the information so the call center can change the member service location within the incentive manager program, prior to the member returning to their County of Responsibility.

Figure 1. Adding a New Member

The screenshot displays the 'CA DHCS State Incentive Manager' interface. A modal window titled 'Add New Member' is open, allowing for the addition of a new member. The background shows a 'Provider Site' dashboard with a table of members and a table of incentives earned.

Provider Site
Total Member Population: 12

Member Table:

Member	Week Number	P
DHCS Member	6	DHC
DHCS Member	6	DHC
DHCS Member	5	DHC
DHCS Member	5	DHC
DHCS Member	4	DHC
DHCS Member	4	DHC
DHCS Member	3	DHC
DHCS Member	2	DHC
DHCS Member	1	DHC
DHCS Member	6	DHC
DHCS Member	5	DHC
DHCS Member	6	DHC

Incentives Earned Table:

Incentives Earned	T	P+	N-	M
\$89.00	10	1	8	1
\$76.00	10	2	7	1
\$40.00	9	3	4	3
\$41.50	9	3	5	1
\$60.00	8	2	6	0
\$30.00	7	3	3	1
\$41.50	5	1	4	0
\$31.50	3	0	3	0
\$10.00	1	0	1	0
\$21.50	10	3	4	3
\$0	8	1	0	7
\$20.00	9	2	2	5

Add New Member Form:

First Name: DHCS
Last Name: Member

Client Identification Number (Medi-Cal CIN): 12345678A
Date of Birth: 01/01/2000

Cell (Optional): (555)-555-5555
Email (Optional): Member@email.com

CM Coordinator: DHS Coordinator

I have verified this Member Is eligible for Medi-Cal and for CM.
☒ Yes

Submit New Member
Submit!

Accessing Member Chart (see Figure 2)

DHCS or County Users may access member charts.

- Click “Manage Users” on left pane
- Find the relevant member
- Enter the member’s date of birth
- Click “Continue”

Figure 2. Accessing Member Chart

The screenshot displays the CA DHCS State Incentive Manager interface. On the left is a navigation pane with icons for Dashboard, Analytics, Reports, and Manage Users. The main area shows a table of members with columns for Member, Results Entered, Week Number, CM Coordinator, CM Start, CM End, Incentives Earned, Incentives Received, and UDT Results. A modal window titled "Access Member Chart" is overlaid on the table, prompting the user to confirm member information and enter the date of birth.

Access Member Chart

To continue, you must confirm the Member's information
Below is correct and enter in their date of birth.

First Name
DHCS

Last Name
Member

Client Identification Number (MediCal CIN)
12345678A

Confirm Member's information above is correct
and enter in the Member's date of birth below.

01/01/2000

I have verified all of the above
information is correct

Continue!

Member	Results Entered	Week Number	CM Coordinator	CM Start	CM End	Incentives Earned	Incentives Received	UDT Results
								T P+ N+ M
DHCS Member	1/2	1	6	DHCS Coordinator	12/6/22	5/23/23	\$89.00	\$79.00 10 1 8 1
DHCS Member	1/2	1	6				\$0.00	\$76.00 10 2 7 1
DHCS Member	0/2	5	5				\$0.00	\$40.00 9 3 4 3
DHCS Member	0/2	6	5				\$0.00	\$30.00 9 3 5 1
DHCS Member	0/2	6	4				\$0.00	\$60.00 8 2 6 0
DHCS Member	0/2	7	4				\$0.00	\$0.00 7 3 3 1
DHCS Member	1/2	2	3				\$0.00	\$20.00 5 1 4 0
DHCS Member	1/2	2	2				\$0.00	\$31.50 3 0 3 0
DHCS Member	1/2	3	1				\$0.00	\$0.00 1 0 1 0
DHCS Member	1/2	6	6				\$0.00	\$21.50 10 3 4 3
DHCS Member	1/2	5	5				\$0.00	\$0 9 1 0 8
DHCS Member	1/2	6	6	DHCS Coordinator	1/12/23	1/29/23	\$20.00	\$10.00 9 2 2 5

Entering Member Changes (see Figure 3)

DHCS or County Users may update member information.

- Click “Manage Users” on left pane.
- Find the relevant member.
- In the data table, click “Update Member Info.”
- At any point, a DHCS or County User can utilize the call center to assist with these changes.

Figure 3. Member Changes

The screenshot displays the 'CA DHCS State Incentive Manager' interface. On the left is a sidebar with navigation options: Dashboard, Analytics, Reports, and Manage Users (highlighted). The main area is titled 'User Management' and shows a table of members. At the top right, there are summary boxes for '12 Members', '2 CM Coordinators', and '1 CM Supervisors'. The table has columns for Member, Status, Provider, CM Start, CM End, Change Status, and Update Info. An 'Update Member Information' modal form is open, showing fields for First Name, Last Name, Treatment County, Client Identification Number (CIN), Date of Birth, Treatment Clinic, Cell (Optional), Email (Optional), and CM Coordinator. The form includes a 'Submit!' button. The table shows several members, with the first one being 'Active' and the others 'Inactive'.

Member	Status	Provider	CM Start	CM End	Change Status	Update Info
DHCS Member	Active	DHCS Coordinator	12/6/22	5/23/23	Change Status (Select Reason)	Update Member Info
DHCS Member						Update Member Info
DHCS Member						Update Member Info
DHCS Member						Update Member Info
DHCS Member						Update Member Info
DHCS Member						Update Member Info
DHCS Member						Update Member Info
DHCS Member						Update Member Info
DHCS Member	Inactive	DHCS Coordinator	1/6/23	6/23/23	Change Status (Select Reason)	Update Member Info
DHCS Member	Inactive	DHCS Coordinator	1/7/22	6/24/23	Change Status (Select Reason)	Update Member Info
DHCS Member	Inactive	DHCS Coordinator	1/12/22	1/29/23	Change Status (Select Reason)	Update Member Info

Selecting a Member to Enter UDT Results (see Figure 4)

- Open the “dashboard pane.”
- Find the member either by sorting or searching.
- Click on the member’s name (it is underlined).
- This action will open that specific member’s chart.

Figure 4. Selecting a Member to Enter UDT Results



CA DHCS State Incentive Manager

[Help](#)
[Sign Out](#)

Dashboard

Analytics

Reports

Manage Users

Provider Site

Total Member Population: 12

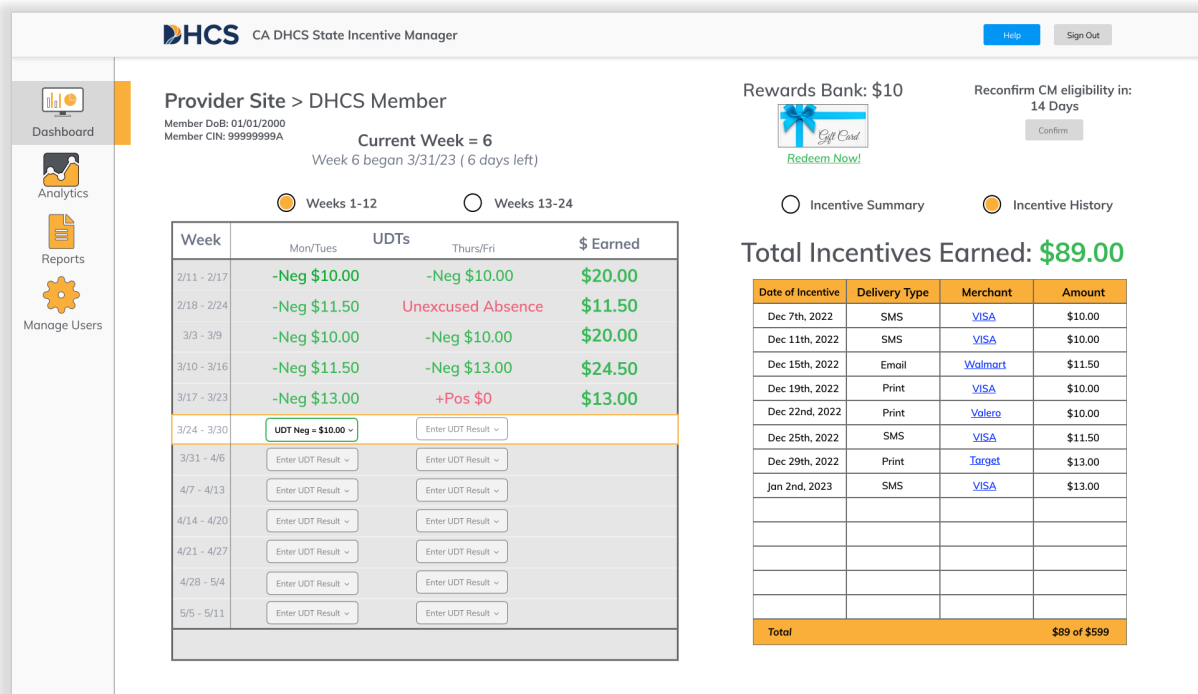
Search Member

Member	Results Entered	Week Number	Week Number	CM Coordinator	CM Start	CM End	Incentives Earned	Incentives Received	T	UDT Results		
										P+	N-	M
DHCS Member	1/2	1	6	DHCS Coordinator	12/6/22	5/23/23	\$89.00	\$79.00	10	1	8	1
DHCS Member	1/2	1	6	DHCS Coordinator	12/6/22	5/24/23	\$76.00	\$76.00	10	2	7	1
DHCS Member	0/2	5	5	DHCS Coordinator	12/11/22	5/28/23	\$40.00	\$40.00	9	3	4	3
DHCS Member	0/2	6	5	DHCS Coordinator	12/13/22	5/30/23	\$41.50	\$30.00	9	3	5	1
DHCS Member	0/2	6	4	DHCS Coordinator	12/18/22	6/4/23	\$60.00	\$60.00	8	2	6	0
DHCS Member	0/2	7	4	DHCS Coordinator	12/20/22	6/6/23	\$30.00	\$0.00	7	3	3	1
DHCS Member	1/2	2	3	DHCS Coordinator	12/28/22	6/14/23	\$41.50	\$20.00	5	1	4	0
DHCS Member	1/2	2	2	DHCS Coordinator	12/30/22	6/16/23	\$31.50	\$31.50	3	0	3	0
DHCS Member	1/2	3	1	DHCS Coordinator	1/2/23	6/19/23	\$10.00	\$0.00	1	0	1	0
DHCS Member	1/2	6	6	DHCS Coordinator	1/6/23	6/23/23	\$21.50	\$21.50	10	3	4	3
DHCS Member	1/2	5	5	DHCS Coordinator	1/7/23	6/24/23	\$0	\$0	9	1	0	8
DHCS Member	1/2	6	6	DHCS Coordinator	1/12/23	1/29/23	\$20.00	\$10.00	9	2	2	5

Member Pane (see Figure 5)

- This page contains member-specific information (from left to right).
- UDT results by visit.
- Incentives earned by week and visit.
- Next incentive amount available if UDT is negative for stimulants.
- Rewards bank.
- Reconfirmation of program eligibility (to be completed monthly; see arrow).
- Summary of incentives earned.
- Incentive history (date, delivery type, merchant, and amount).

Figure 5. Member Pane



Entering UDT Results or Absence (see Figures 6-18)

The next 13 figures walk CM Team Members through the process of entering UDT results (negative or positive), an absence, or an invalid UDT sample. As part of the UDT result entry, CM Team Members are asked to capture additional analyte results associated with stimulant-negative and stimulant-positive UDTs collected. CM Team Members are given the option in the IM Portal as part of the entry process to select which additional substances from the UDT cup panel for which each member tested positive or negative. CM Team Members are required to indicate the UDT cup type on each UDT entry; however, the system is set to automatically select your site's UDT cup.

Once you are on the member pane:

- Identify the next available session.
 - This is the “Enter UDT result” button that is not grayed out.
 - Other session buttons will not work when clicked on as they are locked.
- Click the “Enter UDT result” button.
- From the dropdown list, select the relevant option:
 - If the UDT was **negative for stimulants**, select “Stimulant-Neg (\$).” This will activate a series of screens (see Figures 7-10).
 - If the UDT was **positive for stimulants**, select “Stimulant +Pos”. This will activate a series of screens (see Figures 11-14).
 - If the member's **absence is excused**, select “excused absence” and add a note.
 - If the member's **absence is unexcused**, select “unexcused absence.”
 - If the UDT sample was **invalid**, select “Invalid UDT Sample”. This will activate a series of screens (Figures 15-19).
- When you select the appropriate option, the “submit” button will turn green.
- To submit the result, you must click the “submit” button.
- *Note: If all options are greyed out, look in the upper right and indicate that Medi-Cal eligibility has been confirmed in last 30 days.*
- *Note: UDT results can only be entered at least 48 hours after the previous input.*

Figure 6. Entering UDT Results or Absence

Provider Site > DHCS Member
 Member DoB: 01/01/2000
 Member CIN: 12345678A
 Current Week = 6
 Week 6 began 1/11/23 (6 days left)

Weeks 1-12 ☒ **Weeks 13-24** ☐

Week	Mon/Tues	UDTs	Thurs/Fri	\$ Earned
2/11 - 2/17	-Neg \$10.00	-Neg \$10.00		\$20.00
2/18 - 2/24	-Neg \$11.50	Unexcused Absence		\$11.50
3/3 - 3/9	-Neg \$10.00	-Neg \$13.00		\$23.00
3/10 - 3/16	-Neg \$13.00	-Neg \$14.50		\$27.50
3/17 - 3/23	-Neg \$14.50	+Pos \$0		\$14.50
3/24 - 3/30	UDT Neg = \$10.00		Enter UDT Result	
3/31 - 4/6	Stimulant -Neg (\$)		Enter UDT Result	
4/7 - 4/13	Stimulant +Pos		Enter UDT Result	
4/14 - 4/20	Invalid UDT Sample		Enter UDT Result	
4/21 - 4/27	Unexcused Absence		Enter UDT Result	
4/28 - 5/4	Excused Absence (Note)		Enter UDT Result	
5/5 - 5/11	Submit		Enter UDT Result	

Rewards Bank: \$10
 Reconfirm CM eligibility in: 14 Days
 Confirm

Weeks Completed: 5 of 24
 Total Incentives Earned: \$96.50
 2023 Yearly Earnings: \$96.50 of \$599.00

UDT Results

80% Abstinent
 +Pos 10%
 Missed 10%
 -Neg 80%

Figure 7. Entering a Stimulant-Negative UDT Result with Date of Birth Confirmation

Provider Site > DHCS Member
 Member DoB: 01/01/2000
 Member CIN: 99999999A
 Current Week = 6
 Week 6 began 3/31/23 (6 days left)

Weeks 1-12 ☒ **Weeks 13-24** ☐

Week	Mon/Tues	UDTs	Thurs/Fri	\$ Earned
2/11 - 2/17	-Neg \$10.00	-Neg \$10.00		\$20.00
2/18 - 2/24	-Neg \$11.50	Unexcused Absence		\$11.50
3/3 - 3/9	-Neg \$10.00	-Neg \$13.00		\$23.00
3/10 - 3/16	-Neg \$13.00	-Neg \$14.50		\$27.50
3/17 - 3/23	-Neg \$14.50	+Pos \$0		\$14.50
3/24 - 3/30	UDT Neg = \$10.00		Enter UDT Result	
3/31 - 4/6	Enter UDT Result		Enter UDT Result	
4/7 - 4/13	Enter UDT Result		Enter UDT Result	
4/14 - 4/20	Enter UDT Result		Enter UDT Result	
4/21 - 4/27	Enter UDT Result		Enter UDT Result	
4/28 - 5/4	Enter UDT Result		Enter UDT Result	
5/5 - 5/11	Enter UDT Result		Enter UDT Result	

Rewards Bank: \$10
 Reconfirm CM eligibility in: 14 Days
 Confirm

Weeks Completed: 5 of 24
 Total Incentives Earned: \$96.50
 2023 Yearly Earnings: \$96.50 of \$599.00

UDT Results

80% Abstinent
 +Pos 10%
 Missed 10%
 -Neg 80%

You have selected Stimulant - Neg (\$)
 Week 6 UDT 1
 Sites UDT Cup*
 CLIA - 12 Panel
 If you're using a different cup please choose the correct one*

First Name
 DHCS

Last Name
 Member

Client Identification Number (MediCal CIN)
 12345678A

Confirm Member's information above is correct and enter in the Member's date of birth below.
 01/01/2000

I have verified the CM Visit result entry and all of the Member's information above is correct.

Yes! **No**

Upon entering a stimulant-negative UDT, the cup your site is using is displayed (see Figure 8). The drop-down option will provide a list of all DHCS-approved UDT cups, so you can select a different cup, if needed.

Note: If your site changes UDT cups, please contact the UCLA Training and Implementation Support Team immediately to inform them of this change.

Figure 8. Entering a Stimulant-Negative UDT Result with UDT Cup Confirmation

The screenshot displays the CA DHCS State Incentive Manager interface. A modal window is open, titled "You have selected", showing the selected UDT cup: "Stimulant - Neg (\$)" for "Week 6 UDT 1". The modal also lists the "Sites UDT Cup" options, including "CLIA - 12 Panel", "CLIAWaived, INC", "Lochness Medical", and "Premier Biotech". The user has selected "01/01/2000" as the date. Below the date, there is a confirmation message: "I have verified the CM Visit result entry and all of the Member's information above is correct." with "Yes!" and "No" buttons.

The background interface shows the "Provider Site > DHCS Member" section with member details (DOB: 01/01/2000, CIN: 99999999A). The "Current Week" is "Week 6" starting on 3/31/23. A table lists UDT results for various weeks, with the selected week (3/24 - 3/30) showing a "UDT Neg = \$10.00". The right sidebar displays "Rewards Bank: \$10", "Reconfirm CM eligibility in: 14 Days", and a "Gift Card" option. The "Incentive Summary" section shows "Weeks Completed: 5 of 24" and "Total Incentives Earned: \$96.50". The "UDT Results" donut chart shows "80% Abstinent" (green), "10% Missed" (blue), and "10% +Pos" (orange).

Upon confirmation of the UDT cup and the member’s information and stimulant-specific UDT result, you can then select whether the member tested positive for any other analytes. If the member did not test positive for any other analytes, check the “No” box and click Continue. You will proceed directly to the vendor selection/incentive bank option.

If the member tested positive for at least one other analyte, check the “Yes” box and click Continue (see Figure 9).

Figure 9. Confirming Whether Member Tested Positive for Other Analytes in a Stimulant-Negative Test

The screenshot displays the CA DHCS State Incentive Manager interface. A central dialog box is open, asking the user to confirm if the member tested positive for any substance other than stimulants. The dialog box has a title "You have selected Stimulant - Neg (\$)" and a subtitle "Only Stimulant Negatives Determine the Incentive Amount". It contains a question "Did the member test positive for any substance other than stimulants?" with two radio button options: "Yes" (checked) and "No". At the bottom of the dialog are "Continue!" and "Cancel" buttons.

The background interface shows the "Provider Site > DHCS Member" section with member details: Member DoB: 01/01/2000, Member CIN: 99999999A. It also displays a table of UDT results for weeks 1-12. The table has columns for Week, Mon/Tues, and UDTs. The UDTs column shows results like "-Neg \$10.00", "-Neg \$11.50", "-Neg \$10.00", "-Neg \$13.00", "-Neg \$14.50", and "UDT Neg = \$10.00".

On the right side of the interface, there is a "Reconfirm CM eligibility in: 14 Days" section with a "Confirm" button. Below that is a "Gift Card" section with a "Redeem Now!" button. Further down is a "Weeks Completed: 5 of 24" section with a "Total Incentives Earned: \$96.50" and a "2023 Yearly Earnings: \$96.50 of \$599.00". A "UDT Results" donut chart shows 80% Abstinent, 10% Missed, and 10% +Pos.

Confirm which analyte(s) were positive. Any analytes not marked as “Positive” are recorded as “Negative.” The panel displays all the additional analytes that the UDT cup used for the test captures (Figure 10). Amphetamine, cocaine, and methamphetamine are automatically recorded as “Negative.” Upon confirmation and submission, you then proceed directly to the vendor selection/incentive bank option.

Note: Other analytes do not affect the value or delivery of the incentive. Only abstinence from amphetamine, cocaine, and methamphetamine will determine the result and incentive for the test.

Figure 10. Entering Results of Other Analytes in a Stimulant-Negative Test

The screenshot shows the CA DHCS State Incentive Manager interface. A modal window is open, titled "You have selected Stimulant - Neg (\$)", asking the user to confirm the results of the UDT Cup and determine the incentive amount. The modal includes a section for "Other Analytes" with checkboxes for various substances. The background shows a table of weekly results and a summary of incentives earned.

Provider Site > DHCS Member
 Member DoB: 01/01/2000
 Member CIN: 99999999A
 Current Week: Week 6 began 3/31/24

Weeks 1-12

Week	Mon/Tues	UDTs
2/11 - 2/17	-Neg \$10.00	-Neg
2/18 - 2/24	-Neg \$11.50	Unex
3/3 - 3/9	-Neg \$10.00	-Neg
3/10 - 3/16	-Neg \$13.00	-Neg
3/17 - 3/23	-Neg \$14.50	-Neg
3/24 - 3/30	UDT Neg = \$10.00	Enter
3/31 - 4/6	Enter UDT Result	Enter
4/7 - 4/13	Enter UDT Result	Enter
4/14 - 4/20	Enter UDT Result	Enter
4/21 - 4/27	Enter UDT Result	Enter
4/28 - 5/4	Enter UDT Result	Enter
5/5 - 5/11	Enter UDT Result	Enter

Other Analytes

Bar (Barbituates)	BZO (Benzodiazepines)	MDMA (Ecstasy)
☐ +Pos	☐ +Pos	☐ +Pos
MTD (Methadone)	OPI/MOR (Opiates)	OXY (Oxycodone)
☐ +Pos	☐ +Pos	☐ +Pos
PCP (Phencyclidine)	TCA (Antidepressant)	THC (Cannabis)
☐ +Pos	☐ +Pos	☒ +Pos

I have verified the CM Visit result entry and any associated analytes are correct from the UDT. ☒

Submit **Cancel**

Summary:
 Incentive Bank: \$10
 Reconfirm CM eligibility in: 14 Days
 Incentive Summary | Incentive History
 Weeks Completed: 5 of 24
 Total Incentives Earned: \$96.50
 2023 Yearly Earnings: \$96.50 of \$599.00

UDT Results

- Missed 10%
- +Pos 10%
- Neg 80%
- 80% Abstinent

Figure 11. Entering a Stimulant-Positive UDT Result with Date of Birth Confirmation

The screenshot displays the CA DHCS State Incentive Manager interface. A modal window is open for entering a UDT result. The background shows a dashboard with a sidebar (Dashboard, Analytics, Reports, Manage Users), a header (HCS CA DHCS State Incentive Manager), and a main content area with a table of UDT results and a summary section.

Modal Window Content:

- You have selected:** Stimulant + Pos
- Week 6 UDT 1**
- Sites UDT Cup***: Lochness Medical 18 Panel
- First Name**: DHCS
- Last Name**: Member
- Client Identification Number (Medical CIN)**: 12345678A
- Confirm Member's information above is correct and enter in the Member's date of birth below.**
- Date of Birth**: 01/01/2000
- I have verified the CM Visit result entry and all of the Member's information above is correct.**
- Buttons**: Yes! (green), No (red)

Background Interface Details:

- Header**: HCS CA DHCS State Incentive Manager, Help, Sign Out
- Member Info**: Member DoB: 01/01/2000, Member CIN: 99999999A
- Current Week**: Week 6 began 3/31/23
- Rewards Bank**: \$10
- Reconfirm CM eligibility in**: 14 Days
- Weeks Completed**: 5 of 24
- Total Incentives Earned**: \$96.50
- 2023 Yearly Earnings**: \$96.50 of \$599.00
- UDT Results Donut Chart**:
 - 80% Abstinent (-Neg)
 - 10% Missed
 - 10% +Pos

Upon entering a stimulant-positive UDT, the cup your site is using is displayed (see Figure 12). The drop-down option will provide a list of all DHCS-approved UDT cups, so you can select a different cup, if needed.

Note: If your site changes UDT cups, please contact the UCLA Training and Implementation Support Team immediately to inform them of this change.

Figure 12. Entering a Stimulant-Positive UDT Result with UDT Cup Confirmation

The screenshot displays the CA DHCS State Incentive Manager interface. A modal window is open, titled "You have selected Stimulant + Pos Week 6 UDT 1". The modal lists "Sites UDT Cup*" with a dropdown menu showing "CLIA - 12 Panel". Below this, a list of cups is shown, including "CLIAWaived, INC" (13 Panel IDTC Cup II with Adulterants), "CLIAWaived, INC" (14 Panel IDTC II), "CLIAWaived, INC" (14 Panel Cup with Fentanyl), "CLIAWaived, INC" (13 Panel Cup with Fentanyl), "Lochness Medical" (18 Panel Multi-Drug One Step Cup), "Premier Biotech" (12 Panel Premier Bio-Cup), and "Premier Biotech" (14 Panel Premier Bio-Cup with Fentanyl). A date field shows "01/01/2000". A confirmation message states: "I have verified the CM Visit result entry and all of the Member's information above is correct." with "Yes!" and "No" buttons.

The background interface shows the "Provider Site > DHCS Member" section with member details: Member DoB: 01/01/2000, Member CIN: 99999999A. The "Current Week" is "Week 6 began 3/31/23". A table lists UDT results for weeks 1-12. The table has columns for Week, Mon/Tues, UDTs, and Thu. The table shows results for weeks 2/11-2/17, 2/18-2/24, 3/3-3/9, 3/10-3/16, 3/17-3/23, 3/24-3/30, 3/31-4/6, 4/7-4/13, 4/14-4/20, 4/21-4/27, 4/28-5/4, and 5/5-5/11. The results for week 3/24-3/30 are highlighted: "UDT Neg = \$10.00" and "Enter UDT Result".

The right side of the interface shows the "Rewards Bank: \$10" and "Reconfirm CM eligibility in: 14 Days". A "Gift Card" icon is visible with a "Redeem Now!" button. Below this, the "Incentive Summary" and "Incentive History" tabs are shown. The "Weeks Completed: 5 of 24" and "Total Incentives Earned: \$96.50" are displayed. The "2023 Yearly Earnings: \$96.50 of \$599.00" is also shown. A "UDT Results" donut chart is displayed, showing "80% Abstinent", "10% Missed", and "10% +Pos".

Upon confirmation of the UDT cup and the member's information/result, you are asked to select any of the stimulants (amphetamine, cocaine, methamphetamine) for which the member tested positive. Upon confirmation of the stimulant-specific test results, you can then select whether the member tested positive for any other analytes. If the member did not test positive for any other analytes, check the "No" box and click Continue. You then proceed directly to the vendor selection/incentive bank option.

If the member tested positive for at least one other analyte, check the "Yes" box and click Continue (see Figure 13).

Figure 13. Confirming Whether Member Tested Positive for Other Analytes in a Stimulant-Positive Test

The screenshot displays the DHCS State Incentive Manager interface. A modal window is open, titled "You have selected Stimulant + Positive". The modal prompts the user to "Only Stimulant Negatives Determine the Incentive Amount" and asks to "Please confirm the results of the additional analytes from the UDT Cup that was used:". Below this, there are checkboxes for "AMP (Amphetamine)", "COC (Cocaine)", and "METH (Methamphetamine)", each with a "+Pos" option. The "AMP +Pos" checkbox is checked. The modal also asks, "Did the member test positive for any substance other than stimulants?" with "Yes" and "No" options. The "Yes" option is checked. At the bottom of the modal are "Continue!" and "Cancel" buttons. In the background, the main interface shows a table of UDT results for weeks 1-12, with the current week (Week 6) highlighted. The table shows results for AMP, COC, and METH, with "Neg" (Negative) results for all three. The total incentives earned are \$96.50, and the 2023 Yearly Earnings are \$96.50 of \$599.00. A donut chart shows UDT Results: 80% Abstinent, 10% Missed, and 10% +Pos.

Week	Mon/Tues	UDTs
2/11 - 2/17	-Neg	\$10.00
2/18 - 2/24	-Neg	\$11.50
3/3 - 3/9	-Neg	\$10.00
3/10 - 3/16	-Neg	\$13.00
3/17 - 3/23	-Neg	\$14.50
3/24 - 3/30	UDT Neg = \$10.00	
3/31 - 4/6	Enter UDT Result	
4/7 - 4/13	Enter UDT Result	
4/14 - 4/20	Enter UDT Result	
4/21 - 4/27	Enter UDT Result	
4/28 - 5/4	Enter UDT Result	
5/5 - 5/11	Enter UDT Result	

If the UDT showed positive for any other analyte, you check “Yes” and confirm the analyte(s) that were positive. Any analyte not marked as “Positive” is recorded as “Negative.” The panel will display all the additional analytes that the UDT cup used for the test captures (Figure 14). Upon confirmation and submission, the result are logged and you may proceed (incentives are not awarded for stimulant-positive UDTs).

Note: Other analytes do not affect the value or delivery of the incentive. Only abstinence from amphetamine, cocaine, and methamphetamine will determine the result and incentive for the test.

Figure 14. Entering Results of Other Analytes in a Stimulant-Positive Test

The screenshot shows the HCS CA DHCS State Incentive Manager interface. A modal window is open for entering results of other analytes in a stimulant-positive test. The modal title is "You have selected Stimulant + Positive". Below the title, it says "Only Stimulant Negatives Determine the Incentive Amount" and "Please confirm the results of the additional analytes from the UDT Cup that was used:". The modal contains a table of analytes with checkboxes for "Pos" or "Neg".

STIMULANTS		
AMP (Amphetamine)	COC (Cocaine)	METH (Methamphetamine)
☒ +Pos	☐ +Pos	☐ +Pos

Other Analytes		
Bar (Barbiturates)	BZO (Benzodiazepines)	MDMA (Ecstasy)
☐ +Pos	☐ +Pos	☐ +Pos
MTD (Methadone)	OP/MOR (Opiates)	OXY (Oxycodone)
☒ +Pos	☐ +Pos	☐ +Pos
PCP (Phencyclidine)	TCA (Antidepressant)	THC (Marijuana)
☐ +Pos	☐ +Pos	☒ +Pos

At the bottom of the modal, there is a statement: "I have verified the CM Visit result entry and any associated analytes are correct from the UDT." with a green checkmark icon. Below this are "Submit" and "Cancel" buttons.

The background interface shows a table of UDT results for weeks 1-12. The table has columns for Week, Mon/Tues, and UDTs. The UDTs column shows results like "-Neg \$10.00", "-Neg \$11.50", "-Neg \$10.00", "-Neg \$13.00", "-Neg \$14.50", and "UDT Neg = \$10.00".

On the right side of the interface, there is a summary section showing "Weeks Completed: 5 of 24", "Total Incentives Earned: \$96.50", and "2023 Yearly Earnings: \$96.50 of \$599.00". Below this is a donut chart titled "UDT Results" showing "80% Abstinent", "10% Missed", and "10% +Pos".

Managing Incentive Rewards

How are rewards calculated?

- Rewards are earned after a stimulant-negative UDT is entered into the system.
- Rewards are calculated by the system using a well-defined schedule, which is:
 - **For weeks 1-12 (2 visits per week)**, the reward amount starts at \$10 and increases by \$1.50 for each two consecutive stimulant-negative UDTs. Rewards “reset” (as described above) to \$10 upon the next stimulant-negative UDT following a positive UDT or unexcused absence. Upon the next consecutive stimulant-negative UDT, the reward amount “recovers” to the place in the schedule where

the member would have been if there had been no stimulant-positive UDT or unexcused absence.

- **For weeks 13-24 (1 visit per week)**, the reward amounts do not change. Each stimulant-negative UDT in weeks 13-18 receives a \$15 reward and each stimulant-negative UDT in weeks 19-23 receives a \$10 reward. A stimulant-negative UDT in week 24 receives \$21.

How are rewards delivered?

- Rewards are offered as vendor-specific gift cards delivered in the form of an e-mail, text link, printed voucher, or other mechanism, as approved by DHCS.
- Rewards can be redeemed immediately or “banked” to aggregate earnings to larger amounts
- The CM Team Member should inform members when enrolling them into the IM Portal that they are asking for the member’s mobile number and email address to deliver rewards in the manner they choose.
- If shared via text or email, the reward can be added to an Apple or Google wallet.
- Gift cards are only available for vendors who prohibit purchases of alcohol, tobacco, firearms, lottery tickets, and cannabis.

Figure 15. Entering Results of an Invalid UDT Sample

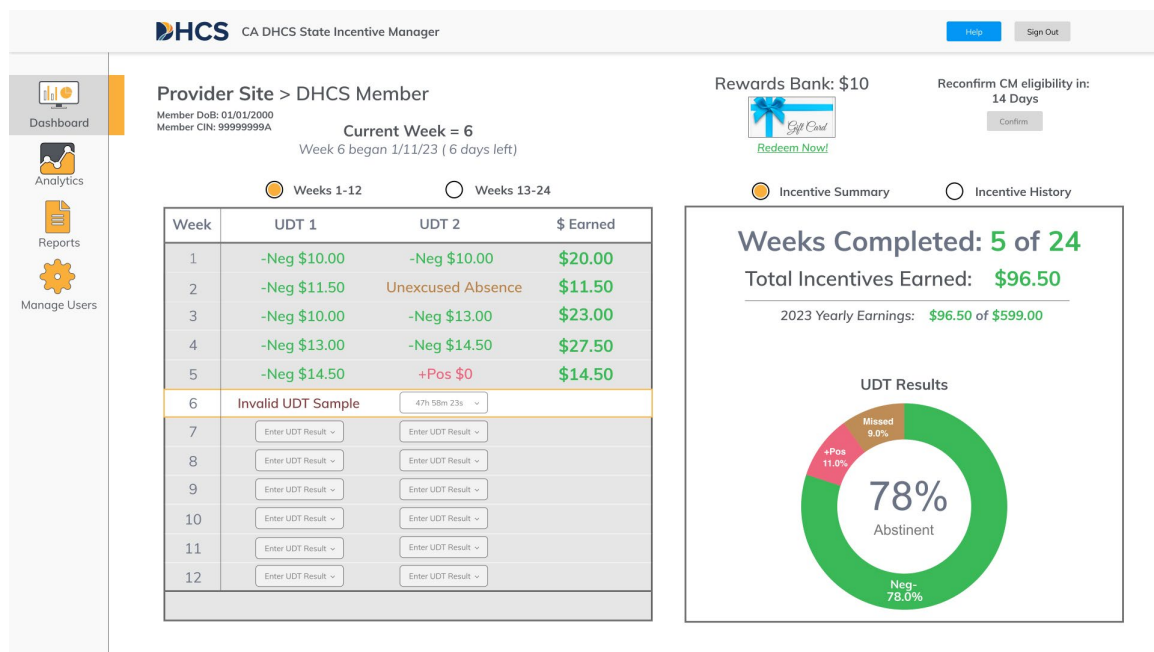


Figure 16. Entering the Details for an Invalid UDT Sample

CA DHCS State Incentive Manager

Provider Site > DHCS Member
 Member DoB: 01/01/2000
 Member CIN: 12345678A

Current Week: Week 6 began 1/11/2023

Weeks 1-12

Week	Mon/Tues	UDTs
2/11 - 2/17	-Neg \$10.00	-Neg \$10.00
2/18 - 2/24	-Neg \$11.50	Unexcused Absence
3/3 - 3/9	-Neg \$10.00	-Neg \$10.00
3/10 - 3/16	-Neg \$13.00	-Neg \$13.00
3/17 - 3/23	-Neg \$14.50	-Neg \$14.50
3/24 - 3/30	UDT Neg = \$10.00	Enter UDT Result
3/31 - 4/6	Stimulant -Neg (\$)	Enter UDT Result
4/7 - 4/13	Stimulant +Pos	Enter UDT Result
4/14 - 4/20	Invalid UDT Sample	Enter UDT Result
4/21 - 4/27	Unexcused Absence	Enter UDT Result
4/28 - 5/4	Excused Absence (Note)	Enter UDT Result
5/5 - 5/11	Submit	Enter UDT Result

You have selected
Invalid UDT Sample

You have selected "Invalid UDT Sample" for the Result of the visit.

What was the reason(s) for invalid sample?

Temperature ☐
 Creatinine ☐
 Specific Gravity ☐
 pH ☐
 Other (Please explain) ☒

UDT Sample provided did not meet the required temperature reading on the adulteration measures, and appeared to be physically damaged.

Submit **Back**

You have indicated this sample is invalid. Invalid samples do not Award incentives and incur a reset.

Weeks Completed: 5 of 24
Total Incentives Earned: \$96.50
 2023 Yearly Earnings: \$96.50 of \$599.00

UDT Results

80% Abstinent
 -Neg 80%
 +Pos 10%
 Missed 10%

Figure 17. Entering the Details for an Invalid UDT Sample with Note for "Other"

CA DHCS State Incentive Manager

Provider Site > DHCS Member
 Member DoB: 01/01/2000
 Member CIN: 12345678A

Current Week: Week 6 began 1/11/2023

Weeks 1-12

Week	Mon/Tues	UDTs
2/11 - 2/17	-Neg \$10.00	-Neg \$10.00
2/18 - 2/24	-Neg \$11.50	Unexcused Absence
3/3 - 3/9	-Neg \$10.00	-Neg \$10.00
3/10 - 3/16	-Neg \$13.00	-Neg \$13.00
3/17 - 3/23	-Neg \$14.50	-Neg \$14.50
3/24 - 3/30	UDT Neg = \$10.00	Enter UDT Result
3/31 - 4/6	Stimulant -Neg (\$)	Enter UDT Result
4/7 - 4/13	Stimulant +Pos	Enter UDT Result
4/14 - 4/20	Invalid UDT Sample	Enter UDT Result
4/21 - 4/27	Unexcused Absence	Enter UDT Result
4/28 - 5/4	Excused Absence (Note)	Enter UDT Result
5/5 - 5/11	Submit	Enter UDT Result

You have selected
Invalid UDT Sample

You have selected "Invalid Sample" for the Result of the UDT.

What was the reason(s) for invalid sample?

Temperature ☒
 Creatinine ☐
 Specific Gravity ☐
 pH ☐
 Other (Please explain) ☒

UDT Sample provided did not meet the required temperature reading on the adulteration measures, and appeared to be physically damaged.

Submit **Back**

You have indicated this sample is invalid. Invalid samples do not Award incentives and incur a reset.

Weeks Completed: 5 of 24
Total Incentives Earned: \$96.50
 2023 Yearly Earnings: \$96.50 of \$599.00

UDT Results

80% Abstinent
 -Neg 80%
 +Pos 10%
 Missed 10%

Figure 18. Submitting an Invalid UDT Sample

The screenshot displays the CA DHCS State Incentive Manager interface. A modal window is open, titled "You have selected Invalid UDT Sample Week 6 UDT 1". The modal contains the following fields and options:

- Sites UDT Cup***: A dropdown menu showing "CLIA - 12 Panel".
- First Name**: A text input field containing "DHCS".
- Last Name**: A text input field containing "Member".
- Client Identification Number (MediCal CIN)**: A text input field containing "12345678A".
- Confirm Member's information above is correct and enter in the Member's date of birth below.**: A text input field containing "01/01/2000" with a calendar icon.
- I have verified the CM Visit result entry and all of the Member's information above is correct.**: A text input field with a yellow smiley face icon.
- Buttons**: "Yes!" (green) and "No" (red).

The background interface shows the "Provider Site > DHCS Member" section with a table of UDT results for Week 6. The table has columns for Week, Mon/Tues, and UDTs. The UDTs column shows results for Week 6, including "Invalid UDT Sample".

Week	Mon/Tues	UDTs
2/11 - 2/17	-Neg \$10.00	-N
2/18 - 2/24	-Neg \$11.50	Unex
3/3 - 3/9	-Neg \$10.00	-N
3/10 - 3/16	-Neg \$13.00	-N
3/17 - 3/23	-Neg \$14.50	-N
3/24 - 3/30	UDT Neg = \$10.00	Enter
3/31 - 4/6	Stimulant -Neg (\$)	Enter
4/7 - 4/13	Stimulant +Pos	Enter
4/14 - 4/20	Invalid UDT Sample	Enter
4/21 - 4/27	Unexcused Absence	Enter
4/28 - 5/4	Excused Absence (Note)	Enter
5/5 - 5/11	Submit	Enter

On the right side of the interface, there is a "Weeks Completed: 5 of 24" section with a "Total Incentives Earned: \$96.50" and a "2023 Yearly Earnings: \$96.50 of \$599.00" section. Below this is a "UDT Results" donut chart showing "80% Abstinent" (green), "10% Missed" (orange), and "10% +Pos" (red).

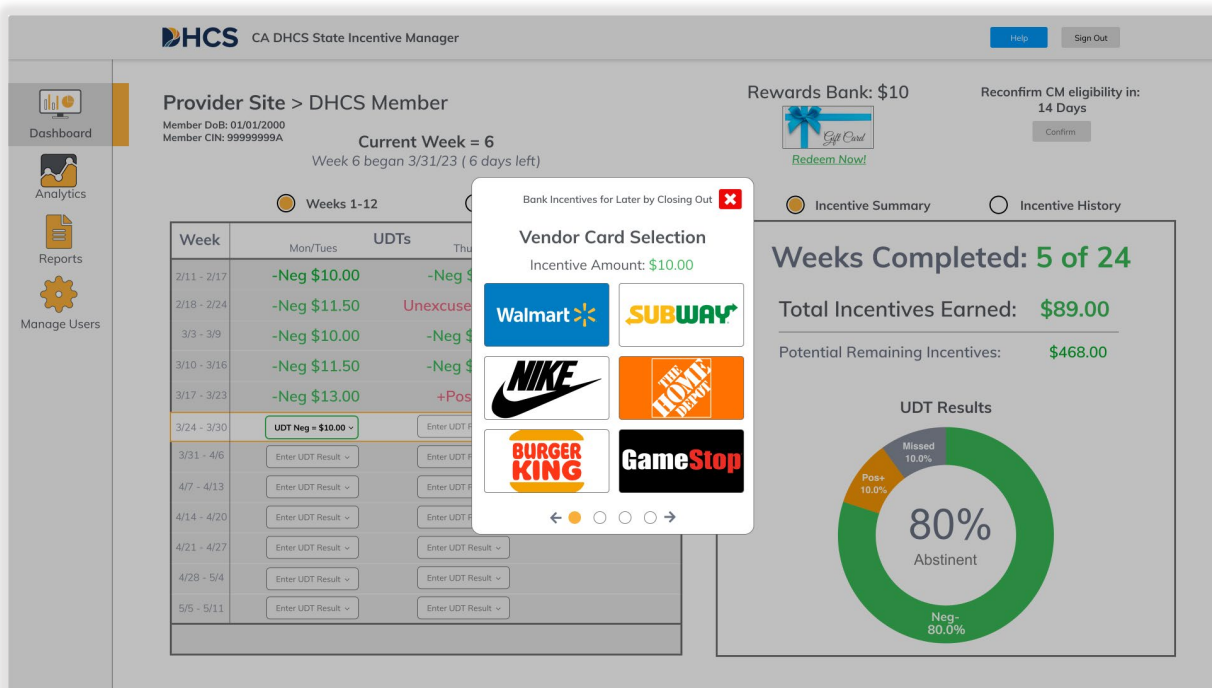
Sample Reward Schedule with all Stimulant-Negative UDTs

Week	Reward for Stimulant-Free Test
Week 1	$\$10 + \$10 = \$20$
Week 2	$\$11.50 + \$11.50 = \$23$
Week 3	$\$13 + \$13 = \$26$
Week 4	$\$14.50 + \$14.50 = \$29$
Week 5	$\$16 + \$16 = \$32$
Week 6	$\$17.50 + \$17.50 = \$35$
Week 7	$\$19 + \$19 = \$38$
Week 8	$\$20.50 + \$20.50 = \$41$
Week 9	$\$22 + \$22 = \$44$
Week 10	$\$23.50 + \$23.50 = \$47$
Week 11	$\$25 + \$25 = \$50$
Week 12	$\$26.50 + \$26.50 = \$53$
Weeks 13-18	\$15 per week/test
Weeks 19-23	\$10 per week/test
Week 24	\$21 per week/test
Total	\$599

Reward Type Selection (see Figure 19)

- Once a negative UDT is entered, the system offers the reward type selection.
- The CM Team Member works with the member to select the preferred vendor.
- There are two options:
 - Gift card for a specific vendor.
 - Adding funds to a virtual “bank.”
- Click the preferred option and proceed to “delivery type” selection.

Figure 19. Reward Type Selection



A full list of gift card vendors is available in the IM Portal.

Generating a Gift Card (see Figure 20)

- To generate a gift card, the CM Team Member must confirm the member's date of birth.

Figure 20. Generating Gift Card with Date of Birth Confirmation

HCS CA DHCS State Incentive Manager

Provider Site > DHCS Member
Member DoB: 01/01/2000
Member CIN: 99999999A

Current Week
Week 6 began 1/11/23

Weeks 1-12

Week	UDT 1	UDT 2
1	-Neg \$10.00	-Neg
2	-Neg \$11.50	Unexcus
3	-Neg \$10.00	-Neg
4	-Neg \$11.50	-Neg
5	-Neg \$13.00	+Po
6	Next Neg = \$10.00	Enter UDT
7	Enter UDT Result	Enter UDT
8	Enter UDT Result	Enter UDT
9	Enter UDT Result	Enter UDT
10	Enter UDT Result	Enter UDT
11	Enter UDT Result	Enter UDT
12	Enter UDT Result	Enter UDT Result

Incentive Selected!

Walmart

You have chosen a \$10.00 Walmart Gift Card

*This card may not be used to purchase alcohol, tobacco, firearms.

First Name
DHCS

Last Name
Member

Client Identification Number (MediCal CIN)
12345678A

IMPORTANT!
Confirm Member's information above is correct and enter in the Member's date of birth below.

Member DoB: 01/01/2000

I have verified all of the above incentive selection and Member information is correct.

[Continue](#) [Back](#)

Rewards Bank: \$10
[Redeem Now!](#)

Reconfirm CM eligibility in: 14 Days
[Confirm](#)

Incentive Summary ☒ Incentive History ☐

Weeks Completed: 5 of 24

Total Incentives Earned: **\$89.00**

Potential Remaining Incentives: **\$468.00**

UDT Results

80% Abstinent

Missed 10.0%
Pos+ 10.0%
Neg- 80.0%

Reward Delivery Type Selection (see Figure 21)

- Once a reward type is selected, the system offers the delivery type option.
- For vendor-specific gift cards, the member can select text, email, or a printed voucher.
- *Note: For “banking” of rewards, this screen will not appear.*
- For texts, members are required to input their phone number.
- For emails, members are required to input their email address.
- For printed gift cards, once they are generated and printed, they *cannot* be reprinted, so the member must keep track of them.
- Text and email gift cards can be added to Apple or Google wallets.

Figure 21. Reward Delivery Type Selection

The screenshot displays the DHCS State Incentive Manager interface. A modal window titled "Choose Delivery Method" is centered on the screen, overlaid on a table of weekly incentives. The modal contains the Walmart logo and asks, "How would you like to receive your \$10.00 Walmart gift card?". It lists three options: "Email: Member@email.com" (selected with a radio button), "Text: (555) 555-5555", and "Print Gift Card". A green "Confirm" button is at the bottom of the modal.

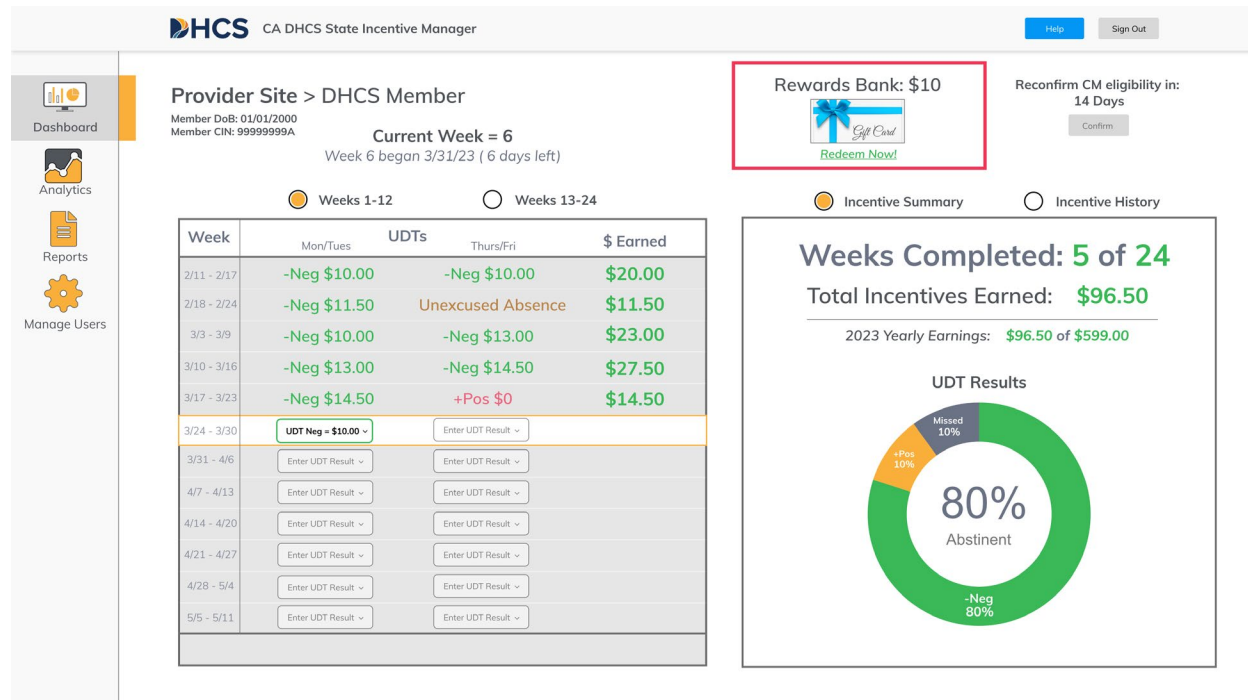
The background interface shows a dashboard for a "Provider Site > DHCS Member". It includes a table of weekly incentives with columns for Week, UDT 1, and UDT 2. The table shows weeks 1 through 12, with week 6 highlighted. To the right of the table, there is a summary section titled "Weeks Completed: 5 of 24" and "Total Incentives Earned: \$99.00". Below this is a "UDT Results" donut chart showing "82% Abstinent" (green), "9.0% Missed" (grey), and "9.0% Pass" (orange).

Week	UDT 1	UDT 2
1	-Neg \$10.00	-Neg \$10.00
2	-Neg \$11.50	Unexcuse
3	-Neg \$10.00	-Neg \$10.00
4	-Neg \$11.50	-Neg \$11.50
5	-Neg \$13.00	+Pos
6	-Neg \$10.00	7th Sdk
7	Enter UDT Result	Enter UDT Result
8	Enter UDT Result	Enter UDT Result
9	Enter UDT Result	Enter UDT Result
10	Enter UDT Result	Enter UDT Result
11	Enter UDT Result	Enter UDT Result
12	Enter UDT Result	Enter UDT Result

Rewards Bank (see Figure 22)

- Once a reward amount has been generated, if the member chooses not to redeem it for an eGift card, unused dollars are stored in the Rewards Bank.
- The Rewards Bank allow the member to “save up” for higher denominations of eGift cards to redeem in the future.
- *Note: Since the member does not receive an immediate reward, the CM Team Member should demonstrate interest and enthusiasm; for instance, by asking the member what they are saving up for and praising them for it.*

Figure 22. Rewards Bank



Rewards history for a specific member can be seen in two ways:

Figure 23. Rewards History

- The CM Team Member should remind members that rewards cannot be used for purchasing alcohol, tobacco, gambling, cannabis, or firearms.
- Vendor-specific gift cards are either for vendors who do not offer these items or have inherent restrictions on purchasing prohibited items.
- The CM Team Member should also remind members that rewards cannot be disbursed again once they have been delivered, so they should make sure to keep track of them.

Certificate of Completion (see Figure 24)

When a member completes the Recovery Incentives Program, CM Team Members can print out a Certificate of Completion to share with the member. The certificate is personalized to include the member's first and last name, the CM Team Member's first and last name, and the date of completion.

Figure 24. Certificate of Completion

The screenshot displays the CA DHCS State Incentive Manager interface. A modal window titled "Certificate of Completion" is centered on the screen. The modal contains the following text:

Certificate of Completion

CA DHCS Recovery Incentives Program

Congratulations to:

DHCS MEMBER

For Completing the DHCS Recovery Incentives Program!

CM Coordinator/Supervisor: **DHCS COORDINATOR**

Date of Completion: **July 25th, 2024**

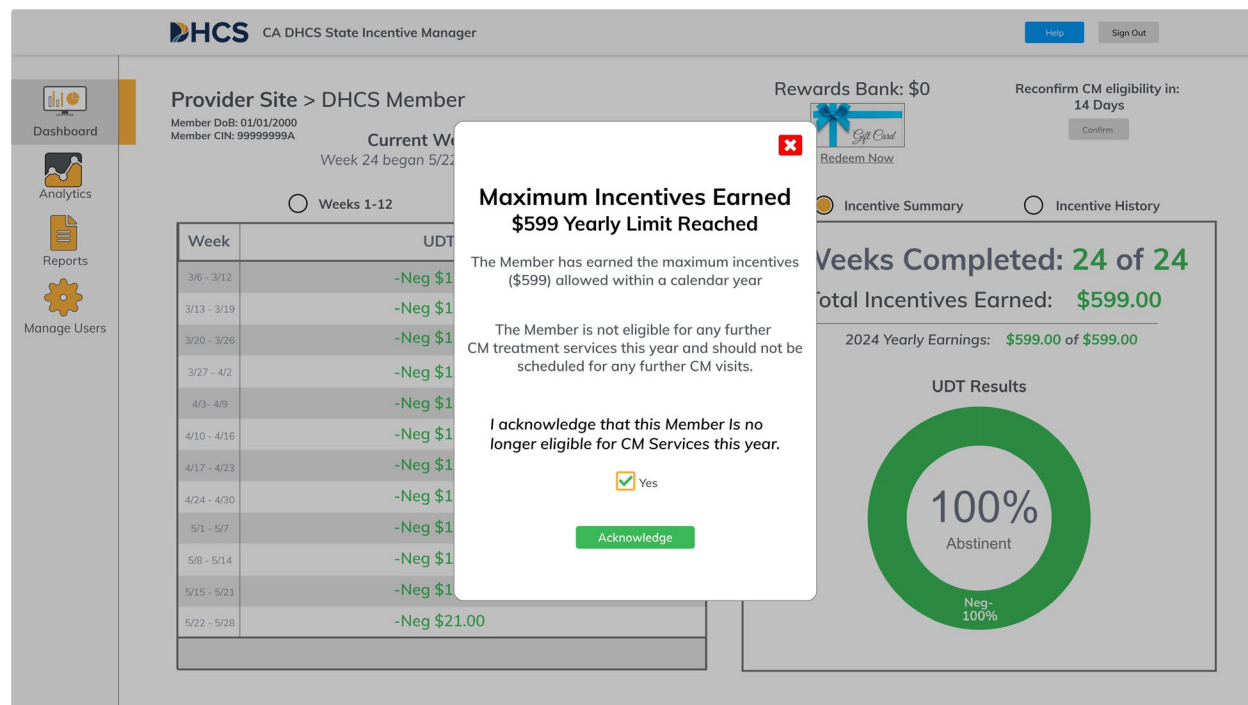
The modal also features the DHCS logo and a trophy icon. In the background, the interface shows a "Provider Site > DHCS Member" section with a table of weekly incentives. The table has columns for "Week" and "Incentive". The "Week" column lists dates from 3/6 to 5/28. The "Incentive" column shows values: -Neg \$10.00, -Neg \$10.00, and -Neg \$21.00. To the right of the table, there is a "Rewards Bank: \$0" section and a "Reconfirm CM eligibility in: 14 Days" section. Below the table, there is a "Launch Certificate" button. On the far right, there is a "Completed: 24 of 24" section with a green progress bar and a "100% Abstinent" section with a green circular progress bar.

Week	Incentive
3/6 - 3/12	-Neg \$10.00
3/13 - 3/19	-Neg \$10.00
3/20 - 3/26	-Neg \$21.00
3/27 - 4/2	
4/3 - 4/9	
4/10 - 4/16	
4/17 - 4/23	
4/24 - 4/30	
5/1 - 5/7	
5/8 - 5/14	
5/15 - 5/21	
5/22 - 5/28	

Maximum Incentives Earned – \$599 Yearly Limit Reached (see Figure 25)

If a member has earned the maximum incentives (\$599) allowed within a calendar year, they are no longer eligible for any further CM treatment services for the remainder of the calendar year and should not be scheduled for any further CM visits. The CM Team Member checks the “Yes” box to acknowledge that the member is no longer eligible for CM services this year.

Figure 25. Maximum Incentives Earned – \$599 Yearly Limit Reached

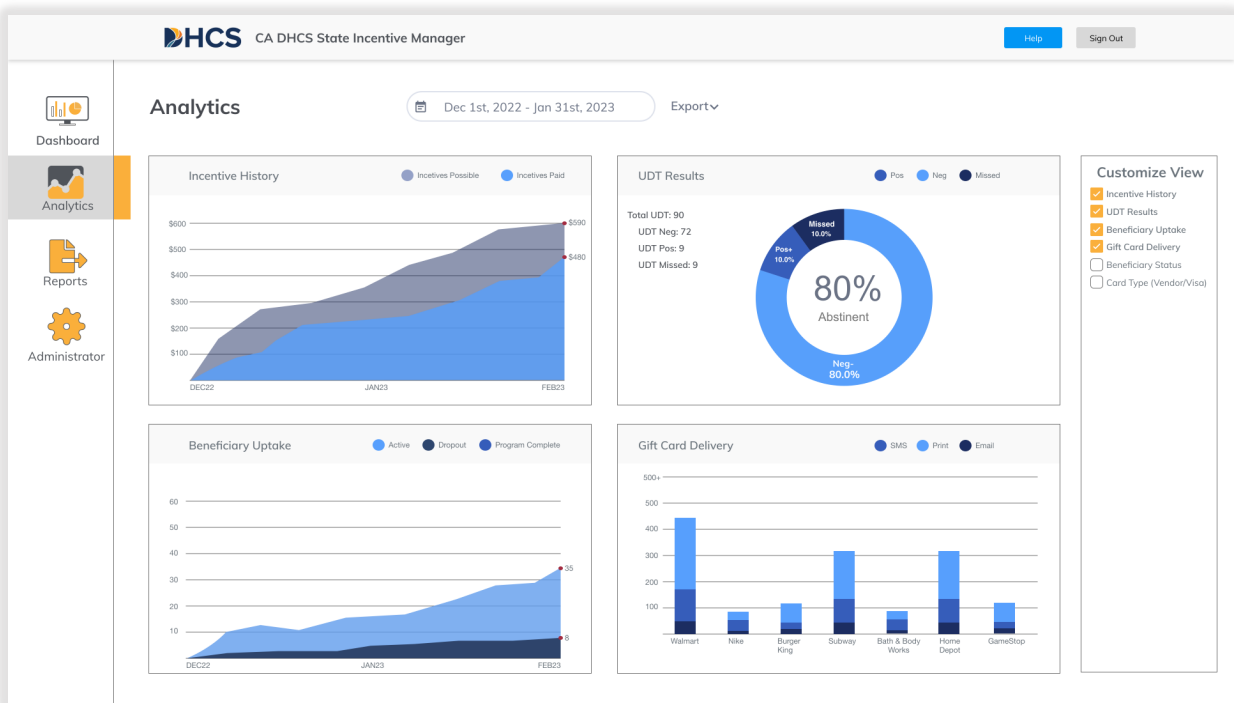


CM Coordinator Analytics (see Figure 26)

CM Team Members can run analyses and reports. Available reports will vary depending on their level of permissions. To run a report, click on the “analytics” button on the left side of the portal pane.

- The analytics pane is highly customizable by the user using the “customize view” pane on the right side.
- Data can be downloaded as charts (i.e., a pdf) or raw data (i.e., csv or json).
- Data can be selected based on a specific date range.

Figure 26. Analytics Pane

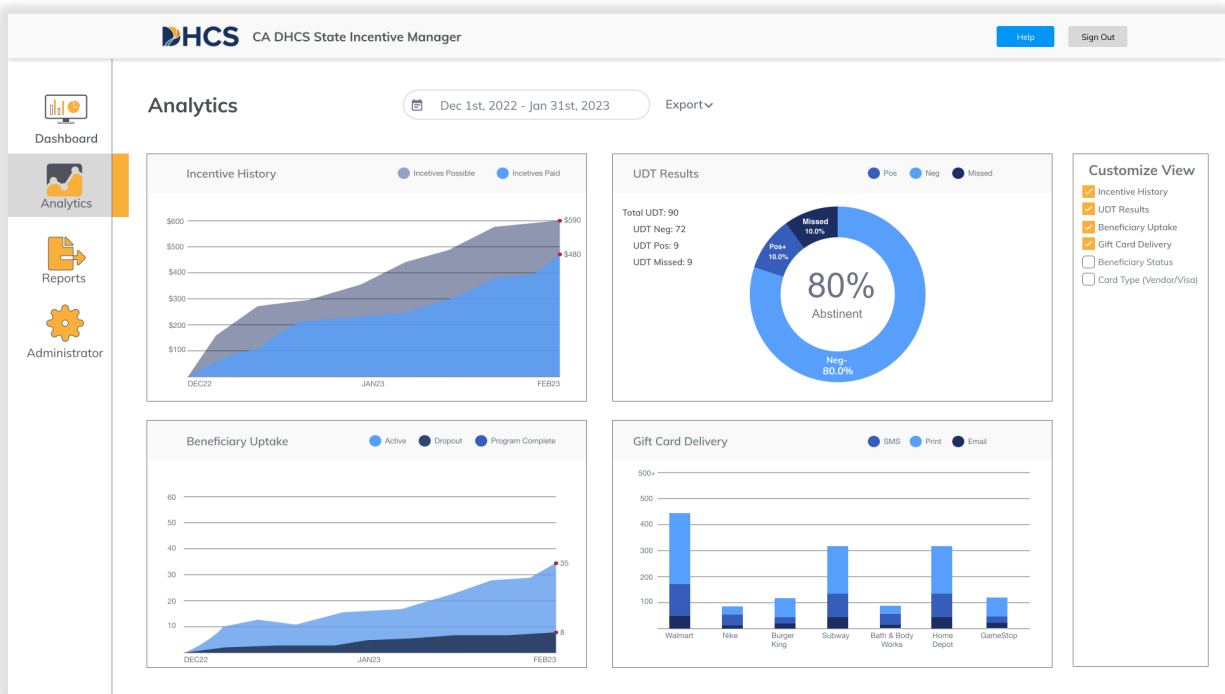


Analytics Customization (see Figure 27)

Analytics panes can be customized based on several factors.

- Selections by county will filter the data available in the charts on the left.
- Other selections will add new charts to the left side (shown in Figure 23 as reward history, UDT results, member uptake, and reward delivery type).

Figure 27. Analytics Customization

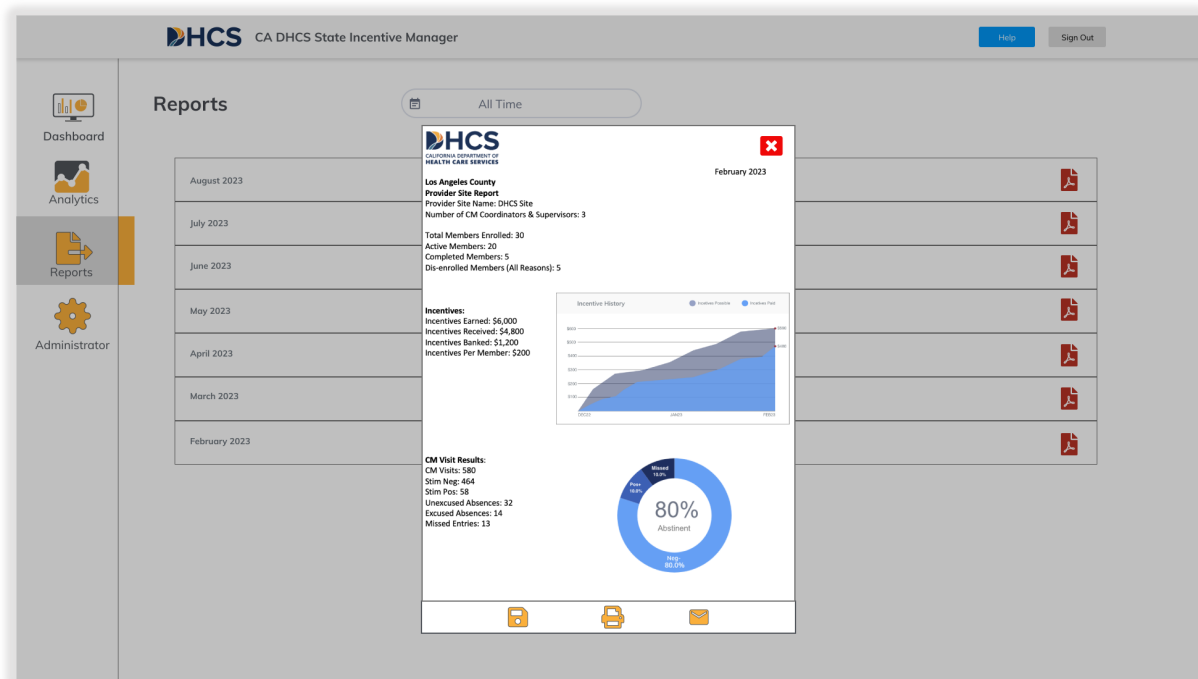


Analytics Report Pane (see Figure 28)

Reports are compiled automatically by the system.

- Reports are available monthly.
- Reports are available at all levels for your role, i.e., CM Coordinator, CM Supervisor, County administrator, etc. and can be selected via a dropdown menu.
- Reports can be selected for specific sites or counties.
- To select a report, click the  icon.
- The reports do not contain any member-level information (i.e., PHI).
- Reports may be downloaded, printed, or emailed.
- Once a specific report is selected, the report preview will pop-up.

Figure 28. Analytics Report Pane



Portal Help Center (see Figure 29)

The help button is on every portal pane/screen, in the upper right-hand side.

Figure 29. Portal Help Button





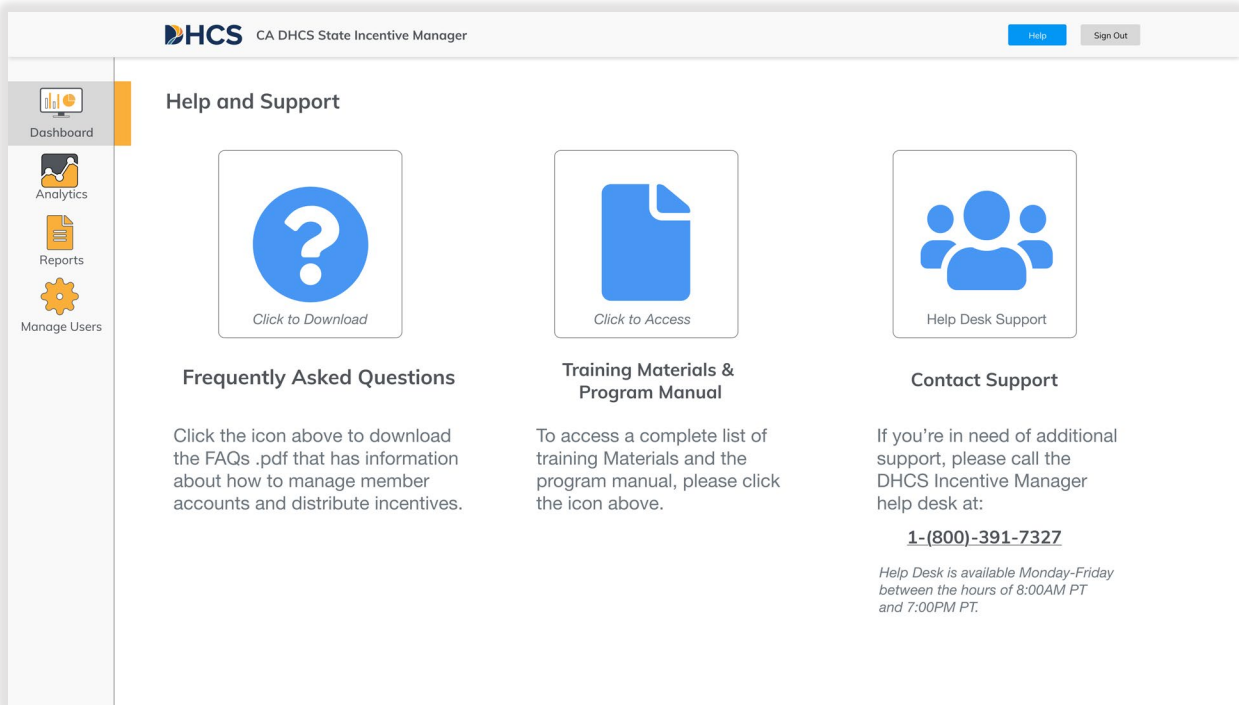
CA DHCS State Incentive Manager

[Help](#)
[Sign Out](#)

Three types of support are available in the IM Portal (see Figure 30):

1. Frequently asked questions documents.
2. Training videos.
3. Call center available by phone.

Figure 30. Portal Help Center



Chapter 6. Other Implementation Issues

Identifying Eligible Members

When beginning a new CM program, it is best to focus on addressing one specific behavior, and therefore not everyone at your treatment site will be eligible. When implementing the Recovery Incentives Program, it is important to follow established criteria to identify eligible members. These criteria can be found in the [BHIN 24-031](#) (see Appendix D) and should be shared with your site's intake staff and/or any treatment providers who may be able to make referrals.

The Recovery Incentives Program developed a series of outreach and communication resources, building on current efforts, for treatment providers to educate and inform Medi-Cal members about CM and its availability for individuals living with StimUD. The Recovery Incentives Program Provider Outreach and Communications Toolkit (see Appendix C) includes sample messaging for providers to use to conduct outreach with members who may be eligible for CM. The guidelines are reflective of the diverse racial/ethnic backgrounds of members who may be eligible for the CM program. A flyer and business cards (of various sizes) are available, as well, in Appendix C.

Program Roles, Supervision, Fidelity, and Evaluation

Once you have set up your CM Program using the instructions provided in this Manual, DHCS policy documents ([BHIN 24-031](#), Appendix D), and other materials generated by UCLA, you can take the following steps to select and train staff, implement the Program, and set up systems for ongoing supervision and monitoring.

Two reasons exist for closely monitoring your CM Program. The first one is, just like all other evidence-based treatments, fidelity to the treatment model is essential to making sure your efforts result in good outcomes. CM is not likely to work if you do not implement the model in a way that is consistent with how it was tested in research studies. Second, you must make sure your Program consistently meets requirements for delivery and documentation of CM services. Unlike other evidence-based interventions, if you don't implement CM correctly, you could be accused of Medicaid fraud.

While we are not lawyers, we have worked closely with leading CM experts, the federal government, and DHCS to develop a research-based protocol and model that is consistent with current requirements. We strongly encourage you to monitor your CM program, so it is consistent with the requirements. Additionally, the County, DHCS, and UCLA will be assisting with monitoring of service documentation and delivery and will notify any site where problems are noted so that they can be quickly addressed and resolved.

Choosing Staff. Contingency management protocols must be delivered consistently to be successful, so it is helpful to identify specific staff members to deliver CM. The great thing about CM is that you do not need to be a clinical treatment provider to deliver CM. CM can be delivered by therapists, counselors, physicians, nurses, peer support specialists, case managers, or medical assistants, as long as the staff have been trained in CM and certified to serve as a CM Coordinator, Back-Up CM Coordinator, or CM Supervisor. For the Recovery Incentives Program, each

participating site will be required to select from existing staff or hire a part-time or full-time staff member to serve in the role of the CM Coordinator.

The CM Team Members implementing the Program must be recovery-oriented and believe in the positive, non-judgmental approach to treatment. If CM Team Members do not have training in motivational interviewing, further training can be requested through UCLA.

It is important that you make sure that the entire outpatient treatment team knows how an individual is doing in CM. If they are doing great, then the whole team should know so they can all celebrate the member's success. If, however, the member is not doing well, it is important that the clinical team knows so that they can offer additional support to them. The member should be made aware that their progress in the CM program will be shared with other providers within the site, so CM is integrated into a "team" approach to their overall clinical care. Your site should include language to that effect in your consent documents.

The CM Coordinator will be the point person for the CM program when questions arise. A list of Frequently Asked Question is available on the [DHCS CM Website](#). UCLA has also set up a [website](#) for consultation and questions. Other staff involved with CM protocols should have their roles clearly defined, as well.

- The only staff members who can administer CM are the CM Coordinator, the Back-up CM Coordinator, and the CM Supervisor. The CM Coordinator may be a Licensed Practitioner of the Healing Arts (LPHA), a certified or registered SUD counselor, certified peer support specialist, or other trained staff under the supervision of an LPHA. NOTE: The designation "Other trained staff under supervision of an LPHA" is specific to CM and does not change existing requirements for providers of other DMC-ODS services. DHCS is working to develop additional guidance to support use of this provider type.

Ongoing Supervision. It is required that the designated CM Supervisor perform fidelity checks for any staff involved in providing CM. This involves scheduling regular check-ins to ensure that your CM Program is being delivered consistently and rigorously over time. This routine can help to detect when a procedural shift or misunderstanding has occurred. A fidelity monitoring tool will be administered by the UCLA Training and Implementation Team.

Research has shown that fidelity to CM procedures is directly tied to CM implementation success and provider satisfaction.¹² Supervision can take the form of recorded or observed CM visits or scheduled paper or in-person assessments where the staff can demonstrate some aspects of CM delivery to their supervisor. CM Supervisors can also use the analytics features of the IM Portal to generate reports to ensure procedures are implemented correctly and consistently. Clinic meetings should occur regularly with the CM Team to address any administrative and clinical issues that arise.

Steps for Training New Staff

1. All CM Team Members must complete the self-paced CM Overview Training (2 hours) and the 2-part live, virtual CM Implementation Training (6 hours total delivered in two 3-hour sessions) and successfully complete a 2-part Readiness Assessment process prior to initiating CM services. Live virtual trainings are scheduled regularly to ensure that we can

accommodate new staff quickly. Training dates and times are available [here](#). See Appendix E for a visual flow chart of the CM Team Requirements for completing all required trainings.

2. Use this Program Manual and other training materials to orient CM Team Members to administer CM for stimulant use disorders.
3. Develop and disseminate site-specific policies and procedures on how this CM protocol will be implemented at your site. This could include preparing or accessing CM protocol checklists, forms, and electronic tools, policies regarding restroom setup and UDT procedures, how space will be utilized, EHR-specific documentation/billing requirements, etc. Site-specific policies and procedures must conform to the requirements set forth in [BHIN 24-031](#) and this Manual.
4. Next, the CM Team can practice CM with role-playing exercises and reviewing their site protocol for various scenarios to ensure they understand the CM principles and protocols. Examples of role-playing activities include practicing how to describe the CM protocol to new members or practicing the delivery of CM.
5. Have trained personnel (i.e., CM Supervisor) observe initial CM visits conducted by new CM Team Members.
6. Regularly review CM documentation conducted by new CM Team Members.

Tips for Handling Contested Stimulant-Positive UDT Results

- Remain non-confrontational (do not be accusatory or defensive) about the results, though stay firm that awarding the reinforcer is contingent on the result of the objective marker (*“The gift cards can only be given out when a stimulant-negative urine test is submitted.”*) Remind the member that this was agreed upon at the start of their participation in the Recovery Incentives Program so there would not be any confusion.
- If the member is insistent that they have remained abstinent since the last test, a second point-of-care UDT can be administered to determine if the first test result was a false positive. The member should be informed that the result of the second test will be the determining factor in whether they receive an incentive that day. This course of action should be used very sparingly and preferably in consultation with the CM Supervisor. If a member is VERY upset and there is concern about them leaving the program over this result, the second test can be offered. It is also important to remember that billable rates include only one UDT per visit, so the second test would not be reimbursed to your agency.
- Remind the member that some over-the-counter cold and flu medications may contain ingredients that will result in a stimulant-positive drug screen. Some amphetamine-based hallucinogens (e.g., MDMA) may also result in an amphetamine-positive drug screen. Review the list of medications to avoid (see last page of Sample Consent Form in Appendix A) with them to see if they have begun using one recently.
- Remind the member that it may take a few days for the drug metabolite to clear their system. It may take two regularly scheduled UDTs after use before a stimulant-negative test occurs.

- As a reminder, members who are taking a prescribed amphetamine (such as Adderall® – amphetamine-dextroamphetamine salts) will not be eligible for participation in the Recovery Incentives Program as there is no way to distinguish between these medications and non-prescribed use of amphetamines. Members who are taking these medications should be offered other treatment services.

Handling Excused Absences

Members will be informed in the Recovery Incentives Program consent form that if they cannot attend a scheduled appointment, they will need to tell the CM Coordinator ahead of time to reschedule or receive an excused absence. An excused absence must be requested and approved by the CM Coordinator prior to the scheduled visit. Absences cannot be approved as excused after the scheduled visit. Reasons for excused absences include having a doctor's appointment that cannot be rescheduled, illness, a court date, or a death in the family. The member must provide documentation of the reason for the absence at the next scheduled visit (i.e., receipt from healthcare clinic, funeral announcement, or court document).

- **Retention is the Goal.** Clearly establish attendance expectations at the beginning and find ways to work with each member on a case-by-case basis. Be flexible if possible and reschedule the appointment. Where possible, members should be rescheduled for the same day. Alternatively, a member can be scheduled on a contiguous day. If they reschedule in this way, they will still receive rewards according to the schedule.
 - For example: If a member tends to get called into work last minute, see if they can commit to providing a urine sample on their way into work or during a lunch break. They can always receive their incentive on a different day when they have more time.
- If the member has an excused absence as defined above, their incentive schedule continues at their next appointment with no reset. They do not receive an incentive for the missed appointment(s), nor does their timeline get to 'make up' the missed appointment, but their gift card value will not be reset.
- Likewise, a staff or member holiday is a valid excused absence. The member should be rescheduled for the day before or after the holiday if possible, or they may be able to provide only one sample during a holiday week, without penalty.
- All absences are entered into the IM Portal as either excused or missed (unexcused) so that incentives can be calculated accurately and there is no confusion later. Absences must be entered into the IM Portal on the day of the appointment since it will not be possible to enter two results on the same day later in the week (or on the following week, in the case of an absence on a Thursday or Friday). The IM Portal automatically accounts for the excused or unexcused absence.
- In the event of one or more missed visits (unexcused absences), the CM Team Member should attempt to contact the member to facilitate their return to the clinic on their next scheduled visit.

Readiness Assessment

After completion of Part 2 of the Recovery Incentives Program: California's Contingency Management Benefit Implementation Training, sites first complete an online Readiness Assessment Self-Study Survey via Qualtrics and then participate in an interactive 1-hour Readiness Assessment Interview with UCLA staff via Zoom. To be eligible to initiate the Readiness Assessment process, at least one CM Coordinator and one CM Supervisor per site must first complete all required trainings (2-hour CM Overview on-demand course and 2-part Implementation Training).

The purpose of the Readiness Assessment is to ensure that sites are fully prepared to offer CM services locally within their site in accordance with DHCS standards and the rules and regulations of the Recovery Incentives Program. Both components of the Readiness Assessment (Qualtrics Survey and Zoom Interview) are required to be completed in full prior to being permitted to administer CM services. The Readiness Assessment process includes:

- Interactive demonstration of procedures and site-specific implementation goals.
- Entering practice cases into the IM Portal to demonstrate proficiency with these tools.
- Responding to pre-set clinical scenarios, including, though not limited to, how to handle unexcused absences, disputes over test results and positive results for drugs other than stimulants.

See Appendix E for a visual flow chart of the CM Team Requirements for completing the Readiness Assessment process.

Evaluation

The evaluation approach is organized around the RE-AIM framework, as follows.

1. **Reach:** This will be measured as the percentage of members in treatment for stimulant use disorder who participate in the Recovery Incentives Program. UCLA will also evaluate whether there are disparities in reaching different member populations.
2. **Effectiveness:** Effectiveness will be based on the results of UDTs. Data will be collected from the IM Portal. UCLA will track the impact of CM on treatment retention and treatment attendance.
3. **Adoption:** Adoption will be measured by evaluating how many treatment sites implement the Recovery Incentives Program. This will be evaluated using DMC-ODS claims data.
4. **Implementation:** Implementation will be evaluated by the degree to which the Recovery Incentives Program is implemented with fidelity to the treatment protocol. Perceptions of challenges and areas for potential improvement will also be collected from treatment program staff and Recovery Incentives Program participants.
5. **Maintenance:** Maintenance will be measured by evaluating the degree to which sites implementing the Recovery Incentives Program continue providing the benefit throughout the evaluation period, based on data collected from the web-based IM Portal

and Medi-Cal claims data. In addition, surveys and qualitative interviews with CM Coordinators and Supervisors will be conducted and focus on factors that could promote or impede the continued delivery of the contingency management benefit.

Additional evaluation expectations for sites:

- Recovery Incentives Program sites will be asked to give an online survey link or QR code to members to participate in a short (5-minute) survey or provide them with a way to participate onsite (e.g., tablet or computer). Ideally this will occur at intake or early in treatment, and members will be encouraged (but not coerced) to participate. Members will be compensated by gift card (disbursed by UCLA, not the IM Portal) and become eligible for additional follow-up surveys (also compensated). Some members participating in a survey may also be invited by UCLA to participate in interviews. Although plans may be revised, we currently anticipate that each site will be required to meet a specified number of members, at which time the site will be contacted and distribution of the survey link can be paused.
- Sites may be contacted by e-mail to participate in surveys and interviews themselves. This will be an opportunity to provide ideas on how to improve the Recovery Incentives Program and describe barriers, successes, and lessons learned that may help others in the field. The CM Coordinator may be asked to distribute an additional survey to counselors at the site.

Planning for both the member and site surveys is currently underway, and additional details and instructions will be forthcoming, but both will be essential to the evaluation of the Recovery Incentives Program, and your participation is greatly appreciated.

Federal Law and Incentive Payments

In general, federal law restricts providers' abilities to offer financial incentives as part of patient therapy or patient recruitment. The Anti-Kickback Statute (AKS) is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).¹ The Civil Monetary Penalties Law (CMPL) authorizes the Secretary of Health and Human Services to impose civil money penalties, an assessment, and program exclusion for various forms of fraud and abuse involving the Medicare and Medicaid programs.²

Over the years, the U.S. Department of Health & Human Services Office of Inspector General (OIG) has cautioned providers about various problematic activities that may create legal risk under the AKS or the CMPL, including paying people to receive care that was not medically necessary.

¹ <https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/>

² Ibid.

However, the federal government has explicitly stated that the AKS and the CMPL do not apply to motivational incentives that are delivered as part of the Medicaid-covered CM benefit, and in compliance with the DHCS-approved CM protocol. For the purpose of the Medi-Cal contingency management benefit authorized under the [CalAIM 1115 demonstration](#):

These motivational incentives are considered a Medicaid-covered item or service and are used to reinforce objectively verified recovery behaviors using a clinically appropriate contingency management protocol consistent with evidence-based research. Consequently, neither the Federal anti-kickback statute (42 U.S.C. § 1320a-7b(b), “AKS”) nor the civil monetary penalty provision prohibiting inducements to members (42 U.S.C. 1320a-7a(a)(5), “Member Inducements CMP”) would be implicated.³

For more information on OIG rules for Non-Medicaid-funded Contingency Management Programs, see Appendix F.

Non-Federal Share of CM Costs

Counties may invoice DHCS for allowable DMC-ODS administrative costs related to the administration of CM. The non-federal share of these administrative costs will initially be covered with state funds that were available for a limited period of time as a result of the DHCS Home and Community Based Spending Plan.

If counties elect to continue participation in this optional benefit, they shall be responsible for covering the non-federal share of administrative costs after the close of the DHCS Home and Community-Based Spending Plan. Because of payment lag, and administrative claiming occurring on a quarterly basis, in effect, this means that counties shall be responsible for the non-federal share of CM administrative costs after June 30, 2024. The MC5312 for the period ending June 30, 2024, must be submitted to DHCS no later than August 15, 2024, for processing to receive state funds. Counties shall implement mechanisms to track administrative costs incurred to implement CM and report these costs on the CM line of the MC5312.

DHCS extended the pilot period through at least the duration of the CalAIM 1115 demonstration period (ending December 31, 2026), allowing approved DMC-ODS counties to continue services beyond the original pilot end date of March 2024.

Please refer to the [DMC-ODS Billing Manual](#) for general guidance about billing.

³ <https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-Approval-Letter-and-STCs.pdf>

Chapter 7. Communicating with Members about the Recovery Incentives Program

Member Outreach

DHCS recognizes that effective outreach and marketing strategies will increase the likelihood that eligible members will learn about the Recovery Incentives program. DHCS' goal in offering CM is to ensure that eligible Medi-Cal members have access to evidence-based treatment for StimUD. Appropriate outreach may increase the likelihood that members will initiate and adhere to a treatment program for StimUD. One of the primary goals of the Recovery Incentives Program is to retain members with StimUD in treatment.

Treatment program communications about CM (and any other health care service) should be accurate, non-misleading, and non-coercive. When communicating about the CM benefit with current members, potential members, or the general public, treatment programs should avoid any statements that are inaccurate, misleading, or coercive.

See below for a list of DOs and DON'Ts, which apply to general CM outreach materials as well as conversations with current or potential CM members.

DO	DON'T
✓ Clarify that the CM benefit is available to individuals who meet certain eligibility criteria, such as having a qualifying StimUD, enrolling in Medi-Cal, and residing in a participating county	✗ Use language that could mislead ineligible people into believing that they will qualify for CM incentives
✓ Explain that CM is intended to support treatment goals over time, such as substance non-use and treatment adherence	✗ Suggest that a member receives an incentive just for showing up
✓ Accurately describe the nature and potential value of the motivational incentives (e.g., "up to \$599," "gift cards to retail and grocery stores").	✗ Overstate the potential value of the incentives (e.g., "almost \$1,000!"), or state that incentives are rewarded in cash
✓ Ensure members understand that the CM benefit is optional	✗ Suggest that a member <i>must</i> enroll in CM to receive other health care services
✓ Let potential members know that CM incentives are conditioned on undergoing a medical assessment and taking regular drug tests, in accordance with DHCS' CM protocol	✗ Suggest that CM incentives are conditioned on members receiving services beyond those required under DHCS' CM protocol

DO	DON'T
✓ Emphasize that CM is a new and exciting option under DMC-ODS to support people with StimUD	✗ Suggest that the CM benefit is unique to a particular provider, or that one provider's CM benefit is better than another's
✓ Emphasize that use of motivational incentives is based on research	✗ Suggest that it is the only proven approach to StimUD treatment

Participating sites have the flexibility to craft their own outreach messages as long as all communications are accurate and are not misleading or coercive. As a component of the 2-part Implementation Training, CM Teams will receive a Provider Outreach Toolkit (see Appendix C) that includes sample messages to communicate about the Recovery Incentives Program with eligible members.

Additional Resources

DHCS Recovery Incentives Program Website:

<https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx>

UCLA Recovery Incentives Program Website and Warmline:

<https://uclaisap.org/recoveryincentives/>

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Date Last Updated: July 22, 2026.

Appendix A

Sample Member Consent Form

Appendix A

Recovery Incentives Program: California's Contingency Management Benefit Sample Member Consent Form/Agreement

NOTE: This template is provided as a guide to counties and treatment provider sites participating in the Recovery Incentives Program. Counties are encouraged to adapt this content to fit within the parameters of existing member consent forms/agreements, including county/agency-specific branding, logos, and letterheads, and larger font size and spacing to meet accessibility standards.

I understand that the goal of the Recovery Incentives Program is to help me reduce my stimulant use and to continue to receive services even if I have use episodes or miss appointments along the way. To accomplish this, I agree with the following statements related to my participation:

1. To participate in the Recovery Incentives Program, I must be admitted to an outpatient, intensive outpatient, partial hospitalization, or narcotic treatment program (also known as opioid treatment program).
2. I confirm that I am not currently enrolled in a residential treatment program.
3. During my enrollment in the Recovery Incentives Program, I will notify the program site if I am admitted into a residential treatment program.
4. I understand that I am ineligible to participate in the Recovery Incentives Program while I am enrolled in a residential treatment program. However, I may be eligible to resume participation in the Recovery Incentives Program on the same date that I am discharged from a residential treatment program.
5. I can start the Recovery Incentives Program at any time. During the first 12 weeks, I will be expected to come to the clinic two (2) times per week and submit a urine sample for a urine drug test (UDT). For the following 12 weeks, I will be expected to come to the clinic one (1) time per week and submit a urine sample for a UDT.
6. I may come to the clinic more often to participate in services, and these visits will not involve submitting a urine sample for a UDT as part of the Recovery Incentives Program.
7. Participation in the Recovery Incentives Program is voluntary, and I can discontinue at any time. Leaving the Recovery Incentives Program will not impact my eligibility to participate in any other medically necessary clinical services.
8. I will receive an incentive payment each time I submit a Recovery Incentives Program scheduled UDT that is stimulant-negative (i.e., free of amphetamine, methamphetamine, and cocaine). The incentive payment will take the form of an electronic or paper gift card.
9. I will receive the incentive payment immediately when I give a stimulant-negative UDT.
10. In the initial 12 weeks, for the first stimulant-negative UDT, the incentive payment will be worth \$10. If I give two (2) stimulant-negative UDTs in a row, the incentive payment will increase to \$11.50. The value of the incentive payment will keep increasing by \$1.50 for every two times I give stimulant-negative UDTs. The highest amount an incentive payment can reach for an individual test is \$26.50.

The Recovery Incentives Program: California's Contingency Management Benefit
Sample Member Consent Form/Agreement

11. During the second 12 weeks of the Program, weekly stimulant-negative UDTs will be worth \$15 in weeks 13-18, \$10 in weeks 19-23, and \$21 in week 24.
12. If all tests are stimulant-negative over 24 weeks, I will earn \$599. If for any reason I need to restart the program, the maximum that I can earn is \$599 per calendar year including current and any previous participation in the Recovery Incentives Program.
13. I will not receive an incentive payment if I submit a UDT that is stimulant-positive (i.e., presence of amphetamine, methamphetamine, and/or cocaine). The results of the urine drug test are final, and I agree to accept the outcome and decision of Recovery Incentives Program staff even if I disagree with it.
14. During the first 12 weeks, if I submit a stimulant-positive UDT, the incentive payment will return to \$10 the next time I provide a stimulant-negative UDT. Once I give a second stimulant-negative UDT, I will get back all the increases I earned previously and will continue to earn increases each time I test negative for stimulants two (2) times in a row.
15. During the second half of the Program (weeks 13-24), if I submit a stimulant-positive UDT, I will not receive an incentive for that visit. On my next stimulant-negative UDT I will receive an incentive in the amount that is scheduled for that week (\$15 in weeks 13-18, \$10 in weeks 19-23, and \$21 in week 24).
16. I understand that certain medications may interact with the UDT resulting in a false positive test for stimulants (see attached list). I understand that all positive UDTs will be treated the same (no incentive will be given) even if it is a result of one of these medications. Taking medications as prescribed is important, and I agree to seek the advice of my medical provider before making any changes in my medication regimen.
17. I agree to inform Recovery Incentives Program staff if I am taking a prescription stimulant medication. Taking prescription stimulant medications will cause my UDTs to always be positive for stimulants (no incentive will be given), and I therefore will not be eligible for the Recovery Incentives Program.
18. I will not receive an incentive payment when my urine sample tests positive for stimulants even if the stimulant-positive UDT is from one of the medications from the list of items known to cause a stimulant-positive UDT result.
19. For unavoidable absences (e.g., a doctor appointment, illness, funeral, etc.), I will reschedule my UDT visit on a contiguous day if at all possible. If I cannot reschedule, I can request an excused absence by notifying the clinic **before** the missed session. I will provide documentation of the reason for the absence at the next scheduled visit (e.g., receipt from the doctor, funeral announcement, travel ticket, employer work schedule, document from judicial authority). I understand that if the clinic approves the absence, it will be recorded as excused, I will not receive an incentive for that visit, and at my next visit the incentive payment will continue at the same level as if the absence had not occurred, for up to two consecutive excused absences. If the excused absence extends to three or more visits, my incentive amount will reset to the original \$10.
20. I understand that excused absences must be requested and approved prior to the scheduled visit. Visits cannot be approved as excused after the date of a scheduled visit and would be recorded as missed.

The Recovery Incentives Program: California's Contingency Management Benefit
Sample Member Consent Form/Agreement

21. If I do not submit a urine sample or have an unexcused absence from the clinic, it will be recorded as a stimulant-positive UDT result. It will not negatively affect any other treatment services I am receiving or eligible to receive.
22. I agree that I will give my own urine for all urine drug tests; I will not tamper with the urine sample; and I commit to following the rules and procedures of the Recovery Incentives Program.
23. I agree to use the incentive payments earned only for my own personal use. I will not sell or trade any incentive payments. I agree that I will not use incentive payments to purchase alcohol, tobacco, cannabis, or lottery tickets.
24. I will not enroll in the Recovery Incentives Program with more than one (1) treatment provider at a time. I understand that if I am registered with more than one (1) Recovery Incentives Program provider, the providers must meet to determine which provider will assume responsibility to continue my treatment.
25. During my enrollment in the Recovery Incentives Program, I will not participate in contingency management services for treatment of Stimulant Use Disorder(s) outside of the Program.
26. The clinic will collect information about me throughout my participation in the Recovery Incentives Program for evaluation and incentive tracking purposes.
27. The Recovery Incentives Program staff will record my attendance, UDT results, and any incentive payments distributed in an electronic database.
28. My personal and medical information will be protected according to required state and federal privacy and confidentiality regulations (HIPAA and 42 CFR Part 2) and will only be shared when medically necessary or with the provider organization, the County, State, UCLA-affiliated staff and Incentive Manager-affiliated staff for program payment, monitoring, oversight, auditing, and/or evaluation purposes.
29. I will be able to submit any feedback about the Recovery Incentives Program by emailing recoveryincentives@dhcs.ca.gov.
30. I agree to complete evaluation surveys and forms related to my participation in the Recovery Incentives Program to help program staff understand how this program helped me and others.

Member Name (Print)

Member Signature

Date

**The Recovery Incentives Program: California's Contingency Management Benefit
Sample Member Consent Form/Agreement**

Medicines that Can Cause You to Test Positive for Stimulants

- **Prescription medicines for Attention Deficit Hyperactivity Disorder (ADHD):** if you take any of these, your urine drug tests will always be positive for stimulants and you will be ineligible to earn incentives in the Recovery Incentives Program.
 - Methylphenidate (Ritalin, Concerta, Dayrana, Quillivant, Mthylin, Aptensio XR, Cotempla XR, Metadate CD)
 - Dexmethylphenidate (Focalin XR)
 - Serdexmethylphenidate/dexmethylphenidate (Azstarys)
 - Amphetamine salts (Adderallm Mydayis)
 - Dextroamphetamine (Dexedrine, Spansule, Zenzdi, ProCentra)
 - Lisdexamfetamine (Vyvanse)
- **Prescription and over-the-counter medicines for cough and cold, with decongestants**
 - Pseudoephedrine (Sudafed, SudoGest, Zephrex-D, Claritin-D, Allegra-D, others)
 - Levmetamfetamine (Vicks Vapo inhaler)
- **Prescription medicines for mental health conditions**
 - Chlorpromazine (Thorazine and Largactil)
 - Trazodone (Desyrel, Desyrel Dividose, Oleptro)
 - Bupropion (Wellbutrin, Forfivo XL, Aplenzin, and Zyban)
- **Prescription and over-the-counter medicines for weight loss/diet aids**
 - Phentermine (Adipex-P, Lomaira)
 - Benzphetamine (Didrex, Regimex)
 - Phenulpropanolamine (PPA, Dexatrim, Accutrim)
 - Ephedra (Ma-huang)
- **Prescription medicine for hypertension**
 - Labetalol
- **Prescription medicine for Parkinson's Disease**
 - Selegiline (Eldepryl, Zelapar, Emsam)
- **Prescription medicine for diabetes**
 - Metformin (Glucophage, Riomet, Glumetza)
- **Prescription and over-the-counter medicines for asthma and allergies**
 - Eldepryl, Zelapar, Emsam (Marax)
 - Ephedrine (Primatene)
 - Promethazine (Phenergan Promacot)
- **Prescription medicines used for bacterial infections**
 - Ofloxacin (Floxin, Ocuflox)
- **Other substances**
 - Methylenedioxymethamphetamine (MDMA, Ecstasy, Molly, Mandy Pingers)
 - Dimethylamylamine (DMAA, Forthane, Geranamine, Geranium Extract)
- **Other considerations**
 - It is possible that other medicines not on this list may cause a urine drug test to be positive for stimulants. If you are concerned about any prescription, over-the-counter medicine, herbal supplement, or other substance that you are taking, please consult with your medical provider or Recovery Incentives Program staff.

Appendix B

Instructions for Administering Approved UDT Kits

NOTE:

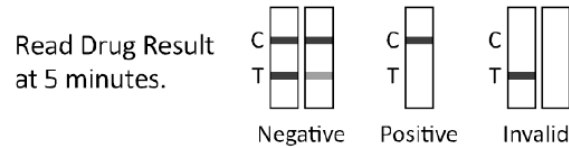
Enclosed files include:

- Tip Sheet for Interpreting UDT Results
- Package Inserts for all approved products (Abbott, CLIAWaived, Inc., Lochness Medical, and Premier Biotech)

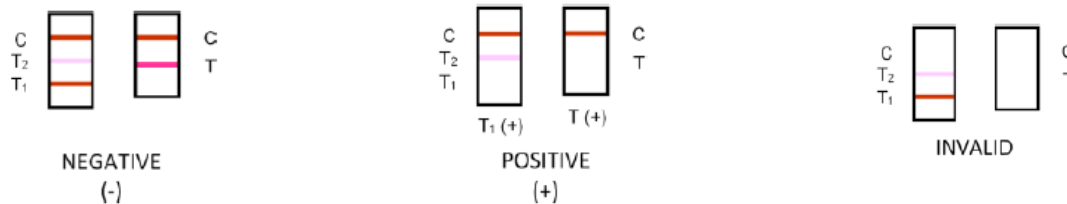
Tip Sheet for Interpreting UDT Results

How to interpret the results for the approved UDT products for the California Recovery Incentives Program. Additional guidance can be found in the individual package inserts for each product.

1) Abbott iScreen Urine Test DX Drug Screen Tox Cup [14-panel]



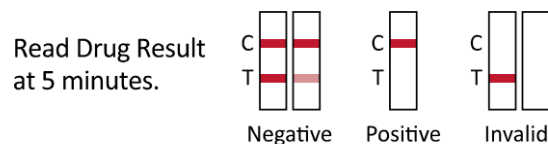
2) CLIAWaived, Inc. 12-Panel IDTC Cups with Adulterants 3) CLIAWaived, Inc. 14-Panel IDTC II



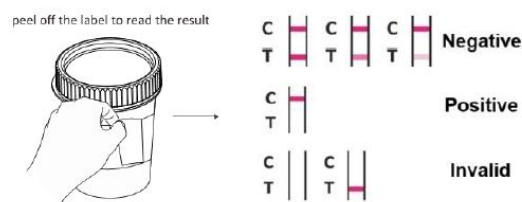
4) CLIAWaived, Inc. 13-Panel Cup CLIA Waived Cup with Fentanyl and Adulterants – CLIAwaived for Fentanyl Testing!



5) CLIAWaived, Inc. Rapid Test Cup “RTC” + Fentanyl [14-panel]



6) CLIAWaived, Inc. 15 Panel IDTC Plus 7) 3) CLIAWaived, Inc. 13-Panel Instant Drug Test Cup Plus

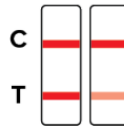


Tip Sheet for Interpreting UDT Results, Page 2

8) Lochness Medical Rapid Response 12-Panel Drug Screen Cup with Fentanyl



POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.



***NEGATIVE:** A colored line appears in the Control region (C) and a colored line appears in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

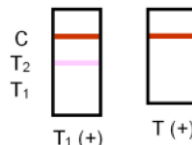


INVALID: NO line appears in the C – Control region, then the result is Invalid.

9) Premier Biotech Premier Bio-Cup



NEGATIVE
(-)



POSITIVE
(+)



INVALID

10) Premier Biotech 14-Panel CLIA Waived Urine Test Cup



NEGATIVE



POSITIVE



INVALID

iSCREEN™
URINE TEST
DX DRUG SCREEN TOX CUP



Package Insert

Instruction Sheet for testing of any combination of the following drugs:

AMP, BAR, BUP, BZO, COC, FTY, MDMA, MET, MOP, MTD, OXY, PCP, TCA, THC

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. Immunoassay for in vitro diagnostic use only.

For medical and other professional use.

【INTENDED USE】

The iSCREEN™ Urine Test DX Drug Screen Tox Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana and Fentanyl in human urine at the cutoff concentrations of:

Drug (Identifier)	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	500
Secobarbital (BAR)	Secobarbital	300
Buprenorphine (BUP)	Buprenorphine	10
Oxazepam (BZO)	Oxazepam	300
Cocaine (COC)	Benzoyllecgonine	150
Fentanyl (FTY)	Fentanyl	1
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Methamphetamine (MET)	d-Methamphetamine	500
Morphine (MOP/OPI)	Morphine	300
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Nortriptyline (TCA)	Nortriptyline	1000
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50

The iSCREEN™ Urine Test DX Drug Screen Tox Cup can be a single drug test cup or used for any combination of the above listed analytes. It is for *in vitro* diagnostic use only. Product is CLIA Waived. The tests may yield positive results for the prescription drugs when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC-MS or LC-MS is the recommended confirmatory method.

【SUMMARY】

The iSCREEN™ Urine Test DX Drug Screen Tox Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

Amphetamine (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.¹

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of amphetamines in urine exceeds detection level.

Secobarbital (BAR)

Secobarbital is one of CNS depressants (barbiturates). They are used therapeutically as sedatives, hypnotics, and anticonvulsants barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most secobarbital are excreted unaltered in the urine.²

The approximate detection time limits for secobarbital are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of secobarbital in urine exceeds detection level.

Buprenorphine (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations. The plasma half -life of Buprenorphine is 2-4 hours. While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.³

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the Buprenorphine in urine exceeds detection level.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced secobarbital in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.⁴

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3-7 days.

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of benzodiazepines in urine exceeds detection level.

Cocaine (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoyllecgonine. Benzoyllecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.⁵

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of Cocaine in urine exceeds detection level.

Fentanyl (FTY)

Fentanyl, belongs to powerful narcotics analgesics, and is a μ special opiates receptor stimulant. Fentanyl is one of the varieties that have been listed in management of United Nations 'Single Convention of narcotic drug in 1961'. Among the opiates agents that are under international control, fentanyl is one of the most commonly used to cure moderate to severe pain. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc, which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose.⁶

The iSCREEN™ Urine Test DX Drug Screen Tox Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of fentanyl in urine. The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when fentanyl in urine exceeds detection level.

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.⁷

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds detection level.

Methamphetamine (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.⁸

The effects of Methamphetamine generally last 2-4 hours and the drug have a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The iSCREEN™ Urine Test DX Drug Screen Tox Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the Methamphetamine in urine exceeds detection level.

Morphine (MOP/OPI 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.⁹

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of morphine in urine exceeds detection level.

Methadone (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.¹⁰ Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of methadone in urine exceeds detection level.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%). The window of detection for Oxycodone in urine is expected to be similar to that of other opioids such as morphine.^{11,12}

The iSCREEN™ Urine Test DX Drug Screen Tox Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Oxycodone in urine. The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when Oxycodone in urine exceeds detection level.

Phencyclidine (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.⁶ PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).¹³

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of phencyclidine in urine exceeds detection level. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

Nortriptyline (TCA)

Nortriptyline is one of the Tricyclic Antidepressants, TCA are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.¹⁴ The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of tricyclic antidepressants in urine exceeds detection level. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

Marijuana (THC)

THC (Δ⁹-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ⁹-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).^{15,16}

The iSCREEN™ Urine Test DX Drug Screen Tox Cup yields a positive result when the concentration of THC-COOH in urine exceeds detection level.

【PRINCIPLE】

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

【PRECAUTIONS】

- Immunoassay for *in vitro* diagnostic use only. The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to federal, state and local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 35.6-86°F (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test cup must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 35.6-46.4°F (2-8°C) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed well before testing.

【MATERIALS】

Materials Provided

- 25 Test Cups
- 1 Package Insert
- 1 Adulteration Color Chart (when applicable)
- 1 Procedure card

Materials Required But Not Provided

- Specimen Collection Containers
- Timer

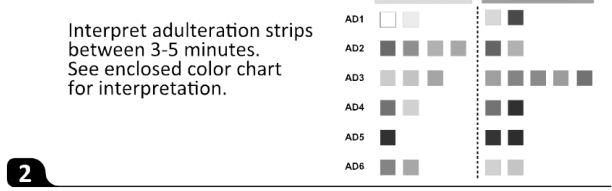
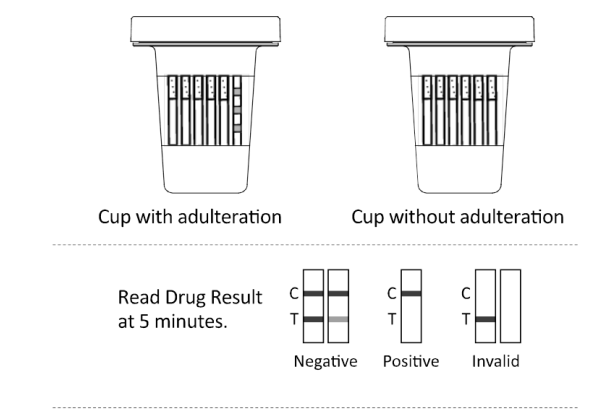
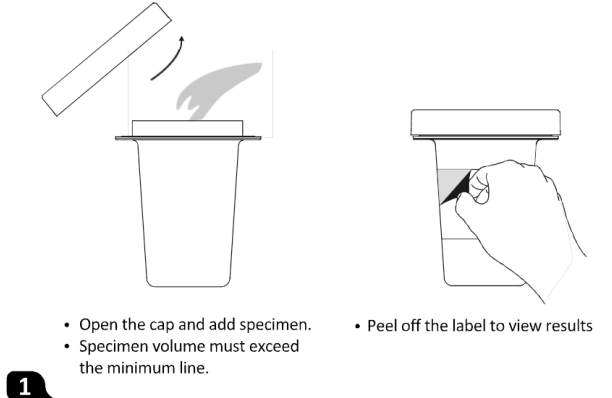
【DIRECTIONS FOR USE】

Allow the test, urine specimen, and/or controls to reach room temperature 59-86°F (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch.
2. Donor provides specimen. Technician sets timer.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100°F (32-38°C).

5. Technician dates and initials the security seal and attaches the security seal over the cup cap.
6. Technician peels off label to reveal adulteration strip(s), if applicable.
7. Technician peels off the label on the multi-drug test cup to view results.
8. The adulteration strip(s), if applicable, should be read between 3-5 minutes. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results. Refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not interpreting the drug test results and either retesting the urine with a new cup or collecting another specimen in case of any positive result for any adulteration test.
9. If results do not indicate adulteration, read the drug test result at 5 minutes. Do not interpret the result after 10 minutes.
10. If preliminary positive results are observed, please send the cup to the laboratory for confirmation.

TEST PROCEDURE Cup



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

***NEGATIVE: A colored line appears in the Control region (C) and a colored line appears in the Test region (T).** This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact your manufacturer.

【INTERPRETATION OF RESULTS (S.V.T ADULTERATION)】

(Please refer to the color chart)

Semi Quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart.

No instrumentation is required.

【QUALITY CONTROL】

A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

Quality control should be performed in accordance with federal, state, and local regulations.

【LIMITATIONS】

1. The iSCREEN™ Urine Test DX Drug Screen Tox Cup provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography-mass spectrometry or Liquid Chromatography-mass spectrometry is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen or another cup.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements. Alcohol in the atmosphere, such as spray from perfumes, deodorizers, glass cleaners etc. can affect the Alcohol Rapid Tests.^{19,20} Therefore, adequate measures should be taken to avoid undue interference from such atmospheric agents in the testing area.

【EXPECTED VALUES】

The negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

【PERFORMANCE CHARACTERSTICS】

Accuracy

About 80 clinical urine specimens with known LC-MS values and tested by iSCREEN™ Urine Test DX Drug Screen Tox Cup. Each test was performed by three operators. Results were as follows:

Amphetamine(AMP500)

Operator	Result	Candidate Device Result		The Agreement Rate
	LC/MS Result	Positive	Negative	
Operator A	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator B	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Secobarbital(BAR300)

Operator	Result	Candidate Device Result		The Agreement Rate
	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Buprenorphine(BUP10)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 10ng/mL (+)	39	1	39/40=97.5%
	Lower 10ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 10ng/mL (+)	40	0	40/40=100%
	Lower 10ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 10ng/mL (+)	40	0	40/40=100%
	Lower 10ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		

Oxazepam (BZO300)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator B	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Cocaine (COC150)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 150ng/mL (+)	39	1	39/40=97.5%
	Lower 150ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 150ng/mL (+)	40	0	40/40=100%
	Lower 150ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 150ng/mL (+)	39	1	39/40=97.5%
	Lower 150ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Fentanyl (FTY1)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 1ng/mL (+)	38	2	38/40=95.0%
	Lower 1ng/mL (-)	2	38	38/40=95.0%
	Accuracy	(38+38)/80=95.0%		
Operator B	Above 1ng/mL (+)	38	2	38/40=95.0%
	Lower 1ng/mL (-)	2	38	38/40=95.0%
	Accuracy	(38+38)/80=95.0%		
Operator C	Above 1ng/mL (+)	38	2	38/40=95.0%
	Lower 1ng/mL (-)	3	37	37/40=92.5%
	Accuracy	(38+37)/80=93.75%		

Ecstasy (MDMA500)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(40+40)/80=100%		

Methamphetamine (MET500)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator	Above 500ng/mL (+)	40	0	40/40=100%

A	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(40+40)/80=100%		
Operator B	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Morphine (MOP/OPI 300)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Methadone (MTD300)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Oxycodone (OXY100)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 100ng/mL (+)	40	0	40/40=100%
	Lower 100ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 100ng/mL (+)	40	0	40/40=100%
	Lower 100ng/mL (-)	0	40	40/40=100%
	Accuracy	(40+40)/80=100%		
Operator C	Above 100ng/mL (+)	39	1	39/40=97.5%
	Lower 100ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Phencyclidine (PCP25)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 25ng/mL (+)	39	1	39/40=97.5%
	Lower 25ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 25ng/mL (+)	39	1	39/40=97.5%
	Lower 25ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 25ng/mL (+)	39	1	39/40=97.5%
	Lower 25ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Nortriptyline (TCA1000)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 1000ng/mL (+)	40	0	40/40=100%
	Lower 1000ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 1000ng/mL (+)	39	1	39/40=97.5%
	Lower 1000ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Operator C	Above 1000ng/mL (+)	40	0	40/40=100%
	Lower 1000ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		

Marijuana (THC50)				
Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 50ng/mL (+)	40	0	40/40=100%
	Lower 50ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 50ng/mL (+)	39	1	39/40=97.5%
	Lower 50ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 50ng/mL (+)	39	1	39/40=97.5%
	Lower 50ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Analytical Specificity

The following table lists compounds that are positively detected in urine by iSCREEN™ Urine Test DX Drug Screen Tox Cup at 5 minutes.

Drug	Concentration (ng/ml)	Cross- Reactivity (%)
Amphetamine (AMP500)		
Hydroxyamphetamine	5000	10%
(+/-)-Methylenedioxyamphetamine(MDA)	25	2000%
D,L-Amphetamine	500	100%
D-Amphetamine	500	100%
Diethylstilbestrol	>100000	<0.5%
L-Amphetamine	500	100%
Phentermine	500	100%
β-Phenylethylamine	>100000	<0.5%
Tyramine	>100000	<0.5%
p-Hydroxynorephedrine	>100000	<0.5%
D,L-Norephedrine	>100000	<0.5%
p-Hydroxyamphetamine	5000	10%
D-Methamphetamine	>100000	<0.5%
L-Methamphetamine	>100000	<0.5%
Ephedrine hydrochloride	>100000	<0.5%
(+/-)3,4- Methyleneioxymethamphetamine (MDMA)	100000	0.5%
Phenylpropanolamine	>100000	<0.5%
Benzphetamine	>100000	<0.5%
L-Ephedrine	>100000	<0.5%
L-Epinephrine	>100000	<0.5%
D,L-Epinephrine	>100000	<0.5%
(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	100000	0.5%

Secobarbital (BAR300)		
Alphenal	300	100%
Amobarbital	300	100%
Aprobarbital	300	100%
Butabarbital	500	60%
Butethal	200	150%
Cyclopentobarbital	500	60%
Pentobarbital	200	150%
Phenobarbital	200	150%
Secobarbital	300	100%
Butalbital	2000	15%
Barbital	300	100%

Buprenorphine (BUP10)		
Buprenorphine	10	100%
Buprenorphine-3-D-Glucuronide	20	50%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	20	50%
Morphine	>100000	<0.01%
Oxymorphone	>100000	<0.01%
Hydromorphone	>100000	<0.01%
Codeine	>100000	<0.01%

Nalorphine	>100000	<0.01%
Oxazepam (BZO300)		
a-Hydroxyalprazolam	10000	3%
Alprazolam	200	150%
Bromazepam	1000	30%
Chlordiazepoxide	300	100%
Clobazam	200	150%
Clonazepam	200	150%
Clorazepate Dipotassium	300	100%
Desalkylflurazepam	>100000	<0.3%
Diazepam	300	100%
Estazolam	100	300%
Flunitrazepam	300	100%
D,L-Lorazepam	1000	30%
Midazolam	1000	30%
Nitrazepam	200	150%
Norchlordiazepoxide	200	150%
Nordiazepam	200	150%
Oxazepam	300	100%
R,S-Lorazepam glucuronide	1000	30%
Temazepam	100	300%
Triazolam	300	100%
Demoxepam	2000	15%
Flurazepam	300	100%
Delorazepam	2000	15%
Lormetazepam	100	300%
Cocaine (COC150)		
Benzoylcogonine	150	100%
Cocaethylene	250	60%
Cocaine hydrochloride	125	120%
Ecgonine	>100000	<0.2%
Norcocaine	>100000	<0.2%
Ecgonine methyl ester	>100000	<0.2%
Fentanyl (FTY1)		
Fentanyl	1	100%
Acetyl fentanyl	1	100%
Acrylfentanyl	1	100%
ω-1-Hydroxyfentanyl	20000	0.005%
Isobutyryl fentanyl	1	100%
Ocfentanil	2.5	40%
Butyryl fentanyl	2.5	40%
Furanyl fentanyl	5	20%
Valeryl fentanyl	10	10%
(±) β-hydroxythiofentanyl	2	50%
4-Fluoro-isobutyrylfentanyl	50	2%
Para-fluorobutyryl fentanyl	4	25%
Para-fluoro fentanyl	3	33.3%
(±)-3-cis-methyl fentanyl	50	2%
Carfentanil	2	50%
Sufentanil	10	10%
Alfentanil	5000	0.02%
Despropionyl fentanyl (4-ANPP)	2500	0.04%
Remifentanil	>100000	<0.001%
Norfentanyl	>100000	<0.001%
Acetyl norfentanyl	>100000	<0.001%
Norcarfentanil	>100000	<0.001%
6-Acetyl morphine	>100000	<0.001%
Amphetamine	>100000	<0.001%
Buprenorphine	>100000	<0.001%
Buprenorphineglucuronide	>100000	<0.001%
Codeine	>100000	<0.001%
Dextromethorphan	>100000	<0.001%

Dihydrocodeine	>100000	<0.001%
EDDP	>100000	<0.001%
EMDP	>100000	<0.001%
Fluoxetine	>100000	<0.001%
Heroin	>100000	<0.001%
Hydrocodone	>100000	<0.001%
Hydromorphone	>100000	<0.001%
Ketamine	>100000	<0.001%
Levorphanol	>100000	<0.001%
Meperidine	>100000	<0.001%
Methadone	>100000	<0.001%
Morphine	>100000	<0.001%
Morphine-3-glucuronide	>100000	<0.001%
Naloxone	>100000	<0.001%
Naltrexone	>100000	<0.001%
Norbuprenorphine	>100000	<0.001%
Norcodeine	>100000	<0.001%
Norketamine	>100000	<0.001%
Normeperidine	>100000	<0.001%
Normorphine	>100000	<0.001%
Noroxycodone	>100000	<0.001%
Oxycodone	>100000	<0.001%
Oxymorphone	>100000	<0.001%
Pentazocine (Talwin)	>100000	<0.001%
Pipamperone	>100000	<0.001%
Risperidone	>100000	<0.001%
Tapentadol	>100000	<0.001%
Thioridazine	>100000	<0.001%
Tilidine	>100000	<0.001%
Tramadol	>100000	<0.001%
Tramadol-O-Desmethyl	>100000	<0.001%
Tramadol-N-Desmethyl	>100000	<0.001%
Ecstasy (MDMA500)		
(+/-)-3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	250	200%
(+/-)-Methylenedioxyamphetamine(MDA)	1000	50%
(±)-MDMA	500	100%
L-Methamphetamine	>100000	<0.5%
d-methamphetamine	>100000	<0.5%
d-amphetamine	>100000	<0.5%
l-amphetamine	>100000	<0.5%
d,l-Amphetamine	>100000	<0.5%
d,l-Methamphetamine	>100000	<0.5%
Phentermine	>100000	<0.5%
Phenylephrine	>100000	<0.5%
Ephedrine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
Methamphetamine (MET500)		
(+/-)-3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	6000	8.3%
MDMA	1000	50%
D-Methamphetamine	500	100%
L-Methamphetamine	10000	5%
Fenfluramine	50000	1%
p-Hydroxymethamphetamine	250	200%
D,L-Methamphetamine	250	200%
β-Phenylethylamine	>100000	<0.5%
Mephetermine	25000	2%
Methoxyphenamine hydrochloride	75000	0.7%
L-Amphetamine	100000	0.5%
D-Amphetamine	100000	0.5%
D,L-Amphetamine	250	200%

Chloroquine	25000	2.0%
Ephedrine hydrochloride	>100000	<0.5%
(+/-)-3,4-Methylenedioxyamphetamine (MDA)	>100000	<0.5%
Trimethobenzamide	>100000	<0.5%
l-phenylephrine	>100000	<0.5%
(1R,2S)-(-)-Ephedrine	>100000	<0.5%
Procaine hydrochloride	>100000	<0.5%
Phentermine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
Morphine (MOP/OPI 300)		
6-acetylmorphine	300	100%
Codeine	250	120%
Dihydrocodeine	5000	6%
EthylMorphine	200	150%
Heroin	500	60%
Hydrocodone	1000	30%
Hydromorphone	10000	3%
Levorphanol tartrate	1500	20%
Morphine	300	100%
Nalorphine hydrochloride	300	100%
Thebaine	20000	1.5%
s-Monoacetylmorphine	300	100%
Morphine-3-β-d-glucuronide	1000	30%
6-Monoacetylmorphine (6-MAM)	300	100%
Codeine-6-β-D-glucuronide	25000	1.2%
Morphine-6-β-D-glucuronide	1000	30%
6-Acetylcodeine	25000	1.2%
Normorphine	50000	0.6%
Oxycodone	>100000	<0.3%
Oxymorphone	>100000	<0.3%
Norcodeine	25000	1.2%
Procaine hydrochloride	>100000	<0.3%
Norpropoxyphene	>100000	<0.3%
Methadone (MTD300)		
(±)-Methadone	300	100%
EDDP	>100000	<0.3%
EMDP	>100000	<0.3%
LAAM	>100000	<0.3%
Alpha Methadol	>100000	<0.3%
Doxylamine	>100000	<0.3%
Disopyramide	6000	5.0%
Esomeprazole	10000	3.0%
Pheniramine	100000	0.3%
Oxycodone (OXY100)		
Ethyl Oxycodone	100	100%
Hydrocodone	50000	0.2%
Hydromorphone	25000	0.4%
Levorphanol tartrate	50000	0.2%
Naloxone hydrochloride	50000	0.2%
Naltrexone hydrochloride	>100000	<0.1%
Oxycodone	100	100%
Oxymorphone	100	100%
Oxymorphone-3β-D-glucuronide	>100000	<0.1%
Noroxycodone	1000	10%
Noroxymorphone	25000	0.4%
Dihydrocodeine	12500	0.8%
Codeine	100000	0.1%
Morphine	>100000	<0.1%
Acetylmorphine	>100000	<0.1%
Buprenorphine	>100000	<0.1%
Ethylmorphine	>100000	<0.1%
Thebaine	>100000	<0.1%

6-acetylmorphine	>100000	<0.1%
Phencyclidine (PCP25)		
PCP (Phencyclidine)	25	100%
4-Hydroxyphencyclidine	15	167%
Pheniramine	50000	0.05%
Nortriptyline (TCA1000)		
Amitriptyline	1500	66.7%
Chlorpheniramine	>100000	<1%
Clomipramine	1000	100%
Cyclobenzaprine Hydrochloride	>100000	<1%
Desipramine	300	333.3%
Doxepine	10000	10%
Duloxetine	>100000	<1%
Imipramine	500	200%
Norclomipramine	250	400%
Nordoxepine	>100000	<1%
Nortriptyline hydrochloride	1000	100%
Promazine	500	200%
Trimipramine	1500	66.7%
Maprotiline	>100000	<1%
Promethazine hydrochloride	50000	2%
Marijuana (THC50)		
11-nor-Δ ⁸ -THC-9-COOH	20000	0.25%
(-)-11-nor-9-carboxy-Δ ⁹ -THC	50	100%
(±)-11-nor-9-Carboxy-Δ ⁹ -THC	50	100%
11-nor-Δ ⁹ -THC -carboxy glucuronide	50	100%
11-hydroxy-Δ ⁹ -Tetrahydrocannabinol	5000	1.0%
Δ ⁸ - Tetrahydrocannabinol	100000	0.05%
Δ ⁹ - Tetrahydrocannabinol	100000	0.05%
Cannabinol	>100000	<0.05%
Cannabidiol	>100000	<0.05%

Precision

This study is performed by three personnel who don't know the sample number system participate in the study. Three lots were run in consecutive business days at each concentration for each lot per day. The results as follows:

Drugs	Concentration	n	Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
AMP 500	0ng/ml	50	0	50	0	50	0	50
	125ng/ml	50	0	50	0	50	0	50
	250ng/ml	50	0	50	0	50	0	50
	375ng/ml	50	1	49	0	50	0	50
	500ng/ml	50	27	23	28	22	30	20
	625ng/ml	50	50	0	49	1	50	0
	750ng/ml	50	50	0	50	0	50	0
	875ng/ml	50	50	0	50	0	50	0
BAR 300	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	27	23	30	20	29	21
	375ng/ml	50	49	1	50	0	49	1
	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
BUP 10	0ng/ml	50	0	50	0	50	0	50
	2.5ng/ml	50	0	50	0	50	0	50
	5ng/ml	50	0	50	0	50	0	50
	7.5ng/ml	50	0	50	1	49	0	50
	10ng/ml	50	29	21	26	24	28	22
	12.5ng/ml	50	49	1	50	0	49	1

		15ng/ml	50	50	0	50	0	50	0
		17.5ng/ml	50	50	0	50	0	50	0
		20ng/ml	50	50	0	50	0	50	0
BZO 300		0ng/ml	50	0	50	0	50	0	50
		75ng/ml	50	0	50	0	50	0	50
		150ng/ml	50	0	50	0	50	0	50
		225ng/ml	50	0	50	1	49	0	50
		300ng/ml	50	28	22	25	25	26	24
		375ng/ml	50	50	0	50	0	50	0
		450ng/ml	50	50	0	50	0	50	0
		525ng/ml	50	50	0	50	0	50	0
		600ng/ml	50	50	0	50	0	50	0
		0ng/ml	50	0	50	0	50	0	50
COC 150		37.5ng/ml	50	0	50	0	50	0	50
		75ng/ml	50	0	50	0	50	0	50
		112.5ng/ml	50	0	50	0	50	1	49
		150ng/ml	50	28	22	28	22	27	23
		187.5ng/ml	50	49	1	50	0	50	0
		225ng/ml	50	50	0	50	0	50	0
		262.5ng/ml	50	50	0	50	0	50	0
		300ng/ml	50	50	0	50	0	50	0
		0ng/ml	50	0	50	0	50	0	50
		0.25ng/ml	50	0	50	0	50	0	50
FTY1		0.5ng/ml	50	0	50	0	50	0	50
		0.75ng/ml	50	2	48	0	50	1	49
		1ng/ml	50	25	25	27	23	27	23
		1.25ng/ml	50	50	0	50	0	50	0
		1.5ng/ml	50	50	0	50	0	50	0
		1.75ng/ml	50	50	0	50	0	50	0
		2ng/ml	50	50	0	50	0	50	0
		0ng/ml	50	0	50	0	50	0	50
		125ng/ml	50	0	50	0	50	0	50
		250ng/ml	50	0	50	0	50	0	50
MDMA 500		375ng/ml	50	0	50	0	50	0	50
		500ng/ml	50	26	24	29	21	28	22
		625ng/ml	50	50	0	50	0	49	1
		750ng/ml	50	50	0	50	0	50	0
		875ng/ml	50	50	0	50	0	50	0
		1000ng/ml	50	50	0	50	0	50	0
MET 500		0ng/ml	50	0	50	0	50	0	50
		125ng/ml	50	0	50	0	50	0	50
		250ng/ml	50	0	50	0	50	0	50
		375ng/ml	50	0	50	0	50	0	50
		500ng/ml	50	27	23	29	21	27	23
		625ng/ml	50	50	0	50	0	49	1
		750ng/ml	50	50	0	50	0	50	0
		875ng/ml	50	50	0	50	0	50	0
		1000ng/ml	50	50	0	50	0	50	0
		0ng/ml	50	0	50	0	50	0	50
MOP /OPI 300		75ng/ml	50	0	50	0	50	0	50
		150ng/ml	50	0	50	0	50	0	50
		225ng/ml	50	0	50	0	50	0	50
		300ng/ml	50	28	22	27	23	30	20
		375ng/ml	50	50	0	49	1	50	0
		450ng/ml	50	50	0	50	0	50	0
		525ng/ml	50	50	0	50	0	50	0
		600ng/ml	50	50	0	50	0	50	0
		0ng/ml	50	0	50	0	50	0	50
		75ng/ml	50	0	50	0	50	0	50
MTD 300		150ng/ml	50	0	50	0	50	0	50
		225ng/ml	50	0	50	0	50	0	50
		300ng/ml	50	26	24	26	24	25	25

		375ng/ml	50	50	0	49	1	50	0
		450ng/ml	50	50	0	50	0	50	0
		525ng/ml	50	50	0	50	0	50	0
		600ng/ml	50	50	0	50	0	50	0
		0ng/ml	50	0	50	0	50	0	50
OXY 100		25ng/ml	50	0	50	0	50	0	50
		50ng/ml	50	0	50	0	50	0	50
		75ng/ml	50	1	49	0	50	0	50
		100ng/ml	50	26	24	25	25	28	22
		125ng/ml	50	50	0	49	1	50	0
		150ng/ml	50	50	0	50	0	50	0
		175ng/ml	50	50	0	50	0	50	0
		200ng/ml	50	50	0	50	0	50	0
		0ng/ml	50	0	50	0	50	0	50
		6.25ng/ml	50	0	50	0	50	0	50
PCP 25		12.5ng/ml	50	0	50	0	50	0	50
		18.75ng/ml	50	0	50	0	50	0	50
		25ng/ml	50	27	23	30	20	29	21
		31.25ng/ml	50	50	0	50	0	49	1
		37.5ng/ml	50	50	0	50	0	50	0
		43.75ng/ml	50	50	0	50	0	50	0
		50ng/ml	50	50	0	50	0	50	0
		0ng/ml	50	0	50	0	50	0	50
TCA 1000		250ng/ml	50	0	50	0	50	0	50
		500ng/ml	50	0	50	0	50	0	50
		750ng/ml	50	0	50	0	50	0	50
		1000ng/ml	50	29	21	28	22	26	24
		1250ng/ml	50	50	0	49	1	50	0
		1500ng/ml	50	50	0	50	0	50	0
		1750ng/ml	50	50	0	50	0	50	0
		2000ng/ml	50	50	0	50	0	50	0
		0ng/ml	50	0	50	0	50	0	50
		12.5ng/ml	50	0	50	0	50	0	50
THC 50		25ng/ml	50	0	50	0	50	0	50
		37.5ng/ml	50	1	49	1	49	0	50
		50ng/ml	50	30	20	28	22	27	23
		62.5ng/ml	50	50	0	50	0	49	1
		75ng/ml	50	50	0	50	0	50	0
		87.5ng/ml	50	50	0	50	0	50	0
		100ng/ml	50	50	0	50	0	50	0

Effect of Urinary Specific Gravity

Total 12 urine samples of specific gravities (SG) ranging from 1.000-1.035 were collected. Values of SG levels were determined by a refractometer. Target drugs were spiked to these urine samples at +50% cut-off and -50% cut-off concentrations. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 and spiked with the target drug at 50% below and 50% above Cutoff levels. The spiked pH-adjusted urine was tested with the iSCREEN™ Urine Test DX Drug Screen Tox Cup. The results demonstrate the varying ranges of urinary pH do not affect the test results.

Interference

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine target drugs urine with concentrations at 50% below and 50% above Cut-Off levels. The following compounds show no cross-reactivity when tested with the iSCREEN™ Urine Test DX Drug Screen Tox Cup at a concentration of 100µg/mL or specified concentrations.

Non Interference Compounds		
3-Hydroxytyramine	Digoxin	Nitroglycerin
Acetaminophen	Diphenhydramine HCl	Nordoxepin
Acetone(1000mg/dL)	Disopyramide (except MTD test)	Norethindrone
Acetophenetidin	DL-Tryptophan	Norfentanyl
Acetylsalicylic acid	DL-Tyrosine	Noscapine
Acyclovir	Dopamine HCl	O-Hydroxyhippuric acid
Albumin(100mg/dL)	Doxepin(except TCA test)	Octopamine
Albuterol sulfate(Proair HFA)	Doxylamine	Olanzapine
Alpha Methadol	Duloxetine	Omeprazole

Aminophylline	Ecgonine methyl ester	Oxalic acid (100 mg/dL)
Aminopyrine	EMDP	Oxolinic acid
Amoxicillin	Ephedrine	Oxymetazoline
Ampicillin	Erythromycin	Paliperidone
Apomorphine	Esomeprazole Magnesium (except MTD test)	Papaverine
Aripiprazole	Ethanol(1%)	Penicillin-G
Ascorbic acid	Fenoprofen	PenicillinV Potassium
Aspartame	Fluoxetine Hydrochloride	Perphenazine
Aspirin	Fluphenazine	Phenacetin
Atomoxetine	Furosemide	Phenelzine
Atorvastatin Calcium	Gabapentin	Phenethylamine
Atropine	Galactose (10mg/dL)	Phenylpropanolamine
Azithromycin	Gamma Globulin (500mg/dL)	Prednisone
Benzilic acid	Gatifloxacin	Pregablin
Benzocaine	Gentisic acid	Procaine
Benzoic acid	Glucose (3000mg/dL)	Promethazine(except TCA test)
Benzphetamine	Hemoglobin	Propoxyphene
Bilirubin	Hydralazine	Propranolol
Boric Acid (1%)	Hydrochlorothiazide	Pseudoephedrine
Bupropion	Hydrocortisone	Quetiapine
Caffeine	Hydroxytyramine	Quinine
Cannabidiol	Ibuprofen	Ranitidine
Captopril	Isoproterenol	Riboflavin (10mg/dL)
Carbamazepine	Isoxsuprine	Rifampicin
Carfentanil(except FTY test)	Ketamine	Risperidone
Cefradine	Ketoprofen	Salicylic acid
Cephalexin	L-Ephedrine	Serotonin (5- Hydroxytyramine)
Chloralhydrate	L-Epinephrine	Sertraline
Chloramphenicol	L-phenylephrine	Sildenafil Citrate
Chloroquine(except MET test)	LAAM HCl	Simvastatin
Chlorothiazide	Labetalol	Sulfamethazine
Chlorpheniramine	Levofloxacin Hydrochloride	Sulindac
Chlorpromazine	Levonorgestrel	Telmisartan
Cholesterol	Levothyroxine Sodium	Tetrahydrocortisone 3-(β-Dglucuronide)
Ciprofloxacin Hydrochloride	Lidocaine Hydrochloride	Tetrahydrocortisone, 3-acetate
Citalopram	Lisinopril	Tetrahydrozoline
Clarithromycin	Loperamide	Theophylline
Clonidine	Loratadine	Thiamine
Clozapine	Magnesium	Thioridazine
Conjugated Estrogens	Maprotiline	Tramadol Hydrochloride
Cortisone	Meperidine	Triamterene
Cotinine	Meprobamate	Trifluoperazine
Creatinine	Methapyrilene	Trimethobenzamide
Cyclobenzaprine	Methaqualone	Trimethoprim
D-Pseudoephedrine	Methoxyphenamine (except AMP/MET test)	Tyramine
D,L-Epinephrine	Metoprolol Tartrate	Urea (2000mg/dL)
D,L-Isoproterenol	Metronidazole (300ug/ml)	Uric acid
D,L-Octopamine	Mifepristone	Valproic acid (250ug/ml)
D,L-Propranolol	N-Acetylprocainamide	Venlafaxine HCl
D,L-Tryptophan	NaCl (4000mg/dL)	Verapamil
D,L-Tyrosine	Nalidixic acid	Vitamin B2
Delorazepam (except BZO test)	Naloxone hydrochloride (except OXY test)	Vitamin C
Deoxycorticosterone	Naltrexone hydrochloride	Zaleplon
Desloratadine	Naproxen	Zomepirac
Dextromethorphan	Niacinamide	β-Estradiol
Diclofenac sodium	Nicotine	
Diflunisal	Nifedipine	

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【GLOSSARY OF SYMBOLS】

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Store between 35.6-86°F (2-30°C)
	In vitro diagnostic medical device		Batch code		Catalogue number
	Keep dry		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Unique device identifier		Keep away from sunlight

Distributed by:
Instant Technologies, Inc.,
Portsmouth, VA 23704 USA
ASSISTANCE
If you have any questions regarding the use of this product, please call our Technical Support
Number 1-877-441-7440, option 2
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Made in China

Number 14602416900
Revision date: 2024-07-24



INSTANT DRUG TEST CUP/CARD II (IDTC II)

Package Insert for OTC Use

For *in vitro* diagnostic use only

The CLIAwaived, Inc. Instant Drug Test Cup/Card II offers a variety of solutions for fast and reliable drug testing in the privacy of your own home. This product can detect up to 15 commonly abused drugs in human urine:

Abbreviation	Drug	Cutoff (ng/ml)
AMP	Amphetamine	500
BAR	Barbiturates	300
BUP	Buprenorphine	10
BZO	Benzodiazepines	300
COC	Cocaine	150
EDDP	Methadone Metabolite	300
MET	Methamphetamine	500
MDMA	Ecstasy	500
MTD	Methadone	300
OPI	Morphine	300
OPI	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	50

This test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC/MS/MS) and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in the evaluation of a preliminary positive test result.

This test does not distinguish between drugs of abuse and certain medications. It may yield preliminary positive results when prescription tricyclic antidepressants, barbiturates, benzodiazepines, methadone, buprenorphine or opiates are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

INSTRUCTIONS FOR OTC USE:

BEFORE TESTING

Read the instructions completely.

Check the expiration date on the box. Do not use the test if it is expired. Have a watch, clock or timer ready.

The following items are needed only if you choose to ship samples for confidential confirmation lab testing:

- Pre-addressed shipping box
- Plastic transportation bag
- Identification label

PERFORMING THE TEST

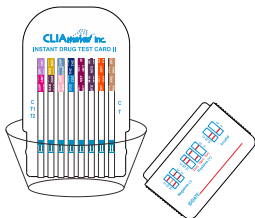
Step 1: Take Out the Test Device

Take the test device from the sealed foil pouch. The CLIAwaived, Inc. Instant Drug Test comes in two (2) types: dip card and cup.

Step 2: Apply Urine to the Test Device

If Using a Dip Card:

1. Remove the dip card from the sealed pouch. Write the donor name or ID in the provided space and then remove the cap.
2. With the arrows pointing toward the urine specimen, **immerse the sample tips vertically** in the urine specimen for **at least 20 seconds**. Put the cap back on the dip card. Place the dip card on a flat surface.



If Using a Cup:

1. Remove the cup from the sealed pouch. Write the donor name or ID in the space provided.
2. **Collect urine** in the cup.



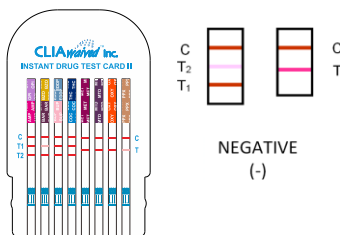
Step 3: Read Result

Read results after 5 minutes. Do not wait longer than 60 minutes.

A red or pink line must appear next to the letter “C” (control) on all of the test strips. The appearance of a red or pink next to the letter “C” on each test strip indicates that the test has worked properly. If you see control lines on all the test strips, you can read your test results.

Negative Result:

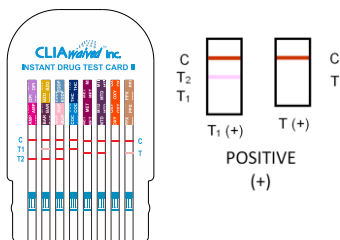
A red or pink line next to the “T1” or “T2” (drug test line) under the drug name indicates a negative result for that drug. If a test line appears next to the “T1” or “T2” for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.



Preliminary Positive Result:

If NO red or pink line appears next to the “T1” or “T2” under the drug name, the sample may contain that drug. Send the sample to a laboratory for confirmation testing.

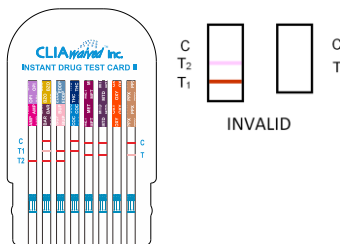
The illustration on the right shows preliminary positive results for OPI, COC and OXY, but negative for all other drugs.



Invalid Result:

A colored line should always appear next to the letter “C” on every test strip. If no control line appears on any of test strips, the result is invalid.

The illustration at right shows no line next to the letter “C” on the first strip (OPI, AMP), third strip (EDDP, BUP) and seventh strip (OXY). The test results for those three test strips are invalid.



QUESTIONS AND ANSWERS

The CLIAwaived, Inc. IDTC II is user friendly, if you have question about the test or result, please call our helpline at 1-888-882-7739, a 24/7-recorded information service is available, please leave your message and your call will be returned the next business day. In addition, the CLIAwaived, Inc. team is available to answer your question weekdays from 8 am to 5 pm PST

What do my test results mean?

Q. The drug line is lighter than control line. Does it mean the drug is present in the urine?

A. No. The drug line may be darker or lighter than the control line. The line intensities of different drugs will vary for many reasons. No matter how faint the drug line appears on the test strip, it is considered a negative result. No further testing is required.

Q. What does a Preliminary Positive Result mean?

A. The sample may contain one or more of the drugs being tested for. It is possible to get a "preliminary positive" when someone has not taken the drug. We recommend you send the urine to our laboratory for additional confirmation testing. Additional fees may apply.

- Medicinal such as diet pills, inhalers, cough syrup, and pain pills may cause a preliminary positive result.
- The tests may yield preliminary positive results with prescription drugs such as tricyclic antidepressants, barbiturates, benzodiazepine, methadone, buprenorphine (including Subutex, Suboxone, Temgesic, Buprenex, Norspan, and Butrans), and opiates (including morphine, hydrocodone, Oxycodone, and codeine) are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine. To find more information on false positive results caused by prescription drugs, see www.askdocweb.com/falsepositives.html.

Q. What does a Negative Result mean?

A. If you get a negative result, the sample did not contain the drug being tested for. No further testing is required. However, it is possible to get a negative result even if a person has taken drugs. Some reasons why this might happen are:

- The urine sample was collected at the wrong time. It was collected before the drug got into the urine or after it was no longer in the urine.
- The person took a drug other than the one tested for in this test; e.g. they might have taken LSD, when this test is for drugs other than LSD.

Q. What does an Invalid Result mean?

A. If any of the strips do not show a control, the result is invalid. We recommend that you re-test or contact your sales representative.

Laboratory Confirmation Testing:

Q. How can a Preliminary Positive Result be confirmed?

A. The urine specimen needs to be sent to our laboratory for confirmation testing. See the shipping instructions in **"Shipping the Urine Sample to the Lab for Confirmation Testing"** section below.

Other Questions:

Q. When is the best time to take the test?

A. The drug test can be used at any time of day. Approximate detection times using each drug are listed in the following table:

Drug	Cutoff	Minimum	Maximum
Amphetamine (AMP)	500 ng/ml	2-7 hours	2-4 days
Cocaine (COC)	150 ng/ml	1-4 hours	2-4 days
Methamphetamine (MET)	500 ng/ml	2-7 hours	2-4 days
Opiates (OPI)	2,000 ng/ml	2 hours	2-3 days
Marijuana (THC)	50 ng/ml	2 hours	Up to 40 days
Tricyclic Antidepressants (TCA)	1,000 ng/ml	8-12 hours	2-7 days
Phencyclidine (PCP)	25 ng/ml	4-6 hours	7-14 days
Barbiturates (BAR)	300 ng/ml	2-4 hours	1-3 weeks
Benzodiazepines (BZO)	300 ng/ml	2-7 hours	1-4 days
Oxycodone (OXY)	100 ng/ml	1-3 hours	1-2 days
Methadone (MTD)	300 ng/ml	3-8 hours	1-3 days
Ecstasy (MDMA)	500 ng/ml	2-7 hours	2-4 days
EDDP	300 ng/ml	3-8 hours	1-3 days
Buprenorphine (BUP)	10 ng/ml	4-24 hours	3-6 days

The Substance Abuse and Mental Health Services Agency (SAMHSA) has set cutoff levels when testing for marijuana, cocaine, amphetamine, opiates, PCP, Ecstasy and methamphetamine. Screening tests may not detect amounts of drugs in a urine sample that are below the cutoff level. Even if some drug is present in a urine sample, the sample would be considered negative if the drug level is below the cutoff level.

Q. How much urine do I need?

A. The CLIAwaived, Inc. Instant Drug Test Cup/Card II requires just 30 ml of urine. Fill the collection cup to the minimum fill line on the side of the cup. This is enough urine for the initial test and confirmation testing if needed.

Q. Do I have to wait the full 5 minutes before reading the test?

A. Yes, we recommend that you wait the full 5 minutes before reading the result.

Q. Are there any factors that could affect the drug testing result?

A. Yes, certain factors may affect the drug testing result.

1. Certain over the counter medicines and prescription medicines may cause a preliminary positive result.
2. Urine can be adulterated (i.e. contaminated or tampered) by using bleach, cleaning supplies and other liquids. This may dilute the urine and the test may not be accurate.
3. Drinking large amount of liquids may dilute the urine so that the drug (if present) cannot be detected.
4. Failure to use the CLIAwaived, Inc. IDTC II as directed may result in an inaccurate screening result.
5. The following compounds are detected positive in urine by the The CLIAwaived, Inc. Instant Drug Test Cup/Card II. Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses.

Compound	Concentration (%)	Compound	Concentration (%)
AMP			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
BAR			
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital	500 (60%)	Phenobarbital	300 (100%)
Butabarbital	100 (300%)	Pentobarbital	250(120%)
BUP			
Buprenorphine	10 (100%)		
BZO			
Oxazepam	300 (100%)	Lorazepam	3,900 (7.7%)
Alprazolam	200 (150%)	Lorazepam-glucuronide	5,000 (6%)
Bromazepam	1,000 (30%)	Nitrazepam	250 (120%)
Clobazam	200 (150%)	Norchlordiazepoxide	500 (60%)
Clorazepate	750 (40%)	Nordazepam	390 (76.9%)
Desalkylflurazepam	1,200 (25%)	Nordiazepoxide	400(75%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
α-Hydroxyalprazolam	1,900 (15.8%)		
COC			
Benzoylcegonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
EDDP			
EDDP	300 (100%)		
MET			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		
OPI			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)	Norcodeine	6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone	2,500 (12%)		
MTD			
Methadone	300 (100%)		
OPI			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)
Hydrocodone	5,000 (40%)		

Compound	Concentration (%)	Compound	Concentration (%)
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
TCA			
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)
THC			
11-nor- Δ^9 -THC-9-COOH	50 (100%)	(-)- Δ^8 -THC	20,000 (0.3%)
(+/-)-11-Hydroxy- Δ^9 -THC	5,000 (1%)	(-)- Δ^9 -THC	20,000 (0.3%)

SHIPPING URINE SAMPLES FOR CONFIRMATION TESTING (OTC ONLY)

About confirmation testing:

Negative samples do not need further testing. You should only send preliminary positive samples to a laboratory for confirmation.

Check the provided shipping package:

The following items are provided (OTC only):

- Mailer: Pre-addressed Mailing Box with Transportation Label
- Zip-lock Plastic Transportation Bag
- Identification Label

Package urine samples for shipping:

- Attach the top portion of the identification label to the urine collection cup.
- Attach the lower portion of the identification label to the instruction sheet where labeled "place identification label here." For security reasons, you will need this number to retrieve your lab test results.
- Place the urine collection cup in the zip-lock plastic transportation bag, seal and place into the pre-addressed mailing box and close. On the pre-addressed mailing box label, fill in the sample collection date.
- On the mailing box label, check off the drug(s) that gave a preliminary positive result. IT IS IMPORTANT THAT YOU INDICATE WHICH DRUG WAS POSITIVE SO THAT A LAB CONFIRMATION TEST CAN BE PERFORMED FOR THAT DRUG. WITHOUT THIS LABEL, YOUR SAMPLE CANNOT BE TESTED.
- Mail the preliminary positive urine sample as soon as possible. Urine samples cannot be accurately tested if more than 7 days old.
- The mailing box is not pre-paid. To ensure prompt delivery, be sure to pay the appropriate shipping charges.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. External controls are available from CLIAwaived, Inc. or other commercial sources. A minimum of 5mL of positive and/or negative control material is required to activate the CLIAwaived, Inc Instant Drug Test Cup II. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators. It is recommended that Quality control testing be performed with each new lot, with each new shipment, and every thirty days when storage conditions may have changed or exceeded storage requirements of the product labeling. External controls can be purchased from the following vendor: CLIAwaived, Inc. 1-888-882-7739, www.cliawaived.com.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

The accuracy of the CLIAwaived, Inc. Instant Drug Test CUP/CARD II (IDTC II) was evaluated in comparison to GC/MS and LC/MS. 40 drug-free urine samples collected from presumed non-user volunteers were tested with the CLIAwaived, Inc. Instant Drug Test CUP/CARD II (IDTC II). Of these 40 negative samples, all were correctly identified as negative. 10% of the negative samples were confirmed with GC/MS as drug negative. At least 40 drug positive urine specimens for each drug test were obtained from reference labs. Drug concentrations were confirmed with GC/MS and LC/MS (for TCA). A summary of the accuracy and discordant results on Dip Card and Cup formats are shown in the following tables:

Summary of Accuracy Results on the CLIAwaived, Inc. Card II

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						
		Drug-free	-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% Agreement
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Discordant Results on the CLIAwaived, Inc Card II

Drug Test/ Cutoff (ng/ml)	CLIAwaived, Inc Dip Card II Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoyllecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine

Drug Test/ Cutoff (ng/ml)	CLIAwaived, Inc Dip Card II Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
OPI/300	Positive	260	Morphine
	Positive	263	Morphine
	Positive	292	Morphine
MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor- Δ^9 -THC-9-COOH

Summary of Accuracy Results on the CLIAwaived, Inc Cup II

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						
		Drug-free	-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% Agreement
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Discordant Results on the CLIAwaived, Inc Cup II

Drug Test/ Cutoff (ng/ml)	CLIAwaived, Inc Cup II Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoyllecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine
OPI/300	Positive	260	Morphine
	Positive	263	Morphine
	Positive	292	Morphine
MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor- Δ^9 -THC-9-COOH

B. ANALYTICAL SENSITIVITY/PRECISION

Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested by 9 operators at 3 physician office laboratories (POL) over 20 non-consecutive days. Each level of solution was tested in 10 replicates randomly by each operator at each POL site. Results showed over 99% agreement at +/-50% cutoff levels with the CLIAwaived, Inc Card and Cup.

C. ANALYTICAL SPECIFICITY

The following compounds are detected positive in urine by the CLIAwaived, Inc Instant Drug Test Cup/Card II. Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses.

Compound	Concentration (%)	Compound	Concentration (%)
AMP			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
BAR			
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital	500 (60%)	Phenobarbital	300 (100%)
Butabarbital	100 (300%)	Pentobarbital	250 (120%)
BUP			
Buprenorphine	10 (100%)		
BZO			
Oxazepam	300 (100%)	Lorazepam	3,900 (7.7%)
Alprazolam	200 (150%)	Lorazepam-glucuronide	5,000 (6%)
Bromazepam	1,000 (30%)	Nitrazepam	250 (120%)
Clobazam	200 (150%)	Norchlordiazepoxide	500 (60%)
Clorazepate	750 (40%)	Nordazepam	390 (76.9%)
Desalkylflurazepam	1,200 (25%)	Nordiazepoxide	400(75%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
α-Hydroxyalprazolam	1,900 (15.8%)		
COC			
Benzoylcegonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
EDDP			
EDDP	300 (100%)		
MET			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		
OPI			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)	Norcodeine	6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone	2,500 (12%)		
MTD			
Methadone	300 (100%)		
OPI			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)
Hydrocodone	5,000 (40%)		
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)

Compound	Concentration (%)	Compound	Concentration (%)
TCA			
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)
THC			
11-nor- Δ^9 -THC-9-COOH	50 (100%)	(-)- Δ^8 -THC	20,000 (0.3%)
(+/-)-11-Hydroxy- Δ^9 -THC	5,000 (1%)	(-)- Δ^9 -THC	20,000 (0.3%)

D. INTERFERENCE

The following compounds were evaluated for potential positive or negative interference with the CLIAwaived, Inc. Instant Drug Test Cup/Card II. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the CLIAwaived, Inc. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/mL when tested with the CLIAwaived, Inc. Instant Drug Test Cup/Card II:

Acetaminophen	Diphenhydramine	Nicotine
Acetone	Dopamine	(+/-)-Norephedrine
Albumin	(+/-)-Isoproterenol	Oxalic acid
Ampicillin	1R,2S(-)-Ephedrine	Penicillin-G
Ascorbic acid	Erythromycin	Pheniramine
Aspartame	Ethanol	Phenothiazine
Aspirin	Furosemide	L-Phenylephrine
Atropine	Glucose	B-Phenylethylamine
Benzocaine	Guaiacol glyceryl ether	Procaine
Bilirubin	Hemoglobin	Quinidine
Caffeine	Ibuprofen	Ranitidine
Chloroquine	(+/-)-Isoproterenol	Riboflavin
(+)-Chlorpheniramine	Ketamine	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Sulindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan	(+)-Naproxen	
4-Dimethylaminoantipyrine	Niacinamide	

ADULTERATION TEST

Urine sample adulteration is usually achieved by substitution, dilution or the addition of adulterants including so-called "masking agents" sold commercially. The use of adulterants can cause false negative results in drug tests by either interfering with the test and/or destroying drugs present in the urine. Dilution may also be used in an attempt to produce false negative drug test results.

The CLIAwaived, Inc. adulteration test is based on the color response of chemical indicators in the presence of adulterants. pH (P), specific gravity (S), oxidant/PCC (O), creatinine (C), nitrite (N) and glutaraldehyde (G) are tested to determine the integrity of urine samples.

pH: The pH determination of urine samples is based on the color change of an indicator in an acidic or basic medium. Normal urine pH ranges from 4 to 9. Values outside of this range may indicate the sample has been altered.

Specific Gravity: The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. The normal range for specific gravity is from 1.003 to 1.030. Values outside this range generally indicate specimen dilution or adulteration.

Oxidants/PCC (Pyridinium Chlorochromate): Bleach, hydrogen peroxide, pyridinium chlorochromate or other oxidizing agents react with an oxidant indicator to form a color complex. A blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents. Normal human urine should not contain oxidants.

Creatinine: Creatinine reacts with an indicator in an alkaline medium to form a purplish-brown color complex. The normal range of creatinine is from 20 to 300 mg/dl. Values outside this range generally indicate a manipulated test.

Nitrite: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. A urine sample containing nitrite at a level greater than 15 mg/dl is considered adulterated.

Glutaraldehyde: Adulterants such as "Clear Choice" contain glutaraldehyde which may cause disrupting the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in human urine.

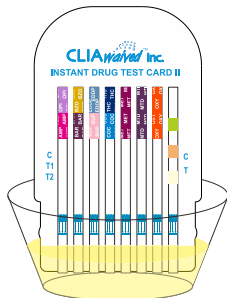
PROCEDURE FOR DRUG TEST WITH ADULTERATION TEST

Preparation:

1. Allow the test device, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Do not open the test device pouch until ready to perform the test.

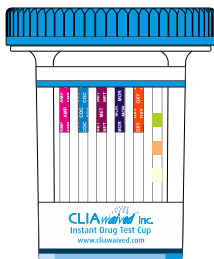
Dip Card:

1. Remove the dip card from the sealed pouch. Write the donor name or ID on the dip card in the provided space, then remove the cap.
2. With the arrows pointing toward the urine specimen, immerse the sample tips vertically in the urine specimen for at least 20 seconds. Replace the cap back onto the dip card and place the dip card on a flat surface.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read urine adulteration test results by visually comparing the color of the reagent pads to the corresponding color blocks on the Color Chart at 3 to 5 minutes.



Cup:

1. Remove cup from the sealed pouch and write the donor name or ID in the provided space.
2. Collect urine in the cup.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read urine adulteration test results by visually comparing the color of the reagent pads to the corresponding color blocks on the Color Chart at 3 to 5 minutes.



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 Do not reuse	 Use by YYY-MM-DD or YYYY-MM
 Batch Code	 Serial number
 Caution, consult accompanying documents	 Catalog number
 Manufacturer	 Temperature limitation
 Contains sufficient for <n> tests	 Keep away from sunlight
 In vitro diagnostic medical device	 Keep away from moisture
 Consult instructions for use	 CE Mark
 Recycle	 Authorized representative in the European Community



Emergo Europe, Molenstraat 15
2513 BH, The Hague, The Netherlands



CLIAwaived, Inc.
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FOR TECHNICAL ASSISTANCE

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OUTSIDE THE USA

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CLIAwaived, Inc.
11578 Sorrento Valley Road Suite 25/26, San Diego, CA 92121
36001-CWII-OTC
Revision 2



Instant Drug Test Cup Plus

Package Insert

For *In Vitro* Diagnostic Use

For HCP/Professional use

INTENDED USE

The CLIAwaived Inc. Instant Drug Test Cup Plus is lateral flow immunoassays for rapid detection of multiple commonly abused drugs in human urine. The detectable drugs and their cutoff concentrations are listed below:

Abbreviation	Analyte	Calibrator	Cutoff (ng/mL)
6AM	6-Acetylmorphine	6-Monoacetylmorphine	10
AMP	Amphetamine	d-Amphetamine	500 / 1000
BAR	Secobarbital	Secobarbital	300
BUP	Buprenorphine	Buprenorphine	10
BZO	Oxazepam	Oxazepam	300
COC	Cocaine	Benzoylcegonine	150 / 300
EDDP	EDDP	2-ethylidene-1,5-dimethyl-3-3-diphenylpyrrolidine	300
FEN	Fentanyl	Fentanyl	1
FEN	Norfentanyl	Norfentanyl	5
MDMA	Ecstasy	d,l-Methylenedioxy methamphetamine	500
MET	Methamphetamine	d-Methamphetamine	500 / 1000
MOR	Morphine	Morphine	300
MTD	Methadone	d/l-Methadone	300
OPI	Opiates	Morphine	2000
OXY	Oxycodone	Oxycodone	100
PCP	Phencyclidine	Phencyclidine	25
PPX	Propoxyphene	Propoxyphene	300
TCA	Nortriptyline	Nortriptyline	1000
THC	Marijuana	11-nor- Δ^9 -THC-9-COOH	20 / 50

The single or multi-test cup can include any combination of the analytes listed above, with and without on-board adulteration tests. However, only one cut-off concentration can be included per analyte per device.

This *in vitro* diagnostic device provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. GC/MS or LC/MS is the preferred confirmatory method.

PRINCIPLE

All tests included in this device are rapid lateral flow immunoassays, based on the principle of competitive binding, between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites, which may be present in the urine sample, competing for the limited antibody binding sites. Urine migrates via capillary action along the nitrocellulose (NC) membrane strip pre-coated with a drug-protein conjugate band on the test line (T) region and a colored antibody-colloidal gold conjugate pad, and rehydrates the antibody colloidal gold conjugate on test strip. This urine-gold conjugate mixture then migrates along the NC membrane to the immobilized drug-protein band. If a target drug is absent or present in the urine specimen below its cut-off concentration, the colored antibody-gold conjugates specifically bind with the immobilized drug-protein conjugates to form a visible line on the (T) region. If the target drug level exceeds its cut-off concentration, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, the formation of the visible T band indicates a negative result, while absence of T band indicates a positive result.

A visible line generated by a different antigen-antibody reaction is also present but located in the control region of the test strip. This line will always appear at the control line region, regardless of the presence of target drugs in urine, as long as proper volume of specimen has been added and membrane wicking has occurred. The presence of a control line serves as a built-in procedural control, which indicates that the test was properly performed.

REAGENTS

Each test strip contains a colloidal gold pad coated with drug-specific antibodies. It also contains a membrane coated with drug-protein conjugates in the test line region and control IgG in the control line region.

ADULTERATION TEST (OPTIONAL COMPONENT)

Urine sample adulteration is usually achieved by substitution, dilution or the addition of adulterants including so-called "masking agents" sold commercially. The use of adulterants can cause false negative results in drug tests by either interfering with the test and/or destroying drugs present in the urine. Dilution may also be used in an attempt to produce false negative drug test results. The adulteration test strip contains chemically treated reagent pads, which can be activated by a urine sample.

PRECAUTIONS

- All urine specimens should be regarded as potentially hazardous or infectious. Wear gloves and proper attire to avoid skin contact and handle with universal precautions.
- Do not open the sealed pouch until ready to perform the test.
- Do not use the device after the expiration date.
- Do not re-use the device.

MATERIAL SUPPLIED

- Twenty-five (25) individually pouched test cups
- One (1) Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer

STORAGE AND STABILITY

- Store as package in the sealed pouch at 2°C - 30°C (35.6°F - 86.0°F).
- Once pouch open, the test cup must be used within 1 hour.
- The test is stable through the expiration date printed on the sealed pouch.
- Do not use beyond the expiration date.
- Do not freeze the pouch.

SPECIMEN COLLECTION AND PREPARATION

- A fresh urine sample should be collected in a clean, dry plastic or glass container.
- Fresh urine does not require any special handling or pretreatment.

DIRECTIONS FOR USE

- Remove the test cup from the pouch and use it within 1 hour after pouch opening.
- Remove the lid of the cup and set it aside.
- Collect urine in the cup.
- Screw the lid back on and place the cup on a flat surface, start the timer and wait for the colored line(s) to appear.
- Remove the Peel-off label and read the test result at 5 minutes, following the result interpretation below.
- The result remains stable for 30 minutes. Do not read the result after 30 minutes.

RESULT INTERPRETATION

Negative (-): Two colored lines appear. One in the control region (C) and another in the test region (T). The line in the control region is to indicate the proper performance of the device. The appearance of another line in the test region indicates that the concentration of target drug in urine is below the cutoff level.

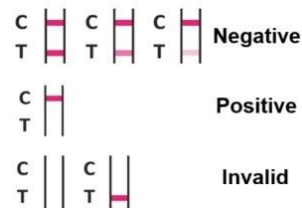
NOTE: The intensity of the test line may vary. It should be considered negative whenever there is even a faint colored line.

Positive (+): One colored line appears in the control region (C). No line appears in the test region (T). A positive result indicates that the concentration of target drug in urine is at or above the cutoff level.

Invalid: No colored line appears in the control region (C).

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test kit. If the problem persists, contact your local distributor.

peel off the label to read the result



QUALITY CONTROL

An internal control is included in the test. A colored line appearing in the control line region (C) is considered a procedural quality control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

- This device provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. GC/MS or LC/MS is the preferred confirmatory methods.
- Both inaccurate techniques or procedures and the existence of interfering substances or adulterants in urine specimen can cause erroneous results.
- A positive result only indicates the presence of drug or its metabolites in urine but does not provide information on drug concentration, administration route and level of intoxication.
- A negative result only indicates that the concentration of drug in urine is below the cutoff level. It may not necessarily indicate drug free.
- The test does not distinguish between drugs of abuse and prescribed medication.

PERFORMANCE CHARACTERISTICS

Precision/Reproducibility

The precision/reproducibility study was carried out by testing samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cut off and -100% cutoff. Samples were prepared by spiking target drugs in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. Each sample was tested in 50 replicates per lot using three lots of devices, and testing was performed two runs per day for 25 days. The results obtained are summarized in the table below:

Drug	Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cutoff
6AM 10	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	49- /1+	50- /0+	50- /0+	50- /0+

AMP 500	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
AMP 1000	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
BAR 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
BUP 10	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	12- /38+	48- /2+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	13- /38+	50- /0+	50- /0+	50- /0+	50- /0+
BZO 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
COC 150	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
COC 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
EDDP 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	2- /48+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	1- /49+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
FEN 1	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	2- /48+	13- /37+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	2- /48+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
FEN 5	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	48- /2+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	2- /48+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
MDMA 500	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	49- /1+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
MET 500	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
MET 1000	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
MOR 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
MTD 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
OPI 2000	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+

OXY 100	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
PCP 25	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
PPX 300	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	49- /1+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
TCA 1000	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
THC 20	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
THC 50	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+

Method Comparison (Accuracy)

Method comparison was performed by testing unaltered clinical urine specimens with both the CLIAwaived Inc. Instant Drug Test Cup Plus and LC/MS as gold standard reference method. Eighty samples (40 negative and 40 positive) with blind labels were tested for each drug by three operators, and then compared to the LC-MS/MS results. The results are presented in the table below:

Drug Test	Test Cup Result		Drug Free	Low Negative by LC/MS (<-50% Cutoff)	Near Cutoff by LC/MS (Between ~50% and Cutoff)	Low Positive by LC/MS (Between Cutoff and +50%)	High Positive by LC/MS (> + 50% Cutoff)
6AM 10	Operator A	-	12	16	11	1	0
		+	0	0	1	15	24
	Operator B	-	12	16	11	0	0
		+	0	0	1	16	24
	Operator C	-	12	16	11	0	0
		+	0	0	1	16	24
AMP 500	Operator A	-	12	16	12	1	0
		+	0	0	0	12	27
	Operator B	-	12	16	12	2	0
		+	0	0	0	11	27
	Operator C	-	12	16	12	1	0
		+	0	0	0	12	27
AMP 1000	Operator A	-	12	17	11	0	0
		+	0	0	0	15	25
	Operator B	-	12	17	11	1	0
		+	0	0	0	14	25
	Operator C	-	12	17	11	1	0
		+	0	0	0	14	25
BAR 300	Operator A	-	8	13	18	0	0
		+	0	0	1	16	24
	Operator B	-	8	13	17	0	0
		+	0	0	2	16	24
	Operator C	-	8	13	17	0	0
		+	0	0	2	16	24
BUP 10	Operator A	-	15	14	10	1	0
		+	0	0	1	17	22
	Operator B	-	15	14	10	1	0
		+	0	0	1	17	22
	Operator C	-	15	14	10	1	0
		+	0	0	1	17	22
BZO 300	Operator A	-	8	17	13	0	0
		+	0	0	2	12	28
	Operator B	-	8	17	14	0	0
		+	0	0	1	12	28
	Operator C	-	8	17	13	0	0
		+	0	0	2	12	28
COC 150	Operator A	-	12	13	14	2	0
		+	0	0	1	13	25
	Operator B	-	12	13	14	1	0
		+	0	0	1	14	25
	Operator C	-	12	13	14	1	0
		+	0	0	1	14	25
COC 300	Operator A	-	12	18	10	1	0
		+	0	0	0	15	24
	Operator B	-	12	18	9	1	0
		+	0	0	1	15	24
	Operator C	-	12	18	10	0	0
		+	0	0	0	16	24

EDDP 300	Operator A	-	11	16	12	1	0
	Operator A	+	0	0	1	13	26
	Operator B	-	11	16	13	1	0
	Operator B	+	0	0	0	13	26
FEN 1	Operator C	-	11	16	11	1	0
	Operator C	+	0	0	2	13	26
	Operator A	-	9	15	14	0	0
	Operator A	+	0	0	2	15	25
FEN 5	Operator B	-	9	15	14	1	0
	Operator B	+	0	0	2	14	25
	Operator C	-	9	15	13	0	0
	Operator C	+	0	0	3	15	25
MDMA 500	Operator A	-	10	16	11	0	0
	Operator A	+	0	0	3	16	24
	Operator B	-	10	16	12	1	0
	Operator B	+	0	0	2	15	24
MET 500	Operator C	-	10	16	11	0	0
	Operator C	+	0	0	3	16	24
	Operator A	-	10	20	10	0	0
	Operator A	+	0	0	0	12	28
MET 1000	Operator B	-	10	20	9	1	0
	Operator B	+	0	0	1	11	28
	Operator C	-	10	20	9	0	0
	Operator C	+	0	0	1	12	28
MOR 300	Operator A	-	13	14	13	1	0
	Operator A	+	0	0	0	11	28
	Operator B	-	13	14	12	0	0
	Operator B	+	0	0	1	12	28
MTD 300	Operator C	-	13	14	11	1	0
	Operator C	+	0	0	2	11	28
	Operator A	-	13	16	11	1	0
	Operator A	+	0	0	0	14	25
MOR 300	Operator B	-	13	16	11	1	0
	Operator B	+	0	0	0	14	25
	Operator C	-	13	16	11	1	0
	Operator C	+	0	0	0	14	25
MTD 300	Operator A	-	11	14	15	1	0
	Operator A	+	0	0	0	12	27
	Operator B	-	11	14	14	0	0
	Operator B	+	0	0	1	13	27
OPI 2000	Operator C	-	11	14	15	1	0
	Operator C	+	0	0	0	12	27
	Operator A	-	12	14	14	0	0
	Operator A	+	0	0	0	18	22
OXY 100	Operator B	-	12	14	14	1	0
	Operator B	+	0	0	0	17	22
	Operator C	-	12	14	14	2	0
	Operator C	+	0	0	0	16	22
PCP 25	Operator A	-	11	15	13	1	0
	Operator A	+	0	0	1	12	27
	Operator B	-	11	15	12	1	0
	Operator B	+	0	0	2	12	27
PPX 300	Operator C	-	13	15	10	0	0
	Operator C	+	0	0	2	14	26
	Operator A	-	13	15	11	0	0
	Operator A	+	0	0	1	14	26
TCA 1000	Operator B	-	13	15	11	1	0
	Operator B	+	0	0	1	13	26
	Operator C	-	11	15	13	0	0
	Operator C	+	0	0	1	13	27
THC 20	Operator A	-	9	16	14	0	0
	Operator A	+	0	0	1	14	26
	Operator B	-	9	16	13	0	0
	Operator B	+	0	0	2	14	26
THC 50	Operator C	-	9	16	14	0	0
	Operator C	+	0	0	1	14	26
	Operator A	-	13	15	12	2	0
	Operator A	+	0	0	0	14	24
THC 50	Operator B	-	13	15	10	1	0
	Operator B	+	0	0	2	15	24
	Operator C	-	13	15	11	1	0
	Operator C	+	0	0	1	15	24
THC 50	Operator A	-	11	17	12	0	0
	Operator A	+	0	0	0	14	26
	Operator B	-	11	17	12	2	0
	Operator B	+	0	0	0	12	26
THC 50	Operator C	-	11	17	12	1	0
	Operator C	+	0	0	0	13	26

Specificity and Cross-Reactivity

Specificity was evaluated by testing various concentrations of compounds that structurally related to each drug. The lowest concentration of each compound leading to positive result and the percent cross reactivity of each compound are listed below. If no cross reactivity was observed, the data are shown with > or < symbols.

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result	% Cross-Reactivity
6AM 10	6-Acetylmorphine	10	100%
	Heroin	25	40%
	Morphine	>100,000	<0.01%
	Normorphine	>100,000	<0.01%
	Nalorphine	>100,000	<0.01%
	Hydrocodone	>100,000	<0.01%
	Hydromorphone	>100,000	<0.01%
	Chlordiazepoxide	>100,000	<0.01%
	Clobazam	>100,000	<0.01%
	D-Amphetamine	>100,000	<0.01%
	(±)-Amphetamine	>100,000	<0.01%
	Levorphanol	>100,000	<0.01%
	Codeine	>100,000	<0.01%
	Ethylmorphine	>100,000	<0.01%
	Morphine3-β-D-glucuronide	>100,000	<0.01%
	Norcodeine	>100,000	<0.01%
	Oxycodone	>100,000	<0.01%
	Oxymorphone	>100,000	<0.01%
	Procaine	>100,000	<0.01%
	Thebaine	>100,000	<0.01%
	6-Acetylcodeine	50,000	0.02%
	Buprenorphine	>10,000	<0.1%
	Dihydrocodeine	>100,000	<0.01%
	Dextromethorphan	>100,000	<0.01%
	Imipramine	>100,000	<0.01%
	Meperidine	>100,000	<0.01%
	(±)-Methadone	>100,000	<0.01%
	Mitragynine(Kratom)	>10,000	<0.1%
	Morphine-6-β-D-glucuronide	>10,000	<0.1%
	Naloxone	>100,000	<0.01%
	Naltrexone	>100,000	<0.01%
	Naproxen	>100,000	<0.01%
	Norbuprenorphine	>10,000	<0.1%
	Norbuprenorphine-3-D-Glucuronide	10,000	0.10%
	Noroxycodone	>100,000	<0.01%
	Noroxymorphone	>10,000	<0.1%
	Norpropoxyphene	>100,000	<0.01%
	Oxymorphone-3β-D-glucuronide	>10,000	<0.1%
	Tapentadol	>100,000	<0.01%
	cis-Tramadol	>100,000	<0.01%
AMP 500	(±)-3,4-Methylenedioxyamphetamine (MDA)	2,000	25%
	(±)-Amphetamine	1,000	50%
	D-Amphetamine	500	100%
	Diethylstilbestrol	>10,000	<5%
	L-Amphetamine	50,000	1%
	Phentermine	15,000	3.33%
	β-Phenylethylamine	>100,000	<0.5%
	Tyramine	>100,000	<0.5%
	p-Hydroxynorephedrine	>100,000	<0.5%
	p-Hydroxyamphetamine	5,000	10%
	D-Methamphetamine	>100,000	<0.5%
	L-Methamphetamine	>100,000	<0.5%
	Ephedrine	>100,000	<0.5%
	(±)-3,4-Methylenedioxymethamphetamine	>100,000	<0.5%
	Phenylpropanolamine (Norephedrine)	>100,000	<0.5%
	Benzphetamine	>100,000	<0.5%
	(1R,2S)-(-)-Ephedrine	>100,000	<0.5%
	L-Epinephrine	>100,000	<0.5%
	D,L-Epinephrine	>100,000	<0.5%

	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	<0.5%
AMP 1000	(±)-3,4-Methylenedioxyamphetamine (MDA)	5,000	20%
	(±)-Amphetamine	2,000	50%
	D-Amphetamine	1,000	100%
	Diethylstilbestrol	>10,000	<10%
	L-Amphetamine	>100,000	<1%
	Phentermine	25,000	4%
	β-Phenylethylamine	>100,000	<1%
	Tyramine	>100,000	<1%
	p-Hydroxynorephedrine	>100,000	<1%
	p-Hydroxyamphetamine	10,000	10%
	D-Methamphetamine	>100,000	<1%
	L-Methamphetamine	>100,000	<1%
	Ephedrine	>100,000	<1%
	(±)-3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	<1%
	Phenylpropanolamine (Norephedrine)	>100,000	<1%
	Benzphetamine	>100,000	<1%
	(1R,2S)-(-)-Ephedrine	>100,000	<1%
	L-Epinephrine	>100,000	<1%
	D,L-Epinephrine	>100,000	<1%
	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	<1%
BAR 300	Alphenal	400	75%
	Amobarbital	500	60%
	Aprobarbital	150	200%
	Barbital	1000	30%
	Butabarbital	70	428.57%
	Butethal	20	1500%
	Cyclopentobarbital	1,000	30%
	Pentobarbital	200	150%
	Phenobarbital	250	120%
	Secobarbital	300	100%
BUP 10	Butalbital	10,000	3%
	Buprenorphine	10	100%
	Buprenorphine -3-D-Glucuronide	20	50%
	Norbuprenorphine	150	6.67%
	Norbuprenorphine glucuronide	500	2%
	Codeine	>100,000	<0.01%
	Nalorphine	>100,000	<0.01%
	Morphine	>100,000	<0.01%
BZO 300	Oxymorphone	>100,000	<0.01%
	Hydromorphone	>100,000	<0.01%
	a-Hydroxyalprazolam	5,000	6%
	Alprazolam	250	120%
	Bromazepam	600	50%
	Chlordiazepoxide	500	60%
	Clobazam	300	100%
	Clonazepam	>100,000	<0.3%
	Clorazepate	500	60%
	Desalkylflurazepam	500	60%
	Diazepam	1,000	30%
	Estazolam	>100,000	<0.3%
	Flunitrazepam	1,000	30%
	Lorazepam	1,000	30%
	Lormetazepam	>100,000	<0.3%
	Midazolam	>100,000	<0.3%
	Nitrazepam	250	120%
	Norchlordiazepoxide	70	428.57%
	Nordiazepam	1,000	30%
	Oxazepam	300	100%
	Oxazepam glucuronide	30	1000%
	Lorazepam glucuronide	100	300%

	Temazepam	200	150%
	Triazolam	5,000	6%
	Demoxepam	25	1200%
	Flurazepam	>100,000	<0.3%
	Delorazepam	>10,000	<3%
COC 150	Benzoylcegonine	150	100%
	Cocaethylene	2,000	7.50%
	Cocaine	>100,000	<0.15%
	Ecgonine	>100,000	<0.15%
	Norcocaine	>100,000	<0.15%
	Ecgonine methyl ester	>100,000	<0.15%
	Benzoylcegonine	300	100%
	Cocaethylene	3,000	10%
COC 300	Cocaine	>100,000	<0.3%
	Ecgonine	>100,000	<0.3%
	Norcocaine	>100,000	<0.3%
	Ecgonine methyl ester	>100,000	<0.3%
	EDDP	300	100%
EDDP 300	Methadone	>100,000	<0.3%
	EMDP	>100,000	<0.3%
	Doxylamine	>100,000	<0.3%
	Disopyramide	>100,000	<0.3%
	LAAM(Levo-alpha-acetylmethadol) hydrochloride	>100,000	<0.3%
	Alpha Methadol	>100,000	<0.3%
	Norfentanyl	25,000	0.004%
	Fentanyl	1	100%
	Acetyl fentanyl	3	33.33%
	Acetyl norfentanyl	20,000	0.005%
FEN 1	(±)-β-Hydroxythiofentanyl	5	20%
	Acryl fentanyl	4	25%
	Butyryl fentanyl	5	20%
	Cyclopropylfentanyl	10	10%
	(±)-cis-3-methyl Fentanyl	1	100%
	Furanyl fentanyl	10	10%
	para-Fluorobutyryl fentanyl (PFBF)	10	10%
	para-Fluorofentanyl	5	20%
	9-Hydroxyrisperidone	>100,000	<0.001%
	Alfentanil	>100,000	<0.001%
	Isobutyryl fentanyl	10	10%
	4-Fluoro-isobutyryl fentanyl	5	20%
	Norcarfentanil	>10,000	<0.01%
	Remifentanil	500	0.20%
	Valeryl fentanyl	10	10%
	Thienyl Fentanyl	30	3.33%
	(±)-trans-3-methyl Fentanyl	5	20%
	Despropionyl fentanyl (4-ANPP)	250	0.4%
	MT-45	50	2%
	Ocfentanil	2	50%
	Risperidone	>100,000	<0.001%
	Sufentanil	20	5%
	Carfentanil	5	20%
	Labetalol	>100,000	<0.001%
	Trazodone	>100,000	<0.001%
	U-47700	>100,000	<0.001%
	ω-1-Hydroxyfentanyl	2	50%
	6-Acetylmorphine	>100,000	<0.001%
	AH-7921 HCL	2,500	0.04%
	Amphetamine	>100,000	<0.001%
	Buprenorphine	>10,000	<0.01%
	Buprenorphine -3-D-Glucuronide	>10,000	<0.01%
	Codeine	>100,000	<0.001%
	Dextromethorphan	>100,000	<0.001%
	Dihydrocodeine	>100,000	<0.001%
	EDDP	>100,000	<0.001%
	EMDP	>100,000	<0.001%

	Fluoxetine	>100,000	<0.001%
	Heroin	>100,000	<0.001%
	Hydrocodone	>100,000	<0.001%
	Hydromorphone	>100,000	<0.001%
	Isotonitazene	>100,000	<0.001%
	Ketamine	>100,000	<0.001%
	Levorphanol	>100,000	<0.001%
	Meperidine	>100,000	<0.001%
	Methadone	>100,000	<0.001%
	Morphine	>100,000	<0.001%
	Morphine-3-β-D-glucuronide	>100,000	<0.001%
	Naloxone	>100,000	<0.001%
	Naltrexone	>100,000	<0.001%
	Norbuprenorphine	5,000	0.02%
	Norcodeine	>100,000	<0.001%
	Norketamine	>100,000	<0.001%
	Normeperidine	>100,000	<0.001%
	Normorphine	>100,000	<0.001%
	Noroxycodone	>100,000	<0.001%
	Oxycodone	>100,000	<0.001%
	Oxymorphone	>100,000	<0.001%
	Pentazocine (Talwin)	80,000	<0.00125%
	Pipamperone	5,000	0.02%
	Tapentadol	>100,000	<0.001%
	Thioridazine	>100,000	<0.001%
	Tilidine	>100,000	<0.001%
	cis-Tramadol	>100,000	<0.001%
	O-Desmethyl-cis-tramadol	80,000	0.00125%
	N-Desmethyl-cis-tramadol	>100,000	<0.001%
FEN 5	Norfentanyl	5	100%
	Fentanyl	10,000	0.05%
	Acetyl fentanyl	>10,000	<0.05%
	Acetyl norfentanyl	200	2.5%
	(±)-β-Hydroxythiofentanyl	>10,000	<0.05%
	Acryl fentanyl	>10,000	<0.05%
	Butyryl fentanyl	>10,000	<0.05%
	Cyclopropylfentanyl	>10,000	<0.05%
	(±)-cis-3-methyl Fentanyl	>10,000	<0.05%
	Furanyl fentanyl	>10,000	<0.05%
	para-Fluorobutyryl fentanyl (PFBF)	10,000	0.05%
	para-Fluorofentanyl	>10,000	<0.05%
	9-Hydroxyrisperidone	>100,000	<0.005%
	Alfentanil	5,000	0.1%
	Isobutyryl fentanyl	>100,000	<0.005%
	4-Fluoro-isobutyryl fentanyl	>100,000	<0.005%
	Norcarfentail	>10,000	<0.05%
	Remifentanil	>10,000	<0.05%
	Valeryl fentanyl	>10,000	<0.05%
	Thienyl Fentanyl	>100,000	<0.005%
	(±)-trans-3-methyl Fentanyl	>10,000	<0.05%
	Despropionyl fentanyl (4-ANPP)	>10,000	<0.05%
	MT-45	>100,000	<0.005%
	Ocfentanil	>10,000	<0.05%
	Risperidone	>100,000	<0.005%
	Sufentanil	>10,000	<0.05%
	Carfentanil	>10,000	<0.05%
	Labetalol	>100,000	<0.005%
	Trazodone	>100,000	<0.005%
	U-47700	>100,000	<0.005%
	ω-1-Hydroxyfentanyl	>100,000	<0.005%
	6-Acetylmorphine	>100,000	<0.005%
	AH-7921 HCL	>100,000	<0.005%
	Amphetamine	>100,000	<0.005%
	Buprenorphine	>10,000	<0.05%
	Buprenorphine -3-D-Glucuronide	>10,000	<0.05%

	Codeine	>100,000	<0.005%
	Dextromethorphan	>100,000	<0.005%
	Dihydrocodeine	>100,000	<0.005%
	EDDP	>100,000	<0.005%
	EMDP	>100,000	<0.005%
	Fluoxetine	>100,000	<0.005%
	Heroin	>100,000	<0.005%
	Hydrocodone	>100,000	<0.005%
	Hydromorphone	>100,000	<0.005%
	Isotonitazene	>100,000	<0.005%
	Ketamine	>100,000	<0.005%
	Levorphanol	>100,000	<0.005%
	Meperidine	>100,000	<0.005%
	Methadone	>100,000	<0.005%
	Morphine	>100,000	<0.005%
	Morphine-3-β-D-glucuronide	>100,000	<0.005%
	Naloxone	>100,000	<0.005%
	Naltrexone	>100,000	<0.005%
	Norbuprenorphine	>100,000	<0.005%
	Norcodeine	>100,000	<0.005%
	Norketamine	>100,000	<0.005%
	Normeperidine	>100,000	<0.005%
	Normorphine	>100,000	<0.005%
	Noroxycodone	>100,000	<0.005%
	Oxycodone	>100,000	<0.005%
	Oxymorphone	>100,000	<0.005%
	Pentazocine (Talwin)	>100,000	<0.005%
	Pipamperone	>100,000	<0.005%
	Tapentadol	>100,000	<0.005%
	Thioridazine	>100,000	<0.005%
	Tilidine	>100,000	<0.005%
	cis-Tramadol	>100,000	<0.005%
	O-Desmethyl-cis-tramadol	>100,000	<0.005%
	N-Desmethyl-cis-tramadol	>100,000	<0.005%
MDMA 500	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	500	100%
	(±)-3,4-Methylenedioxyamphetamine (MDA)	5,000	10%
	(±)-3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
	L-Methamphetamine	>100,000	<0.5%
	7-Aminoclonazepam	>100,000	<0.5%
	D-Methamphetamine	>100,000	<0.5%
	D-Amphetamine	>100,000	<0.5%
	L-Amphetamine	>100,000	<0.5%
	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	30,000	1.67%
	(±)-3,4-Methylenedioxymethamphetamine (MDMA)	5,000	10%
MET 500	D-Methamphetamine	500	100%
	L-Methamphetamine	15,000	3.33%
	Fenfluramine	>100,000	<0.5%
	p-Hydroxymethamphetamine	3,000	16.67%
	(±)-Methamphetamine	500	100%
	β-Phenylethylamine	>100,000	<0.5%
	Mephetermine	10,000	5%
	Methoxyphenamine	>100,000	<0.5%
	L-Amphetamine	>100,000	<0.5%
	D-Amphetamine	>100,000	<0.5%
	(±)-Amphetamine	>100,000	<0.5%
	Chloroquine	>100,000	<0.5%
	Ephedrine	>100,000	<0.5%
	(±)-3,4-Methylenedioxyamphetamine (MDA)	>100,000	<0.5%
	Trimethobenzamide	>100,000	<0.5%
	l-phenylephrine	>100,000	<0.5%

	(1R,2S)-(-)-Ephedrine	>100,000	<0.5%
	Procaine	>100,000	<0.5%
MET 1000	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	<1%
	(±)-3,4-Methylenedioxymethamphetamine (MDMA)	10,000	10%
	D-Methamphetamine	1,000	100%
	L-Methamphetamine	25,000	4%
	Fenfluramine	>100,000	<1%
	p-Hydroxymethamphetamine	5,000	20%
	(±)-Methamphetamine	2,000	50%
	β-Phenylethylamine	>100,000	<1%
	Mephetermine	30,000	3.33%
	Methoxyphenamine	>100,000	<1%
	L-Amphetamine	>100,000	<1%
	D-Amphetamine	>100,000	<1%
	(±)-Amphetamine	>100,000	<1%
	Chloroquine	>100,000	<1%
	Ephedrine	>100,000	<1%
	(±)-3,4-Methylenedioxyamphetamine (MDA)	>100,000	<1%
	Trimethobenzamide	>100,000	<1%
	l-phenylephrine	>100,000	<1%
	(1R,2S)-(-)-Ephedrine	>100,000	<1%
	Procaine	>100,000	<1%
MOR 300	6-Acetylmorphine	500	60%
	Codeine	250	120%
	Dihydrocodeine	500	60%
	Ethylmorphine	300	100%
	Heroin	500	60%
	Hydrocodone	500	60%
	Hydromorphone	500	60%
	Levorphanol	5,000	6%
	Morphine	300	100%
	Nalorphine	3,000	10%
	Thebaine	>100,000	<0.3%
	Morphine-3-β-D-glucuronide	300	100%
	Codeine-6-β-D-glucuronide	250	120%
	Morphine-6-β-D-glucuronide	5,000	6%
	6-Acetylcodeine	1,000	30%
	Normorphine	>100,000	<0.3%
	Oxycodone	>100,000	<0.3%
	Oxymorphone	50,000	0.6%
	Norcodeine	>100,000	<0.3%
	Procaine	>100,000	<0.3%
	Norpropoxyphene	>100,000	<0.3%
MTD 300	(±)-Methadone	300	100%
	EDDP	>100,000	<0.3%
	EMDP	>100,000	<0.3%
	LAAM (Levo-alpha-acetylmethadol)	10,000	3%
	Alpha Methadol	100	300%
	Doxylamine	50,000	0.6%
OPI 2000	6-Acetylmorphine	10,000	20%
	Codeine	10,000	20%
	Dihydrocodeine	10,000	20%
	Ethylmorphine	5,000	40%
	Heroin	20,000	10%
	Hydrocodone	25,000	8%
	Hydromorphone	25,000	8%
	Levorphanol	>100,000	<2%
	Morphine	2,000	100%
	Nalorphine	>100,000	<2%
	Thebaine	>100,000	<2%
	Morphine-3-β-D-glucuronide	50,000	4%
	Codeine-6-β-D-glucuronide	2,500	80%
	Morphine-6-β-D-glucuronide	500	400%

OXY 100	6-Acetylcodeine	10,000	20%
	Normorphine	>100,000	<2%
	Oxycodone	>100,000	<2%
	Oxymorphone	>100,000	<2%
	Norcodeine	>100,000	<2%
	Procaine	>100,000	<2%
	Norpropoxyphene	>100,000	<2%
	Hydrocodone	20,000	0.5%
	Hydromorphone	25,000	0.4%
	Levorphanol	50,000	0.2%
	Naloxone	30,000	0.33%
	Naltrexone	20,000	0.5%
	Oxycodone	100	100%
	Oxymorphone	200	50%
	Oxymorphone-3β-D-glucuronide	750	13.33%
	Noroxycodone	2,500	4%
	Noroxymorphone	1,000	10%
	Dihydrocodeine	>100,000	<0.1%
	Codeine	>100,000	<0.1%
	Morphine	>100,000	<0.1%
PCP 25	Buprenorphine	>10,000	<0.1%
	Ethylmorphine	>100,000	<0.1%
PPX 300	Thebaine	>100,000	<0.1%
	6-Acetylmorphine	>100,000	<0.1%
TCA 1000	Phencyclidine	25	100%
	4-Hydroxyphencyclidine	>100,000	<0.025%
	Norpropoxyphene	500	60%
	Propoxyphene	300	100%
	Amitriptyline	10,000	10%
	Chlorpheniramine	>100,000	<1%
	Clomipramine	50,000	2%
	Cyclobenzaprine	>100,000	<1%
	Desipramine	500	200%
	Doxepine	10,000	10%
	Duloxetine	>100,000	<1%
	Imipramine	50,000	2%
	Norclomipramine	>100,000	<1%
	Nordoxepin	5,000	20%
	Nortriptyline	1,000	100%
	Promazine	10,000	10%
	Trimipramine	10,000	10%
	Maprotiline	5,000	20%
	Promethazine	>100,000	<1%
THC 20	(-)-11-nor-Δ ⁸ -THC -9-COOH	50	40%
	(-)-11-nor-9-carboxy-Δ ⁹ -THC	20	100%
	(±)-11-nor-9-carboxy-Δ ⁹ -THC	50	40%
	11-nor-Δ ⁹ -THC-carboxy glucuronide	5,000	0.4%
	Δ ⁸ -THC	8,000	0.25%
	Δ ⁹ -THC	>10,000	<0.2%
	Cannabinol	>10,000	<0.2%
	Cannabidiol	>100,000	<0.02%
	(±)-11-hydroxy-Δ ⁸ -THC	8,000	0.25%
	(-)-11-nor-Δ ⁸ -THC -9-COOH	70	71.43%
THC 50	(-)-11-nor-9-carboxy-Δ ⁹ -THC	50	100%
	(±)-11-nor-9-carboxy-Δ ⁹ -THC	150	33.33%
	11-nor-Δ ⁹ -THC-carboxy glucuronide	7,500	66.67%
	Δ ⁸ -THC	10,000	0.5%
	Δ ⁹ -THC	>10,000	<0.5%
	Cannabinol	>10,000	<0.5%
	Cannabidiol	>100,000	<0.05%
	(±)-11-hydroxy-Δ ⁸ -THC	10,000	0.5%

Interference Substance

Potential interfering substances that could be found in human urine under physiological and pathological conditions compounds were added to drug-free urine and to urine samples containing the target drugs at 50% below and 50% above each corresponding cutoff. These urine samples

were tested in triplicates with 3 lots of CLIAwaived Inc. Instant Drug Test Cup Plus. Compounds that showed no interference at a concentration of 100 µg/ml are listed in the following table.

(-) Cotinine	Conjugated Estrogens	LAAM (except MTD test)	Phenobarbital (except BAR test)
7-Aminoclonazepam	Cortisone	Labetalol	Phentermine (except AMP test)
7-Aminoflunitrazepam	Creatine	Lamotrigine	Phenylpropanolamine
7-Aminonitrazepam	Creatinine	L-Ephedrine	Prednisone
Acetaminophen	Cyclobenzaprine	L-Epinephrine	Pregabalin
Acetone (1000 mg/dL)	Cyproheptadine	Levofloxacin	Procaine
Acetophenetidin	D,L-Epinephrine	Levonorgestrel	Promazine (except TCA test)
Acyclovir	D,L-Isoproterenol	Levothyroxine sodium	Promethazine
Albumin (100mg/dL)	D,L-Lorazepam (except BZO test)	Lidocaine	Propoxyphene (except PPX test)
Albuterol	D,L-Octopamine	Lisinopril	Propranolol
Alpha Methadol (except MTD test)	D,L-Propranolol	Loperamide	Pseudoephedrine
Aminophylline	D,L-Tryptophan	Lorazepam	Pyridoxine
Aminopyrine	D,L-Tyrosine	Lorazepam Glucuronide (except BZO test)	Pyrimidine
Amitriptyline (except TCA test)	Delorazepam (10ug/mL)	L-phenylephrine	Pyrogallol
Amlodipine	Demoxepam (except BZO test)	LSD	Quetiapine
Amobarbital (except BAR test)	Deoxycorticosterone	Maprotiline (except TCA test)	Quinidine
Amoxicillin	Desloratadine	Meperidine	Quinine
Ampicillin	Desipramine (except TCA test)	Meprobamate	Quinolinic Acid
Apomorphine	Dextromethorphan	Metformin	Ranitidine
Aripiprazole	Diclofenac	Methapyrilene	Riboflavin
Ascorbic acid (Vitamin C)	Diclofenac sodium	Methaqualone	Rifampicin
Aspartame	Diffunisal	Methoxyphenamine	Risperidone
Aspirin (Acetylsalicylic acid)	Digoxin	Methylphenidate	Salicylic acid
Atomoxetine	Diphenhydramine	Metoprolol	Secobarbital (except BAR test)
Atorvastatin Calcium	Diphenylhydantoin	Metronidazole	Serotonin (5- Hydroxytyramine)
Atropine	Disopyramide	Mifepristone	Sertraline
Azithromycin	Dopamine (3-Hydroxytyramine)	N-Acetylprocainamide	Sildenafil Citrate
Baclofen	Doxepine (except TCA test)	NaCl (4000 mg/dL)	Simvastatin
Benzilic acid	Doxylamine (except MTD test)	Nalidixic acid	Sodium Azide
Benzocaine	Duloxetine	Naloxone (except OXY test)	Sulfamethazine
Benzoic acid	Ecgonine methyl ester	Naltrexone (except OXY test)	Sulindac
Benzoyllecgonine (except COC test)	EMDP	Naproxen	Telmisartan
Benzphetamine	Ephedrine	N-desmethyl Tapentadol	Tetracycline
Benzylpiperazine	Erythromycin	Nicotine	Tetrahydrocortisone 3- (β-Dglucuronide)
Bilirubin	Esomeprazole Magnesium	Nicotinamide (Niacinamide)	Tetrahydrocortisone, 3- acetate
Boric Acid (1%)	Estrone	Nicotinic Acid	Tetrahydrozoline
4-Bromo-2,5- dimethoxyphenethyla mine	Ethanol (1%)	Nifedipine	(-)-11-nor-9-carboxy-Δ ⁹ - THC (except THC test)
Brompheniramine	Fenfluramine	Nitroglycerin	Theophylline
Bupropion	Fenofibrate	Nordoxepin (except TCA test)	Thiamine
Caffeine	Fenoprofen	Norethindrone	Thioridazine
Cannabidiol	Fentanyl (except FEN1 and FEN5 tests)	Norfentanyl (except FEN1 and FEN5 tests)	Tramadol
Captopril	Fluoxetine	Norpropoxyphene (except PPX test)	Trazodone
Carbamazepine	Fluphenazine	Norpseudoephedrine	Triamterene
Carfentanil (10ug/mL) (except FEN1 test)	Fotemustine	Nortriptyline (except TCA test)	Trifluoperazine

Carisoprodol	Furosemide	Noscapine	Trifluoromethylphenyl- piperazine
Cefradine	Gabapentin	O-Hydroxyhippuric acid	Trimethobenzamide
Cephalexin	Galactose	Olanzapine	Trimethoprim
Cetirizine	Gatifloxacin	Omeprazole	Tryptamine
Chloral hydrate	Gemfibrozil	Oxalic acid (100mg/dL)	Tyramine
Chloramphenicol	Gentisic acid	Oxazepam (except BZO test)	Urea (2000 mg/dL)
Chlordiazepoxide (except BZO test)	D-(+)-Glucose (3000 mg/dL)	Oxazepam Glucuronide (except BZO test)	Uric acid
Chloroquine	Guaiacolglycerol ether	Oxolinic acid	Valproic acid (250 µg/mL)
Chlorothiazide	Hemoglobin	Oxymetazoline	Venlafaxine
Chlorpheniramine	Hexobarbital	Paliperidone	Verapamil
Chlorpromazine	Hydralazine	Papaverine	Vitamin B2
Cholesterol	Hydrochlorothiazide	Penicillin-G	Zaleplon
Ciprofloxacin	Hydrocortisone	PenicillinV Potassium	Zolpidem
Citalopram	Hydroxybutyric Acid	Perphenazine	Zomepirac
Clarithromycin	Ibuprofen	Phenacetin	β-Estradiol
Clofibrate	Imipramine (except TCA test)	Phencyclidine (except PCP test)	γ-Cyclodextrin
Clomipramine (except TCA test)	Isoxsuprine	Phenelzine	γ-Globulin (500mg/dL)
Clonidine	Ketamine	Pheniramine	L-thyroxine
Clozapine	Ketoprofen	Phenylethylamine	Magnesium Chloride

Effect of Urinary pH and Specific Gravity

Interference by pH and specific gravity were also evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 50% below and 50% above each corresponding cutoff. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

Index of Symbols

	Consult Instruction for use		Contains sufficient for <n> tests		Store between 2-30°C
	For in vitro diagnostic use only		Use by		Do not reuse
	Do not use if package is damaged		Lot Number		Catalog #



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V36001-CWII-P-V01

Instructions

FOR *IN VITRO* DIAGNOSTIC USE ONLY

Multi-Panel Drug Screen Cup Tests

This is a CLIA Waived test. You need a CLIA certificate of waiver to perform the test in waived settings. Go to <http://www.cms.hhs.gov/CLIA/> for more information.

It is an in vitro diagnostic device and rapid lateral flow immunoassay for the qualitative detection of drugs in human urine. The test cut-off concentrations and calibrators are listed below:

Analyte	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	300 ng/mL
Amphetamine (AMP)	d-Amphetamine	500 ng/mL
Amphetamine (AMP)	d-Amphetamine	1000 ng/mL
Barbiturates (BAR)	Secobarbital / Pentobarbital	200 ng/mL
Barbiturates (BAR)	Secobarbital / Pentobarbital	300 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Benzodiazepines (BZO)	Oxazepam	200 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoyllecgonine	150 ng/mL
Cocaine (COC)	Benzoyllecgonine	300 ng/mL
Ecstasy (MDMA)	d,l-Methylenedioxymethamphetamine	500 ng/mL
Norfentanyl (FYL)	Norfentanyl	5 ng/mL
Marijuana (THC)	11-nor- Δ^9 -THC-9-COOH	50 ng/mL
Methamphetamine (MET)	d-Methamphetamine	300 ng/mL
Methamphetamine (MET)	d-Methamphetamine	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	1000 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Morphine (MOR)	Morphine	300 ng/mL
Opiates (OPI)	Morphine	2000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL
Tramadol (TML)	Tramadol	100 ng/mL

The multi-panel tests can consist of any combination of the drug analytes listed above. Only one cut-off concentration will be included per analyte per device. The test is intended for healthcare professional use.

The test provides only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to the drug test result, particularly when preliminary positive result is indicated.

The test is not intended to differentiate between drugs of abuse and prescription use of Amphetamine, Benzodiazepines, Barbiturates, Buprenorphine, Cocaine, Ecstasy, Fentanyl, Marijuana, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Methadone, Propoxyphene, Tricyclic Antidepressants (TCA) and Tramadol. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Test Instructions

Do not use the test if it is expired. Do not open pouches until ready to do the test.

1. Remove the test from the pouch and use it as soon as possible.
2. Collect the urine into the Cup. The urine must meet the minimum level as shown on the side of the Cup.



3. Screw the lid back on and place the cup on a flat surface. Start the timer and wait for the colored line(s) to appear.
4. Remove the Peel-Off Label.
5. Negative result(s) can be read as early as 1 minute, as long as the “C” line appears. Confirm the result(s) at 5 minutes. The result(s) remain stable for 30 minutes.

Preliminary positive test results must be confirmed by another test method.

Read Results

Negative: A “C” line appears in the “C” region and a colored line appears in the “T” region. This negative result indicates that the drug is below the cut-off level. The line intensity for the drug may be weaker or stronger than that of the “C” line.

Preliminary Positive: “C” line(s) appears in the “C” region and no colored line in the “T” region shows a preliminary positive result.

Invalid: No line appears in the “C” region. A preliminary positive sample should not be determined until the “C” line forms. If the “C” line does not form, the test result is invalid and should be repeated with a new test.



Kit Contents

Each Test Kit contains one (1) test instruction and 25 test devices. Store at room temperature (2°C to 30°C).

Quality Control

If you work in a laboratory, quality control testing should be performed and you should read this section. A procedural control is included in the test by the “C” region on each test strip. This “C” line should always appear, if the control line does not appear, the test should be discarded. This “C” line confirms that enough volume was added and proper flow was obtained.

Good Laboratory Practice recommends that quality control testing be performed with each new lot, each new shipment and every thirty days to check storage. External controls are available from commercial sources. It is recommended that positive and negative controls be used to verify proper test performance.

Limitation and Precautions

- For *In Vitro* Diagnostic use and for healthcare professional use.
- The pouch containing the device should be sealed. Discard the test device if package is ripped or torn.
- Urine specimens may be potentially hazardous and should be handled in the same manner as an infectious agent.
- Avoid cross-contamination of urine samples by using a new container for a different urine sample. Do not reuse the container for different urine sample collection.

Performance Characteristics – Accuracy Study Data

Qualitative Accuracy study data in comparison with LC/MS assay values:

Drug Test/Cutoff (ng/mL)	Result	Range of LC-MS/MS Data				
		Negative	Near cutoff (50% to the C/O)	Near cutoff (Cutoff to 150% of the C/O)	High positive (≥ 150% of the C/O)	% Agreement
FYL 5	(+)	1	2	6	26	100%
	(-)	51	7	0	0	95%
TML 100	(+)	0	0	8	23	100%
	(-)	40	12	0	0	100%

Discordant Results

(ng/mL)	Analyte assay (+/-)	Drug	LC/MS Value (ng/mL)
FYL 5	+	Norfentanyl	3.38
	+	Norfentanyl	4.94
	+	Norfentanyl	2.03*

Two (2) of the discordant results were at or near the norfentanyl cut off level of 5 ng/mL. One FYL sample with a * mark contains a norfentanyl concentration of 2.03 ng/mL and Fentanyl concentration of 15.43 ng/ml yielded a positive result. Further analysis indicated that the cross-reactive level of Fentanyl is 10 ng/ml. So the positive result was caused by the high concentration of Fentanyl.

The method comparison (Accuracy) study data for Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Ecstasy, Marijuana, Methamphetamine, Methadone, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants were reported in k153192.

OTC Lay-User Accuracy and Usability Studies

140 OTC lay-users from three sites performed the test with spiked urine samples. See table below.

Drug Test	Negative	(-)		(+) (+)		% Agreement
		LC/MS Negative (50% of the C/O)	Near cutoff Negative (75% of the C/O)	Near cutoff Positive (125% of the C/O)	Positive (150% of the C/O)	
AMP1000 (+)	0	0	0	10	10	100%
(-) (-)	60	10	10	0	0	100%
AMP500 (+)	0	0	0	23	23	100%
(-) (-)	47	23	23	0	0	100%
AMP300 (+)	0	0	0	23	23	100%
(-) (-)	47	23	23	0	0	100%
BAR300 (+)	0	0	0	10	10	100%
(-) (-)	60	10	10	0	0	100%
BAR200 (+)	0	0	0	23	23	100%
(-) (-)	93	23	23	0	0	100%
BUP 100 (+)	0	0	0	23	23	100%
(-) (-)	93	23	23	0	0	100%
BZO300 (+)	0	0	0	10	10	100%
(-) (-)	60	10	10	0	0	100%
BZO200 (+)	0	0	0	23	23	100%
(-) (-)	93	23	23	0	0	100%
COC300 (+)	0	0	0	10	10	100%
(-) (-)	60	10	10	0	0	100%
COC150 (+)	0	0	0	23	23	100%
(-) (-)	93	23	23	0	0	100%
FYL 5 (+)	0	0	0	22	23	100%
(-) (-)	93	25	24	0	0	100%
MDMA500 (+)	0	0	1	24	22	100%
(-) (-)	93	23	22	0	0	99.3%
MET 1000 (+)	0	0	0	10	10	100%
(-) (-)	60	10	10	0	0	100%
MET 500 (+)	0	0	0	23	23	100%
(-) (-)	47	23	23	0	0	100%
MET 300 (+)	0	0	1	23	23	100%
(-) (-)	47	23	22	0	0	98.9%
MTD 300 (+)	0	0	0	22	23	97.8%
(-) (-)	93	23	23	1	0	100%
MOR 300 (+)	0	0	0	23	23	100%
(-) (-)	37	23	23	0	0	100%
OPI 2000 (+)	0	0	0	23	23	100%
(-) (-)	37	23	23	0	0	100%
OXY 100 (+)	0	0	1	23	23	100%
(-) (-)	93	23	22	0	0	99.3%
PCP 25 (+)	0	0	1	23	23	100%
(-) (-)	93	23	22	0	0	99.3%
PPX 300 (+)	0	0	0	23	23	100%
(-) (-)	93	23	23	0	0	100%
TCA 1000 (+)	0	0	0	22	23	97.8%
(-) (-)	93	23	23	1	0	100%
THC 50 (+)	0	0	0	23	23	100%
(-) (-)	93	23	23	0	0	100%
TML 100 (+)	0	0	0	24	23	100%
(-) (-)	93	24	23	0	0	100%

Discordant Results

Drug Test and Cutoff (ng/mL)	Test Result (+/-)	Drug	LC/MS Conc. (ng/mL)
MET 300	+	d-Methamphetamine	258
MTD 300	-	Methadone	367
MDMA 500	+	MDMA	433
OXY 100	+	Oxycodone	78
TCA 1000	-	Tricyclic Antidepressants	1272
PCP 25	+	Phencyclidine	14

Precision and Reproducibility

The urine controls listed below were tested by 3 operators with three lots in five (5) consecutive days. The data is shown below:

FYL Test (cut off 5 ng/mL):

Lot No.	0	-50% Cut off	-25% Cut off	Cut Off	+25% Cut off	+50% Cut off
Lot 1	10- / 0+	10- / 0+	10- / 0+	9+ / 1-	10+ / 0-	10+ / 0-
Lot 2	10- / 0+	10- / 0+	10- / 0+	9+ / 1-	10+ / 0-	10+ / 0-
Lot 3	10- / 0+	10- / 0+	10- / 0+	8+ / 2-	10+ / 0-	10+ / 0-
SUM	30- / 0+	30- / 0+	30- / 0+	26+ / 4-	30+ / 0-	30+ / 0-

TML Test (cut off 100 ng/mL):

Lot No.	0	-50% Cut off	-25% Cut off	Cut Off	+25% Cut off	+50% Cut off
Lot 1	10- / 0+	10- / 0+	10- / 0+	9+ / 1-	10+ / 0-	10+ / 0-
Lot 2	10- / 0+	10- / 0+	10- / 0+	7+ / 3-	10+ / 0-	10+ / 0-
Lot 3	10- / 0+	10- / 0+	10- / 0+	8+ / 2-	10+ / 0-	10+ / 0-
SUM	30- / 0+	30- / 0+	30- / 0+	24+ / 6-	30+ / 0-	30+ / 0-

The Precision/Reproducibility study data for Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Ecstasy, Marijuana, Methamphetamine, Methadone, Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants were reported in k153192

Specificity

The following compounds were found to produce positive results when tested at the concentrations listed below:

AMP 1000:

Substances	ng/ml	% Cross Reactivity
d-Amphetamine	1,000	100
d,l-Amphetamine	1,600	62.5
l-Amphetamine	>100,000	< 1
S-(+) Amphetamine	1,000	100
d-Methamphetamine	>100,000	< 1
l-Methamphetamine	>100,000	< 1
d,l-MDMA	>100,000	< 1
Ephedrine	>100,000	< 1
Pseudoephedrine	>100,000	< 1
d,l-MDA	1,000	100
Phentermine	7,000	14
MDEA	>100,000	< 1
d,l-Methamphetamine	>100,000	< 1
Phenylephrine	>100,000	< 1
PMA	1,000	100
Tyramine	>100,000	< 1

AMP 500:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Amphetamine	500	100
d,l-Amphetamine	800	62.5
l-Amphetamine	>50,000	< 1
S-(+) Amphetamine	500	100
d-Methamphetamine	>50,000	< 1
l-Methamphetamine	>50,000	< 1
d,l-Methamphetamine	>50,000	< 1
d,l-MDMA	>50,000	< 1
Ephedrine	>50,000	< 1
Pseudoephedrine	>50,000	< 1
d,l-MDA	800	62.5
Phentermine	5,000	10
MDEA	>50,000	< 1
d,l-Phenylpropanolamine	>50,000	< 1
Phenylephrine	>50,000	< 1
Phenylethylamine	>50,000	< 1
PMA	500	100
Tyramine	>50,000	< 1

AMP 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Amphetamine	300	100
d,l-Amphetamine	600	50
l-Amphetamine	>30,000	< 1
S-(+) Amphetamine	300	100
d-Methamphetamine	>30,000	< 1
l-Methamphetamine	>30,000	< 1
d,l-Methamphetamine	>30,000	< 1
d,l-MDMA	>30,000	< 1
Ephedrine	>30,000	< 1
Pseudoephedrine	>30,000	< 1
d,l-MDA	300	100
Phentermine	4,000	7.5
MDEA	>30,000	< 1
d,l-Phenylpropanolamine	>30,000	< 1
Phenylephrine	>30,000	< 1
Phenylethylamine	>30,000	< 1
PMA	300	100
Tyramine	>30,000	< 1

BAR 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Secobarbital	300	100
Pentobarbital	300	100
Alphenal	500	60
Amobarbital	600	50
Aprobarbital	500	60
Barbital	10,000	3
Butabarbital	500	60
Butalbital	2,000	15
Cyclopentobarbital	500	60
Phenobarbital	2,000	15

BAR 200:

Substances	Concentration (ng/mL)	% Cross Reactivity
Secobarbital	200	100
Pentobarbital	200	100
Alphenal	300	67
Amobarbital	400	50
Aprobarbital	400	50
Barbital	6,000	3.3
Butabarbital Butisol	300	67
Butalbital	1,000	20
Cyclopentobarbital	240	83
Phenobarbital	1,200	16.7

BZO 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Oxazepam	300	100
Alprazolam	300	100
Alpha-Hydroxyalprazolam	300	100
Bromazepam	300	100
Chlordiazepoxide	600	50
Clobazam	800	37.5
Clonazepam	30,000	<1
Clorazepate	2,000	15
Desalkylflurazepam	1,000	30
Demoxepam	3,000	10
Diazepam	500	60
Estazolam	300	100
Flunitrazepam	4,800	6.3
Flurazepam	300	100
Lorazepam	800	37.5
Lormetazepam	3,600	8.3
Midazolam	10,000	3
Nitrazepam	1,000	30
Nordiazepam	8,000	3.8
Temazepam	600	50
Triazolam	1,800	16.7

BZO 200:

Substances	Concentration (ng/mL)	% Cross Reactivity
Oxazepam	200	100
Alprazolam	200	100
Hydroxyalprazolam	200	100
Bromazepam	200	100
Chlordiazepoxide	400	50
Clobazam	600	33
Clonazepam	20,000	< 1
Clorazepate	1,800	11
Desalkylflurazepam	800	25
Demoxepam	3,000	6.7
Diazepam	300	67
Estazolam	200	100
Flunitrazepam	4,600	4.4
Flurazepam	200	100
Lorazepam	600	33.3
Lormetazepam	2,800	7
Midazolam	8,000	2.5
Nitrazepam	800	25
Nordiazepam	5,200	3.9
Temazepam	400	50
Triazolam	1,200	16.7

BUP 10:

Substances	Concentration (ng/mL)	% Cross Reactivity
Buprenorphine	10	100
Norbuprenorphine	10	100
Morphine	1,000	< 1
Codeine	1,000	< 1

COC 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Benzoylcegonine	300	100
Cocaine	300	100
Cocaeethylene	300	100
Ecgonine Hcl	>30,000	< 1
Ecgonine Methylester	>30,000	< 1

COC 150:

Substances	Concentration (ng/mL)	% Cross Reactivity
Benzoylecgonine	150	100
Cocaine	180	83
Cocaethylene	150	100
Egonine Hcl	>15,000	< 1
Egonine Methylester	>15,000	< 1

FYL 5:

Substances	Concentration (ng/mL)	% Cross Reactivity
Norfentanyl	5	100
Fentanyl	10	50
4-Fluoro-isobutyryl Fentanyl	>20,000	<1
9-HydroxyRisperidone	10,000	<1
Acetyl Fentanyl	200	2.5
(±) - β -Hydroxythiofentanyl Hcl	20	25
Acetyl Norfentanyl	200	2.5
Acryl Fentanyl	30	16.7
Alfentanil	1,000	<1
Butyryl Fentanyl	15	33.3
Carfentanil Oxalate	>10,000	<1
Cis-d, 1 3-Methylfentanyl	70	7.1
Despropionylfentanyl (4-ANPP)	>20,000	<1
Furanyl Fentanyl	80	6.25
Isobutyryl Fentanyl	5,000	<1
Labetalol Hydrochloride	>100,000	<1
MT-45	7,500	<1
Norcarfentanil Oxalate	>20,000	<1
Ocfentanil	1,000	<1
Para-fluoro butyryl Fentanyl (P-FBF)	20	25
para-Fluorofentanyl	10	50
Remifentanil	>20,000	<1
Risperidone	10,000	<1
Sufentanil	3,000	<1
Thienyl Fentanyl	40	12.5
Trans-d, 1 3-Methylfentanyl	30	16.7
Trazodone	>100,000	<1
U-47700	>100,000	<1

Note: The cross-reactivity of o-1-Hydroxyfentanyl was not tested in this product and may be a source of false positive results.

MDMA 500:

Substances	Concentration (ng/mL)	% Cross Reactivity
d,l MDMA	500	100
MDA	15,000	3.3
MDEA	1,000	50
d-Methamphetamine	50,000	< 1
d-Amphetamine	50,000	< 1

MTD 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Methadone	300	100
Doxylamine	30,000	< 1
EDDP	30,000	< 1
Pheniramine	30,000	< 1

THC 50:

Substances	Concentration (ng/mL)	% Cross Reactivity
11-nor-Δ ⁹ -THC-9-COOH	50	100
11-nor-Δ ⁸ -THC-9-COOH	30	167
Δ ⁹ -Tetrahydrocannabinol	5,000	< 1
11-nor-9-Carboxy THC	1,000	5
Cannabidiol	5,000	< 1
Cannabinol	5,000	< 1

MET 1000:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Methamphetamine	1,000	100
d,l-Methamphetamine	5,000	20
d-Amphetamine	>100,000	<1
l-Amphetamine	>100,000	< 1
Ephedrine	>100,000	< 1
Phenylephrine	>100,000	< 1
Pseudoephedrine	>100,000	< 1
d,l-MDMA	3,000	33
d,l-MDEA	30,000	3.3
d,l-MDA	>100,000	< 1
d,l- Amphetamine	>100,000	< 1
Phentermine	>100,000	< 1

MET 500:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Methamphetamine	500	100
d,l-Methamphetamine	2,000	25
l-Methamphetamine	2,500	20
d-Amphetamine	>50,000	< 1
l-Amphetamine	>50,000	< 1
d,l-Amphetamine	>50,000	< 1
Ephedrine	>50,000	< 1
Phenylephrine	>50,000	< 1
Phenylethylamine	>50,000	< 1
Pseudoephedrine	>50,000	< 1
d,l-MDMA	2,600	19

d,l-MDEA	25,000	2
d,l-MDA	>50,000	< 1
Phentermine	>50,000	< 1

MET 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Methamphetamine	300	100
d,l-Methamphetamine	1,600	18.8
l-Methamphetamine	2,000	15
d-Amphetamine	>30,000	< 1
l-Amphetamine	>30,000	< 1
d,l-Amphetamine	>30,000	< 1
Ephedrine	>30,000	< 1
Phenylephrine	>30,000	< 1
Phenylethylamine	>30,000	< 1
Pseudoephedrine	>30,000	< 1
d,l-MDMA	2,000	15
d,l-MDEA	20,000	1.5
d,l-MDA	>30,000	< 1
Phentermine	>30,000	< 1

MOR 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
Morphine	300	100
Codeine	300	100
6- Acetylcodeine	300	100
6-Acetylmorphine	500	60
Heroin	2,000	15
Hydrocodone	5,000	6
Hydromorphone	5,000	6
Oxycodone	30,000	< 1
Oxymorphone	30,000	< 1
Procaine	30,000	< 1

OPI 2000:

Substances	Concentration (ng/mL)	% Cross Reactivity
Morphine	2000	100
Codeine	2000	100
6- Acetylcodeine	2,000	100
6-Acetylmorphine	1,500	133.3
Diacetyl morphin (Heroin)	2,000	100
Hydrocodone	50,000	4
Hydromorphone	50,000	4
Oxycodone	100,000	2
Oxymorphone	100,000	2
Acetaminophen	100,000	2
Normorphine	100,000	2
Ethylmorphine	1,500	133.3
Norcodeine	100,000	2

OXY 100:

Substances	Concentration (ng/mL)	% Cross Reactivity
Oxycodone	100	100
Codeine	10,000	< 1
Hydrocodone	10,000	< 1
Oxymorphone	100	100

PCP 25:

Substances	Concentration (ng/mL)	% Cross Reactivity
Phencyclidine	25	100
Pheniramine	2,500	< 1

PPX 300:

Substances	Concentration (ng/mL)	% Cross Reactivity
d-Propoxyphene	300	100
d-Norpoxoxyphene	300	100

TCA 1000:

Substances	Concentration (ng/mL)	% Cross Reactivity
Nortriptyline	1000	100
Amitriptyline	1000	100
Desipramine	300	333
Doxepin HCl	2,000	50
Imipramine	50	2000
Protriptyline	4750	21.1
Trimipramine	2,000	50

TML 100:

Substances	Concentration (ng/mL)	% Cross Reactivity
Tramadol	100	100
n-Desmethyl Tramadol	400	25
o-Desmethyl Tramadol	1,000	10
Venlafaxine	>100,000	<1
o-Desmethyl Venlafaxine	>10,000	<1

Interference

The following compounds did not interfere when tested at concentrations of 100 µg/mL in above and below 25% of the drug cut-off.

Endogenous Compounds:

Albumin	Creatinine	r-Globulin	Octopamine
Acetone	Dopamine	Hemoglobin	Riboflavin
Ascorbic Acid	Ethanol	Human serum Albumin	Sodium Chloride
Atropine	Galactose	B-Hydroxybutyric Acid(F)	Uric Acid
Bilirubin	Glucose	Oxalic Acid	Urea
Cholesterol			

Structurally Unrelated Compounds:

Amlodipine Besylate	I-Erythromycin,	Norethindrone
7-Aminonitrazepam	Estradiol	Noscapine
Amoxicillin	Estrone	Octopamine
Ampicillin	Fenfluramine	Papaverine
Apomorphine	Fenofibrate	Penicillin-G
Aspirin	Fluphenazine(F)	Pentazocine
Aspartame	Fotemustine	Perphenazine
Baclofen	Furosemide	Phenelzine
Benzocaine	Gemfibrozil	Phenylethylamine
Benzylpiperazine	Guaiaacolglyceryl ether	Phenterminr
Benzoic Acid	Gentisic acid	Prednisone
4-Bromo-2,5-Dimethoxyphenethylamine	Hexobarbital	Promazine
Carisoprodol	Hydralazine	Promethazine
Clomipramine	Hydrocortisone	Propoxyphene
Cetirizine	3-Hydroxytyramine	Propranolol
Chloramphenicol	β-Hydroxybutyric Acid	Pyridoxine
Chlordiazepoxide	Ibuprofen	Pyrilamine
Chlorpheniramine	d,l-Isoproterenol	Pyrogallol
Chlorpromazine	Ketamine	Norpropoxyphene
Clofibrate	Lamotrigine	Quinidine
Clonidine	Lisinopril	Quinine
Cortisone	Loratidine	Quinolinic Acid
I-Cotinine	Maprotiline	Ranitidine
Creatine Hydrate	Meprobamate	Salicylic Acid
Cyclobenzaprine	Metoprolol	Sodium Azide
Cyclodextrin-r	Methapyrilene	Sulfamethazine
Cyproheptadine	Methylphenidate	Sulindac
Demoxepam	Nalidixic Acid	Tetracycline
Deoxycorticosterone	Naloxone	Tetrahydrozoline
Dextromethorphan	Naltrexone	Thiamine
Diclofenac	Naproxen	Thiuridazine
	Niacinamide	Trifluoromethylphenyl- piperazine
Dimethyl-aminoantipyrine	N-desmethyapentadol	Trifluoperazine
Diphenhydramine	Nicotinic Acid	Tryptamine
Diphenylhydantoin	Nifedipine	Tyramine
		Zolpidem

Symbols Used in the Labels with Adjacent Explanatory Text

SYMBOL	EXPLANATORY TEXT
	Indicates the medical device manufacturer.
	Indicates the date when the medical device was manufactured.
	Indicates the date after which the medical device is not to be used.
	Indicates the manufacturer's catalog number and the medical device can be identified.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates the need for user to consult the instructions for use.
	Indicates the device that is intended to be used "For In Vitro Diagnostic Use Only".
	Indicates the total number of tests in each kit box.
	Indicates the device that is intended for single use only. Do not reuse!

Ditributed By:
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Part Number: 66205-G; Revision: 01172024

The following compounds showed no interference at the concentrations below:

Compound	Conc. (ng/mL)	Compound	Conc. (ng/mL)
Acetylsalicylic Acid	500,000	Metformin	25,000
7-Aminoflunitrazepam	25,000	Norpseudoephedrine	25,000
Bupropion	25,000	Oxazepam Glucuronide	25,000
Caffeine	500,000	Sufentanil Citrate	25,000
Carbamazepine	25,000	11-nor-9 carboxy THC	50,000
Lorazepam Glucuronide	50,000	L-thyroxine	25,000
LSD	50,000	Zolpidem Tartrate	50,000

In addition, further testing with the following opioids compounds /drugs at a concentration of 100 µg/mL in ±25% of the cutoff drug urine controls confirm that no interference or cross-reactivity was observed with the Drug Screen FYL/TML Tests.

6-Acetylmorphine	Hydrocodone	Norcodeine
Amphetamine	Hydromorphone	Norketamine
Buprenorphine	Levorphanol	Normorphine
Codeine	Methadone	Noroxycodone
Dihydrocodeine	Morphine	Oxycodone
EDDP	Morphine-3-glucuronide	Oxymorphone
Fluoxetine	Naloxone	Pentazocine (Talwin)
Heroin	Norbuprenorphine	Tramadol

The following opioids compounds /drugs do not interfere or cross-react at a concentration of 10 µg/mL in ±25% of the cutoff drug urine controls:

Meperidine	Normeperidine	Risperidone
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Effect of Urine pH

The pH ranges 2.0 to 9.0 were prepared by adjusting the drug urine controls at ±25% of the drug cut-off levels. The test results show that the ranges of urine pH do not affect the test results.

Effect of Urine Specific Gravity (SG)

The SG ranges of 1.010, 1.015, 1.020, 1.025 and 1.030 were prepared by adjusting the drug urine controls at ±25% of the drug cut-off levels, respectively. The results demonstrate that the ranges of urine SG do not affect the test results.

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INSTANT DRUG TEST CUP/CARD II (IDTC II)

Package Insert for OTC Use

For *in vitro* diagnostic use only

The CLIAwaived, Inc. Instant Drug Test Cup/Card II offers a variety of solutions for fast and reliable drug testing in the privacy of your own home. This product can detect up to 15 commonly abused drugs in human urine:

Abbreviation	Drug	Cutoff (ng/ml)
AMP	Amphetamine	500
BAR	Barbiturates	300
BUP	Buprenorphine	10
BZO	Benzodiazepines	300
COC	Cocaine	150
EDDP	Methadone Metabolite	300
MET	Methamphetamine	500
MDMA	Ecstasy	500
MTD	Methadone	300
OPI	Morphine	300
OPI	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	50

This test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC/MS/MS) and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in the evaluation of a preliminary positive test result.

This test does not distinguish between drugs of abuse and certain medications. It may yield preliminary positive results when prescription tricyclic antidepressants, barbiturates, benzodiazepines, methadone, buprenorphine or opiates are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

INSTRUCTIONS FOR OTC USE:

BEFORE TESTING

Read the instructions completely.

Check the expiration date on the box. Do not use the test if it is expired. Have a watch, clock or timer ready.

The following items are needed only if you choose to ship samples for confidential confirmation lab testing:

- Pre-addressed shipping box
- Plastic transportation bag
- Identification label

PERFORMING THE TEST

Step 1: Take Out the Test Device

Take the test device from the sealed foil pouch. The CLIAwaived, Inc. Instant Drug Test comes in two (2) types: dip card and cup.

Step 2: Apply Urine to the Test Device

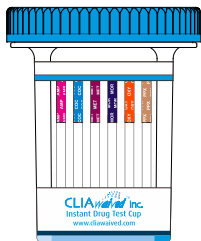
If Using a Dip Card:

1. Remove the dip card from the sealed pouch. Write the donor name or ID in the provided space and then remove the cap.
2. With the arrows pointing toward the urine specimen, **immerse the sample tips vertically** in the urine specimen for **at least 20 seconds**. Put the cap back on the dip card. Place the dip card on a flat surface.



If Using a Cup:

1. Remove the cup from the sealed pouch. Write the donor name or ID in the space provided.
2. **Collect urine** in the cup.



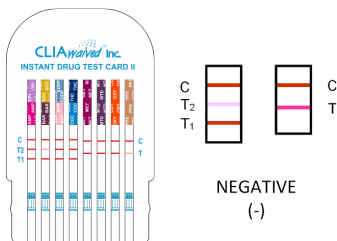
Step 3: Read Result

Read results after 5 minutes. Do not wait longer than 60 minutes.

A red or pink line must appear next to the letter “C” (control) on all of the test strips. The appearance of a red or pink next to the letter “C” on each test strip indicates that the test has worked properly. If you see control lines on all the test strips, you can read your test results.

Negative Result:

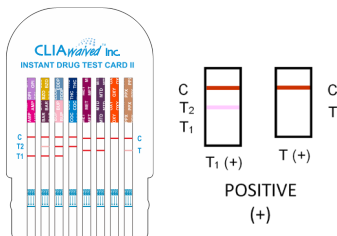
A red or pink line next to the “T1” or “T2” (drug test line) under the drug name indicates a negative result for that drug. If a test line appears next to the “T1” or “T2” for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.



Preliminary Positive Result:

If NO red or pink line appears next to the “T1” or “T2” under the drug name, the sample may contain that drug. Send the sample to a laboratory for confirmation testing.

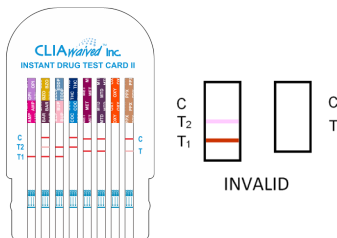
The illustration on the right shows preliminary positive results for OPI, COC and OXY, but negative for all other drugs.



Invalid Result:

A colored line should always appear next to the letter “C” on every test strip. If no control line appears on any of test strips, the result is invalid.

The illustration at right shows no line next to the letter “C” on the first strip (OPI, AMP), third strip (EDDP, BUP) and seventh strip (OXY). The test results for those three test strips are invalid.



QUESTIONS AND ANSWERS

The CLIAwaived, Inc. IDTC II is user friendly, if you have question about the test or result, please call our helpline at 1-888-882-7739, a 24/7-recorded information service is available, please leave your message and your call will be returned the next business day. In addition, the CLIAwaived, Inc. team is available to answer your question weekdays from 8 am to 5 pm PST

What do my test results mean?

Q. The drug line is lighter than control line. Does it mean the drug is present in the urine?

A. No. The drug line may be darker or lighter than the control line. The line intensities of different drugs will vary for many reasons. No matter how faint the drug line appears on the test strip, it is considered a negative result. No further testing is required.

Q. What does a Preliminary Positive Result mean?

A. The sample may contain one or more of the drugs being tested for. It is possible to get a "preliminary positive" when someone has not taken the drug. We recommend you send the urine to our laboratory for additional confirmation testing. Additional fees may apply.

- Medicinal such as diet pills, inhalers, cough syrup, and pain pills may cause a preliminary positive result.
- The tests may yield preliminary positive results with prescription drugs such as tricyclic antidepressants, barbiturates, benzodiazepine, methadone, buprenorphine (including Subutex, Suboxone, Temgesic, Buprenex, Norspan, and Butrans), and opiates (including morphine, hydrocodone, Oxycodone, and codeine) are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

Q. What does a Negative Result mean?

A. If you get a negative result, the sample did not contain the drug being tested for. No further testing is required. However, it is possible to get a negative result even if a person has taken drugs. Some reasons why this might happen are:

- The urine sample was collected at the wrong time. It was collected before the drug got into the urine or after it was no longer in the urine.
- The person took a drug other than the one tested for in this test; e.g. they might have taken LSD, when this test is for drugs other than LSD.

Q. What does an Invalid Result mean?

A. If any of the strips do not show a control, the result is invalid. We recommend that you re-test or contact your sales representative.

Laboratory Confirmation Testing:

Q. How can a Preliminary Positive Result be confirmed?

A. The urine specimen needs to be sent to our laboratory for confirmation testing. See the shipping instructions in **"Shipping the Urine Sample to the Lab for Confirmation Testing"** section below.

Other Questions:

Q. When is the best time to take the test?

A. The drug test can be used at any time of day. Approximate detection times using each drug are listed in the following table:

Drug	Cutoff	Minimum	Maximum
Amphetamine (AMP)	500 ng/ml	2-7 hours	2-4 days
Cocaine (COC)	150 ng/ml	1-4 hours	2-4 days
Methamphetamine (MET)	500 ng/ml	2-7 hours	2-4 days
Opiates (OPI)	2,000 ng/ml	2 hours	2-3 days
Marijuana (THC)	50 ng/ml	2 hours	Up to 40 days
Tricyclic Antidepressants (TCA)	1,000 ng/ml	8-12 hours	2-7 days
Phencyclidine (PCP)	25 ng/ml	4-6 hours	7-14 days
Barbiturates (BAR)	300 ng/ml	2-4 hours	1-3 weeks
Benzodiazepines (BZO)	300 ng/ml	2-7 hours	1-4 days
Oxycodone (OXY)	100 ng/ml	1-3 hours	1-2 days
Methadone (MTD)	300 ng/ml	3-8 hours	1-3 days
Ecstasy (MDMA)	500 ng/ml	2-7 hours	2-4 days
EDDP	300 ng/ml	3-8 hours	1-3 days
Buprenorphine (BUP)	10 ng/ml	4-24 hours	3-6 days

The Substance Abuse and Mental Health Services Agency (SAMHSA) has set cutoff levels when testing for marijuana, cocaine, amphetamine, opiates, PCP, Ecstasy and methamphetamine. Screening tests may not detect amounts of drugs in a urine sample that are below the cutoff level. Even if some drug is present in a urine sample, the sample would be considered negative if the drug level is below the cutoff level.

Q. How much urine do I need?

A. The CLIAwaived, Inc. Instant Drug Test Cup/Card II requires just 30 ml of urine. Fill the collection cup to the minimum fill line on the side of the cup. This is enough urine for the initial test and confirmation testing if needed.

Q. Do I have to wait the full 5 minutes before reading the test?

A. Yes, we recommend that you wait the full 5 minutes before reading the result.

Q. Are there any factors that could affect the drug testing result?

A. Yes, certain factors may affect the drug testing result.

1. Certain over the counter medicines and prescription medicines may cause a preliminary positive result.
2. Urine can be adulterated (i.e. contaminated or tampered) by using bleach, cleaning supplies and other liquids. This may dilute the urine and the test may not be accurate.
3. Drinking large amount of liquids may dilute the urine so that the drug (if present) cannot be detected.
4. Failure to use the CLIAwaived, Inc. IDTC II as directed may result in an inaccurate screening result.
5. The following compounds are detected positive in urine by the The CLIAwaived, Inc. Instant Drug Test Cup/Card II. Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses.

Compound	Concentration (%)	Compound	Concentration (%)
AMP			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
BAR			
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital	500 (60%)	Phenobarbital	300 (100%)
Butabarbital	100 (300%)	Pentobarbital	250(120%)
BUP			
Buprenorphine	10 (100%)		
BZO			
Oxazepam	300 (100%)	Lorazepam	3,900 (7.7%)
Alprazolam	200 (150%)	Lorazepam-glucuronide	5,000 (6%)
Bromazepam	1,000 (30%)	Nitrazepam	250 (120%)
Clobazam	200 (150%)	Norchlordiazepoxide	500 (60%)
Clorazepate	750 (40%)	Nordazepam	390 (76.9%)
Desalkylflurazepam	1,200 (25%)	Nordiazepoxide	400(75%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
α-Hydroxyalprazolam	1,900 (15.8%)		
COC			
Benzoylcegonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
EDDP			
EDDP	300 (100%)		
MET			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		
OPI			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)	Norcodeine	6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone	2,500 (12%)		
MTD			
Methadone	300 (100%)		
OPI			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)
Hydrocodone	5,000 (40%)		

Compound	Concentration (%)	Compound	Concentration (%)
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
TCA			
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)
THC			
11-nor- Δ^9 -THC-9-COOH	50 (100%)	(-)- Δ^8 -THC	20,000 (0.3%)
(+/-)-11-Hydroxy- Δ^9 -THC	5,000 (1%)	(-)- Δ^9 -THC	20,000 (0.3%)

SHIPPING URINE SAMPLES FOR CONFIRMATION TESTING (OTC ONLY)

About confirmation testing:

Negative samples do not need further testing. You should only send preliminary positive samples to a laboratory for confirmation.

Check the provided shipping package:

The following items are provided (OTC only):

- Mailer: Pre-addressed Mailing Box with Transportation Label
- Zip-lock Plastic Transportation Bag
- Identification Label

Package urine samples for shipping:

- Attach the top portion of the identification label to the urine collection cup.
- Attach the lower portion of the identification label to the instruction sheet where labeled "place identification label here." For security reasons, you will need this number to retrieve your lab test results.
- Place the urine collection cup in the zip-lock plastic transportation bag, seal and place into the pre-addressed mailing box and close. On the pre-addressed mailing box label, fill in the sample collection date.
- On the mailing box label, check off the drug(s) that gave a preliminary positive result. IT IS IMPORTANT THAT YOU INDICATE WHICH DRUG WAS POSITIVE SO THAT A LAB CONFIRMATION TEST CAN BE PERFORMED FOR THAT DRUG. WITHOUT THIS LABEL, YOUR SAMPLE CANNOT BE TESTED.
- Mail the preliminary positive urine sample as soon as possible. Urine samples cannot be accurately tested if more than 7 days old.
- The mailing box is not pre-paid. To ensure prompt delivery, be sure to pay the appropriate shipping charges.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. External controls are available from CLIAwaived, Inc. or other commercial sources. A minimum of 5mL of positive and/or negative control material is required to activate the CLIAwaived, Inc Instant Drug Test Cup II. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators. It is recommended that Quality control testing be performed with each new lot, with each new shipment, and every thirty days when storage conditions may have changed or exceeded storage requirements of the product labeling. External controls can be purchased from the following vendor: CLIAwaived, Inc. 1-888-882-7739, www.cliawaived.com.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

The accuracy of the CLIAwaived, Inc. Instant Drug Test CUP/CARD II (IDTC II) was evaluated in comparison to GC/MS and LC/MS. 40 drug-free urine samples collected from presumed non-user volunteers were tested with the CLIAwaived, Inc. Instant Drug Test CUP/CARD II (IDTC II). Of these 40 negative samples, all were correctly identified as negative. 10% of the negative samples were confirmed with GC/MS as drug negative. At least 40 drug positive urine specimens for each drug test were obtained from reference labs. Drug concentrations were confirmed with GC/MS and LC/MS (for TCA). A summary of the accuracy and discordant results on Dip Card and Cup formats are shown in the following tables:

Summary of Accuracy Results on the CLIAwaived, Inc. Card II

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						
		Drug-free	-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% Agreement
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Discordant Results on the CLIAwaived, Inc Card II

Drug Test/ Cutoff (ng/ml)	CLIAwaived, Inc Dip Card II Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoyllecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine

Drug Test/ Cutoff (ng/ml)	CLIAwaived, Inc Dip Card II Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
OPI/300	Positive	260	Morphine
	Positive	263	Morphine
	Positive	292	Morphine
MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor- Δ^9 -THC-9-COOH

Summary of Accuracy Results on the CLIAwaived, Inc Cup II

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS Data						
		Drug-free	-50% C/O to -25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	% Agreement
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%

Discordant Results on the CLIAwaived, Inc Cup II

Drug Test/ Cutoff (ng/ml)	CLIAwaived, Inc Cup II Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
AMP/500	Positive	477	Amphetamine
BAR/300	Positive	265	Barbital
	Positive	286	Barbital
BUP/10	Positive	8	Buprenorphine
	Positive	9	Buprenorphine
BZO/300	Positive	244	Oxazepam
	Positive	252	Oxazepam
	Positive	295	Oxazepam
COC/150	Positive	146	Benzoyllecgonine
EDDP/300	Positive	250	EDDP
	Positive	263	EDDP
	Positive	275	EDDP
MDMA/500	Positive	368	MDMA
	Positive	381	MDMA
MET/500	Positive	394	Methamphetamine
	Positive	461	Methamphetamine
	Positive	478	Methamphetamine
OPI/300	Positive	260	Morphine
	Positive	263	Morphine
	Positive	292	Morphine
MTD/300	Positive	266	Methadone
	Positive	273	Methadone
OPI/2000	Positive	1,898	Morphine
	Positive	1,990	Morphine
OXY/100	Positive	88	Oxycodone
	Positive	98	Oxycodone
	Positive	99	Oxycodone
PCP/25	Positive	22.9	Phencyclidine
TCA/1000	Positive	786	Nortriptyline
	Positive	859	Nortriptyline
THC/50	Positive	49	11-nor- Δ^9 -THC-9-COOH

B. ANALYTICAL SENSITIVITY/PRECISION

Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested by 9 operators at 3 physician office laboratories (POL) over 20 non-consecutive days. Each level of solution was tested in 10 replicates randomly by each operator at each POL site. Results showed over 99% agreement at +/-50% cutoff levels with the CLIAwaived, Inc Card and Cup.

C. ANALYTICAL SPECIFICITY

The following compounds are detected positive in urine by the CLIAwaived, Inc Instant Drug Test Cup/Card II. Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses.

Compound	Concentration (%)	Compound	Concentration (%)
AMP			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
BAR			
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital	500 (60%)	Phenobarbital	300 (100%)
Butabarbital	100 (300%)	Pentobarbital	250 (120%)
BUP			
Buprenorphine	10 (100%)		
BZO			
Oxazepam	300 (100%)	Lorazepam	3,900 (7.7%)
Alprazolam	200 (150%)	Lorazepam-glucuronide	5,000 (6%)
Bromazepam	1,000 (30%)	Nitrazepam	250 (120%)
Clobazam	200 (150%)	Norchlordiazepoxide	500 (60%)
Clorazepate	750 (40%)	Nordazepam	390 (76.9%)
Desalkylflurazepam	1,200 (25%)	Nordiazepoxide	400 (75%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
α -Hydroxyalprazolam	1,900 (15.8%)		
COC			
Benzoylcegonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
EDDP			
EDDP	300 (100%)		
MET			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		
OPI			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)	Norcodeine	6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone	2,500 (12%)		
MTD			
Methadone	300 (100%)		
OPI			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)
Hydrocodone	5,000 (40%)		
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)

Compound	Concentration (%)	Compound	Concentration (%)
TCA			
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)
THC			
11-nor- Δ^9 -THC-9-COOH	50 (100%)	(-)- Δ^8 -THC	20,000 (0.3%)
(+/-)-11-Hydroxy- Δ^9 -THC	5,000 (1%)	(-)- Δ^9 -THC	20,000 (0.3%)

D. INTERFERENCE

The following compounds were evaluated for potential positive or negative interference with the CLIAwaived, Inc. Instant Drug Test Cup/Card II. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the CLIAwaived, Inc. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/mL when tested with the CLIAwaived, Inc. Instant Drug Test Cup/Card II:

Acetaminophen	Diphenhydramine	Nicotine
Acetone	Dopamine	(+/-)-Norephedrine
Albumin	(+/-)-Isoproterenol	Oxalic acid
Ampicillin	1R,2S(-)-Ephedrine	Penicillin-G
Ascorbic acid	Erythromycin	Pheniramine
Aspartame	Ethanol	Phenothiazine
Aspirin	Furosemide	L-Phenylephrine
Atropine	Glucose	B-Phenylethylamine
Benzocaine	Guaiacol glyceryl ether	Procaine
Bilirubin	Hemoglobin	Quinidine
Caffeine	Ibuprofen	Ranitidine
Chloroquine	(+/-)-Isoproterenol	Riboflavin
(+)-Chlorpheniramine	Ketamine	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Sulindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan	(+)-Naproxen	
4-Dimethylaminoantipyrine	Niacinamide	

ADULTERATION TEST

Urine sample adulteration is usually achieved by substitution, dilution or the addition of adulterants including so-called "masking agents" sold commercially. The use of adulterants can cause false negative results in drug tests by either interfering with the test and/or destroying drugs present in the urine. Dilution may also be used in an attempt to produce false negative drug test results.

The CLIAwaived, Inc. adulteration test is based on the color response of chemical indicators in the presence of adulterants. pH (P), specific gravity (S), oxidant/PCC (O), creatinine (C), nitrite (N) and glutaraldehyde (G) are tested to determine the integrity of urine samples.

pH: The pH determination of urine samples is based on the color change of an indicator in an acidic or basic medium. Normal urine pH ranges from 4 to 9. Values outside of this range may indicate the sample has been altered.

Specific Gravity: The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. The normal range for specific gravity is from 1.003 to 1.030. Values outside this range generally indicate specimen dilution or adulteration.

Oxidants/PCC (Pyridinium Chlorochromate): Bleach, hydrogen peroxide, pyridinium chlorochromate or other oxidizing agents react with an oxidant indicator to form a color complex. A blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents. Normal human urine should not contain oxidants.

Creatinine: Creatinine reacts with an indicator in an alkaline medium to form a purplish-brown color complex. The normal range of creatinine is from 20 to 300 mg/dl. Values outside this range generally indicate a manipulated test.

Nitrite: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. A urine sample containing nitrite at a level greater than 15 mg/dl is considered adulterated.

Glutaraldehyde: Adulterants such as "Clear Choice" contain glutaraldehyde which may cause disrupting the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in human urine.

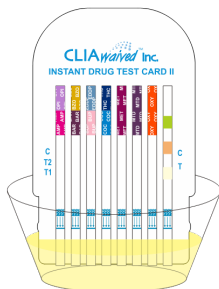
PROCEDURE FOR DRUG TEST WITH ADULTERATION TEST

Preparation:

1. Allow the test device, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Do not open the test device pouch until ready to perform the test.

Dip Card:

1. Remove the dip card from the sealed pouch. Write the donor name or ID on the dip card in the provided space, then remove the cap.
2. With the arrows pointing toward the urine specimen, immerse the sample tips vertically in the urine specimen for at least 20 seconds. Replace the cap back onto the dip card and place the dip card on a flat surface.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read urine adulteration test results by visually comparing the color of the reagent pads to the corresponding color blocks on the Color Chart at 3 to 5 minutes.



Cup:

1. Remove cup from the sealed pouch and write the donor name or ID in the provided space.
2. Collect urine in the cup.
3. Read drug test results at 5 minutes. Results remain stable for 60 minutes.
4. Read urine adulteration test results by visually comparing the color of the reagent pads to the corresponding color blocks on the Color Chart at 3 to 5 minutes.



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 Do not reuse	 Use by YYY-MM-DD or YYYY-MM
 Batch Code	 Serial number
 Caution, consult accompanying documents	 Catalog number
 Manufacturer	 Temperature limitation
 Contains sufficient for <n> tests	 Keep away from sunlight
 In vitro diagnostic medical device	 Keep away from moisture
 Consult instructions for use	 CE Mark
 Recycle	 Authorized representative in the European Community



Emergo Europe, Molenstraat 15
2513 BH, The Hague, The Netherlands



CLIAwaived, Inc.
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www.cliawaived.com

FOR TECHNICAL ASSISTANCE

Call 1-888-882-7739

OUTSIDE THE USA

Call 1-858-481-5031

CLIAwaived, Inc.
11578 Sorrento Valley Road Suite 25/26, San Diego, CA 92121
36001-CWII-OTC
Revision 3



Instant Drug Test Cup Plus

Package Insert

For *In Vitro* Diagnostic Use

For HCP/Professional use

INTENDED USE

The CLIAwaived Inc. Instant Drug Test Cup Plus is lateral flow immunoassays for rapid detection of multiple commonly abused drugs in human urine. The detectable drugs and their cutoff concentrations are listed below:

Abbreviation	Analyte	Calibrator	Cutoff (ng/mL)
6AM	6-Acetylmorphine	6-Monoacetylmorphine	10
AMP	Amphetamine	d-Amphetamine	500 / 1000
BAR	Secobarbital	Secobarbital	300
BUP	Buprenorphine	Buprenorphine	10
BZO	Oxazepam	Oxazepam	300
COC	Cocaine	Benzoylcegonine	150 / 300
EDDP	EDDP	2-ethylidene-1,5-dimethyl-3-3-diphenylpyrrolidine	300
FEN	Fentanyl	Fentanyl	1
FEN	Norfentanyl	Norfentanyl	5
MDMA	Ecstasy	d,l-Methylenedioxy methamphetamine	500
MET	Methamphetamine	d-Methamphetamine	500 / 1000
MOR	Morphine	Morphine	300
MTD	Methadone	d,l-Methadone	300
OPI	Opiates	Morphine	2000
OXY	Oxycodone	Oxycodone	100
PCP	Phencyclidine	Phencyclidine	25
PPX	Propoxyphene	Propoxyphene	300
TCA	Nortriptyline	Nortriptyline	1000
THC	Marijuana	11-nor- Δ^9 -THC-9-COOH	20 / 50

The single or multi-test cup can include any combination of the analytes listed above, with and without on-board adulteration tests. However, only one cut-off concentration can be included per analyte per device.

This *in vitro* diagnostic device provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. GC/MS or LC/MS is the preferred confirmatory method.

PRINCIPLE

All tests included in this device are rapid lateral flow immunoassays, based on the principle of competitive binding, between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites, which may be present in the urine sample, competing for the limited antibody binding sites. Urine migrates via capillary action along the nitrocellulose (NC) membrane strip pre-coated with a drug-protein conjugate band on the test line (T) region and a colored antibody-colloidal gold conjugate pad, and rehydrates the antibody colloidal gold conjugate on test strip. This urine-gold conjugate mixture then migrates along the NC membrane to the immobilized drug-protein band. If a target drug is absent or present in the urine specimen below its cut-off concentration, the colored antibody-gold conjugates specifically bind with the immobilized drug-protein conjugates to form a visible line on the (T) region. If the target drug level exceeds its cut-off concentration, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, the formation of the visible T band indicates a negative result, while absence of T band indicates a positive result.

A visible line generated by a different antigen-antibody reaction is also present but located in the control region of the test strip. This line will always appear at the control line region, regardless of the presence of target drugs in urine, as long as proper volume of specimen has been added and membrane wicking has occurred. The presence of a control line serves as a built-in procedural control, which indicates that the test was properly performed.

REAGENTS

Each test strip contains a colloidal gold pad coated with drug-specific antibodies. It also contains a membrane coated with drug-protein conjugates in the test line region and control IgG in the control line region.

ADULTERATION TEST (OPTIONAL COMPONENT)

Urine sample adulteration is usually achieved by substitution, dilution or the addition of adulterants including so-called "masking agents" sold commercially. The use of adulterants can cause false negative results in drug tests by either interfering with the test and/or destroying drugs present in the urine. Dilution may also be used in an attempt to produce false negative drug test results. The adulteration test strip contains chemically treated reagent pads, which can be activated by a urine sample.

PRECAUTIONS

- All urine specimens should be regarded as potentially hazardous or infectious. Wear gloves and proper attire to avoid skin contact and handle with universal precautions.
- Do not open the sealed pouch until ready to perform the test.
- Do not use the device after the expiration date.
- Do not re-use the device.

MATERIAL SUPPLIED

- Twenty-five (25) individually pouched test cups
- One (1) Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer

STORAGE AND STABILITY

- Store as package in the sealed pouch at 2°C - 30°C (35.6°F - 86.0°F).
- Once pouch open, the test cup must be used within 1 hour.
- The test is stable through the expiration date printed on the sealed pouch.
- Do not use beyond the expiration date.
- Do not freeze the pouch.

SPECIMEN COLLECTION AND PREPARATION

- A fresh urine sample should be collected in a clean, dry plastic or glass container.
- Fresh urine does not require any special handling or pretreatment.

DIRECTIONS FOR USE

- Remove the test cup from the pouch and use it within 1 hour after pouch opening.
- Remove the lid of the cup and set it aside.
- Collect urine in the cup.
- Screw the lid back on and place the cup on a flat surface, start the timer and wait for the colored line(s) to appear.
- Remove the Peel-off label and read the test result at 5 minutes, following the result interpretation below.
- The result remains stable for 30 minutes. Do not read the result after 30 minutes.

RESULT INTERPRETATION

Negative (-): Two colored lines appear. One in the control region (C) and another in the test region (T). The line in the control region is to indicate the proper performance of the device. The appearance of another line in the test region indicates that the concentration of target drug in urine is below the cutoff level.

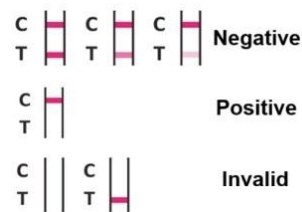
NOTE: The intensity of the test line may vary. It should be considered negative whenever there is even a faint colored line.

Positive (+): One colored line appears in the control region (C). No line appears in the test region (T). A positive result indicates that the concentration of target drug in urine is at or above the cutoff level.

Invalid: No colored line appears in the control region (C).

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test kit. If the problem persists, contact your local distributor.

peel off the label to read the result



QUALITY CONTROL

An internal control is included in the test. A colored line appearing in the control line region (C) is considered a procedural quality control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

- This device provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. GC/MS or LC/MS is the preferred confirmatory methods.
- Both inaccurate techniques or procedures and the existence of interfering substances or adulterants in urine specimen can cause erroneous results.
- A positive result only indicates the presence of drug or its metabolites in urine but does not provide information on drug concentration, administration route and level of intoxication.
- A negative result only indicates that the concentration of drug in urine is below the cutoff level. It may not necessarily indicate drug free.
- The test does not distinguish between drugs of abuse and prescribed medication.

PERFORMANCE CHARACTERISTICS

Precision/Reproducibility

The precision/reproducibility study was carried out by testing samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cut off and -100% cutoff. Samples were prepared by spiking target drugs in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. Each sample was tested in 50 replicates per lot using three lots of devices, and testing was performed two runs per day for 25 days. The results obtained are summarized in the table below:

Drug	Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cutoff
6AM 10	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	49- /1+	50- /0+	50- /0+	50- /0+

AMP 500	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
AMP 1000	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
BAR 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
BUP 10	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	12- /38+	48- /2+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	13- /38+	50- /0+	50- /0+	50- /0+	50- /0+
BZO 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
COC 150	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
COC 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
EDDP 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	2- /48+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	1- /49+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
FEN 1	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	2- /48+	13- /37+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	2- /48+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
FEN 5	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	48- /2+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	2- /48+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
MDMA 500	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	49- /1+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	12- /38+	50- /0+	50- /0+	50- /0+	50- /0+
MET 500	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
MET 1000	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
MOR 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
MTD 300	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
OPI 2000	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+

OXY 100	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
PCP 25	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	11- /39+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
PPX 300	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	49- /1+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	7- /43+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
TCA 1000	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
THC 20	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	10- /40+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+
THC 50	Lot 1	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 2	0- /50+	0- /50+	0- /50+	0- /50+	8- /42+	50- /0+	50- /0+	50- /0+	50- /0+
	Lot 3	0- /50+	0- /50+	0- /50+	0- /50+	9- /41+	50- /0+	50- /0+	50- /0+	50- /0+

Method Comparison (Accuracy)

Method comparison was performed by testing unaltered clinical urine specimens with both the CLIAwaived Inc. Instant Drug Test Cup Plus and LC/MS as gold standard reference method. Eighty samples (40 negative and 40 positive) with blind labels were tested for each drug by three operators, and then compared to the LC-MS/MS results. The results are presented in the table below:

Drug Test	Test Cup Result		Drug Free	Low Negative by LC/MS (<-50% Cutoff)	Near Cutoff by LC/MS (Between -50% and Cutoff)	Low Positive by LC/MS (Between Cutoff and +50%)	High Positive by LC/MS (> + 50% Cutoff)
6AM 10	Operator A	-	12	16	11	1	0
		+	0	0	1	15	24
	Operator B	-	12	16	11	0	0
		+	0	0	1	16	24
	Operator C	-	12	16	11	0	0
		+	0	0	1	16	24
AMP 500	Operator A	-	12	16	12	1	0
		+	0	0	0	12	27
	Operator B	-	12	16	12	2	0
		+	0	0	0	11	27
	Operator C	-	12	16	12	1	0
		+	0	0	0	12	27
AMP 1000	Operator A	-	12	17	11	0	0
		+	0	0	0	15	25
	Operator B	-	12	17	11	1	0
		+	0	0	0	14	25
	Operator C	-	12	17	11	1	0
		+	0	0	0	14	25
BAR 300	Operator A	-	8	13	18	0	0
		+	0	0	1	16	24
	Operator B	-	8	13	17	0	0
		+	0	0	2	16	24
	Operator C	-	8	13	17	0	0
		+	0	0	2	16	24
BUP 10	Operator A	-	15	14	10	1	0
		+	0	0	1	17	22
	Operator B	-	15	14	10	1	0
		+	0	0	1	17	22
	Operator C	-	15	14	10	1	0
		+	0	0	1	17	22
BZO 300	Operator A	-	8	17	13	0	0
		+	0	0	2	12	28
	Operator B	-	8	17	14	0	0
		+	0	0	1	12	28
	Operator C	-	8	17	13	0	0
		+	0	0	2	12	28
COC 150	Operator A	-	12	13	14	2	0
		+	0	0	1	13	25
	Operator B	-	12	13	14	1	0
		+	0	0	1	14	25
	Operator C	-	12	13	14	1	0
		+	0	0	1	14	25
COC 300	Operator A	-	12	18	10	1	0
		+	0	0	0	15	24
	Operator B	-	12	18	9	1	0
		+	0	0	1	15	24
	Operator C	-	12	18	10	0	0
		+	0	0	0	16	24

EDDP 300	Operator A	-	11	16	12	1	0
	Operator A	+	0	0	1	13	26
	Operator B	-	11	16	13	1	0
	Operator B	+	0	0	0	13	26
FEN 1	Operator C	-	11	16	11	1	0
	Operator C	+	0	0	2	13	26
	Operator A	-	9	15	14	0	0
	Operator A	+	0	0	2	15	25
FEN 5	Operator B	-	9	15	14	1	0
	Operator B	+	0	0	2	14	25
	Operator C	-	9	15	13	0	0
	Operator C	+	0	0	3	15	25
MDMA 500	Operator A	-	10	16	11	0	0
	Operator A	+	0	0	3	16	24
	Operator B	-	10	16	12	1	0
	Operator B	+	0	0	2	15	24
MET 500	Operator C	-	10	16	11	0	0
	Operator C	+	0	0	3	16	24
MET 1000	Operator A	-	10	20	10	0	0
	Operator A	+	0	0	0	12	28
	Operator B	-	10	20	9	1	0
	Operator B	+	0	0	1	11	28
MOR 300	Operator C	-	10	20	9	0	0
	Operator C	+	0	0	1	12	28
MTD 300	Operator A	-	13	14	13	1	0
	Operator A	+	0	0	0	11	28
	Operator B	-	13	14	12	0	0
	Operator B	+	0	0	1	12	28
MET 500	Operator C	-	13	14	11	1	0
	Operator C	+	0	0	2	11	28
MET 1000	Operator A	-	13	16	11	1	0
	Operator A	+	0	0	0	14	25
	Operator B	-	13	16	11	1	0
	Operator B	+	0	0	0	14	25
MOR 300	Operator C	-	13	16	11	1	0
	Operator C	+	0	0	0	14	25
MTD 300	Operator A	-	12	15	12	0	0
	Operator A	+	0	0	1	14	26
	Operator B	-	12	15	13	1	0
	Operator B	+	0	0	0	13	26
OPI 2000	Operator C	-	12	15	13	1	0
	Operator C	+	0	0	0	13	26
OXY 100	Operator A	-	11	14	15	1	0
	Operator A	+	0	0	0	12	27
	Operator B	-	11	14	14	0	0
	Operator B	+	0	0	1	13	27
PCP 25	Operator C	-	11	14	15	1	0
	Operator C	+	0	0	0	12	27
PPX 300	Operator A	-	11	15	14	0	0
	Operator A	+	0	0	0	18	22
	Operator B	-	12	14	14	1	0
	Operator B	+	0	0	0	17	22
TCA 1000	Operator C	-	12	14	14	2	0
	Operator C	+	0	0	0	16	22
THC 20	Operator A	-	11	15	13	1	0
	Operator A	+	0	0	1	12	27
	Operator B	-	11	15	12	1	0
	Operator B	+	0	0	2	12	27
THC 50	Operator C	-	13	15	10	0	0
	Operator C	+	0	0	2	14	26
	Operator A	-	13	15	11	0	0
	Operator A	+	0	0	1	14	26
THC 50	Operator B	-	13	15	11	1	0
	Operator B	+	0	0	1	14	26
	Operator C	-	13	15	11	1	0
	Operator C	+	0	0	1	15	24
THC 50	Operator A	-	11	17	12	0	0
	Operator A	+	0	0	0	14	26
	Operator B	-	11	17	12	2	0
	Operator B	+	0	0	0	12	26
THC 50	Operator C	-	11	17	12	1	0
	Operator C	+	0	0	0	13	26

Specificity and Cross-Reactivity

Specificity was evaluated by testing various concentrations of compounds that structurally related to each drug. The lowest concentration of each compound leading to positive result and the percent cross reactivity of each compound are listed below. If no cross reactivity was observed, the data are shown with > or < symbols.

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result	% Cross-Reactivity
6AM 10	6-Acetylmorphine	10	100%
	Heroin	25	40%
	Morphine	>100,000	<0.01%
	Normorphine	>100,000	<0.01%
	Nalorphine	>100,000	<0.01%
	Hydrocodone	>100,000	<0.01%
	Hydromorphone	>100,000	<0.01%
	Chlordiazepoxide	>100,000	<0.01%
	Clobazam	>100,000	<0.01%
	D-Amphetamine	>100,000	<0.01%
	(±)-Amphetamine	>100,000	<0.01%
	Levorphanol	>100,000	<0.01%
	Codeine	>100,000	<0.01%
	Ethylmorphine	>100,000	<0.01%
	Morphine3-β-D-glucuronide	>100,000	<0.01%
	Norcodeine	>100,000	<0.01%
	Oxycodone	>100,000	<0.01%
	Oxymorphone	>100,000	<0.01%
	Procaine	>100,000	<0.01%
	Thebaine	>100,000	<0.01%
	6-Acetylcodeine	50,000	0.02%
	Buprenorphine	>10,000	<0.1%
	Dihydrocodeine	>100,000	<0.01%
	Dextromethorphan	>100,000	<0.01%
	Imipramine	>100,000	<0.01%
	Meperidine	>100,000	<0.01%
	(±)-Methadone	>100,000	<0.01%
	Mitragynine(Kratom)	>10,000	<0.1%
	Morphine-6-β-D-glucuronide	>10,000	<0.1%
	Naloxone	>100,000	<0.01%
	Naltrexone	>100,000	<0.01%
	Naproxen	>100,000	<0.01%
	Norbuprenorphine	>10,000	<0.1%
	Norbuprenorphine-3-D-Glucuronide	10,000	0.10%
	Noroxycodone	>100,000	<0.01%
	Noroxymorphone	>10,000	<0.1%
	Norpropoxyphene	>100,000	<0.01%
	Oxymorphone-3β-D-glucuronide	>10,000	<0.1%
	Tapentadol	>100,000	<0.01%
	cis-Tramadol	>100,000	<0.01%
AMP 500	(±)-3,4-Methylenedioxyamphetamine (MDA)	2,000	25%
	(±)-Amphetamine	1,000	50%
	D-Amphetamine	500	100%
	Diethylstilbestrol	>10,000	<5%
	L-Amphetamine	50,000	1%
	Phentermine	15,000	3.33%
	β-Phenylethylamine	>100,000	<0.5%
	Tyramine	>100,000	<0.5%
	p-Hydroxynorephedrine	>100,000	<0.5%
	p-Hydroxyamphetamine	5,000	10%
	D-Methamphetamine	>100,000	<0.5%
	L-Methamphetamine	>100,000	<0.5%
	Ephedrine	>100,000	<0.5%
	(±)-3,4-Methylenedioxymethamphetamine	>100,000	<0.5%
	Phenylpropanolamine (Norephedrine)	>100,000	<0.5%
	Benzphetamine	>100,000	<0.5%
	(1R,2S)-(-)-Ephedrine	>100,000	<0.5%
	L-Epinephrine	>100,000	<0.5%
	D,L-Epinephrine	>100,000	<0.5%

	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	<0.5%
AMP 1000	(±)-3,4-Methylenedioxyamphetamine (MDA)	5,000	20%
	(±)-Amphetamine	2,000	50%
	D-Amphetamine	1,000	100%
	Diethylstilbestrol	>10,000	<10%
	L-Amphetamine	>100,000	<1%
	Phentermine	25,000	4%
	β-Phenylethylamine	>100,000	<1%
	Tyramine	>100,000	<1%
	p-Hydroxynorephedrine	>100,000	<1%
	p-Hydroxyamphetamine	10,000	10%
	D-Methamphetamine	>100,000	<1%
	L-Methamphetamine	>100,000	<1%
	Ephedrine	>100,000	<1%
	(±)-3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	<1%
	Phenylpropanolamine (Norephedrine)	>100,000	<1%
	Benzphetamine	>100,000	<1%
	(1R,2S)-(-)-Ephedrine	>100,000	<1%
	L-Epinephrine	>100,000	<1%
	D,L-Epinephrine	>100,000	<1%
	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	<1%
BAR 300	Alphenal	400	75%
	Amobarbital	500	60%
	Aprobarbital	150	200%
	Barbital	1000	30%
	Butabarbital	70	428.57%
	Butethal	20	1500%
	Cyclopentobarbital	1,000	30%
	Pentobarbital	200	150%
	Phenobarbital	250	120%
	Secobarbital	300	100%
BUP 10	Butalbital	10,000	3%
	Buprenorphine	10	100%
	Buprenorphine -3-D-Glucuronide	20	50%
	Norbuprenorphine	150	6.67%
	Norbuprenorphine glucuronide	500	2%
	Codeine	>100,000	<0.01%
	Nalorphine	>100,000	<0.01%
	Morphine	>100,000	<0.01%
BZO 300	Oxymorphone	>100,000	<0.01%
	Hydromorphone	>100,000	<0.01%
	a-Hydroxyalprazolam	5,000	6%
	Alprazolam	250	120%
	Bromazepam	600	50%
	Chlordiazepoxide	500	60%
	Clobazam	300	100%
	Clonazepam	>100,000	<0.3%
	Clorazepate	500	60%
	Desalkylflurazepam	500	60%
	Diazepam	1,000	30%
	Estazolam	>100,000	<0.3%
	Flunitrazepam	1,000	30%
	Lorazepam	1,000	30%
	Lormetazepam	>100,000	<0.3%
	Midazolam	>100,000	<0.3%
	Nitrazepam	250	120%
	Norchlordiazepoxide	70	428.57%
	Nordiazepam	1,000	30%
	Oxazepam	300	100%
	Oxazepam glucuronide	30	1000%
	Lorazepam glucuronide	100	300%

	Temazepam	200	150%
	Triazolam	5,000	6%
	Demoxepam	25	1200%
	Flurazepam	>100,000	<0.3%
	Delorazepam	>10,000	<3%
COC 150	Benzoylcegonine	150	100%
	Cocaethylene	2,000	7.50%
	Cocaine	>100,000	<0.15%
	Ecgonine	>100,000	<0.15%
	Norcocaine	>100,000	<0.15%
	Ecgonine methyl ester	>100,000	<0.15%
	Benzoylcegonine	300	100%
	Cocaethylene	3,000	10%
COC 300	Cocaine	>100,000	<0.3%
	Ecgonine	>100,000	<0.3%
	Norcocaine	>100,000	<0.3%
	Ecgonine methyl ester	>100,000	<0.3%
	EDDP	300	100%
EDDP 300	Methadone	>100,000	<0.3%
	EMDP	>100,000	<0.3%
	Doxylamine	>100,000	<0.3%
	Disopyramide	>100,000	<0.3%
	LAAM(Levo-alpha-acetylmethadol) hydrochloride	>100,000	<0.3%
	Alpha Methadol	>100,000	<0.3%
	Norfentanyl	25,000	0.004%
	Fentanyl	1	100%
	Acetyl fentanyl	3	33.33%
	Acetyl norfentanyl	20,000	0.005%
FEN 1	(±)-β-Hydroxythiofentanyl	5	20%
	Acryl fentanyl	4	25%
	Butyryl fentanyl	5	20%
	Cyclopropylfentanyl	10	10%
	(±)-cis-3-methyl Fentanyl	1	100%
	Furanyl fentanyl	10	10%
	para-Fluorobutyryl fentanyl (PFBF)	10	10%
	para-Fluorofentanyl	5	20%
	9-Hydroxyrisperidone	>100,000	<0.001%
	Alfentanil	>100,000	<0.001%
	Isobutyryl fentanyl	10	10%
	4-Fluoro-isobutyryl fentanyl	5	20%
	Norcarfentanil	>10,000	<0.01%
	Remifentanil	500	0.20%
	Valeryl fentanyl	10	10%
	Thienyl Fentanyl	30	3.33%
	(±)-trans-3-methyl Fentanyl	5	20%
	Despropionyl fentanyl (4-ANPP)	250	0.4%
	MT-45	50	2%
	Ocfentanil	2	50%
	Risperidone	>100,000	<0.001%
	Sufentanil	20	5%
	Carfentanil	5	20%
	Labetalol	>100,000	<0.001%
	Trazodone	>100,000	<0.001%
	U-47700	>100,000	<0.001%
	ω-1-Hydroxyfentanyl	2	50%
	6-Acetylmorphine	>100,000	<0.001%
	AH-7921 HCL	2,500	0.04%
	Amphetamine	>100,000	<0.001%
	Buprenorphine	>10,000	<0.01%
	Buprenorphine -3-D-Glucuronide	>10,000	<0.01%
	Codeine	>100,000	<0.001%
	Dextromethorphan	>100,000	<0.001%
	Dihydrocodeine	>100,000	<0.001%
	EDDP	>100,000	<0.001%
	EMDP	>100,000	<0.001%

	Fluoxetine	>100,000	<0.001%
	Heroin	>100,000	<0.001%
	Hydrocodone	>100,000	<0.001%
	Hydromorphone	>100,000	<0.001%
	Isotonitazene	>100,000	<0.001%
	Ketamine	>100,000	<0.001%
	Levorphanol	>100,000	<0.001%
	Meperidine	>100,000	<0.001%
	Methadone	>100,000	<0.001%
	Morphine	>100,000	<0.001%
	Morphine-3-β-D-glucuronide	>100,000	<0.001%
	Naloxone	>100,000	<0.001%
	Naltrexone	>100,000	<0.001%
	Norbuprenorphine	5,000	0.02%
	Norcodeine	>100,000	<0.001%
	Norketamine	>100,000	<0.001%
	Normeperidine	>100,000	<0.001%
	Normorphine	>100,000	<0.001%
	Noroxycodone	>100,000	<0.001%
	Oxycodone	>100,000	<0.001%
	Oxymorphone	>100,000	<0.001%
	Pentazocine (Talwin)	80,000	<0.00125%
	Pipamperone	5,000	0.02%
	Tapentadol	>100,000	<0.001%
	Thioridazine	>100,000	<0.001%
	Tilidine	>100,000	<0.001%
	cis-Tramadol	>100,000	<0.001%
	O-Desmethyl-cis-tramadol	80,000	0.00125%
	N-Desmethyl-cis-tramadol	>100,000	<0.001%
FEN 5	Norfentanyl	5	100%
	Fentanyl	10,000	0.05%
	Acetyl fentanyl	>10,000	<0.05%
	Acetyl norfentanyl	200	2.5%
	(±)-β-Hydroxythiofentanyl	>10,000	<0.05%
	Acryl fentanyl	>10,000	<0.05%
	Butyryl fentanyl	>10,000	<0.05%
	Cyclopropylfentanyl	>10,000	<0.05%
	(±)-cis-3-methyl Fentanyl	>10,000	<0.05%
	Furanyl fentanyl	>10,000	<0.05%
	para-Fluorobutyryl fentanyl (PFBF)	10,000	0.05%
	para-Fluorofentanyl	>10,000	<0.05%
	9-Hydroxyrisperidone	>100,000	<0.005%
	Alfentanil	5,000	0.1%
	Isobutyryl fentanyl	>100,000	<0.005%
	4-Fluoro-isobutyryl fentanyl	>100,000	<0.005%
	Norcarfentail	>10,000	<0.05%
	Remifentanil	>10,000	<0.05%
	Valeryl fentanyl	>10,000	<0.05%
	Thienyl Fentanyl	>100,000	<0.005%
	(±)-trans-3-methyl Fentanyl	>10,000	<0.05%
	Despropionyl fentanyl (4-ANPP)	>10,000	<0.05%
	MT-45	>100,000	<0.005%
	Ocfentanil	>10,000	<0.05%
	Risperidone	>100,000	<0.005%
	Sufentanil	>10,000	<0.05%
	Carfentanil	>10,000	<0.05%
	Labetalol	>100,000	<0.005%
	Trazodone	>100,000	<0.005%
	U-47700	>100,000	<0.005%
	ω-1-Hydroxyfentanyl	>100,000	<0.005%
	6-Acetylmorphine	>100,000	<0.005%
	AH-7921 HCL	>100,000	<0.005%
	Amphetamine	>100,000	<0.005%
	Buprenorphine	>10,000	<0.05%
	Buprenorphine -3-D-Glucuronide	>10,000	<0.05%

	Codeine	>100,000	<0.005%
	Dextromethorphan	>100,000	<0.005%
	Dihydrocodeine	>100,000	<0.005%
	EDDP	>100,000	<0.005%
	EMDP	>100,000	<0.005%
	Fluoxetine	>100,000	<0.005%
	Heroin	>100,000	<0.005%
	Hydrocodone	>100,000	<0.005%
	Hydromorphone	>100,000	<0.005%
	Isotonitazene	>100,000	<0.005%
	Ketamine	>100,000	<0.005%
	Levorphanol	>100,000	<0.005%
	Meperidine	>100,000	<0.005%
	Methadone	>100,000	<0.005%
	Morphine	>100,000	<0.005%
	Morphine-3-β-D-glucuronide	>100,000	<0.005%
	Naloxone	>100,000	<0.005%
	Naltrexone	>100,000	<0.005%
	Norbuprenorphine	>100,000	<0.005%
	Norcodeine	>100,000	<0.005%
MDMA 500	Norketamine	>100,000	<0.005%
	Normeperidine	>100,000	<0.005%
	Normorphine	>100,000	<0.005%
	Noroxycodone	>100,000	<0.005%
	Oxycodone	>100,000	<0.005%
	Oxymorphone	>100,000	<0.005%
	Pentazocine (Talwin)	>100,000	<0.005%
	Pipamperone	>100,000	<0.005%
	Tapentadol	>100,000	<0.005%
	Thioridazine	>100,000	<0.005%
MET 500	Tilidine	>100,000	<0.005%
	cis-Tramadol	>100,000	<0.005%
	O-Desmethyl-cis-tramadol	>100,000	<0.005%
	N-Desmethyl-cis-tramadol	>100,000	<0.005%
	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	500	100%
	(±)-3,4-Methylenedioxyamphetamine (MDA)	5,000	10%
	(±)-3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
	L-Methamphetamine	>100,000	<0.5%
	7-Aminoclonazepam	>100,000	<0.5%
	D-Methamphetamine	>100,000	<0.5%
	D-Amphetamine	>100,000	<0.5%
	L-Amphetamine	>100,000	<0.5%
	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	30,000	1.67%
	(±)-3,4-Methylenedioxymethamphetamine (MDMA)	5,000	10%
	D-Methamphetamine	500	100%
	L-Methamphetamine	15,000	3.33%
	Fenfluramine	>100,000	<0.5%
	p-Hydroxymethamphetamine	3,000	16.67%
	(±)-Methamphetamine	500	100%
	β-Phenylethylamine	>100,000	<0.5%
	Mephetermine	10,000	5%
	Methoxyphenamine	>100,000	<0.5%
	L-Amphetamine	>100,000	<0.5%
	D-Amphetamine	>100,000	<0.5%
	(±)-Amphetamine	>100,000	<0.5%
	Chloroquine	>100,000	<0.5%
	Ephedrine	>100,000	<0.5%
	(±)-3,4-Methylenedioxyamphetamine (MDA)	>100,000	<0.5%
	Trimethobenzamide	>100,000	<0.5%
	l-phenylephrine	>100,000	<0.5%

	(1R,2S)-(-)-Ephedrine	>100,000	<0.5%
	Procaine	>100,000	<0.5%
MET 1000	(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	<1%
	(±)-3,4-Methylenedioxymethamphetamine (MDMA)	10,000	10%
	D-Methamphetamine	1,000	100%
	L-Methamphetamine	25,000	4%
	Fenfluramine	>100,000	<1%
	p-Hydroxymethamphetamine	5,000	20%
	(±)-Methamphetamine	2,000	50%
	β-Phenylethylamine	>100,000	<1%
	Mephetermine	30,000	3.33%
	Methoxyphenamine	>100,000	<1%
	L-Amphetamine	>100,000	<1%
	D-Amphetamine	>100,000	<1%
	(±)-Amphetamine	>100,000	<1%
	Chloroquine	>100,000	<1%
	Ephedrine	>100,000	<1%
	(±)-3,4-Methylenedioxyamphetamine (MDA)	>100,000	<1%
	Trimethobenzamide	>100,000	<1%
	l-phenylephrine	>100,000	<1%
	(1R,2S)-(-)-Ephedrine	>100,000	<1%
	Procaine	>100,000	<1%
MOR 300	6-Acetylmorphine	500	60%
	Codeine	250	120%
	Dihydrocodeine	500	60%
	Ethylmorphine	300	100%
	Heroin	500	60%
	Hydrocodone	500	60%
	Hydromorphone	500	60%
	Levorphanol	5,000	6%
	Morphine	300	100%
	Nalorphine	3,000	10%
	Thebaine	>100,000	<0.3%
	Morphine-3-β-d-glucuronide	300	100%
	Codeine-6-β-D-glucuronide	250	120%
	Morphine-6-β-D-glucuronide	5,000	6%
	6-Acetylcodeine	1,000	30%
	Normorphine	>100,000	<0.3%
	Oxycodone	>100,000	<0.3%
	Oxymorphone	50,000	0.6%
	Norcodeine	>100,000	<0.3%
	Procaine	>100,000	<0.3%
	Norpropoxyphene	>100,000	<0.3%
MTD 300	(±)-Methadone	300	100%
	EDDP	>100,000	<0.3%
	EMDP	>100,000	<0.3%
	LAAM (Levo-alpha-acetylmethadol)	10,000	3%
	Alpha Methadol	100	300%
	Doxylamine	50,000	0.6%
OPI 2000	6-Acetylmorphine	10,000	20%
	Codeine	10,000	20%
	Dihydrocodeine	10,000	20%
	Ethylmorphine	5,000	40%
	Heroin	20,000	10%
	Hydrocodone	25,000	8%
	Hydromorphone	25,000	8%
	Levorphanol	>100,000	<2%
	Morphine	2,000	100%
	Nalorphine	>100,000	<2%
	Thebaine	>100,000	<2%
	Morphine-3-β-d-glucuronide	50,000	4%
	Codeine-6-β-D-glucuronide	2,500	80%
	Morphine-6-β-D-glucuronide	500	400%

OXY 100	6-Acetylcodeine	10,000	20%
	Normorphine	>100,000	<2%
	Oxycodone	>100,000	<2%
	Oxymorphone	>100,000	<2%
	Norcodeine	>100,000	<2%
	Procaine	>100,000	<2%
	Norpropoxyphene	>100,000	<2%
	Hydrocodone	20,000	0.5%
	Hydromorphone	25,000	0.4%
	Levorphanol	50,000	0.2%
	Naloxone	30,000	0.33%
	Naltrexone	20,000	0.5%
	Oxycodone	100	100%
	Oxymorphone	200	50%
	Oxymorphone-3β-D-glucuronide	750	13.33%
	Noroxycodone	2,500	4%
	Noroxymorphone	1,000	10%
	Dihydrocodeine	>100,000	<0.1%
	Codeine	>100,000	<0.1%
	Morphine	>100,000	<0.1%
PCP 25	Buprenorphine	>10,000	<0.1%
	Ethylmorphine	>100,000	<0.1%
PPX 300	Thebaine	>100,000	<0.1%
	6-Acetylmorphine	>100,000	<0.1%
TCA 1000	Phencyclidine	25	100%
	4-Hydroxyphencyclidine	>100,000	<0.025%
	Norpropoxyphene	500	60%
	Propoxyphene	300	100%
	Amitriptyline	10,000	10%
	Chlorpheniramine	>100,000	<1%
	Clomipramine	50,000	2%
	Cyclobenzaprine	>100,000	<1%
	Desipramine	500	200%
	Doxepine	10,000	10%
	Duloxetine	>100,000	<1%
	Imipramine	50,000	2%
	Norclomipramine	>100,000	<1%
	Nordoxepin	5,000	20%
	Nortriptyline	1,000	100%
	Promazine	10,000	10%
	Trimipramine	10,000	10%
	Maprotiline	5,000	20%
	Promethazine	>100,000	<1%
THC 20	(-)-11-nor-Δ ⁸ -THC -9-COOH	50	40%
	(-)-11-nor-9-carboxy-Δ ⁹ -THC	20	100%
	(±)-11-nor-9-carboxy-Δ ⁹ -THC	50	40%
	11-nor-Δ ⁹ -THC-carboxy glucuronide	5,000	0.4%
	Δ ⁸ -THC	8,000	0.25%
	Δ ⁹ -THC	>10,000	<0.2%
	Cannabinol	>10,000	<0.2%
	Cannabidiol	>100,000	<0.02%
	(±)-11-hydroxy-Δ ⁸ -THC	8,000	0.25%
	(-)-11-nor-Δ ⁸ -THC -9-COOH	70	71.43%
THC 50	(-)-11-nor-9-carboxy-Δ ⁹ -THC	50	100%
	(±)-11-nor-9-carboxy-Δ ⁹ -THC	150	33.33%
	11-nor-Δ ⁹ -THC-carboxy glucuronide	7,500	66.67%
	Δ ⁸ -THC	10,000	0.5%
	Δ ⁹ -THC	>10,000	<0.5%
	Cannabinol	>10,000	<0.5%
	Cannabidiol	>100,000	<0.05%
	(±)-11-hydroxy-Δ ⁸ -THC	10,000	0.5%

Interference Substance

Potential interfering substances that could be found in human urine under physiological and pathological conditions compounds were added to drug-free urine and to urine samples containing the target drugs at 50% below and 50% above each corresponding cutoff. These urine samples

were tested in triplicates with 3 lots of CLIAwaived Inc. Instant Drug Test Cup Plus. Compounds that showed no interference at a concentration of 100 µg/ml are listed in the following table.

(-) Cotinine	Conjugated Estrogens	LAAM (except MTD test)	Phenobarbital (except BAR test)
7-Aminoclonazepam	Cortisone	Labetalol	Phentermine (except AMP test)
7-Aminoflunitrazepam	Creatine	Lamotrigine	Phenylpropanolamine
7-Aminonitrazepam	Creatinine	L-Ephedrine	Prednisone
Acetaminophen	Cyclobenzaprine	L-Epinephrine	Pregabalin
Acetone (1000 mg/dL)	Cyproheptadine	Levofloxacin	Procaine
Acetophenetidin	D,L-Epinephrine	Levonorgestrel	Promazine (except TCA test)
Acyclovir	D,L-Isoproterenol	Levothyroxine sodium	Promethazine
Albumin (100mg/dL)	D,L-Lorazepam (except BZO test)	Lidocaine	Propoxyphene (except PPX test)
Albuterol	D,L-Octopamine	Lisinopril	Propranolol
Alpha Methadol (except MTD test)	D,L-Propranolol	Loperamide	Pseudoephedrine
Aminophylline	D,L-Tryptophan	Lorazepam	Pyridoxine
Aminopyrine	D,L-Tyrosine	Lorazepam Glucuronide (except BZO test)	Pyrimidine
Amitriptyline (except TCA test)	Delorazepam (10ug/mL)	L-phenylephrine	Pyrogallol
Amlodipine	Demoxepam (except BZO test)	LSD	Quetiapine
Amobarbital (except BAR test)	Deoxycorticosterone	Maprotiline (except TCA test)	Quinidine
Amoxicillin	Desloratadine	Meperidine	Quinine
Ampicillin	Desipramine (except TCA test)	Meprobamate	Quinolinic Acid
Apomorphine	Dextromethorphan	Metformin	Ranitidine
Aripiprazole	Diclofenac	Methapyrilene	Riboflavin
Ascorbic acid (Vitamin C)	Diclofenac sodium	Methaqualone	Rifampicin
Aspartame	Diffunisal	Methoxyphenamine	Risperidone
Aspirin (Acetylsalicylic acid)	Digoxin	Methylphenidate	Salicylic acid
Atomoxetine	Diphenhydramine	Metoprolol	Secobarbital (except BAR test)
Atorvastatin Calcium	Diphenylhydantoin	Metronidazole	Serotonin (5- Hydroxytyramine)
Atropine	Disopyramide	Mifepristone	Sertraline
Azithromycin	Dopamine (3-Hydroxytyramine)	N-Acetylprocainamide	Sildenafil Citrate
Baclofen	Doxepine (except TCA test)	NaCl (4000 mg/dL)	Simvastatin
Benzilic acid	Doxylamine (except MTD test)	Nalidixic acid	Sodium Azide
Benzocaine	Duloxetine	Naloxone (except OXY test)	Sulfamethazine
Benzoic acid	Ecgonine methyl ester	Naltrexone (except OXY test)	Sulindac
Benzoyllecgonine (except COC test)	EMDP	Naproxen	Telmisartan
Benzphetamine	Ephedrine	N-desmethyl Tapentadol	Tetracycline
Benzylpiperazine	Erythromycin	Nicotine	Tetrahydrocortisone 3- (β-Dglucuronide)
Bilirubin	Esomeprazole Magnesium	Nicotinamide (Niacinamide)	Tetrahydrocortisone, 3- acetate
Boric Acid (1%)	Estrone	Nicotinic Acid	Tetrahydrozoline
4-Bromo-2,5- dimethoxyphenethyla mine	Ethanol (1%)	Nifedipine	(-)-11-nor-9-carboxy-Δ ⁹ - THC (except THC test)
Brompheniramine	Fenfluramine	Nitroglycerin	Theophylline
Bupropion	Fenofibrate	Nordoxepin (except TCA test)	Thiamine
Caffeine	Fenoprofen	Norethindrone	Thioridazine
Cannabidiol	Fentanyl (except FEN1 and FEN5 tests)	Norfentanyl (except FEN1 and FEN5 tests)	Tramadol
Captopril	Fluoxetine	Norpropoxyphene (except PPX test)	Trazodone
Carbamazepine	Fluphenazine	Norpseudoephedrine	Triamterene
Carfentanil (10ug/mL) (except FEN1 test)	Fotemustine	Nortriptyline (except TCA test)	Trifluoperazine

Carisoprodol	Furosemide	Noscapine	Trifluoromethylphenyl- piperazine
Cefradine	Gabapentin	O-Hydroxyhippuric acid	Trimethobenzamide
Cephalexin	Galactose	Olanzapine	Trimethoprim
Cetirizine	Gatifloxacin	Omeprazole	Tryptamine
Chloral hydrate	Gemfibrozil	Oxalic acid (100mg/dL)	Tyramine
Chloramphenicol	Gentisic acid	Oxazepam (except BZO test)	Urea (2000 mg/dL)
Chlordiazepoxide (except BZO test)	D-(+)-Glucose (3000 mg/dL)	Oxazepam Glucuronide (except BZO test)	Uric acid
Chloroquine	Guaiacolglycerol ether	Oxolinic acid	Valproic acid (250 µg/mL)
Chlorothiazide	Hemoglobin	Oxymetazoline	Venlafaxine
Chlorpheniramine	Hexobarbital	Paliperidone	Verapamil
Chlorpromazine	Hydralazine	Papaverine	Vitamin B2
Cholesterol	Hydrochlorothiazide	Penicillin-G	Zaleplon
Ciprofloxacin	Hydrocortisone	PenicillinV Potassium	Zolpidem
Citalopram	Hydroxybutyric Acid	Perphenazine	Zomepirac
Clarithromycin	Ibuprofen	Phenacetin	β-Estradiol
Clofibrate	Imipramine (except TCA test)	Phencyclidine (except PCP test)	γ-Cyclodextrin
Clomipramine (except TCA test)	Isoxsuprine	Phenelzine	γ-Globulin (500mg/dL)
Clonidine	Ketamine	Pheniramine	L-thyroxine
Clozapine	Ketoprofen	Phenylethylamine	Magnesium Chloride

Effect of Urinary pH and Specific Gravity

Interference by pH and specific gravity were also evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 50% below and 50% above each corresponding cutoff. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

Index of Symbols

	Consult Instruction for use		Contains sufficient for <n> tests		Store between 2-30°C
	For in vitro diagnostic use only		Use by		Do not reuse
	Do not use if package is damaged		Lot Number		Catalog #



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V36001-CWII-P-V01

“RTC” + Fentanyl

Package Insert

Instruction Sheet for testing of any combination of the following drugs:
AMP/BAR/BZO/COC/THC/MOP/MET/MTD/PCP/TCA/OXY/MDMA/BUPI/FYL.

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. Immunoassay for *in vitro* diagnostic use only.

Medical and other professional *in vitro* diagnostic use labeling.

【INTENDED USE】

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana and Fentanyl in human urine at the cutoff concentrations of:

Drug (Identifier)	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	500
Buprenorphine (BUP)	Buprenorphine	10
Secobarbital (BAR)	Secobarbital	300
Oxazepam (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylcegonine	150
Methamphetamine (MET)	d-Methamphetamine	500
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP/OPI)	Morphine	300
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Nortriptyline (TCA)	Nortriptyline	1000
Marijuana (THC)	11-nor-Δ ⁹ -THC-9 COOH	50
Fentanyl (FYL)	Fentanyl	1

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl can be a single drug test cup or used for any combination of the above listed analytes. It is for *in vitro* diagnostic use only.

The tests may yield positive results for the prescription drugs when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

【SUMMARY】

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

Amphetamine (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body’s natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the concentration of amphetamines in urine exceeds detectable level.

Secobarbital (BAR)

Secobarbital is one of CNS depressants (barbiturates). They are used therapeutically as sedatives, hypnotics, and anticonvulsants barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most secobarbital are excreted unaltered in the urine.

The approximate detection time limits for secobarbital are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the

concentration of secobarbital in urine exceeds detective level.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced secobarbital in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for benzodiazepines in urine is 3-7 days.

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the concentration of benzodiazepines in urine exceeds detective level.

Buprenorphine (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations. The plasma half-life of Buprenorphine is 2-4 hours. While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days.

Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the Buprenorphine in urine exceeds detective level.

Cocaine (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine. Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the concentration of Cocaine in urine exceeds detective level.

Marijuana (THC)

THC (Δ⁹-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ⁹-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the concentration of THC-COOH in urine exceeds detective level.

Methadone (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the concentration of methadone in urine exceeds detective level.

Methamphetamine (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours and the drug have a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the Methamphetamine in urine exceeds detective level.

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds detective level.

Morphine (MOP/OPI 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the concentration of morphine in urine exceeds detective level.

Phencyclidine (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950’s. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user’s age, weight, activity, and diet.6 PCP is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the concentration of phencyclidine in urine exceeds detective level. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

Nortriptyline (TCA)

Nortriptyline is one of the Tricyclic Antidepressants, TCA are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl yields a positive result when the concentration of tricyclic antidepressants in urine exceeds detective level. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%). The window of detection for Oxycodone in urine is expected to be similar to that of other opioids such as morphine.

The CLIAwaived, Inc. Rapid Test Cup "RTC" + Fentanyl is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Oxycodone in urine. The CLIAwaived, Inc. Rapid Test Cup "RTC" + Fentanyl yields a positive result when Oxycodone in urine exceeds detectable level.

Fentanyl (FYL)

Fentanyl, belongs to powerful narcotics analgesics, and is a μ special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations 'Single Convention of narcotic drug in 1961'. Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc, which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose.

The CLIAwaived, Inc. Rapid Test Cup "RTC" + Fentanyl is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of fentanyl in urine. The CLIAwaived, Inc. Rapid Test Cup "RTC" + Fentanyl yields a positive result when fentanyl in urine exceeds detectable level.

【PRINCIPLE】

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

【PRECAUTIONS】

- Immunoassay for *in vitro* diagnostic use only. The test Cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test Cup should be discarded according to federal, state and local regulations.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 35.6-86°F (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test Cup must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 35.6-46.4°F (2-8°C) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed well before testing.

【MATERIALS】

Materials Provided

- Test Cups
- Package Insert
- Procedure Card
- Adulteration Color Chart (when applicable)

Materials Required But Not Provided

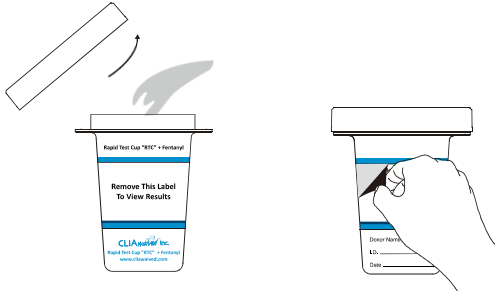
- Specimen Collection Containers
- Timer

【DIRECTIONS FOR USE】

Allow the test, urine specimen, and/or controls to reach room temperature 59-86°F (15-30°C) prior to testing.

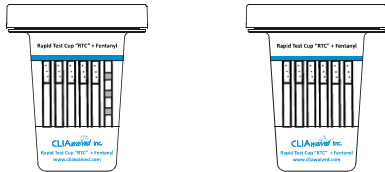
1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch.
2. Donor provides specimen.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100°F (32-38°C).
5. Technician dates and initials the security seal and attaches the security seal over the cup cap.
6. Technician peels off label to reveal adulteration strip(s), if applicable.
7. Technician peels off the label on the multi-drug test cup to view results.
8. The adulteration strip(s), if applicable, should be read between **3-5 minutes**. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results. Refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not interpret the drug test results and either retest the urine or collect another specimen in case of any positive result for any adulteration test.
9. If results do not indicate adulteration, read the drug test result at **5 minutes**. Do not interpret the result after 10 minutes.
10. If preliminary positive results are observed, please send the cup to the laboratory for confirmation.

TEST PROCEDURE Cup



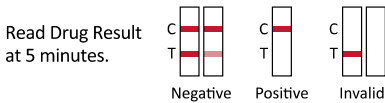
- Open the cap and add specimen.
- Peel off the label to view results
- Specimen volume must exceed the minimum line.

1

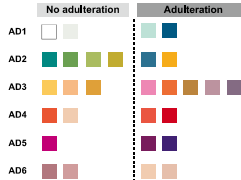


Cup with adulteration

Cup without adulteration



Interpret adulteration strips between 3-5 minutes. See enclosed color chart for interpretation.



2

【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

***NEGATIVE: A colored line appears in the Control region (C) and a colored line appears in the Test region (T).** This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact your manufacturer.

【INTERPRETATION OF RESULTS (S.V.T ADULTERATION)】

(Please refer to the color chart)

Semi Quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart.

No instrumentation is required.

【QUALITY CONTROL】

A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

Quality control should be performed in accordance with federal, state, and local regulations.

【LIMITATIONS】

1. The CLIAwaived, Inc. Rapid Test Cup "RTC" + Fentanyl provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry or Liquid Chromatography/mass spectrometry is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements. Alcohol in the atmosphere, such as spray from perfumes, deodorizers, glass cleaners etc. can affect the Alcohol Rapid Tests. Therefore, adequate measures should be taken to avoid undue interference from such atmospheric agents in the testing area.

【EXPECTED VALUES】

The negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

【PERFORMANCE CHARACTERISTICS】

Accuracy

About 80 clinical urine specimens with known LC/MS values and tested by CLIAwaived, Inc. Rapid Test Cup "RTC" + Fentanyl. Each test was performed by three operators. Results were as follows:

Amphetamine(AMP500)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator B	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Secobarbital(BAR300)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%

Operator B	Accuracy	(40+39)/80=98.75%		
	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	0	40	40/40=100%
Accuracy (39+40)/80=98.75%				
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Oxazepam (BZO300)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator B	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Cocaine(COC150)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 150ng/mL (+)	39	1	39/40=97.5%
	Lower 150ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 150ng/mL (+)	40	0	40/40=100%
	Lower 150ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 150ng/mL (+)	39	1	39/40=97.5%
	Lower 150ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Marijuana(THC50)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 50ng/mL (+)	40	0	40/40=100%
	Lower 50ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 50ng/mL (+)	39	1	39/40=97.5%
	Lower 50ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 50ng/mL (+)	39	1	39/40=97.5%
	Lower 50ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Morphine(MOP/OPI 300)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Methamphetamine(MET500)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(40+40)/80=100%		

Operator B	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Methadone(MTD300)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 300ng/mL (+)	40	0	40/40=100%
	Lower 300ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 300ng/mL (+)	39	1	39/40=97.5%
	Lower 300ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Phencyclidine(PCP25)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 25ng/mL (+)	39	1	39/40=97.5%
	Lower 25ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 25ng/mL (+)	39	1	39/40=97.5%
	Lower 25ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 25ng/mL (+)	39	1	39/40=97.5%
	Lower 25ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		

Nortriptyline(TCA1000)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 1000ng/mL (+)	40	0	40/40=100%
	Lower 1000ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 1000ng/mL (+)	39	1	39/40=97.5%
	Lower 1000ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator C	Above 1000ng/mL (+)	40	0	40/40=100%
	Lower 1000ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		

Oxycodone(OXY100)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 100ng/mL (+)	40	0	40/40=100%
	Lower 100ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator B	Above 100ng/mL (+)	40	0	40/40=100%
	Lower 100ng/mL (-)	0	40	40/40=100%
	Accuracy	(40+40)/80=100%		
Operator C	Above 100ng/mL (+)	39	1	39/40=97.5%
	Lower 100ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		

Ecstasy(MDMA500)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		

Operator B	Above 500ng/mL (+)	39	1	39/40=97.5%
	Lower 500ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(39+39)/80=97.5%		
Operator C	Above 500ng/mL (+)	40	0	40/40=100%
	Lower 500ng/mL (-)	0	40	40/40=100%
	Accuracy	(40+40)/80=100%		

Buprenorphine(BUP10)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 10ng/mL (+)	39	1	39/40=97.5%
	Lower 10ng/mL (-)	0	40	40/40=100%
	Accuracy	(39+40)/80=98.75%		
Operator B	Above 10ng/mL (+)	40	0	40/40=100%
	Lower 10ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		
Operator C	Above 10ng/mL (+)	40	0	40/40=100%
	Lower 10ng/mL (-)	1	39	39/40=97.5%
	Accuracy	(40+39)/80=98.75%		

Fentanyl(FYL1)

Result		Candidate Device Result		The Agreement Rate
Operator	LC/MS Result	Positive	Negative	
Operator A	Above 1ng/mL (+)	38	2	38/40=95.0%
	Lower 1ng/mL (-)	2	38	38/40=95.0%
	Accuracy	(38+38)/80=95.0%		
Operator B	Above 1ng/mL (+)	38	2	38/40=95.0%
	Lower 1ng/mL (-)	2	38	38/40=95.0%
	Accuracy	(38+38)/80=95.0%		
Operator C	Above 1ng/mL (+)	38	2	38/40=95.0%
	Lower 1ng/mL (-)	3	37	37/40=92.5%
	Accuracy	(38+37)/80=93.75%		

Analytical Specificity
The following table lists compounds that are positively detected in urine by the CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl at 5 minutes.

Drug	Concentration (ng/ml)	Cross- Reactivity (%)
Amphetamine(AMP500)		
Hydroxyamphetamine	5000	10%
(+/-)-Methylenedioxamphetamine(MDA)	25	2000%
D,L-Amphetamine	500	100%
D-Amphetamine	500	100%
Diethylstilbestrol	>100000	<0.5%
L-Amphetamine	500	100%
Phentermine	500	100%
β-Phenylethylamine	>100000	<0.5%
Tyramine	>100000	<0.5%
p-Hydroxynorephedrine	>100000	<0.5%
D,L-Norephedrine	>100000	<0.5%
p-Hydroxyamphetamine	5000	10%
D-Methamphetamine	>100000	<0.5%
L-Methamphetamine	>100000	<0.5%
Ephedrine hydrochloride	>100000	<0.5%
(+/-)3,4- Methylenedioxymethamphetamine (MDMA)	100000	0.5%
Phenylpropanolamine	>100000	<0.5%
Benzphetamine	>100000	<0.5%
L-Ephedrine	>100000	<0.5%
L-Epinephrine	>100000	<0.5%
D,L-Epinephrine	>100000	<0.5%
(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	100000	0.5%
Secobarbital(BAR300)		
Alphenal	300	100%
Amobarbital	300	100%
Aprobarbital	300	100%
Butabarbital	500	60%

Butethal	200	150%
Cyclopentobarbital	500	60%
Pentobarbital	200	150%
Phenobarbital	200	150%
Secobarbital	300	100%
Butalbital	2000	15%
Barbital	300	100%
Oxazepam(BZO300)		
a-Hydroxylalprazolam	10000	3%
Alprazolam	200	150%
Bromazepam	1000	30%
Chlordiazepoxide	300	100%
Clobazam	200	150%
Clonazepam	200	150%
Clorazepate Dipotassium	300	100%
Desalkylflurazepam	>100000	<0.3%
Diazepam	300	100%
Estazolam	100	300%
Flunitrazepam	300	100%
D,L-Lorazepam	1000	30%
Midazolam	1000	30%
Nitrazepam	200	150%
Norchlordiazepoxide	200	150%
Nordiazepam	200	150%
Oxazepam	300	100%
R,S-Lorazepam glucuronide	1000	30%
Temazepam	100	300%
Triazolam	300	100%
Demoxepam	2000	15%
Flurazepam	300	100%
Delorazepam	2000	15%
Lormetazepam	100	300%
Buprenorphine(BUP10)		
Buprenorphine	10	100%
Buprenorphine-3-D-Glucuronide	20	50%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	20	50%
Morphine	>100000	<0.01%
Oxymorphone	>100000	<0.01%
Hydromorphone	>100000	<0.01%
Codeine	>100000	<0.01%
Nalorphine	>100000	<0.01%
Cocaine(COC150)		
Benzoylecogonine	150	100%
Cocaehtylene	250	60%
Cocaine hydrochloride	125	120%
Ecgonine	>100000	<0.2%
Norcocaine	>100000	<0.2%
Ecgonine methyl ester	>100000	<0.2%
Methamphetamine(MET500)		
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	6000	8.3%
MDMA	1000	50%
D-Methamphetamine	500	100%
L-Methamphetamine	10000	5%
Fenfluramine	50000	1%
p-Hydroxymethamphetamine	250	200%
D,L-Methamphetamine	250	200%
β-Phenylethylamine	>100000	<0.5%
Mephetermine	25000	2%
Methoxyphenamine hydrochloride	75000	0.7%
L-Amphetamine	100000	0.5%
D-Amphetamine	100000	0.5%

D,L-Amphetamine	250	200%
Chloroquine	25000	2.0%
Ephedrine hydrochloride	>100000	<0.5%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000	<0.5%
Trimethobenzamide	>100000	<0.5%
l-phenylephrine	>100000	<0.5%
(1R,2S)-(-)-Ephedrine	>100000	<0.5%
Procaine hydrochloride	>100000	<0.5%
Phentermine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
Morphine(MOP/OPI 300)		
6-acetylmorphine	300	100%
Codeine	250	120%
Dihydrocodeine	5000	6%
EthylMorphine	200	150%
Heroin	500	60%
Hydrocodone	1000	30%
Hydromorphone	10000	3%
Levorphanol tartrate	1500	20%
Morphine	300	100%
Nalorphine hydrochloride	300	100%
Thebaine	20000	1.5%
s-Monoacetylmorphine	300	100%
Morphine-3-β-d-glucuronide	1000	30%
6-Monoacetylmorphine (6-MAM)	300	100%
Codeine-6-β-D-glucuronide	25000	1.2%
Morphine-6-β-D-glucuronide	1000	30%
6-Acetylcodeine	25000	1.2%
Normorphine	50000	0.6%
Oxycodone	>100000	<0.3%
Oxymorphone	>100000	<0.3%
Norcodeine	25000	1.2%
Procaine hydrochloride	>100000	<0.3%
Norpropoxyphene	>100000	<0.3%
Phencyclidine(PCP25)		
PCP (Phencyclidine)	25	100%
4-Hydroxyphencyclidine	15	167%
Pheniramine	50000	0.05%
Methadone(MTD300)		
(±)-Methadone	300	100%
EDDP	>100000	<0.3%
EMDP	>100000	<0.3%
LAAM	>100000	<0.3%
Alpha Methadol	>100000	<0.3%
Doxylamine	>100000	<0.3%
Disopyramide	6000	5.0%
Esomeprazole	10000	3.0%
Pheniramine	100000	0.3%
Oxycodone(OXY100)		
Ethyl Oxycodone	100	100%
Hydrocodone	50000	0.2%
Hydromorphone	25000	0.4%
Levorphanol tartrate	50000	0.2%
Naloxone hydrochloride	50000	0.2%
Naltrexone hydrochloride	>100000	<0.1%
Oxycodone	100	100%
Oxymorphone	100	100%
Oxymorphone-3β-D-glucuronide	>100000	<0.1%
Noroxycodone	1000	10%
Noroxymorphone	25000	0.4%
Dihydrocodeine	12500	0.8%
Codeine	100000	0.1%

Morphine	>100000	<0.1%
Acetylmorphine	>100000	<0.1%
Buprenorphine	>100000	<0.1%
Ethylmorphine	>100000	<0.1%
Thebaine	>100000	<0.1%
6-acetylmorphine	>100000	<0.1%
Marijuana (THC50)		
11-nor-Δ ⁸ -THC-9-COOH	20000	0.25%
(-)-11-nor-9-carboxy-Δ ⁸ -THC	50	100%
(±)-11-nor-9-Carboxy-Δ ⁹ -THC	50	100%
11-nor-Δ ⁹ -THC -carboxy glucuronide	50	100%
11-hydroxy-Δ ⁹ -Tetrahydrocannabinol	5000	1.0%
Δ ⁸ - Tetrahydrocannabinol	100000	0.05%
Δ ⁹ - Tetrahydrocannabinol	100000	0.05%
Cannabinol	>100000	<0.05%
Cannabidiol	>100000	<0.05%
Ecstasy(MDMA500)		
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	250	200%
(+/-)-Methylenedioxyamphetamine(MDA)	1000	50%
(±)-MDMA	500	100%
L-Methamphetamine	>100000	<0.5%
d-methamphetamine	>100000	<0.5%
d-amphetamine	>100000	<0.5%
l-amphetamine	>100000	<0.5%
d,l-Amphetamine	>100000	<0.5%
d,l-Methamphetamine	>100000	<0.5%
Phentermine	>100000	<0.5%
Phenylephrine	>100000	<0.5%
Ephedrine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
Nortriptyline (TCA1000)		
Amitriptyline	1500	66.7%
Chlorpheniramine	>100000	<1%
Clomipramine	1000	100%
Cyclobenzaprine Hydrochloride	>100000	<1%
Desipramine	300	333.3%
Doxepine	10000	10%
Duloxetine	>100000	<1%
Imipramine	500	200%
Norclomipramine	250	400%
Nordoxepine	>100000	<1%
Nortriptyline hydrochloride	1000	100%
Promazine	500	200%
Trimipramine	1500	66.7%
Maprotiline	>100000	<1%
Promethazine hydrochloride	50000	2%
Fentanyl(FYL1)		
Fentanyl	1	100%
Acetyl fentanyl	1	100%
Acrylfentanyl	1	100%
ω-1-Hydroxyfentanyl	20000	0.005%
Isobutryl fentanyl	1	100%
Ocfentanil	2.5	40%
Butyryl fentanyl	2.5	40%
Furanyl fentanyl	5	20%
Valeryl fentanyl	10	10%
(±) β-hydroxythiofentanyl	2	50%
4-Fluoro-isobutyrylfentanyl	50	2%
Para-fluorobutyryl fentanyl	4	25%
Para-fluoro fentanyl	3	33.3%
(±)-3-cis-methyl fentanyl	50	2%
Carfentanil	2	50%

Sufentanil	10	10%
Alfentanil	5000	0.02%
Despropionyl fentanyl (4-ANPP)	2500	0.04%
Remifentanil	>100000	<0.001%
Norfentanyl	>100000	<0.001%
Acetyl norfentanyl	>100000	<0.001%
Norcarfentanil	>100000	<0.001%
6-Acetyl morphine	>100000	<0.001%
Amphetamine	>100000	<0.001%
Buprenorphine	>100000	<0.001%
Buprenorphineglucuronide	>100000	<0.001%
Codeine	>100000	<0.001%
Dextromethorphan	>100000	<0.001%
Dihydrocodeine	>100000	<0.001%
EDDP	>100000	<0.001%
EMDP	>100000	<0.001%
Fluoxetine	>100000	<0.001%
Heroin	>100000	<0.001%
Hydrocodone	>100000	<0.001%
Hydromorphone	>100000	<0.001%
Ketamine	>100000	<0.001%
Levorphanol	>100000	<0.001%
Meperidine	>100000	<0.001%
Morphine	>100000	<0.001%
Morphine-3-glucuronide	>100000	<0.001%
Naloxone	>100000	<0.001%
Naltrexone	>100000	<0.001%
Norbuprenorphine	>100000	<0.001%
Norcodeine	>100000	<0.001%
Norketamine	>100000	<0.001%
Normeperidine	>100000	<0.001%
Normorphine	>100000	<0.001%
Noroxycodone	>100000	<0.001%
Oxycodone	>100000	<0.001%
Oxymorphone	>100000	<0.001%
Pentazocine (Talwin)	>100000	<0.001%
Pipamperone	>100000	<0.001%
Risperidone	>100000	<0.001%
Tapentadol	>100000	<0.001%
Thioridazine	>100000	<0.001%
Tilidine	>100000	<0.001%
Tramadol	>100000	<0.001%
Tramadol-O-Desmethyl	>100000	<0.001%
Tramadol-N-Desmethyl	>100000	<0.001%

Precision

This study is performed by three personnel who don't know the sample number system participate in the study. Three lots were run in consecutive business days at each concentration for each lot per day. The results as follows:

Drugs	Concentration	n	Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
MOP /OPI 300	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	28	22	27	23	30	20
	375ng/ml	50	50	0	49	1	50	0
	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
MDMA 500	0ng/ml	50	0	50	0	50	0	50
	125ng/ml	50	0	50	0	50	0	50
	250ng/ml	50	0	50	0	50	0	50

	375ng/ml	50	0	50	0	50	0	50
	500ng/ml	50	26	24	29	21	28	22
	625ng/ml	50	50	0	50	0	49	1
	750ng/ml	50	50	0	50	0	50	0
	875	50	50	0	50	0	50	0
	1000ng/ml	50	50	0	50	0	50	0
	0ng/ml	50	0	50	0	50	0	50
OXY 100	25ng/ml	50	0	50	0	50	0	50
	50ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	1	49	0	50	0	50
	100ng/ml	50	26	24	25	25	28	22
	125ng/ml	50	50	0	49	1	50	0
	150ng/ml	50	50	0	50	0	50	0
	175ng/ml	50	50	0	50	0	50	0
	200ng/ml	50	50	0	50	0	50	0
	0ng/ml	50	0	50	0	50	0	50
	6.25ng/ml	50	0	50	0	50	0	50
	12.5ng/ml	50	0	50	0	50	0	50
	18.75ng/ml	50	0	50	0	50	0	50
	25ng/ml	50	27	23	30	20	29	21
	31.25ng/ml	50	50	0	50	0	49	1
PCP 25	37.5ng/ml	50	50	0	50	0	50	0
	43.75ng/ml	50	50	0	50	0	50	0
	50ng/ml	50	50	0	50	0	50	0
	0ng/ml	50	0	50	0	50	0	50
	37.5ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	112.5ng/ml	50	0	50	0	50	1	49
	150ng/ml	50	28	22	28	22	27	23
	187.5ng/ml	50	49	1	50	0	50	0
COC 150	225ng/ml	50	50	0	50	0	50	0
	262.5ng/ml	50	50	0	50	0	50	0
	300ng/ml	50	50	0	50	0	50	0
	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	26	24	26	24	25	25
	375ng/ml	50	50	0	49	1	50	0
MTD 300	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	27	23	30	20	29	21
	375ng/ml	50	49	1	50	0	49	1
	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
BZO 300	300ng/ml	50	28	22	25	25	26	24
	375ng/ml	50	50	0	50	0	50	0
	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
	0ng/ml	50	0	50	0	50	0	50
	125ng/ml	50	0	50	0	50	0	50

	250ng/ml	50	0	50	0	50	0	50
	375ng/ml	50	1	49	0	50	0	50
	500ng/ml	50	27	23	28	22	30	20
	625ng/ml	50	50	0	49	1	50	0
	750ng/ml	50	50	0	50	0	50	0
	875ng/ml	50	50	0	50	0	50	0
	1000ng/ml	50	50	0	50	0	50	0
MET 500	0ng/ml	50	0	50	0	50	0	50
	125ng/ml	50	0	50	0	50	0	50
	250ng/ml	50	0	50	0	50	0	50
	375ng/ml	50	0	50	0	50	0	50
	500ng/ml	50	27	23	29	21	27	23
	625ng/ml	50	50	0	50	0	49	1
	750ng/ml	50	50	0	50	0	50	0
	875ng/ml	50	50	0	50	0	50	0
	1000ng/ml	50	50	0	50	0	50	0
TCA 1000	0ng/ml	50	0	50	0	50	0	50
	250ng/ml	50	0	50	0	50	0	50
	500ng/ml	50	0	50	0	50	0	50
	750ng/ml	50	0	50	0	50	0	50
	1000ng/ml	50	29	21	28	22	26	24
	1250ng/ml	50	50	0	49	1	50	0
	1500ng/ml	50	50	0	50	0	50	0
	1750ng/ml	50	50	0	50	0	50	0
	2000ng/ml	50	50	0	50	0	50	0
THC 50	0ng/ml	50	0	50	0	50	0	50
	12.5ng/ml	50	0	50	0	50	0	50
	25ng/ml	50	0	50	0	50	0	50
	37.5ng/ml	50	1	49	1	49	0	50
	50ng/ml	50	30	20	28	22	27	23
	62.5ng/ml	50	50	0	50	0	49	1
	75ng/ml	50	50	0	50	0	50	0
	87.5ng/ml	50	50	0	50	0	50	0
	100ng/ml	50	50	0	50	0	50	0
BUP 10	0ng/ml	50	0	50	0	50	0	50
	2.5ng/ml	50	0	50	0	50	0	50
	5ng/ml	50	0	50	0	50	0	50
	7.5ng/ml	50	0	50	1	49	0	50
	10ng/ml	50	29	21	26	24	28	22
	12.5ng/ml	50	49	1	50	0	49	1
	15ng/ml	50	50	0	50	0	50	0
	17.5ng/ml	50	50	0	50	0	50	0
	20ng/ml	50	50	0	50	0	50	0
FYL1	0ng/ml	50	0	50	0	50	0	50
	0.25ng/ml	50	0	50	0	50	0	50
	0.5ng/ml	50	0	50	0	50	0	50
	0.75ng/ml	50	2	48	0	50	1	49
	1ng/ml	50	25	25	27	23	27	23
	1.25ng/ml	50	50	0	50	0	50	0
	1.5ng/ml	50	50	0	50	0	50	0
	1.75ng/ml	50	50	0	50	0	50	0
	2ng/ml	50	50	0	50	0	50	0

Effect of Urinary Specific Gravity

Total 12 urine samples of specific gravities (SG) ranging from 1.000-1.035 were collected. Values of SG levels were determined by a refractometer. Target drugs were spiked to these urine samples at +50% cut-off and -50% cut-off concentrations. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 and spiked with the target drug at 50% below and 50% above Cutoff levels. The spiked pH-adjusted urine was tested with the CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl. The results demonstrate the varying ranges of urinary pH do not affect the test results.

Interference

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine target drugs urine with concentrations at 50% below and 50% above Cut-Off

levels. The following compounds show no cross-reactivity when tested with the CLIAwaived,Inc. Rapid Test Cup “RTC” + Fentanyl at a concentration of 100µg/ml or specified concentrations.

Non Interference Compounds		
3-Hydroxytyramine	Digoxin	Nitroglycerin
Acetaminophen	Diphenhydramine HCl	Nordoxepin
Acetone(1000mg/dL)	Disopyramide (except MTD test)	Norethindrone
Acetophenetidin	DL-Tryptophan	Norfentanyl
Acetylsalicylic acid	DL-Tyrosine	Noscapine
Acyclovir	Dopamine HCl	O-Hydroxyhippuric acid
Albumin(100mg/dL)	Doxepin(except TCA test)	Octopamine
Albuterol sulfate(Proair HFA)	Doxylamine	Olanzapine
Alpha Methadol	Duloxetine	Omeprazole
Aminophylline	Ecgonine methyl ester	Oxalic acid (100 mg/dL)
Aminopyrine	EMDP	Oxolinic acid
Amoxicillin	Ephedrine	Oxymetazoline
Ampicillin	Erythromycin	Paliperidone
Apomorphine	Esomeprazole Magnesium (except MTD test)	Papaverine
Aripiprazole	Ethanol(1%)	Penicillin-G
Ascorbic acid	Fenoprofen	PenicillinV Potassium
Aspartame	Fluoxetine Hydrochloride	Perphenazine
Aspirin	Fluphenazine	Phenacetin
Atomoxetine	Furosemide	Phenelzine
Atorvastatin Calcium	Gabapentin	Phenethylamine
Atropine	Galactose (10mg/dL)	Phenylpropanolamine
Azithromycin	Gamma Globulin (500mg/dL)	Prednisone
Benzilic acid	Gatifloxacin	Pregablin
Benzocaine	Gentisic acid	Procaine
Benzoic acid	Glucose (3000mg/dL)	Promethazine(except TCA test)
Benzphetamine	Hemoglobin	Propoxyphene
Bilirubin	Hydralazine	Propranolol
Boric Acid (1%)	Hydrochlorothiazide	Pseudoephedrine
Bupropion	Hydrocortisone	Quetiapine
Caffeine	Hydroxytyramine	Quinine
Cannabidiol	Ibuprofen	Ranitidine
Captopril	Isoproterenol	Riboflavin (10mg/dL)
Carbamazepine	Isoxsuprine	Rifampicin
Carfentanil(except FYL test)	Ketamine	Risperidone
Cefradine	Ketoprofen	Salicylic acid
Cephalexin	L-Ephedrine	Serotonin (5- Hydroxytyramine)
Chloralhydrate	L-Epinephrine	Sertraline
Chloramphenicol	L-phenylephrine	Sildenafil Citrate
Chloroquine(except MET test)	LAAM HCl	Simvastatin
Chlorothiazide	Labetalol	Sulfamethazine
Chlorpheniramine	Levofloxacin Hydrochloride	Sulindac
Chlorpromazine	Levonorgestrel	Telmisartan
Cholesterol	Levothyroxine Sodium	Tetrahydrocortisone 3-(β-Dglucuronide)
Ciprofloxacin Hydrochloride	Lidocaine Hydrochloride	Tetrahydrocortisone, 3-acetate
Citalopram	Lisinopril	Tetrahydrozoline
Clarithromycin	Loperamide	Theophylline
Clonidine	Loratadine	Thiamine
Clozapine	Magnesium	Thioridazine
Conjugated Estrogens	Maprotiline	Tramadol Hydrochloride
Cortisone	Meperidine	Triamterene
Cotinine	Meprobamate	Trifluoperazine
Creatinine	Methapyrilene	Trimethobenzamide
Cyclobenzaprine	Methaqualone	Trimethoprim
D-Pseudoephedrine	Methoxyphenamine (except AMP/MET test)	Tyramine
D,L-Epinephrine	Metoprolol Tartrate	Urea (2000mg/dL)
D,L-Isoproterenol	Metronidazole (300ug/ml)	Uric acid
D,L-Octopamine	Mifepristone	Valproic acid (250ug/ml)
D,L-Propranolol	N-Acetylprocainamide	Venlafaxine HCl
D,L-Tryptophan	NaCl (4000mg/dL)	Verapamil
D,L-Tyrosine	Nalidixic acid	Vitamin B2
Delorazepam (except BZO test)	Naloxone hydrochloride (except OXY test)	Vitamin C

Deoxycorticosterone	Naltrexone hydrochloride	Zaleplon
Desloratadine	Naproxen	Zomepirac
Dextromethorphan	Niacinamide	β-Estradiol
Diclofenac sodium	Nicotine	
Diflunisal	Nifedipine	

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【GLOSSARY OF SYMBOLS】

Index of Symbols					
	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Store between 35.6-86°F (2-30°C)
	In vitro diagnostic medical device		Batch code		Catalogue number
	Unique device identifier		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use				

Manufactured for:
CLIAwaived, Inc.
2721 Loker Ave W
Carlsbad CA 92010
www.cliawaived.com

Toll-free number:
1-888-882-7739

Number 14602420900
Revison date: 2024-07-03

Rapid Response™

Multi-Drug Testing Cup

For *in vitro* diagnostic use only.

For HCP/Professional use.

Intended Use

The Rapid Response™ Multi-Drug Testing Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, EDDP, Fentanyl, Ecstasy, Propoxyphene, Morphine, Methadone, Phencyclidine, Oxycodone, Norfentanyl, Methamphetamine, Nortriptyline, 6-Monoacetylmorphine, Tramadol and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	Calibrator	Cut-off level
Amphetamine(AMP)	d-Amphetamine	500 ng/mL or 300 ng/mL
Secobarbital (BAR)	Secobarbital	300 ng/mL
Buprenorphine(BUP)	BUP-3-D-Glucuronide	10 ng/mL
Oxazepam (BZO)	Oxazepam	300 ng/mL
Cocaine(COC)	Benzoyllecgonine	150 ng/mL
EDDP	2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL
Fentanyl (FYL)	Fentanyl	1 ng/mL
Ecstasy (MDMA)	3,4-Methylenedioxy-MET	500 ng/mL
Propoxyphene (PPX)	D-Propoxyphene	300 ng/mL
Morphine (MOR)	Morphine	2000 ng/mL or 300 ng/mL
Methadone(MTD)	Methadone	300 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Norfentanyl (NFYL)	Norfentanyl	5 ng/mL
Methamphetamine(MET)	Methamphetamine	500 ng/mL or 300 ng/mL
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10 ng/mL
Tramadol (TML)	Cis-Tramadol	100 ng/mL
Marijuana (THC)	11-nor- Δ^9 -THC-9-COOH	50 ng/mL or 20 ng/mL

Configuration of the Rapid Response™ Multi-Drug Testing Cup can consist of any combination of the above listed drug analytes. It is for *in vitro* diagnostic use only. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

Precautions

- For *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch or canister is damaged.
- Do not reuse tests.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Humidity and temperature can adversely affect results.

Materials

Materials provided

- One Test Device
- Instructions for Use

- Adulteration Color Chart

Materials required but not provided

- Watch, timer, or clock

Storage and Stability

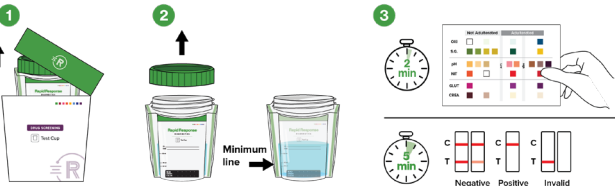
- Stored at 36-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch or closed canister until use.
- DO NOT FREEZE.
- Keep away from direct sunlight, moisture and heat

Test Procedure

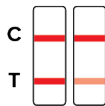
- Remove the cup from the sealed pouch and use it within the first hour after opening
- Collect urine above the Minimum level on the label into the cup.
- Screw the cap onto the cup and immediately start the timer.

Reading Result:

- The result should be read at 5 minutes. Do not interpret the result after 10 minutes.
- For the adulteration, compare with the color card. The result should be read at 2 minutes. Do not interpret the result after 5 minutes.



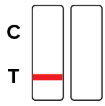
Results Interpretation



NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



PRELIMINARY POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



INVALID: NO line appears in the C – Control region, then the result is Invalid.

NOTE:

- The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Adulteration Strips

Semiquantitative results are obtained by visually comparing the reacted color blocks

on the strip to the printed color blocks on the color chart.

Please refer to the color card provided in this kit for adulteration result interpretation. Read adulteration test pads at 2 minutes.

	Not Adulterated	Adulterated
OXI		
S.G.		
pH		
NIT		
GLUT		
CREA		

Limitations

- The device should be only used for the qualitative detection of target drugs.
- This assay provides a preliminary analytical test result only.
- There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
- A positive result indicates the presence of target drugs only and does not indicate or measure intoxication.
- A negative result does not at any time rule out the presence of target drugs in urine, as they may be present below the minimum detection level of the test.

Performance Characteristics

A. Accuracy

The accuracy of the test was confirmed by testing clinical urine specimens in parallel with LC-MS. The results are shown below.

TML (Cut-off=100 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	2	19	20
A Negative	2	18	18	1	0
Operator Positive	0	0	1	19	20
B Negative	2	18	19	1	0
Operator Positive	0	0	0	19	20
C Negative	2	18	20	1	0

% agreement among positives is 97.5%

% agreement among negatives is 97.6%

FYL (Cut-off=1 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	3	19	20
A Negative	1	19	17	1	0
Operator Positive	0	0	2	19	20
B Negative	1	19	18	1	0
Operator Positive	0	0	2	18	20
C Negative	1	19	18	2	0

% agreement among positives is 96.7%

% agreement among negatives is 94.2%

NFYL (Cut-off=5 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	2	18	20
A Negative	12	8	18	2	0
Operator Positive	0	0	3	19	20
B Negative	12	8	17	1	0
Operator Positive	0	0	2	19	20
C Negative	12	8	18	1	0

% agreement among positives is 96.7%

% agreement among negatives is 94.3%

AMP (Cut-off=500 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	0	15	25
A Negative	10	20	10	0	0
Operator Positive	0	0	1	14	25
B Negative	10	20	9	1	0
Operator Positive	0	0	1	14	25
C Negative	10	20	9	1	0

% agreement among positives is 98.3%

% agreement among negatives is 98.3%

AMP (Cut-off=300 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	1	24	16
A Negative	5	15	19	0	0
Operator Positive	0	0	2	24	16
B Negative	5	15	18	0	0
Operator Positive	0	0	1	23	16
C Negative	5	15	19	1	0

% agreement among positives is 99.3%

% agreement among negatives is 96.8%

COC (Cut-off=150 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	0	14	26
A Negative	10	20	10	0	0
Operator Positive	0	0	0	14	26
B Negative	10	20	10	0	0
Operator Positive	0	0	0	14	26
C Negative	10	20	10	0	0

% agreement among positives is 100.0%

% agreement among negatives is 100.0%

MET (Cut-off=500 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
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			cutoff conc)	cutoff conc)	conc)
Operator Positive	0	0	0	13	26
A Negative	10	20	10	1	0
Operator Positive	0	0	0	13	26
B Negative	10	20	10	1	0
Operator Positive	0	0	0	14	26
C Negative	10	20	10	0	0

% agreement among positives is 98.3%

% agreement among negatives is 100.0%

MET (Cut-off=300 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	0	20	20
A Negative	4	13	23	0	0
Operator Positive	0	0	2	18	20
B Negative	4	13	21	2	0
Operator Positive	0	0	1	19	20
C Negative	4	13	22	1	0

% agreement among positives is 97.6%

% agreement among negatives is 97.7%

EDDP (Cut-off=300 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	1	15	25
A Negative	10	20	9	0	0
Operator Positive	0	0	1	14	25
B Negative	10	20	9	1	0
Operator Positive	0	0	1	14	25
C Negative	10	20	9	1	0

% agreement among positives is 98.3%

% agreement among negatives is 97.5%

TCA (Cut-off=1000 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	0	14	25
A Negative	10	20	10	1	0
Operator Positive	0	0	0	14	25
B Negative	10	20	10	1	0
Operator Positive	0	0	1	15	25
C Negative	10	20	9	0	0

% agreement among positives is 98.3%

% agreement among negatives is 99.2%

PPX (Cut-off=300 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	0	14	25
A Negative	10	20	10	1	0
Operator Positive	0	0	1	15	25
B Negative	10	20	9	0	0
Operator Positive	0	0	1	14	25

C	Negative	10	20	9	1	0
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% agreement among positives is 98.3%

% agreement among negatives is 98.3%

BZO (Cut-off=300 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	0	14	25
A Negative	10	20	10	1	0
Operator Positive	0	0	0	14	25
B Negative	10	20	10	1	0
Operator Positive	0	0	1	15	25
C Negative	10	20	9	0	0

% agreement among positives is 98.3%

% agreement among negatives is 99.2%

MDMA (Cut-off=500 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	1	14	25
A Negative	10	20	9	1	0
Operator Positive	0	0	1	15	25
B Negative	10	20	9	0	0
Operator Positive	0	0	1	14	25
C Negative	10	20	9	1	0

% agreement among positives is 98.3%

% agreement among negatives is 97.5%

MOR (Cut-off=2000 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	2	14	25
A Negative	10	20	8	1	0
Operator Positive	0	0	1	14	25
B Negative	10	20	9	1	0
Operator Positive	0	0	1	14	25
C Negative	10	20	9	1	0

% agreement among positives is 97.5%

% agreement among negatives is 96.7%

MOR (Cut-off=300 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	1	15	25
A Negative	10	20	9	0	0
Operator Positive	0	0	1	14	25
B Negative	10	20	9	1	0
Operator Positive	0	0	0	15	25
C Negative	10	20	10	0	0

% agreement among positives is 99.2%

% agreement among negatives is 98.3%

PCP (Cut-off=25 ng/mL)

Test	Drug-free	Low	Near Cutoff	Near Cutoff	High
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	free	Negative (<50% the cutoff conc)	Negative (Between <50% below up to the cutoff conc)	Positive (Between the cutoff and 50% above cutoff conc)	Positive (>50% above the cutoff conc)
Operator Positive	0	0	1	15	25
A Negative	10	20	9	0	0
Operator Positive	0	0	2	14	25
B Negative	10	20	8	1	0
Operator Positive	0	0	0	14	25
C Negative	10	20	10	1	0

% agreement among positives is 98.3%

% agreement among negatives is 97.5%

THC (Cut-off=50 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	0	14	25
A Negative	10	20	10	1	0
Operator Positive	0	0	1	15	25
B Negative	10	20	9	0	0
Operator Positive	0	0	0	14	25
C Negative	10	20	10	1	0

% agreement among positives is 98.3%

% agreement among negatives is 99.2%

THC (Cut-off=20 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	0	14	25
A Negative	10	20	10	1	0
Operator Positive	0	0	0	15	25
B Negative	10	20	10	0	0
Operator Positive	0	0	1	15	25
C Negative	10	20	9	0	0

% agreement among positives is 99.2%

% agreement among negatives is 99.2%

BUP (Cut-off=10 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	1	14	25
A Negative	10	20	9	1	0
Operator Positive	0	0	1	15	25
B Negative	10	20	9	0	0
Operator Positive	0	0	2	14	25
C Negative	10	20	8	1	0

% agreement among positives is 98.3%

% agreement among negatives is 96.7%

MTD (Cut-off=300 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
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Operator Positive	0	0	1	14	25
A Negative	10	20	9	1	0
Operator Positive	0	0	2	14	25
B Negative	10	20	8	1	0
Operator Positive	0	0	1	15	25
C Negative	10	20	9	0	0

% agreement among positives is 98.3%

% agreement among negatives is 96.7%

BAR (Cut-off=300 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	1	14	25
A Negative	10	20	9	1	0
Operator Positive	0	0	1	15	25
B Negative	10	20	9	0	0
Operator Positive	0	0	1	15	25
C Negative	10	20	9	0	0

% agreement among positives is 99.2%

% agreement among negatives is 97.5%

OXY (Cut-off=100 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	1	14	25
A Negative	10	20	9	1	0
Operator Positive	0	0	0	14	25
B Negative	10	20	10	1	0
Operator Positive	0	0	1	14	25
C Negative	10	20	9	1	0

% agreement among positives is 97.5%

% agreement among negatives is 98.3%

6-MAM (Cut-off=10 ng/mL)

Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator Positive	0	0	0	15	25
A Negative	10	20	10	0	0
Operator Positive	0	0	0	15	25
B Negative	10	20	10	0	0
Operator Positive	0	0	0	15	25
C Negative	10	20	10	0	0

% agreement among positives is 100%

% agreement among negatives is 100%

B. Specificity and Cross-reactivity

The minimum concentration required to obtain a positive result of the drug metabolites and other components for the test is listed below.

Tramadol (Cutoff=100ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Tramadol	100	100
(+/-)Chlorpheniramine	50000	0.2
Dimenhydrinate	50000	0.2
Diphenhydramine	50000	0.2
Phencyclidine	50000	0.2

(+)-Chlorpheniramine	>100000	<0.1
Tramadol-N-Desmethyl	300	33.33
Tramadol-O-Desmethyl	5,000	2
Venlafaxine	>100000	<0.1
o-Desmethyl Venlafaxine	>100000	<0.1

Fentanyl (Cut-off=1 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
(±) β-Hydroxythiofentanyl	5	20.00
(±)-3-cis-methyl fentanyl	50	2.00
4-Fluoro-isobutyrylfentanyl	50	2.00
Acetyl fentanyl	5	20.00
Acryl fentanyl	5	20.00
Butyryl fentanyl	25	4.00
Carfentanil	≥10000	≤0.01
Despropionyl fentanyl (4-ANPP)	≥50000	≤0.002
Fentanyl	1	100.00
Furanyl fentanyl	10	10.00
Isobutyryl fentanyl	5	20.00
Ocfentanil	100	1.00
Para-fluoro fentanyl	25	4.00
Para-fluorobutyryl fentanyl	25	4.00
Valeryl fentanyl	50	2.00
ω-1-Hydroxyfentanyl	50000	0.002
Acetyl norfentanyl	>100000	<0.001
Alfentanil	>100000	<0.001
Norcarfentanil	>10000	<0.01
Norfentanyl	>100000	<0.001
Remifentanil	>10000	<0.01
Sufentanil	>10000	<0.01

Norfentanyl (Cut-off=5 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
(±)-β-Hydroxythiofentanyl	80	6.25
4-Fluoro-isobutyryl Fentanyl	250	2.00
9-HydroxyRisperidone	10000	0.05
Acetyl Fentanyl	500	1.00
Acetyl Norfentanyl	50	10.00
Acryl Fentanyl	100	5.00
Alfentanil	>100000	<0.005
Butyryl Fentanyl	500	1.00
(±)-3-cis-methyl fentanyl	200	2.50
Fentanyl	500	1.00
Furanyl Fentanyl	1000	0.50
Isobutyryl Fentanyl	75	6.67
Labetalol Hydrochloride	100000	0.005
MT-45	8000	0.06
Norfentanyl	5	100.00
Ocfentanil	5000	0.10
Para-fluorobutyryl fentanyl	100	5.00
Para-fluoro fentanyl	100	5.00
Risperidone	800	0.63
Thienyl Fentanyl	100	5.00
Valeryl Fentanyl	500	1.00
Carfentanil	>10000	<0.05
Despropionyl fentanyl (4-ANPP)	>50000	<0.01
Norcarfentanil	>10000	<0.05
Remifentanil	>10000	<0.05
Sufentanil	>10000	<0.05
Trazodone	>10000	<0.05
U-47700	>100000	<0.005

Amphetamine (Cut-off=500 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
D - Amphetamine	500	100%
L - Amphetamine	10000	5%
DL - Amphetamine	1200	42%
Phentermine	15000	3.3%
Hydroxyamphetamine	4000	12.5%

Methylenedioxyamphetamine (MDA)	500	100%
d-Methamphetamine	> 100000	<0.5%
l-Methamphetamine	> 100000	<0.5%
Ephedrine	> 100000	<0.5%
Methylenedioxyethylamphetamine (MDE)	> 100000	<0.5%
3,4-methylenedioxy-methamphetamine (MDMA)	> 100000	<0.5%

Amphetamine (Cutoff=300ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
d-Amphetamine	300	100
l-Amphetamine	50000	0.6
Mephentermine hemisulfate salt	100000	0.3
3.4-Methylenedioxyamphetamine (MDA)	625	48
Phentermine	625	48
Paramethoxyamphetamine (PMA)	625	48
Paramethoxymethamphetamine(PMMA)	100000	0.3
Tyramine	100000	0.3
d,l-Amphetamine	600	50
d,l-Methamphetamine	>100000	<0.3
Pseudoephedrine	>100000	<0.3
Phenylephrine	>100000	<0.3
Phenylethylamine	>100000	<0.3
Hydroxyamphetamine	2000	15
β-Phenylethylamine	>100000	<0.3
p-Hydroxynorephedrine	>100000	<0.3
D,L-Norephedrine	>100000	<0.3
(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	>100000	<0.3
d-Methamphetamine	>100000	<0.3
l-Methamphetamine	>100000	<0.3
(+/-)3,4-Methylenedioxy-methamphetamine(MDMA)	>100000	<0.3
Ephedrine hydrochloride	>100000	<0.3
Phenylpropanolamine	>100000	<0.3
Benzphetamine	>100000	<0.3
L-Epinephrine	>100000	<0.3
D,L-Epinephrine	>100000	<0.3

Cocaine (Cut-off=150 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Benzoylcgonine	150	100%
Cocaine HCl	500	30%
Cocaethylene	7500	2%
Ecgonine	15000	1%
Norcocaine	50000	0.3%

Methamphetamine (Cut-off=500 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
D(+)-Methamphetamine	500	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	5000	10%
D/L-Methamphetamine	500	100%
p-Hydroxymethamphetamine	5000	10%
D-Amphetamine	> 100000	<0.5%
L-Amphetamine	> 100000	<0.5%
Chloroquine	40000	1.25%
(+/-)-Ephedrine	2000	25%
L-Methamphetamine	5000	10%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	> 100000	<0.5%
(+/-)3,4-methylenedioxy-methamphetamine(MDMA)	5000	10%
β-Phenylethylamine	4000	12.5%
Trimethobenzamide	10000	5%

Methamphetamine (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
d-Methamphetamine	300	100
Chloroquine	7,500	4

(-)-Ephedrine	2,000	15
Fenfluramine	12,500	2.4
l-Methamphetamine	1,000	30
Mephentermine hemisulfate salt	31,250	0.96
MDEA	50,000	0.6
MDMA	313	95.85
PMMA	625	48
d,l-Methamphetamine	1250	24
p-Hydroxymethamphetamine	4000	7.5%
(+/-)-Ephedrine	2000	15%
d-Amphetamine	>100000	<0.3
d,l-Amphetamine	>100000	<0.3
l-Amphetamine	>100000	<0.3
Phenylephrine	>100000	<0.3
Phenylethylamine	>100000	<0.3
Pseudoephedrine	>100000	<0.3
d,l-(MDA)	>100000	<0.3
Phentermine	>100000	<0.3
Methoxyphenamine hydrochloride	2500	12
Trimethobenzamide	>100000	<0.3
Procaine hydrochloride	>100000	<0.3

Barbiturates (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Secobarbital	300	100%
Amobarbital	1000	30%
Alphenal	62.5	480%
Aprobarbital	250	120%
Butabarbital	100	300%
Butethal	500	60%
Butalbital	5000	6%
Cyclopentobarbital	500	60%
Pentobarbital	200	150%
Phenobarbital	300	100%

Buprenorphine (Cut-off=10 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	50	20%
Norbuprenorphine-3-D-Glucuronide	100	10%
Morphine	> 100000	<0.01%
Oxymorphone	> 100000	<0.01%
Hydromorphone	> 100000	<0.01%

Oxazepam (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Oxazepam	300	100%
Alprazolam	150	200%
a-Hydroxyalprazolam	1000	30%
Bromazepam	1000	30%
Chlordiazepoxide	63	476.2%
Clonazepam HCl	2500	12%
Clobazam	75	400%
Clorazepate dipotassium	100	300%
Desalkylflurazepam	500	60%
Diazepam	500	60%
Estazolam	500	60%
Flunitrazepam	> 50000	<0.6%
D,L-Lorazepam	10000	3%
Midazolam	10000	3%
Nitrazepam	75	400%
Norchlordiazepoxide	62.5	480%
Nordiazepam	125	240%
EDDP	75	400%
Triazolam	1000	30%

EDDP	Result	% Cross-Reactivity
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(Cut-off=300 ng/mL)	Positive at (ng/mL)	
EDDP(2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine)	300	100%
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	> 100000	<0.3%
Disopyramide	75	400%
Methadone	> 100000	<0.3%
LAAM (Levo-alpha-acetylmethadol) HCl	> 100000	<0.3%
Alpha Methadol	> 100000	<0.3%
Doxylamine	> 100000	<0.3%

Ecstasy (Cut-off=500 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Methylenedioxy-methamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine (MDA)	5000	10%
3,4-Methylenedioxyethylamphetamine (MDEA)	300	166.7%
d-methamphetamine	>50000	< 1%
d-amphetamine	>50000	< 1%
l-amphetamine	>50000	< 1%
l-methamphetamine	>50000	< 1%

Morphine (Cut-off=2000 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Morphine	2000	100%
Acetylmorphine	2500	80%
Codeine	1000	200%
Ethylmorphine	250	800%
Heroin	5000	40%
Hydromorphone	2500	80%
Hydrocodone	5000	40%
Thebaine	13000	15.4%
Morphine-3- β-glucuronide	Negative at 200000	<1%
Oxycodone	Negative at 400000	<0.5%
Oxymorphone	Negative at 400000	<0.5%
Procaine	Negative at 400000	<0.5%
Levorphanol	Negative at 400000	<0.5%

Morphine (Cut-off=300 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Morphine	300	100%
Codeine	300	100%
Ethylmorphine	310	96.8%
Hydrocodone	25000	1.2%
Hydromorphone	10000	3%
Levorphanol	> 100000	0.3%
6-Acetylmorphine	250	120%
Morphine -3-β-D-glucuronide	10000	3%
Normorphine	100000	0.3%
Oxycodone	> 10000	<3%
Oxymorphone	>10000	<3%
Procaine	>10000	<3%
Thebaine	>10000	<3%
Heroin	500	60%

Methadone (Cut-off=300 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Methadone	300	100%
Doxylamine	5000	6%
LAAM HCl	10000	3%
Alpha Methadol	2000	15%
EDDP	> 100000	<0.3%
EMDP	> 100000	<0.3%

Oxycodone (Cut-off=100 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
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Oxycodone	100	100%
Dihydrocodeine	>100000	<0.1%
Codeine	>100000	<0.1%
Hydromorphone	>100000	<0.1%
Morphine	>100000	<0.1%
Buprenorphine	>100000	<0.1%
Ethylmorphine	>100000	<0.1%
Oxymorphone	250	40%
Hydrocodone	3125	3.2%

Phencyclidine (Cut-off=25 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	75	33.3%

Propoxyphene (Cut-off=300 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
d-Propoxyphene	300	100%
Norpropoxyphene	333	90.1%

Nortriptyline (Cut-off=1000 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Nortriptyline	1000	100%
Amitriptyline	750	133.3%
Clomipramine	10000	10%
Desipramine	200	500%
Doxepin	1250	80%
Imipramine	625	160%
Maprotiline	2000	50%
Nordoxepin	1000	100%
Promazine	1500	66.7%
Promethazine	25000	4%
Trimipramine	3000	33.3%
Cyclobenzaprine Hydrochloride	5000	20%
Nordclomipramine	3000	33.3%

Marijuana (Cut-off=50 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH	50	100%
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	50	100%
11-Nor- Δ^8 -Tetrahydrocannabinol-9-COOH	50	100%
Cannabinol	20000	0.25%
Δ^8 -Tetrahydrocannabinol	15000	0.33%
Δ^9 -Tetrahydrocannabinol	15000	0.33%
Cannabidiol	>100000	<0.05%
11-Nor- Δ^9 -THC-carboxy glucuronide	75	66.7%
(-)-11-nor-9-carboxy- Δ 9-THC	50	100%

Marijuana (Cut-off=20 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
11-nor-D ⁹ -THC-9 COOH	20	100%
11-nor-D ⁸ -THC-9 COOH	20	100%
Δ^8 -Tetrahydrocannabinol	>10000	<0.25%
Δ^9 -Tetrahydrocannabinol	>10000	<0.25%
Cannabinol	>10000	<0.25%

6-monoacetylmorphine (Cut-off=10 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
6-monoacetylmorphine	10	100%
Acetylcodeine	>10,000	<0.1%
Buprenorphine	>10,000	<0.1%
Codeine	>10,000	<0.1%
Diacetylmorphine	1,000	1%
Dihydrocodeine	>10,000	<0.1%
Ethylmorphine	>10,000	<0.1%
Hydrocodone	>10,000	<0.1%
Hydromorphone	5,000	0.2%
Morphine	10,000	0.1%
Morphine-3-glucuronide	>10,000	<0.1%

Nalorphine	5,000	0.2%
Thebaine	>20,000	<0.05%
Dextromethorphan	>100,000	<0.01%
Heroin	100,000	0.01%
Imipramine	>100,000	<0.01%
LAAM (Levacetylmethadol)	>100,000	<0.01%
Levorphanol	>100,000	<0.01%
Meperidine	>100,000	<0.01%
Methadone	>100,000	<0.01%
Mitragynine (kratom)	>20,000	<0.05%
Morphine 6-D-glucuronide	>100,000	<0.01%
Naloxone	>100,000	<0.01%
Naltrexone	>100,000	<0.01%
Naproxen	>100,000	<0.01%
Norbuprenorphine	>10,000	<0.1%
Norbuprenorphine glucuronide	>100,000	<0.01%
Norcodeine	>100,000	<0.01%
Norhydrocodone	>100,000	<0.01%
Normorphine	>100,000	<0.01%
Noroxycodone	>100,000	<0.01%
Noroxymorphone	>100,000	<0.01%
Norpropoxyphene	>100,000	<0.01%
Oxycodone	>100,000	<0.01%
Oxymorphone	>100,000	<0.01%
Oxymorphone- β 3-D-glucuronide	>100,000	<0.01%
Tapentadol HCl	>100,000	<0.01%
Tramadol	>100,000	<0.01%

C. Precision

Drug Conc. % of cutoff	Result FYL (Cut-off=1 ng/mL)			Result NFYL (Cut-off=5 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	49-/1+	50/-0+	49-/1+	49-/1+	49-/1+	50/-0+
cutoff	29+/21-	27+/23-	29+/21-	29+/21-	27+/23-	28+/22-
+25%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result AMP (Cut-off=500 ng/mL)			Result AMP (Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
cutoff	43+/7-	41+/9-	42+/8-	30+/20-	32+/18-	34+/16-
+25%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result MET (Cut-off=500 ng/mL)			Result MET (Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
cutoff	41+/9-	39+/11-	37+/13-	35+/15-	33+/17-	36+/14-
+25%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result BUP (Cut-off=10 ng/mL)			Result BZO (Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3

-100%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
cutoff	48+/2-	48+/2-	47+/3-	42+/8-	41+/9-	39+/11-
+25%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result EDDP (Cut-off=300 ng/mL)			Result MDMA (Cut-off=500 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
cutoff	40+/10-	41+/9-	41+/9-	41+/9-	39+/11-	38+/12-
+25%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result MOR (Cut-off=2000 ng/mL)			Result MOR (Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
cutoff	39+/11-	40+/10-	41+/9-	42+/8-	41+/9-	41+/9-
+25%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result OXY (Cut-off=100 ng/mL)			Result PCP (Cut-off=25 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	50/-0+50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
cutoff	47+/3-48+/2-	48+/2-	39+/11-	40+/10-	40+/10-	40+/10-
+25%	50/+0-50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result PPX (Cut-off=300 ng/mL)			Result TCA (Cut-off=1000 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
cutoff	41+/9-	42+/8-	41+/9-	41+/9-	42+/8-	42+/8-
+25%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result THC (Cut-off=50 ng/mL)			Result THC (Cut-off=20 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+	50/-0+	50/-0+	30/-0+	30/-0+	30/-0+
-75%	50/-0+	50/-0+	50/-0+	30/-0+	30/-0+	30/-0+
-50%	50/-0+	50/-0+	50/-0+	30/-0+	30/-0+	30/-0+
-25%	50/-0+	50/-0+	50/-0+	30/-0+	30/-0+	30/-0+
cutoff	38+/12-	38+/12-	40+/10-	23+/7-	24+/6-	24+/6-
+25%	50/+0-	50/+0-	50/+0-	30/+0-	30/+0-	30/+0-

+50%	50/+0-	50/+0-	50/+0-	30/+0-	30/+0-	30/+0-
+75%	50/+0-	50/+0-	50/+0-	30/+0-	30/+0-	30/+0-
+100%	50/+0-	50/+0-	50/+0-	30/+0-	30/+0-	30/+0-

Drug Conc. % of cutoff	Result TML (Cut-off=100 ng/mL)			Result BAR (Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
cutoff	36+/14-	34+/16-	32+/18-	48+/2-	48+/2-	49+/1-
+25%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result MTD (Cut-off=300 ng/mL)			Result COC (Cut-off=150 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-75%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-50%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
-25%	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+	50/-0+
cutoff	47+/3-	48+/2-	48+/2-	39+/11-	43+/7-	40+/10-
+25%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+50%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+75%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-
+100%	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-	50/+0-

Drug Conc. % of cutoff	Result
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Amoxicillin	Pentazocine
Ampicillin	Perphenazine
Apomorphine	Phencyclidine (except for PCP/TML)
Ascorbic Acid	Phenelzine
Aspartame	Phenobarbital (except for BAR)
Aspirin	Phentermine (except for AMP)
Atropine	Phenylethylamine (except for MET)
Baclofen	Prednisone
Benzilic acid	Promazine (except for TCA/EDDP)
Benzocaine	Promethazine (except for BZO/EDDP/TCA)
Benzoic Acid	Propoxyphene (except for PPX)
Benzoylcegonine (except for COC)	Propranolol
Benzylpiperazine	Pseudoephedrine
Bilirubin	Pyridoxine
Boric Acid (1%)	Pyrilamine
Bupropion	Pyrogallol
Caffeine (500 µg/mL)	Quinidine
Carbamazepine	Quinine
Carisoprodol	Quinolinic Acid
Cetirizine	Ranitidine
Chloral hydrate	r-Globulin
Chloramphenicol	Riboflavin
Chlordiazepoxide (except for BZO)	Salicylic Acid
Chlorothiazide	Secobarbital (except for BAR)
Chlorpheniramine	Serotonin(5-Hydroxytyramine)
Chlorpromazine	Sodium Azide
Cholesterol	Sufentanil Citrate
Clofibrate	Sulfamethazine
Clomipramine (except for TCA)	Sulindac
Clonidine	Tetracycline
Cortisone	Tetrahydrocortisone 3-acetate
Cotinine	Tetrahydrocortisone3-(β-Dglucuronide)
Creatine Hydrate	Tetrahydrozoline
Creatinine	Thiamine
Cyclobenzaprine (except for TCA)	Thioridazine
Cyclodextrin-r	Triamterene
Cyproheptadine	Trifluoperazine
d,l-Isoproterenol	Trifluoromethylphenyl- piperazine
Demoxepam	Trimethoprim
Deoxycorticosterone	Tryptamine
Desipramine (except for TCA)	Tyramine
Dextromethorphan	Urea (2000 mg/dL)
Diclofenac	Uric Acid
Diflunisal	Valproic acid (250 µg/mL)
Digoxin	Venlafaxine
Dimethyl-aminoantipyrine	Verapamil
Diphenhydramine (except for TML)	Zolpidem
Diphenylhydantoin	Zolpidem Tartrate
DL-Tryptophan	Zomepirac
DL-Tyrosine	β-Estradiol
Dopamine	β-Hydroxybutyric Acid
Doxepin (except for TCA)	Alpha Methadol (except for MTD)
Ecgonine methyl ester	Cannabidiol
Ephedrine (except for MET)	Carfentanil (except for FYL/NFYL)
Erythromycin	Chloroquine (except for MET)
Estradiol	Disopyramide (except for EDDP)
Estrone	Doxylamine (except for MTD)
Ethanol (1%)	Procaine
Fenfluramine (except for MET)	LAAM HCl (except for MTD)
Fenofibrate	Trimethobenzamide (except for MET)
Fenoprofen	Phenylpropanolamine
Fluphenazine	L-phenylephrine
Fotemustine	THC (except for THC)
Furosemide	Theophylline
Galactose	Rifampicin
Gamma Globulin (500 mg/dL)	Magnesium

Gemfibrozil	Desloratadine
Gentisic acid	Zaleplon
Glucose (3000 mg/dL)	Mifepristone
Guaiacolglyceryl ether	D,L-Epinephrine
Hemoglobin	L-Epinephrine
Hexobarbital	Levonorgestrel
Hydralazine	Vitamin B2
Hydrochlorothiazide	Delorazepam (except for BZO)
Hydrocortisone	Levothyroxine Sodium
Hydroxytyramine	Quetiapine
Ibuprofen	Telmisartan
I-Cotinine	Loratadine
I-Erythromycin	Sertraline
Imipramine (except for TCA)	Pregablin
Isoproterenol	Sildenafil Citrate
Isoxsuprine	Gabapentin
Ketamine	Levofloxacin Hydrochloride
Ketoprofen	Simvastatin
Labetalol	Trazodone Hydrochloride
Lamotrigine	Fluoxetine Hydrochloride
Lidocaine	Paliperidone
Lisinopril	Esomeprazole Magnesium
Loperamide	PenicillinV Potassium
Loratidine	Gatifloxacin
Lorazepam (except for BZO)	Oxalinic acid
LSD	Duloxetine
L-thyroxine	Omeprazole
Maprotiline (except for TCA)	Aripiprazole
Meperidine	Aminophylline
Meprobamate	Acyclovir
Metformin	7-Aminoclonazepam
Methapyrilene	Atomoxetine
Methaqualone	Atorvastatin Calcium
Methoxyphenamine (except for AMP/MET)	Azithromycin
Methylphenidate	Benzphetamine
Metoprolol	Cefradine
Metronidazole (300 µg/mL)	Cephalexin
N-Acetylprocainamide	Ciprofloxacin Hydrochloride
NaCl (40000 µg/mL)	Citalopram
Nalidixic Acid	Clarithromycin
Naloxone (except for OXY)	Clozapine
Naltrexone	Conjugated Estrogens
Naproxen	Nitroglycerin
N-desmethyl Tapentadol	Olanzapine
Niacinamide	Captopril
Nicotine	

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Glossary of Symbols



Consult instructions for use



Tests per Kit



Lot Number



Store between 35.6°F to 86°F (2-30°C)



Unique device identifier



Do Not Reuse



For *in vitro* diagnostic use only



Catalogue #



Use by



Do not use if package is damaged

Manufactured for:
BTNX Inc.
722 Rosebank Road,
Pickering, ON L1W 4B2 Canada
Technical Support (Toll-Free): +1-888-339-9964
Email: support@btnx.com
Website : www.btnx.com
Monday-Friday 9:00AM - 5:30PM EST





Premier Bio-Cup & Bio-Dip

For Forensic Use Only

The Premier Bio-Cup and Bio-Dip detect multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

Abbreviation	Drug	Cutoff (ng/mL)
6AM	6-Acetylmorphine	10
AMP 300	Amphetamine	300
AMP 500	Amphetamine	500
AMP 1000	Amphetamine	1,000
BAR	Barbiturates	300
BAR 200	Barbiturates	200
BUP	Buprenorphine	10
BUP 5	Buprenorphine	5
BZO	Benzodiazepines	300
BZO 200	Benzodiazepines	200
CLO	Clonazepam	300
COC 100	Cocaine	100
COC 150	Cocaine	150
COC	Cocaine	300
COT	Cotinine	200
EDDP	Methadone Metabolite	300
EtG	Ethyl Glucuronide	500
FYL	Norfentanyl	10
K2	Synthetic Marijuana	50
K2 25	Synthetic Marijuana	25
K3	AB-PINACA	10
KET	Ketamine	1,000
KRA	Mitragynine	100
MDMA	Ecstasy	500
MET	Methamphetamine	1,000
MET 500	Methamphetamine	500
MTD	Methadone	300
MTD 200	Methadone	200
OPI 100	Opiates/Morphine	100
OPI 300	Opiates/Morphine	300
OPI 2000	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	20
THC	Marijuana	40
THC	Marijuana	50
TML	Tramadol	100

The single or multi-test panels can consist of the above listed analytes in any combination, up to a maximum of 18 analytes, with and without on-board adulteration/specimen validity tests (SVT) in the dip card format or in the cup format. Only one cutoff concentration per analyte will be included per device. The tests provide only a preliminary result. A more specific alternative chemical method should be used in order to obtain a confirmed presumptive positive result if the donor doesn't admit use or anytime required by testing procedures. Gas Chromatography / Mass Spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry (LC/MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

WARNINGS AND PRECAUTIONS

- Treat all urine specimens and materials as if capable of transmitting infection. Wear gloves and proper laboratory attire to avoid skin contact with urine specimens. Proper handling and disposal methods should be established.
- Use a new specimen collection container for each urine sample to avoid cross-contamination of urine samples.
- Collect a fresh urine sample in the container provided or a clean, dry plastic or glass container. Fresh urine does not require any special pretreatment. If the specimen is not tested immediately, it may be refrigerated at 2-8°C up to 2 days, but must be thawed and mixed thoroughly prior to testing.
- Do not use the test kit after the expiration date.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Specimen collection container

PROCEDURE

Preparation:

1. Allow the test device, controls, and/or specimens to equilibrate to room temperature (15-30°C) prior to testing.
2. Do not open the test device pouch until ready to perform the test.

Dip Card:

1. Remove the dip card from the sealed pouch. Write the donor name or ID on the dip card in the provided space, then remove the cap.
2. With the arrows pointing downward, dip the card into the urine specimen for at least 20 seconds. Replace the cap and place the card on a flat surface. Alternatively, the dip card can remain in the specimen throughout the testing process.
3. Negative results can be interpreted as soon as the control lines appear and there are visible Test lines which usually occurs within 1 minute. Positive drug screen test results should be read at 5 minutes. All results remain stable for 60 minutes.
4. Read Specimen Validity Test (SVT) results by comparing the color of the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.Position of SVT pads may vary based on the drug strip configuration.



Cup:

1. Remove cup from the sealed pouch and write the donor name or ID in the provided space.
2. Collect urine in the cup.
3. Peel off label to view results. Negative results can be interpreted as soon as the control lines appear and there are visible Test lines which usually occurs within 1 minute. Positive drug screen test results should be read at 5 minutes. All results remain stable for 60 minutes.
4. Read Specimen Validity Test (SVT) results by comparing the color of the reagent pads to the corresponding color blocks on the color chart at 3 to 5 minutes.



RESULT INTERPRETATION

A red or pink line must appear next to the “C” (control) on all of the test strips. The appearance of a red or pink line next to the “C” on each test strip indicates that the test has worked properly.

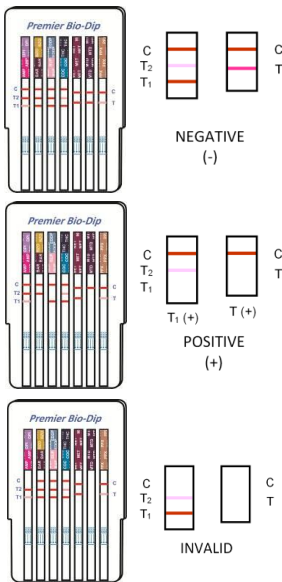
Negative Result:

A red or pink line next to the “T1” or “T2” (drug test line) under the drug name indicates a negative result for that drug. If a test line appears next to the “T1” or “T2” for all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.

Preliminary Positive Result:

If NO red or pink line appears next to the “T1” or “T2” under the drug name, the sample may contain that drug. Send the sample to a laboratory for confirmation testing.

The illustration on the right shows preliminary positive results for BAR, EDDP and MTD, but negative for all other drugs.



Invalid Result:

A colored line should always appear next to the letter “C” on every test strip. If no control line appears on any of test strips, the result is invalid.

The illustration at right shows no line next to the letter “C” on the first strip (OPI, AMP) and sixth strip (MTD). The test results for those two test strips are invalid.

STORAGE

The Premier Drug Screen DOA Test should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze. Do not store and/or expose reagent kits to temperatures greater than 30°C.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique.

To ensure proper kit performance, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Additional testing may be necessary to comply with the requirements of accrediting organizations and/or local, state, and/or federal regulators. External controls can be purchased from the following vendor: Biomedical Diagnostics,1-631-595-9200, www.biochemicaldiagnostics.com. or contact Premier Biotech Inc. for further information.

PERFORMANCE CHARACTERISTICS

A. ACCURACY

The accuracy of the Premier Bio-Cup and Bio-Dip was evaluated in comparison to GC/MS and LC/MS. Drug-free urine samples collected from presumed non-user volunteers were tested with the Premier Bio-Cup and Bio-Dip. Of these negative samples, all were correctly identified as negative. 10% of the negative samples were confirmed with GC/MS as drug negative. At least 30 drug positive urine specimens for each drug test were obtained from reference labs. Drug concentrations were confirmed with GC/MS and LC/MS (for TCA, FYL, 6-AM, K3 and EtG). A summary of the accuracy results on the Bio-Cup and Bio-Dip are shown in the following table.

Summary of Accuracy Results on the Premier Bio-Cup and Bio-Dip

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS and LC/MS Data						% Agreement
		Drug -free	-50% - <25% C/O	-25% C/O - C/O	C/O - +25% C/O	>+25% - +50% C/O	>+50/% C/O	
6AM/10	Neg	40	4	1	0	0	0	>99%
	Pos	0	0	0	1	4	36	>99%
AMP/300	Neg	40	0	0	0	0	0	>99%
	Pos	0	0	0	0	0	52	>99%
AMP/500	Neg	40	3	0	0	0	0	97.7%
	Pos	0	0	1	2	2	45	100%
AMP/1000	Neg	40	2	0	0	0	0	97.7%
	Pos	0	0	1	3	2	42	100%
BAR/300	Neg	40	1	1	0	0	0	95.2%
	Pos	0	0	2	5	2	36	100%
BAR/200	Neg	40	1	1	0	0	0	95.45%
	Pos	0	0	2	2	3	42	100%
BUP/10	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	8	0	32	100%
BUP/5	Neg	40	0	2	1	0	0	97.7%
	Pos	0	0	2	1	1	39	97.6%
BZO/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	1	6	34	100%
BZO/200	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	2	2	43	94%
CLO/300	Neg	40	4	2	0	0	0	95.83%
	Pos	0	0	2	3	4	41	100%
COC/100	Neg	40	0	0	0	0	0	>99%
	Pos	0	0	0	0	0	40	>99%
COC/150	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	4	1	53	100%
COC/300	Neg	40	0	3	1	0	0	100%
	Pos	0	0	0	4	1	46	98.0%
COT/200	Neg	40	0	0	0	0	0	>99.0%
	Pos	0	0	0	0	0	40	>99.0%
EDDP/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	5	2	33	100%
EtG/500	Neg	141	15	8	5	0	0	99.40%
	Pos	0	0	1	2	13	65	97.65%
FYL/10	Neg	40	0	0	0	0	0	100%
	Pos	0	0	0	0	0	22	100%
K2/50	Neg	40	3	1	0	0	0	95.7%
	Pos	0	0	2	2	4	22	100%
K2/25	Neg	40	2	1	0	0	0	93.5%
	Pos	0	0	3	2	3	21	100%
K3/10	Neg	40	0	0	0	0	0	100%
	Pos	0	0	0	0	4	0	100%
KET/1000	Neg	40	19	2	0	0	0	95.30%
	Pos	0	0	2	4	2	35	100%
KRA/100	Neg	40	2	0	0	0	0	97.67%
	Pos	0	0	1	1	3	14	>99%
MDMA/500	Neg	40	1	1	0	0	0	95.5%
	Pos	0	0	2	5	1	34	100%
MET/500	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	1	3	51	100%
MET/1000	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	2	3	45	100%
MTD/300	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	4	0	37	100%
MTD/200	Neg	40	0	0	0	0	0	>99%
	Pos	0	0	0	2	2	36	>99%
OPI/100	Neg	40	0	0	0	0	0	>99%
	Pos	0	0	0	0	0	40	>99%
OPI/300	Neg	40	0	1	0	0	0	93.2%
	Pos	0	0	3	4	0	53	100%
OPI/2000	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	2	4	3	40	100%
OXY/100	Neg	40	1	0	0	0	0	93.2%
	Pos	0	0	3	7	1	33	100%
PCP/25	Neg	40	0	3	0	0	0	97.7%
	Pos	0	0	1	3	8	33	100%
PPX/300	Neg	40	0	1	0	0	0	95.3%
	Pos	0	0	2	5	2	33	100%
TCA/1000	Neg	40	0	2	0	0	0	95.5%
	Pos	0	0	2	5	7	28	100%
THC 20	Neg	40	7	4	0	0	0	96.2%
	Pos	0	0	2	0	0	14	100%
THC/40	Neg	40	0	0	0	0	0	>99%
	Pos	0	0	0	0	0	40	>99%

Drug Test/ Cutoff (ng/ml)	Result	Range of GC/MS and LC/MS Data						
		Drug -free	-50% - <-25% C/O	-25% C/O - C/O	C/O - +25% C/O	>+25% - +50% C/O	>+50/% C/O	% Agreement
THC/50	Neg	40	1	2	0	0	0	97.7%
	Pos	0	0	1	4	7	44	100%
TML/100	Neg	40	8	4	0	0	0	>99%
	Pos	0	0	0	1	4	62	>99%

B. ANALYTICAL SENSITIVITY/PRECISION

An Internal Study using Drug-free urine and urine with drug concentrations at +/-50% cutoff and +/-25% cutoff were tested. Each solution was tested in 10 replicates. Results showed over 99% agreement at +/-50% cutoff levels with the Premier Bio-Cup and Bio-Dip.

C. ANALYTICAL SPECIFICITY

The following compounds are detected positive in urine by the Premier Bio-Cup and Bio-Dip. Concentrations are given in ng/ml; percent cross-reactivity is shown in parentheses.

Compound	Conc. (%)	Compound	Conc. (%)
6-AM			
6-Acetylmorphine	10 (100%)	Morphine	>100,000 (<0.1%)
Diacetylmorphine (heroin)	300 (3%)	Codeine	>100,000 (<0.1%)
Oxycodone	>100,000 (<0.1%)	Oxymorphone	>100,000 (<0.1%)
AMP 300			
D-Amphetamine	300 (100%)	MDA	1,000 (30%)
L-Amphetamine	27,500 (1.10%)	Phentermine	3,000 (10%)
AMP 500			
D-Amphetamine	500 (100%)	MDA	8,000 (6.5%)
L-Amphetamine	50,000 (1%)	Phentermine	45,000 (1.1%)
AMP 1000			
D-Amphetamine	1,000 (100%)	MDA	15,000 (6.7%)
L-Amphetamine	100,000 (1%)	Phentermine	100,000 (1.0%)
BAR			
Secobarbital	300 (100%)	Butalbital	300 (100%)
Amobarbital	2,500 (12%)	Cyclopentobarbital	500 (60%)
Aprobarbital	500 (60%)	Phenobarbital	300 (100%)
Butabarbital	100 (300%)	Pentobarbital	250 (120%)
BAR 200			
Secobarbital	200 (100%)	Butalbital	200 (100%)
Amobarbital	1,660 (12%)	Cyclopentobarbital	330 (66.7%)
Aprobarbital	330 (66.7%)	Phenobarbital	200 (100%)
Butabarbital	60 (333%)		
BUP			
Buprenorphine	10 (100%)	Norbuprenorphine	7.5 (133%)
Buprenorphine-3-β-D-glucuronide	3.5 (286%)	Norbuprenorphineglucuronide	35 (28%)
BUP 5			
Buprenorphine	5 (100%)	Norbuprenorphine	4 (125%)
Buprenorphine-3-β-D-glucuronide	2 (250%)	Norbuprenorphineglucuronide	18 (28%)
BZO			
Oxazepam	300 (100%)	α-Hydroxylprazolam	1,900 (15.8%)
Alprazolam	200 (150%)	Lorazepam	3,900 (7.7%)
Bromazepam	1,000 (30%)	Lorazepam-glucuronide	5,000 (6%)
Clobazam	200 (150%)	Nitrazepam	250 (120%)
Clorazepate	750 (40%)	Norchlordiazepoxide	500 (60%)
Desalkylflurazepam	1,200 (25%)	Nordazepam	390 (76.9%)
Diazepam	1,000 (30%)	Temazepam	150 (200%)
Flunitrazepam	250 (120%)	Triazolam	2,500 (12%)
BZO 200			
Oxazepam	200 (100%)	α-Hydroxylprazolam	1,300 (15.3%)
Alprazolam	130 (153%)	Lorazepam	2,600 (7.7%)
Bromazepam	650 (30.7%)	Lorazepam-glucuronide	3,500 (5.7%)
Clobazam	130 (153.8%)	Nitrazepam	160 (125%)
Clorazepate	500 (40%)	Norchlordiazepoxide	330 (60.6%)
Desalkylflurazepam	800 (25%)	Nordazepam	260 (76.9%)
Diazepam	1,650 (30.7%)	Temazepam	100 (200%)
Flunitrazepam	600 (125%)	Triazolam	1,650 (12.1%)
CLO			
7-Amino Clonazepam	300 (100%)	Clonazepam	75,000 (0.4%)
Meclonazepam	>100,000 (<0.3%)	Oxazepam	>100,000 (<0.3%)
Alprazolam	>100,000 (<0.3%)	Bromazepam	>100,000 (<0.3)
Clobazam	>100,000 (<0.3%)	Clorazepate dipotassium	>100,000 (<0.3%)
Desalkylflurazepam	100,000 (0.30%)	Diazepam	>100,000 (<0.3%)
Flunitrazepam	>100,000 (<0.3%)	α-Hydroxylprazolam	>100,000 (<0.3%)
Lorazepam	>100,000 (<0.3)	Lorazepam glucuronide	>100,000 (<0.3%)
Nitrazepam	>100,000 (<0.3%)	Norchlordiazepoxide	>100,000 (<0.3%)
Nordiazepam	>100,000 (<0.3%)	Temazepam	>100,000 (<0.3%)
Triazolam	>100,000 (<0.3%)		
COC 100			
Benzoyllecgonine	100 (100%)	Cocaine	5,000 (2%)
Cocaethylene	45,000 (0.22%)	Ecgonine	20,000 (0.5%)
COC 150			
Benzoyllecgonine	150 (100%)	Cocaine	5,000 (3%)
Cocaethylene	50,000 (0.3%)	Ecgonine	50,000 (0.3%)
COC			
Benzoyllecgonine	300 (100%)	Cocaine	10,000 (3%)
Cocaethylene	100,000 (0.3%)	Ecgonine	100,000 (0.3%)

Compound	Conc. (%)	Compound	Conc. (%)
COT			
(-)-Cotinine	200 (100%)	(R,S)-Norcotine	100,000 (0.2%)
Trans-3'-hydroxycotinine	5,000 (4%)	S(-)-Nicotine	>100,000 (<0.2%)
EDDP			
EDDP	300 (100%)		
EtG			
Ethyl glucuronide	500 (100%)		
FYL			
Norfentanyl	10 (100%)	Fentanyl	500 (2%)
K2			
JWH-073 N-Butanoic acid metabolite	50 (100%)	JWH-018 4N-(4-Hydroxypentyl) metabolite	750 (6.7%)
JWH-018 5-Pentanoic acid metabolite	50 (100%)	JWH-018 5-Hydroxypentyl metabolite	1500 (3.3%)
K2 25			
JWH-018 5- Pentanoic acid metabolite	25 (100%)	JWH-018 4N-(4-Hydroxypentyl) metabolite	2000 (1%)
JWH-073 N- Butanoic acid metabolite	40 (62%)	JWH-018 5-Hydroxypentyl metabolite	1250 (2%)
K3 10			
AB-PINACA pentanoic acid metabolite	10 (100%)	AB-PINACA N-(4-hydroxypentyl) metabolite	10 (100%)
ADB-PINACA N-(4-hydroxypentyl) metabolite	15 (66.7%)	ADB-PINACA N-(5-hydroxypentyl) metabolite	20 (50%)
5-fluoro AB-PINACA	20 (50%)	AB-PINACA N-(5-hydroxypentyl) metabolite	30 (33.3%)
N-(4-hydroxypentyl) metabolite		AB-PINACA	
ADB-PINACA pentanoic acid metabolite	20 (50%)	AB-PINACA	100 (10%)
5-fluoro AB-PINACA	50 (20%)		
AB-FUBINACA	150 (6.67%)	5-fluoro ADB-PINACA	250 (40%)
5-chloro AB-PINACA	1000 (1%)	APINACA(AKB-48)	>10,000 (<0.1%)
APINACA(AKB-48) 5-Hydroxypentyl metabolite	>10,000 (<0.1%)	CUMPY-THPINACA	>100,000 (<0.01%)
5-fluoro AEB	>100,000 (<0.01%)	AB-CHMINACA metabolite M2	>100,000 (<0.01%)
PX 1(5-fluoro APP-PICA)	>100,000 (<0.01%)	5-fluoro ADB(5-fluoro MDMB-PINACA)	>100,000 (<0.01%)
PX 2(5-fluoro APP-PINACA)	>100,000 (<0.01%)	MMB-FUBINACA	>100,000 (<0.01%)
4-cyano CUMYL-BUTINACA	>100,000 (<0.01%)	5-fluoro MN-18	>100,000 (<0.01%)
CUMYL-PICA	>100,000 (<0.01%)	5- fluoro PB-22 3-carboxyindole	>100,000 (<0.01%)
MN-18	>100,000 (<0.01%)		
BB-22 3-carboxyindole metabolite	>100,000 (<0.01%)		
AM2201 N-(4-hydroxypentyl) metabolite	>100,000 (<0.01%)		
KET			
Ketamine	1,000 (100%)	Dehydronorketamine (100000ng/ml)	>10000 (<10%)
(±)-Norketamine	5000 (20%)		
KRA 100			
Mitragynine	100 (100%)	Olanzapine	50,000 (0.02%)
7-Hydroxymitragynine	125 (80%)		
MDMA			
(+/-)-MDMA	500 (100%)	(+/-)-MDEA	500 (100%)
(+/-)-MDA	3,900 (12.8%)		
MET			
D-Methamphetamine	1,000 (100%)	MDEA	60,000 (1.7%)
D-Amphetamine	100,000 (1%)	MDMA	8,000 (12.5%)
L-Amphetamine	100,000 (1%)	Mephentermine	100,000 (1%)
1R,2S(-)-Ephedrine	>100,000 (<0.5%)		
MET 500			
D-Methamphetamine	500 (100%)	MDEA	30,000 (1.7%)
D-Amphetamine	50,000 (1%)	MDMA	3,500 (14.3%)
L-Amphetamine	50,000 (1%)	Mephentermine	75,000 (0.7%)
1R,2S(-)-Ephedrine	100,000 (0.5%)		
MTD			
Methadone	300 (100%)		
MTD 200			
Methadone	200 (100%)		
OPI 100			
Morphine	100 (100%)	Levorphanol	35,000 (0.29%)
Codeine	50 (200%)	Morphine 3-glucuronide	150 (66.67%)
Ethylmorphine	70 (142.86%)	Norcodeine	5,000 (2%)
Heroin	1,500 (6.67%)	Oxycodone	15,000 (0.67%)
Hydrocodone	550 (18.18%)	Thebaine	75,000 (0.13%)
Hydromorphone	350 (28.57%)		
OPI 300			
Morphine	300 (100%)	Levorphanol	50,000 (0.6%)
Codeine	100 (300%)	Morphine 3-glucuronide	400 (75%)
Ethylmorphine	100 (300%)	Norcodeine	6,000 (1.9%)
Heroin	8,000 (37.5%)	Oxycodone	75,000 (0.4%)
Hydrocodone	1,250 (24%)	Thebaine	90,000 (0.3%)
Hydromorphone	2,500 (12%)		
OPI 2000			
Morphine	2,000 (100%)	Hydromorphone	5,000 (40%)
Codeine	1,800 (111.1%)	Morphine-3-glucuronide	2,600 (76.9%)
Ethylmorphine	1,500 (133.3%)	Oxycodone	70,000 (2.9%)
Heroin	11,000 (18.2%)	Thebaine	95,000 (2.1%)
Hydrocodone	5,000 (40%)		

Compound	Conc. (%)	Compound	Conc. (%)
OXY			
Oxycodone	100 (100%)	Hydrocodone	5,000 (2%)
Codeine	50,000 (0.2%)	Hydromorphone	25,000 (0.4%)
Ethylmorphine	50,000 (0.2%)	Oxymorphone	12,500 (0.8%)
PCP			
Phencyclidine	25 (100%)	4-Hydroxy-PCP	1,500 (1.7%)
PPX			
Propoxyphene	300 (100%)	Norpropoxyphene	300 (100%)
TCA			
Nortriptyline	1,000 (100%)	Doxepine	1,000 (100%)
Amitriptyline	4,000 (25%)	Imipramine	1,000 (100%)
Clomipramine	2,000 (50%)	Promethazine	1,000 (100%)
Desipramine	500 (200%)	Trimipramine	5,000 (20%)

THC 20			
11-nor-Δ9-THC-9-COOH (+/-)-11-Hydroxy-Δ9-THC	20	(-)-Δ8-THC	7,000
Cannabinol	8,000	(-)-Δ9-THC	4,500
	20,000	Cannabidiol	>100,000
THC 40			
11-nor-Δ9-THC-9-COOH (+/-)-11-Hydroxy-Δ9-THC	40 (100%)	(-)-Δ8-THC	35,000 (0.11%)
	4,750 (0.84%)	(-)-Δ9-THC	17,000 (0.24%)
THC 50			
11-nor-Δ9-THC-9-COOH (+/-)-11-Hydroxy-Δ9-THC	50 (100%)	(-)-Δ8-THC	20,000 (0.3%)
	5,000 (1%)	(-)-Δ9-THC	20,000 (0.3%)
TML			
Tramadol	100 (100%)	N-Desmethyl-cis-tramadol	700 (14.28%)
O-Desmethyl-cis-tramadol	9,000 (1.11%)		

D. INTERFERENCE

The following compounds were evaluated for potential positive or negative interference with the Premier Bio-Cup and Bio-Dip. All compounds were dissolved in drug control solutions 50% below and 50% above their respective cutoff concentrations and tested with the Premier Bio-Cup and Bio-Dip. An unaltered sample was used as control. No interference was found for following compounds at a concentration of 100 µg/mL.

Acetaminophen	4-Dimethylaminoantipyrine	Niacinamide
Acetone	Diphenhydramine	(+/-)-Norephedrine
Albumin	Dopamine	Oxalic acid
Ampicillin	(+/-)-Isoproterenol	Penicillin-G
Ascorbic acid	(+)-Naproxen	Pheniramine
Aspartame	Erythromycin	Phenothiazine
Aspirin	Ethanol (except EtG)	L-Phenylephrine
Atropine	Furosemide	B-Phenylethylamine
Benzocaine	Glucose	Procaine
Bilirubin	Guaiacolglyceryl ether	Quinidine
Caffeine	Hemoglobin	Ranitidine
Chloroquine	Ibuprofen	Riboflavin
(+)-Chlorpheniramine	(+/-)-Isoproterenol	Sodium chloride
(+/-)-Chlorpheniramine	Levorphanol	Sulindac
Creatine	Lidocaine	Theophylline
Dexbrompheniramine	(1R,2S)-(-)-n-Methylephedrine	Tyramine
Dextromethorphan		

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Provided By: Premier Biotech Inc.
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www.premierbiotech.com
G36002-PB2 Revision 12

For in vitro diagnostic use only.

Intended Use

The Premier Biotech Cup is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, EDDP, Fentanyl, Ecstasy, Propoxyphene, Morphine, Methadone, Phencyclidine, Oxycodone, Norfentanyl, Methamphetamine, Nortriptyline, 6-Monoacetylmorphine, Tramadol and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	Calibrator	Cut-off level
Amphetamine(AMP)	d-Amphetamine	500 ng/mL or 300 ng/mL
Secobarbital (BAR)	Secobarbital	300 ng/mL
Buprenorphine(BUP)	BUP-3-D-Glucuronide	10 ng/mL
Oxazepam (BZO)	Oxazepam	300 ng/mL
Cocaine(COC)	Benzoylcegonine	150 ng/mL
EDDP	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL
Fentanyl (FYL)	Fentanyl	1 ng/mL
Ecstasy (MDMA)	3,4-Methylenedioxy-MET	500 ng/mL
Propoxyphene (PPX)	D-Propoxyphene	300 ng/mL
Morphine (MOR)	Morphine	2000 ng/mL or 300 ng/mL
Methadone(MTD)	Methadone	300 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Norfentanyl (NFYL)	Norfentanyl	5 ng/mL
Methamphetamine(MET)	Methamphetamine	500 ng/mL or 300 ng/mL
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10 ng/mL
Tramadol (TML)	Cis-Tramadol	100 ng/mL
Marijuana (THC)	11-nor- Δ^9 -THC-9-COOH	50 ng/mL or 20 ng/mL

Configuration of the Premier Biotech Cup can consist of any combination of the above listed drug analytes. It is for *in vitro* diagnostic use only.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Contents of the Kit

- One Test Device
- Instructions for Use
- Adulteration color chart

Not included in package

- Watch, timer or clock

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch or canister is damaged.
- Do not reuse tests.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Humidity and temperature can adversely affect results.

STORAGE

- Stored at 36-86°F(2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch or closed canister until use.
- DO NOT FREEZE.
- Keep away from direct sunlight, moisture and heat.

PROCEDURE

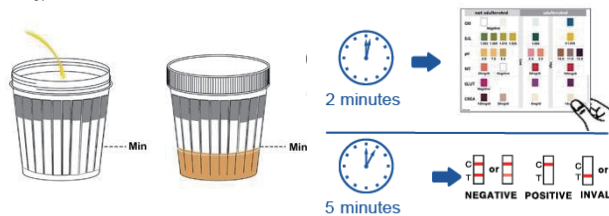
- Remove the Cup from the sealed pouch and use it within the first hour after opening
- Collect urine above the Minimum level on the label into the cup.
- Screw the cap onto the cup and immediately start the timer.

Reading Result:

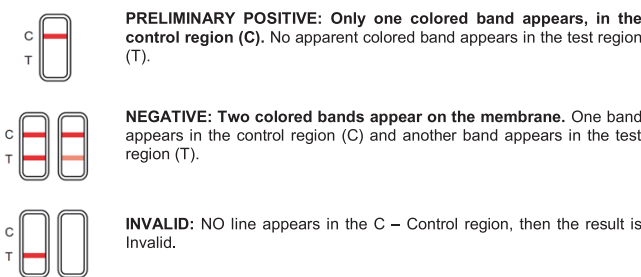
- The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

- For the adulteration, compare with the color card. The result should be read at 2 minutes. Do not interpret the result after 5 minutes.

6.



INTERPRETATION OF RESULTS



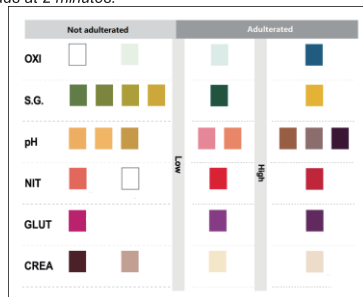
NOTE:

- The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Adulteration Strips

Semiquantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart.

Please refer to the color card provided in this kit for adulteration result interpretation. Read adulteration test pads at 2 minutes.



LIMITATIONS

- The device should be only used for the qualitative detection of target drugs.
- This assay provides a preliminary analytical test result only.
- There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
- A positive result indicates the presence of target drugs only, and does not indicate or measure intoxication.

- A negative result does not at any time rule out the presence of target drugs in urine, as they may be present below the minimum detection level of the test.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the test was confirmed by testing clinical urine specimens in parallel with LC-MS. The results are shown below.

TML (Cut-off=100 ng/mL)					
Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	2	19	20
	Negative	2	18	1	0
Operator B	Positive	0	1	19	20
	Negative	2	18	1	0
Operator C	Positive	0	0	19	20
	Negative	2	18	20	1

% agreement among positives is 97.5%

% agreement among negatives is 97.6%

FYL (Cut-off=1 ng/mL)					
Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	3	19	20
	Negative	1	19	1	0
Operator B	Positive	0	2	19	20
	Negative	1	19	1	0
Operator C	Positive	0	2	18	20
	Negative	1	19	2	0

% agreement among positives is 96.7%

% agreement among negatives is 94.2%

NFYL (Cut-off=5 ng/mL)					
Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	2	18	20
	Negative	12	8	2	0
Operator B	Positive	0	3	19	20
	Negative	12	8	1	0
Operator C	Positive	0	2	19	20
	Negative	12	8	1	0

% agreement among positives is 96.7%

% agreement among negatives is 94.3%

AMP (Cut-off=500 ng/mL)					
Test	Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	15	25
	Negative	10	20	0	0
Operator B	Positive	0	1	14	25
	Negative	10	20	1	0
Operator C	Positive	0	1	14	25
	Negative	10	20	9	0

% agreement among positives is 98.3%

% agreement among negatives is 98.3%

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1	24	16
	Negative	5	15	19	0	0
Operator B	Positive	0	0	2	24	16
	Negative	5	15	18	0	0
Operator C	Positive	0	0	1	23	16
	Negative	5	15	19	1	0

% agreement among negatives is 96.8%

Test		Drug-free	Low Negative ($<50\%$ the cutoff conc)	Near Cutoff Negative (Between $<50\%$ below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive ($>50\%$ above the cutoff conc)
Operator A	Positive	0	0	0	14	26
	Negative	10	20	10	0	0
Operator B	Positive	0	0	0	14	26
	Negative	10	20	10	0	0
Operator C	Positive	0	0	0	14	26
	Negative	10	20	10	0	0

% agreement among negatives is 100.0%

Test		Drug-free	Low Negative ($<50\%$ the cutoff conc)	Near Cutoff Negative (Between $<50\%$ below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive ($>50\%$ above the cutoff conc)
Operator A	Positive	0	0	0	13	26
	Negative	10	20	10	1	0
Operator B	Positive	0	0	0	13	26
	Negative	10	20	10	1	0
Operator C	Positive	0	0	0	14	26
	Negative	10	20	10	0	0

% agreement among negatives is 100.0%

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	0	20	20
	Negative	4	13	23	0	0
Operator B	Positive	0	0	2	18	20
	Negative	4	13	21	2	0
Operator C	Positive	0	0	1	19	20
	Negative	4	13	22	1	0

% agreement among negatives is 97.7%

Test		Drug-free	Low Negative ($<50\%$ the cutoff conc)	Near Cutoff Negative (Between $<50\%$ below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive ($>50\%$ above the cutoff conc)
Operator A	Positive	0	0	1	15	25
	Negative	10	20	9	0	0

Test	Drug-free	Low Negative	Near Cutoff	Near Cutoff	High Positive
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Test		Drug-free	Low Negative ($<50\%$ the cutoff conc)	Near Cutoff Negative (Between $<50\%$ below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive ($>50\%$ above the cutoff conc)
Operator A	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Operator B	Positive	0	0	0	15	25
	Negative	10	20	10	0	0

Cocaine HCl	500	30%
Cocaethylene	7500	2%
Ecgonine	15000	1%
Norcocaine	50000	0.3%

Methamphetamine (Cut-off=500 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
D(+)-Methamphetamine	500	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	5000	10%
D/L-Methamphetamine	500	100%
p-Hydroxymethamphetamine	5000	10%
D-Amphetamine	> 100000	< 0.5%
L-Amphetamine	> 100000	< 0.5%
Chloroquine	40000	1.25%
(+/-)-Ephedrine	2000	25%
L-Methamphetamine	5000	10%
(+/-)3,4-Methylenedioxymphetamine (MDA)	> 100000	< 0.5%
(+/-)3,4-methylenedioxymethamphetamine(MD MA)	5000	10%
β-Phenylethylamine	4000	12.5%
Trimethobenzamide	10000	5%

Methamphetamine (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
d-Methamphetamine	300	100
Chloroquine	7,500	4
(-)-Ephedrine	2,000	15
Fenfluramine	12,500	2.4
l-Methamphetamine	1,000	30
Mephentermine hemisulfate salt	31,250	0.96
MDEA	50,000	0.6
MDMA	313	95.85
PMMA	625	48
d,l-Methamphetamine	1250	24
p-Hydroxymethamphetamine	4000	7.5%
(+/-)-Ephedrine	2000	15%
d-Amphetamine	>100000	<0.3
d,l-Amphetamine	>100000	<0.3
l-Amphetamine	>100000	<0.3
Phenylephrine	>100000	<0.3
Phenylethylamine	>100000	<0.3
Pseudoephedrine	>100000	<0.3
d,l-(MDA)	>100000	<0.3
Phentermine	>100000	<0.3
Methoxyphenamine hydrochloride	2500	12
Trimethobenzamide	>100000	<0.3
Procaine hydrochloride	>100000	<0.3

Barbiturates (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Secobarbital	300	100%
Amobarbital	1000	30%
Alphenal	62.5	480%
Aprobarbital	250	120%
Butabarbital	100	300%
Butethal	500	60%
Butalbital	5000	6%
Cyclopentobarbital	500	60%
Pentobarbital	200	150%
Phenobarbital	300	100%

Buprenorphine (Cut-off=10 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	50	20%
Norbuprenorphine-3-D-Glucuronide	100	10%
Morphine	> 100000	< 0.01%

Oxymorphone	> 100000	< 0.01%
Hydromorphone	> 100000	< 0.01%

Oxazepam (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Reactivity	Cross-
Oxazepam	300	100%	
Alprazolam	150	200%	
a-Hydroxyalprazolam	1000	30%	
Bromazepam	1000	30%	
Chlordiazepoxide	63	476.2%	
Clonazepam HCl	2500	12%	
Clobazam	75	400%	
Clorazepate dipotassium	100	300%	
Desalkylflurazepam	500	60%	
Diazepam	500	60%	
Estazolam	500	60%	
Flunitrazepam	> 50000	< 0.6%	
D,L-Lorazepam	10000	3%	
Midazolam	10000	3%	
Nitrazepam	75	400%	
Norchlordiazepoxide	62.5	480%	
Nordiazepam	125	240%	
Temazepam	75	400%	
Triazolam	1000	30%	

EDDP (Cut-off=300 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
EDDP(2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	300	100%
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	> 100000	<0.3%
Disopyramide	75	400%
Methadone	> 100000	<0.3%
LAAM (Levo-alpha-acetylmethadol) HCl	> 100000	<0.3%
Alpha Methadol	> 100000	<0.3%
Doxylamine	> 100000	<0.3%

Ecstasy (Cut-off=500 ng/mL)	Result Positive at(ng/ml)	% Reactivity	Cross-
Methylenedioxymethamphetamine (MDMA)	500	100%	
3,4-Methylenedioxymphetamine (MDA)	5000	10%	
3,4-Methylenedioxyethylamphetamine (MDEA)	300	166.7%	
d-methamphetamine	>50000	< 1%	
d-amphetamine	>50000	< 1%	
l-amphetamine	>50000	< 1%	
l-methamphetamine	>50000	< 1%	

Morphine (Cut-off=2000 ng/mL)	Result Positive at(ng/ml)	%Cross-Reactivity
Morphine	2000	100%
Acetylmorphine	2500	80%
Codeine	1000	200%
Ethyl Morphine	250	800%
Heroin	5000	40%
Hydromorphone	25000	8%
Hydrocodone	5000	40%
Thebaine	13000	15.4%
Morphine-3- β-glucuronide	Negative at 200000	<1%
Oxycodone	Negative at 400000	<0.5%
Oxymorphone	Negative at 400000	<0.5%
Procaine	Negative at 400000	<0.5%
Levorphanol	Negative at 400000	<0.5%

Morphine (Cut-off=300 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Morphine	300	100%

Codeine	300	100%
Ethylmorphine	310	96.8%
Hydrocodone	25000	1.2%
Hydromorphone	10000	3%
Levorphanol	>100000	0.3%
6-Acetylmorphine	250	120%
Morphine -3-β-D-glucuronide	10000	3%
Normorphine	100000	0.3%
Oxycodone	>10000	< 3%
Oxymorphone	>10000	< 3%
Procaine	>10000	< 3%
Thebaine	>10000	< 3%
Heroin	500	60%

Methadone (Cut-off=300 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Methadone	300	100%
Doxylamine	5000	6%
LAAM HCl	10000	3%
Alpha Methadol	2000	15%
EDDP	> 100000	< 0.3%
EMDP	> 100000	< 0.3%

Oxycodone (Cut-off=100 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
Oxycodone	100	100%
Dihydrocodeine	>100000	<0.1%
Codeine	>100000	<0.1%
Hydromorphone	>100000	<0.1%
Morphine	>100000	<0.1%
Buprenorphine	>100000	<0.1%
Ethylmorphine	>100000	<0.1%
Oxymorphone	250	40%
Hydrocodone	3125	3.2%

Phencyclidine (Cut-off=25 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	75	33.3%

Propoxyphene (Cut-off=300 ng/mL)	Result Positive at(ng/ml)	% Cross-Reactivity
d-Propoxyphene	300	100%
Norpropoxyphene	333	90.1%

Nortriptyline (Cut-off=1000 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
Nortriptyline	1000	100%
Amitriptyline	750	133.3%
Clomipramine	10000	10%
Desipramine	200	500%
Doxepin	1250	80%
Imipramine	625	160%
Maprotiline	2000	50%
Nordoxepin	1000	100%
Promazine	1500	66.7%
Promethazine	25000	4%
Trimipramine	3000	33.3%
Cyclobenzaprine Hydrochloride	5000	20%
Norclomipramine	3000	33.3%

Marijuana (Cut-off=50 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
11-Nor-Δ ⁹ -Tetrahydrocannabinol-9-COOH	50	100%
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	50	100%
11-Nor-Δ ⁸ -Tetrahydrocannabinol-9-COOH	50	100%
Cannabinol	20000	0.25%
Δ ⁸ -Tetrahydrocannabinol	15000	0.33%
Δ ⁹ -Tetrahydrocannabinol	15000	0.33%
Cannabidiol	> 100000	< 0.05%

11-Nor- Δ^8 -THC-carboxy glucuronide	75	66.7%
(-)-11-nor-9-carboxy- Δ 9-THC	50	100%

Marijuana (Cut-off=20 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
11-nor-D ⁹ -THC-9 COOH	20	100%
11-nor-D ⁸ -THC-9 COOH	20	100%
Δ^8 -Tetrahydrocannabinol	>10000	<0.25%
Δ^9 -Tetrahydrocannabinol	>10000	<0.25%
Cannabinol	>10000	<0.25%

6-monoacetylmorphine (Cut-off=10 ng/mL)	Result Positive at (ng/mL)	% Cross-Reactivity
6-monoacetylmorphine	10	100%
Acetylcodeine	>10,000	<0.1%
Buprenorphine	>10,000	<0.1%
Codeine	>10,000	<0.1%
Diacetylmorphine	1,000	1%
Dihydrocodeine	>10,000	<0.1%
Ethylmorphine	>10,000	<0.1%
Hydrocodone	>10,000	<0.1%
Hydromorphone	5,000	0.2%
Morphine	10,000	0.1%
Morphine-3-glucuronide	>10,000	<0.1%
Nalorphine	5,000	0.2%
Thebaine	>20,000	<0.05%
Dextromethorphan	>100,000	<0.01%
Heroin	100,000	0.01%
Imipramine	>100,000	<0.01%
LAAM (Levacetylmethadol)	>100,000	<0.01%
Levorphanol	>100,000	<0.01%
Meperidine	>100,000	<0.01%
Methadone	>100,000	<0.01%
Mitragynine (kratom)	>20,000	<0.05%
Morphine 6-D-glucuronide	>100,000	<0.01%
Naloxone	>100,000	<0.01%
Naltrexone	>100,000	<0.01%
Naproxen	>100,000	<0.01%
Norbuprenorphine	>10,000	<0.1%
Norbuprenorphine glucuronide	>100,000	<0.01%
Norcodeine	>100,000	<0.01%
Norhydrocodone	>100,000	<0.01%
Normorphine	>100,000	<0.01%
Noroxycodone	>100,000	<0.01%
Noroxymorphone	>100,000	<0.01%
Norpropoxyphene	>100,000	<0.01%
Oxycodone	>100,000	<0.01%
Oxymorphone	>100,000	<0.01%
Oxymorphone-3 β -D-glucuronide	>100,000	<0.01%
Tapentadol HCl	>100,000	<0.01%
Tramadol	>100,000	<0.01%

C. Precision

Result Drug Conc. % of cutoff	FYL(Cut-off=1 ng/mL)			NFYL(Cut-off=5 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	49-/1+	50-/0+	49-/1+	49-/1+	49-/1+	50-/0+
cutoff	29+/21-	27+/23-	29+/21-	29+/21-	27+/23-	28+/22-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	AMP(Cut-off=500 ng/mL)			AMP(Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+

cutoff	43+/-	41+/-	42+/-	30+/-	32+/-	34+/-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	MET(Cut-off=500 ng/mL)			MET(Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
cutoff	41+/-	39+/11-	37+/-13-	35+/-15-	33+/-17-	36+/-14-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	BUP(Cut-off=10 ng/mL)			BZO(Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
cutoff	48+/-	48+/-	47+/-	42+/-	41+/-	39+/-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	EDDP(Cut-off=300 ng/mL)			MDMA(Cut-off=500 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
cutoff	40+/-	41+/-	41+/-	41+/-	39+/-	38+/-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	MOR(Cut-off=2000 ng/mL)			MOR(Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
cutoff	39+/11-	40+/-	41+/-	42+/-	41+/-	41+/-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	OXY(Cut-off=100 ng/mL)			PCP(Cut-off=25 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
cutoff	47+/-	48+/-	48+/-	39+/-	40+/-	40+/-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	PPX(Cut-off=300 ng/mL)			TCA(Cut-off=1000 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
cutoff	41+/-	42+/-	41+/-	41+/-	42+/-	42+/-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	THC(Cut-off=50 ng/mL)			THC(Cut-off=20 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	30-/0+	30-/0+	30-/0+
-75%	50-/0+	50-/0+	50-/0+	30-/0+	30-/0+	30-/0+
-50%	50-/0+	50-/0+	50-/0+	30-/0+	30-/0+	30-/0+
-25%	50-/0+	50-/0+	50-/0+	30-/0+	30-/0+	30-/0+
cutoff	38+/-	38+/-	40+/-	23+/-	24+/-	24+/-
+25%	50+/0-	50+/0-	50+/0-	30+/0-	30+/0-	30+/0-
+50%	50+/0-	50+/0-	50+/0-	30+/0-	30+/0-	30+/0-
+75%	50+/0-	50+/0-	50+/0-	30+/0-	30+/0-	30+/0-
+100%	50+/0-	50+/0-	50+/0-	30+/0-	30+/0-	30+/0-

Result Drug Conc. % of cutoff	TML(Cut-off=100 ng/mL)			BAR(Cut-off=300 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
cutoff	36+/-	34+/-	32+/-	48+/-	48+/-	49+/-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	MTD(Cut-off=300 ng/mL)			COC(Cut-off=150 ng/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
-100%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-75%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-50%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
-25%	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+	50-/0+
cutoff	47+/-	48+/-	48+/-	39+/-	43+/-	40+/-
+25%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+50%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+75%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-
+100%	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug Conc. % of cutoff	6-MAM(Cut-off=10 ng/mL)		
	Lot 1	Lot 2	Lot 3
-100%	30-/0+	30-/0+	30-/0+
-75%	30-/0+	30-/0+	30-/0+
-50%	30-/0+	30-/0+	30-/0+
-25%	30-/0+	30-/0+	30-/0+
cutoff	24+/-	23+/-	23+/-
+25%	30+/0-	30+/0-	30+/0-
+50%	30+/0-	30+/0-	30+/0-
+75%	30+/0-	30+/0-	30+/0-
+100%	30+/0-	30+/0-	30+/0-

D. Effect of Urine Density and pH

Urine samples of different urine density were tested. The results showed that varying urine density did not affect the test results.

Urine samples of different pH from acidic to basic were tested. The results showed that varying ranges of pH did not affect the test results.

E. Interference

The compounds listed below showed no interference at a concentration of 100 ug/mL or specified concentrations.

11-nor-9 carboxy THC (except for THC)	Nicotinic Acid
3-Hydroxytyramine	Nifedipine
4-Bromo- 2,5,Dimethoxyphenethylamine	Norethindrone
7-Aminoflunitrazepam	Norpropoxyphene (except for PPX)
7-Aminonitrazepam	Norpseudoephedrine
Acetaminophen	Nortriptyline (except for TCA)
Acetone (1000 mg/dL)	Noscapine
Acetophenetidin	Octopamine
Acetylsalicylic Acid (500 µg/mL)	O-Hydroxyhippuric acid
Albumin (100 mg/dL)	Oxalic Acid (100 mg/dL)
Albuterol	Oxazepam (except for BZO)
Aminopyrine	Oxolinic acid
Amitriptyline (except for TCA)	Oxymetazoline
Amlodipine besylate	Papaverine
Amobarbital (except for BAR)	Penicillin-G
Amoxicillin	Pentazocine
Ampicillin	Perphenazine
Apomorphine	Phencyclidine (except for PCP/TML)
Ascorbic Acid	Phenelzine
Aspartame	Phenobarbital (except for BAR)
Aspirin	Phentermine (except for AMP)
Atropine	Phenylethylamine (except for MET)
Baclofen	Prednisone
Benzilic acid	Promazine (except for TCA/EDDP)
Benzocaine	Promethazine (except for BZO/EDDP/TCA)
Benzoic Acid	Propoxyphene (except for PPX)
Benzoylcegonine (except for COC)	Propranolol
Benzylpiperazine	Pseudoephedrine
Bilirubin	Pyridoxine
Boric Acid (1%)	Pyrilamine
Bupropion	Pyrogallol
Caffeine (500 µg/mL)	Quinidine
Carbamazepine	Quinine
Carisoprodol	Quinolinic Acid
Cetirizine	Ranitidine
Chloral hydrate	r-Globulin
Chloramphenicol	Riboflavin
Chlordiazepoxide (except for BZO)	Salicylic Acid
Chlorothiazide	Secobarbital (except for BAR)
Chlorpheniramine	Serotonin(5-Hydroxytyramine)
Chlorpromazine	Sodium Azide
Cholesterol	Sufentanil Citrate
Clofibrate	Sulfamethazine
Clomipramine (except for TCA)	Sulindac
Clonidine	Tetracycline
Cortisone	Tetrahydrocortisone 3-acetate
Cotinine	Tetrahydrocortisone3-(β-Dglucuronide)
Creatine Hydrate	Tetrahydrozoline
Creatinine	Thiamine
Cyclobenzaprine (except for TCA)	Thioridazine
Cyclodextrin-r	Triamterene
Cyproheptadine	Trifluoperazine
d,l-Isoproterenol	Trifluoromethylphenyl- piperazine
Demoxepam	Trimethoprim
Deoxycorticosterone	Tryptamine
Desipramine (except for TCA)	Tyramine
Dextromethorphan	Urea (2000 mg/dL)
Diclofenac	Uric Acid
Diflunisal	Valproic acid (250 µg/mL)
Digoxin	Venlafaxine
Dimethyl-aminoantipyrine	Verapamil

Diphenhydramine (except for TML)	Zolpidem
Diphenylhydantoin	Zolpidem Tartrate
DL-Tryptophan	Zomepirac
DL-Tyrosine	β-Estradiol
Dopamine	β-Hydroxybutyric Acid
Doxepin (except for TCA)	Alpha Methadol (except for MTD)
Ecgonine methyl ester	Cannabidiol
Ephedrine (except for MET)	Carfentanil (except for FYL/NFYL)
Erythromycin	Chloroquine (except for MET)
Estradiol	Disopyramide (except for EDDP)
Estrone	Doxylamine (except for MTD)
Ethanol (1%)	Procaine
Fenfluramine (except for MET)	LAAM HCl (except for MTD)
Fenofibrate	Trimethobenzamide (except for MET)
Fenoprofen	Phenylpropanolamine
Fluphenazine	L-phenylephrine
Fotemustine	THC (except for THC)
Furosemide	Theophylline
Galactose	Rifampicin
Gamma Globulin (500 mg/dL)	Magnesium
Gemfibrozil	Desloratadine
Gentisic acid	Zaleplon
Glucose (3000 mg/dL)	Mifepristone
Guaiacolglyceryl ether	D,L-Epinephrine
Hemoglobin	L-Epinephrine
Hexobarbital	Levonorgestrel
Hydralazine	Vitamin B2
Hydrochlorothiazide	Delorazepam (except for BZO)
Hydrocortisone	Levothyroxine Sodium
Hydroxytyramine	Quetiapine
Ibuprofen	Telmisartan
l-Cotinine	Loratadine
l-Erythromycin	Sertraline
Imipramine (except for TCA)	Pregablin
Isoproterenol	Sildenafil Citrate
Isoxsuprine	Gabapentin
Ketamine	Levofloxacin Hydrochloride
Ketoprofen	Simvastatin
Labetalol	Trazodone Hydrochloride
Lamotrigine	Fluoxetine Hydrochloride
Lidocaine	Paliperidone
Lisinopril	Esomeprazole Magnesium
Loperamide	PenicillinV Potassium
Loratidine	Gatifloxacin
Lorazepam (except for BZO)	Oxalinic acid
LSD	Duloxetine
L-thyroxine	Omeprazole
Maprotiline (except for TCA)	Aripiprazole
Meperidine	Aminophylline
Meprobamate	Acyclovir
Metformin	7-Aminoclonazepam
Methapyrilene	Atomoxetine
Methaqualone	Atorvastatin Calcium
Methoxyphenamine (except for AMP/MET)	Azithromycin
Methylphenidate	Benzphetamine
Metoprolol	Cefradine
Metronidazole (300 µg/mL)	Cephalexin
N-Acetylprocainamide	Ciprofloxacin Hydrochloride
NaCl (40000 µg/mL)	Citalopram
Nalidixic Acid	Clarithromycin
Naloxone (except for OXY)	Clozapine
Naltrexone	Conjugated Estrogens
Naproxen	Nitroglycerin
N-desmethyl Tapentadol	Olanzapine
Niacinamide	Captopril
Nicotine	

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GLOSSARY OF SYMBOLS

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Store between 35.6-86°F (2-30°C)
	In vitro diagnostic medical device		Batch code		Catalog number
	Manufacturer		Use-by date		Do not reuse
	Do not use if package is damaged and consult instructions for use		Unique device identifier		

Manufactured for:
Premier Biotech, LLC
725 Kasota Ave SE
Minneapolis, MN 55414
Phone: 888-686- 9909 8AM-5PM CST (M-F)
www.premierbiotech.com

PI-UCD-IVD-AU-002 (DOC-2619) Ver. 0

Approved By:
[\(CO-134\) PI-UCD-AU-002](#)

Description

Release of package insert for PB Cup with new fentanyl 1 ng/mL.

Justification

New release

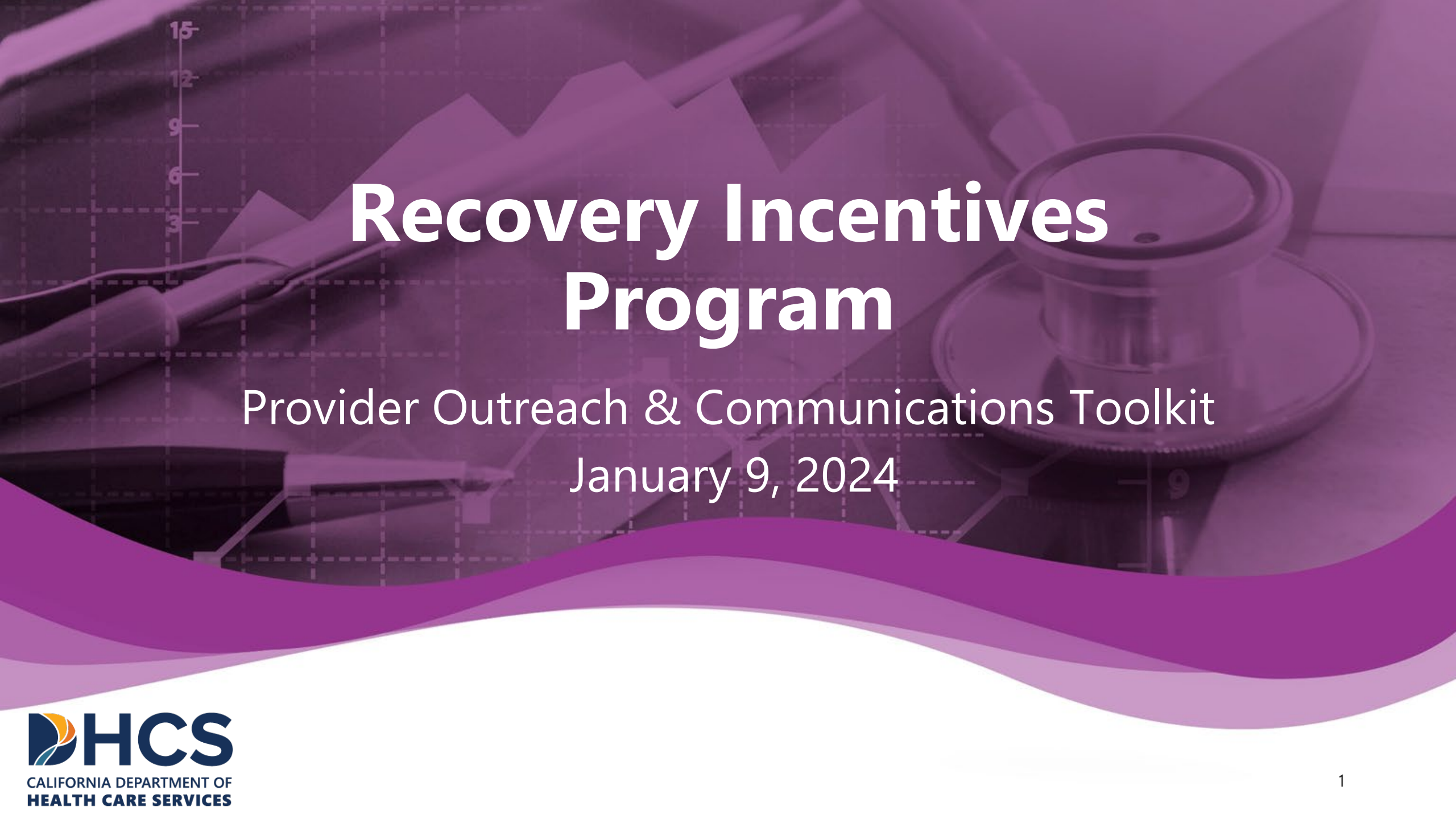
Assigned To:	Initiated By:	Priority:	Impact:
Matt Kennedy	Matt Kennedy	Low	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Matt Kennedy	January 29, 2026 1:32 PM CST	CO-134	0	Published

Appendix C

Provider Outreach and Communications Toolkit, Flyer, and Business Cards



Recovery Incentives Program

Provider Outreach & Communications Toolkit
January 9, 2024

Contents

- » Toolkit Introduction
- » Sample Messages
 - » Website Text
 - » Email Newsletter
 - » Social Media Posts
- » Sample Outreach Materials
 - » Flier
 - » Frequently Asked Questions

Toolkit Introduction

To expand access to evidence-based treatment for stimulant use disorder, DHCS is piloting Medi-Cal coverage of contingency management services in participating counties through the Recovery Incentives Program. Contingency management is an evidence-based practice that recognizes and reinforces individual positive behavior change consistent with meeting treatment goals, including medication adherence, as well as substance and stimulant nonuse.

The purpose of this Toolkit is to provide organizations offering the Recovery Incentives Program with messaging and resources to spread awareness about the new program among Medi-Cal members living with stimulant use disorder. This Toolkit includes sample messages and templates that can be used in various forms of outreach, including print and digital media. DHCS encourages organizations to integrate this messaging into existing communications channels. Outreach efforts may include, but are not limited to:

- » Updating website text and scheduling email newsletters for Medi-Cal members (see “Sample Messages”)
- » Printing and distributing fliers to provider sites to increase referrals
- » Preparing and sharing social media posts

DHCS recommends providers begin outreach to Medi-Cal members one month in advance of the launch of the Recovery Incentives Program. Find additional information about the Recovery Incentives Program on the [DHCS Website](#).

Sample Messages

Sample Messages: Overview & Objectives

Overview

This section includes sample messages related to the efficacy and availability of the Recovery Incentives Program. DHCS encourages participating organizations to use the sample messages included in this Toolkit to ensure consistency in messaging throughout the State.

Target Audience

The messages included in this section are intended primarily, but not exclusively, for Medi-Cal members diagnosed with stimulant use disorder.

Objectives

The messages included in this Toolkit are intended to provide information about:

- » Evidence of the effectiveness of contingency management services in treating stimulant use disorder;
 - » Role of incentives in driving positive behavior change over time; and
 - » Eligibility criteria for the Recovery Incentives Program.
-

Sample Messages: Website Text

Do you or someone you know use cocaine, methamphetamine, or other stimulants? An effective new treatment can help you or someone you know stop using and recover from stimulant use disorder. It's called the Recovery Incentives Program.

Beginning [Date], the Recovery Incentives Program is available to individuals who are enrolled in Medi-Cal and diagnosed with stimulant use disorder. The Recovery Incentives Program works by giving participants up to \$599 in gift cards for not using cocaine, meth and other stimulants. The program measures changes in stimulant use with negative drug tests.

Please visit [Provider Name] or contact [Contact Information] to learn more about the Recovery Incentives Program.

Sample Messages: Email Newsletter

Subject: Recovery Incentives Program Now Available at [Provider Name].

Do you or someone you know use cocaine, methamphetamine, or other stimulants? An effective new treatment can help you or someone you know stop using and recover from stimulant use disorder. It's called the Recovery Incentives Program.

Beginning [Date], the Recovery Incentives Program is available to individuals who are enrolled in Medi-Cal and diagnosed with stimulant use disorder. The Recovery Incentives Program works by giving participants up to \$599 in gift cards for not using cocaine, meth and other stimulants. The program measures changes in stimulant use with negative drug tests.

Please visit [Provider Name] or contact [Contact Information] to learn more about the Recovery Incentives Program.

Sample Messages: Social Media Posts

Sample Post 1

Beginning [date], individuals enrolled in Medi-Cal member can join the Recovery Incentives Program and may receive up to \$599 for not using meth, cocaine, and other stimulants. Learn more at: [Website Link]

Sample Post 2

Do you or someone you know use cocaine, methamphetamine, or other stimulants? An effective new treatment can help. It's called the Recovery Incentives Program. Learn more at: [Website Link].

Sample Post 3

[Provider Name] is participating in the Recovery Incentives Program. Medi-Cal members may receive up to \$599 to support recovery from stimulant use disorder. Learn more at: [Website Link].



Outreach Materials



Outreach Materials: Overview

Overview

This section includes materials developed by DHCS to support outreach to Medi-Cal members living with stimulant use disorder. Participating organizations should use these outreach materials to share information about the efficacy and availability of the Recovery Incentives Program with Medi-Cal members in their communities.

Materials

The outreach materials in this Toolkit include:

- » Recovery Incentives Program Flyer
- » Recovery Incentives Program Wallet Card
- » Frequently Asked Questions

Outreach Materials: Flyer



An effective new treatment can help you or someone you know stop using and recover from stimulant use disorder.
It's called the **Recovery Incentives Program**.

- ☒ If you are enrolled in Medi-Cal, **you may get up to \$599 in gift cards** for not using meth, cocaine, and other stimulants.
- ☒ The program measures changes in stimulant use with negative drug tests.

WHY USE THIS PROGRAM?

Giving someone money or a gift card can trigger the same feeling of reward in their brain as cocaine or meth. This can help them replace their stimulant use with the rewards.
Research shows many benefits to treating stimulant use with programs like this, including:

- ☒ Reduce stimulant use
- ☒ Reduce stimulant cravings
- ☒ Increased number of days in treatment

Site/Name: Phone #:	Site/Name: Phone #:	Site/Name: Phone #:	Site/Name: Phone #:	Site/Name: Phone #:	Site/Name: Phone #:	Site/Name: Phone #:	Site/Name: Phone #:	Site/Name: Phone #:
--	--	--	--	--	--	--	--	--

Recovery Incentives Program

HOW DOES THE RECOVERY INCENTIVES PROGRAM WORK?

The Recovery Incentives Program provides Medi-Cal members with small gift cards totaling up to \$599 for not using meth, cocaine, and other stimulants, as measured by negative drug tests. Participants are rewarded for changing their behavior and receive support on their path to recovery.

HOW LONG IS THE PROGRAM?

- » The outpatient treatment lasts 24 weeks.
- » You must attend an in-office visit 2 times a week for 12 weeks.
- » You then must attend an in-office visit 1 time a week for 12 more weeks.

HOW DO YOU QUALIFY FOR THE PROGRAM?

- » If you are enrolled in Medi-Cal and have a diagnosis of medium or severe stimulant use disorder, you can use this program.
- » To learn more about program requirements and which counties and provider organizations take part, go to <https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx>

CAN YOU GET MEDICATION ASSISTED TREATMENT (MAT) OR OTHER TREATMENTS WHILE IN THE PROGRAM?

- » If you have Medi-Cal and qualify for the program, you can keep getting other substance use disorder treatments, including MAT.
- » This program is not meant to replace MAT for opioid use or alcohol use disorders.



Recovery Incentives Program	Recovery Incentives Program	Recovery Incentives Program	Recovery Incentives Program	Recovery Incentives Program	Recovery Incentives Program	Recovery Incentives Program	Recovery Incentives Program	Recovery Incentives Program
--	--	--	--	--	--	--	--	--

Outreach Materials: Wallet Card

Recovery Incentives Program Now Available

Provider Name:

Provider Name

Phone Number:

(123) 456-7890

Physical Address:

123 Main Street, Ste. 100, Anytown, US 54321

Email:

YourEmail@providername.com

Website:

ProviderName.com



Beginning , eligible Medi-Cal
members at
can join the Recovery Incentives Program

The Recovery Incentives Program is an effective new treatment
that can help you or someone you know stop using and
recover from stimulant use disorder

If you are enrolled in Medi-Cal, you may get **up to \$599**
in gift cards for not using meth, cocaine, and other stimulants

Learn more at:

Outreach Materials: Frequently Asked Questions

What is the Recovery Incentives Program?

The Recovery Incentives Program is an evidence-based treatment for stimulant use disorder. The Recovery Incentives Program provides Medi-Cal members with small gift cards totaling up to \$599 for not using meth, cocaine, and other stimulants, as measured by negative drug tests. Program participants are rewarded for changing their behavior and receive support on their path to recovery.

How does the program work?

Unlike with opioids, there is no approved medication to treat meth, cocaine, or other stimulants. Substance use offers a powerful, immediate reward. The Recovery Incentives Program confronts this challenge by offering financial incentives for not using stimulants. Giving someone money or a gift card can trigger the same feeling of reward in their brain as cocaine or meth. This can help them replace their stimulant use with the rewards.

How do you qualify for this program?

If you are enrolled in Medi-Cal and have a diagnosis of medium or severe stimulant use disorder, you can use this program. To learn more about program requirements and which counties and provider organizations take part, go to <https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx>.

Outreach Materials: Frequently Asked Questions

How long is the Recovery Incentives Program treatment?

The Recovery Incentives Program outpatient treatment lasts 24 weeks. Eligible Medi-Cal members must attend an in-office visit 2 times a week for 12 weeks, and then must attend an in-office visit 1 time a week for 12 more weeks.

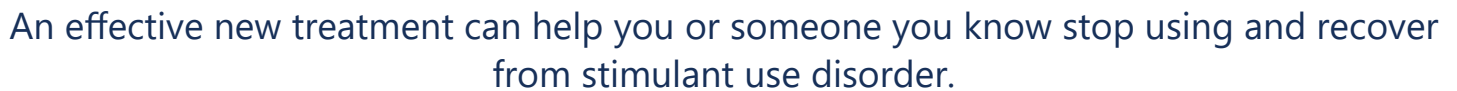
Can you get Medication Assisted Treatment (MAT) or other treatments while in the program?

If you have Medi-Cal and qualify for the program, you can keep getting other substance use disorder treatments, including MAT. This program is not meant to replace MAT for opioid use or alcohol use disorders.

What happens if I test positive for stimulants during the Recovery Incentives Program?

Members will not be kicked out of the Recovery Incentives Program if they test positive for stimulants during an in-office visit. For each visit a member has a positive test, they will not receive an incentive. The member will have an opportunity to test negative for stimulants and re-earn the incentive in a follow-up visit.

DO YOU OR SOMEONE YOU KNOW
USE COCAINE, METHAMPHETAMINE, OR OTHER STIMULANTS?



 If you are enrolled in Medi-Cal, **you may get up to \$599 in gift cards** for not using meth, cocaine, and other stimulants.

- Giving someone money or a gift card can trigger the same feeling of reward in their brain as cocaine or meth. This can help them replace their stimulant use with the rewards.

- ✓ Reduce stimulant use
- ✓ Reduce stimulant cravings
- ✓ Increased number of days in treatment

[illegible]

Recovery Incentives Program

HOW DOES THE RECOVERY INCENTIVES PROGRAM WORK?

The Recovery Incentives Program provides Medi-Cal members with small gift cards totaling up to \$599 for not using meth, cocaine, and other stimulants, as measured by negative drug tests. Participants are rewarded for changing their behavior and receive support on their path to recovery.

HOW LONG IS THE PROGRAM?

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- » You must attend an in-office visit 2 times a week for 12 weeks.
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HOW DO YOU QUALIFY FOR THE PROGRAM?

- » If you are enrolled in Medi-Cal and have a diagnosis of medium or severe stimulant use disorder, you can use this program.
- » To learn more about program requirements and which counties and provider organizations take part, go to <https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx>

CAN YOU GET MEDICATION ASSISTED TREATMENT (MAT) OR OTHER TREATMENTS WHILE IN THE PROGRAM?

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- » This program is not meant to replace MAT for opioid use or alcohol use disorders.



Recovery Incentives
Program

Recovery Incentives
Program

Recovery Incentives
Program

Recovery Incentives
Program

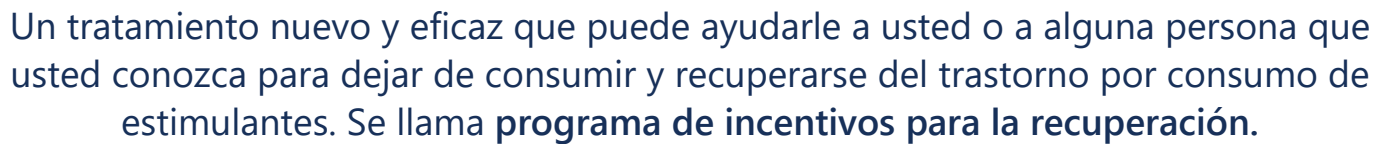
Recovery Incentives
Program

Recovery Incentives
Program

Recovery Incentives
Program

Recovery Incentives
Program

¿USTED O ALGUIEN QUE USTED CONOCE CONSUME COCAÍNA, METANFETAMINAS U OTROS ESTIMULANTES?



- ## ¿POR QUÉ UTILIZAR ESTE PROGRAMA?

Las investigaciones muestran muchos beneficios de tratar el uso de estimulantes con programas como éste, incluyendo:

- [illegible]

Programa de incentivos para la recuperación

¿CÓMO FUNCIONA EL PROGRAMA DE INCENTIVOS PARA LA RECUPERACIÓN?

El programa de incentivos para la recuperación ofrece a los miembros de Medi-Cal pequeñas tarjetas de regalo de hasta \$599 por no consumir metanfetamina, cocaína y otros estimulantes, medidos con pruebas de drogas negativas. Los participantes reciben recompensas por cambiar su comportamiento y reciben apoyo en su camino a la recuperación.

¿CUÁNTO DURA EL PROGRAMA?

- » El tratamiento como paciente externo dura 24 semanas.
- » Usted deberá asistir a una cita al consultorio 2 veces a la semana durante 12 semanas.
- » Después usted deberá asistir a una cita al consultorio 1 vez a la semana durante 12 semanas más.

¿CÓMO CALIFICA USTED PARA EL PROGRAMA?

- » Si está inscrito en Medi-Cal y tiene un diagnóstico de trastorno por consumo de estimulantes media o grave, usted puede utilizar este programa.
- » Para obtener más información sobre los requisitos del programa y cuáles condados y organizaciones de proveedores participan, ir a <https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx>

¿PUEDE UNO RECIBIR TRATAMIENTO ASISTIDO POR MEDICAMENTOS (MAT, POR SUS SIGLAS EN INGLÉS) U OTROS TRATAMIENTOS MIENTRAS ESTÉ EN EL PROGRAMA?

- » Si tiene Medi-Cal y califica para el programa, usted puede seguir recibiendo otros tratamientos para enfermedades por abuso en el consumo de sustancias, incluyendo MAT.
- » Este programa no pretende reemplazar a MAT para enfermedades por consumo de opioides o por consumo de alcohol.



Program de incentivos
para la recuperación

Program de incentivos
para la recuperación

Program de incentivos
para la recuperación

Program de incentivos
para la recuperación

Program de incentivos
para la recuperación

Program de incentivos
para la recuperación

Program de incentivos
para la recuperación

Program de incentivos
para la recuperación

Recovery Incentives Program Now Available

Provider Name:

Provider Name

Phone Number:

(123) 456-7890

Physical Address:

123 Main Street, Ste. 100, Anytown, US 54321

Email:

YourEmail@providername.com

Website:

ProviderName.com



Beginning , **eligible Medi-Cal members at**
can join the Recovery Incentives Program

The Recovery Incentives Program is an effective new treatment that can help you or someone you know stop using and recover from stimulant use disorder

If you are enrolled in Medi-Cal, you may get **up to \$599** in gift cards for not using meth, cocaine, and other stimulants

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Learn more at:

Appendix D

Behavioral Health Information Notice No: 24-031

NOTE:

Behavioral Health Information Notice No. 24-031 was released on August 22, 2024, and supersedes BHIN 22-056 (released on October 14, 2022) and BHIN 23-040 (released on August 18, 2023). To ensure that you are reading the most up-to-date version of the BHIN, visit <https://www.dhcs.ca.gov/Pages/DMC-ODS-Contingency-Management.aspx>, and scroll down to the Resources and Documents – Policy Documents section of the website.

Appendix E

CM Team Requirements Flow Chart

RECOVERY INCENTIVES: CALIFORNIA'S CONTINGENCY MANAGEMENT BENEFIT - CM TEAM REQUIREMENTS

Individuals serving as CM Coordinator, Back-up CM Coordinator, and CM Supervisor must complete all steps prior to initiating services at their site. More information about the Recovery Incentives Program, including Implementation training slides and handouts, training dates/times, contact information, and warmline assistance can be found here:

<https://uclaisap.org/recoveryincentives/index.html>

Step 1

Completion of Recovery Incentives: California's Contingency Management Program – Contingency Management Overview Training, a 2-hour self-paced overview course. This can be found [here](#).

Step 2

Attend Part 1 and Part 2 of the Implementation Trainings. Registration for Part 2 will be confirmed following attendance at a Part 1 session. Dates and times for sessions can be found [here](#). Completion of the post-test with an 16/20 (80%) or higher is required for all participants.

Step 4

Entry of 3 practice cases in the IM Portal Sandbox by all CM team members. The login for the IM Portal can be found at the end of the Readiness Assessment self-study. **All CM Team members, including those who join later, must successfully enter 3 practice cases into the IM Portal prior to delivering CM services**

Step 3

Complete the Readiness Assessment Self-Study in Qualtrics. Only one Self-Study is needed per physical site. Following the completion of Part 1 and Part 2 of the Implementation Trainings by at least 1 CM Coordinator and 1 CM Supervisor, the link for the self-study will be sent to the site.

Step 5

Complete the interactive Zoom Portion of the Readiness Assessment with a UCLA Team Member. This will be scheduled within a week of the submission of the Qualtrics self-study, including entry of the 3 practice cases into the IM Portal.

Step 6

Following the successful completion of the Readiness Assessment, personalized logins for the IM Portal will be sent. **Sites will not be able to launch services until sites have at least 1 CM Coordinator, 1 Back-up CM Coordinator, and 1 CM Supervisor complete this process.**

Appendix F

OIG Rules Applying to Non-Medicaid-Funded Contingency Management Programs

Appendix F

OIG rules applying to non-Medicaid funded Contingency Management programs

In general, federal law restricts providers' abilities to offer financial incentives as part of patient therapy or patient recruitment. The Anti-Kickback Statute (AKS) is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).¹ The Civil Monetary Penalties Law (CMPL) authorizes the Secretary of Health and Human Services to impose civil money penalties, an assessment, and program exclusion for various forms of fraud and abuse involving the Medicare and Medicaid programs.²

Over the years, the U.S. Department of Health & Human Services Office of Inspector General (OIG) has cautioned providers about various problematic activities that may create legal risk under the AKS or the CMP, including paying people to receive care that was not medically necessary.

However, the federal government has explicitly stated that the AKS and the CMP do not apply to motivational incentives that are delivered as part of the Medicaid-covered CM benefit, and in compliance with the DHCS-approved CM protocol. For the purpose of the Medi-Cal contingency management benefit authorized under the [CalAIM 1115 demonstration](#):

These motivational incentives are considered a Medicaid-covered item or service and are used to reinforce objectively verified recovery behaviors using a clinically appropriate contingency management protocol consistent with evidence-based research.

Consequently, neither the Federal anti-kickback statute (42 U.S.C. § 1320a-7b(b), "AKS") nor the civil monetary penalty provision prohibiting inducements to beneficiaries (42 U.S.C. 1320a-7a(a)(5), "Beneficiary Inducements CMP") would be implicated.³

Providers may offer and promote this benefit as they would any other benefit under DMC-ODS, subject to the CM protocols established by DHCS, outlined in BHIN #23-040. This protection does **not** apply to any patient incentives beyond those authorized in DHCS' contingency management protocol. Standard AKS and CMP principles will apply if a provider offers other types of patient incentives outside the CM benefit. For example, depending on the circumstances, it may create legal risk if a provider were to:

¹ <https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/>

² Ibid.

³ <https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-Approval-Letter-and-STCs.pdf>

- Offer motivational incentives to patients who do not qualify for the DMC-ODS CM benefit.
- Market the CM benefit in a manner that is inaccurate, misleading, or coercive (see below for best practices).
- Offer financial incentives to Medi-Cal patients over and above the motivational incentives available under the CM benefit.
- Offer the CM benefit in a manner inconsistent with DHCS' contingency management policies and protocols.
- Pay for marketing or patient recruitment services on a commission basis, or in a manner that otherwise takes into account the volume or value of business generated.
- Offer financial incentives to other health care providers in exchange for telling patients about, or referring patients for, CM and related SUD services.

State Requirements

To ensure contingency management services meet federal requirements, providers participating in the CA Recovery Incentives Program must abide by all policies and protocols established by DHCS.

CM services are only available to Medi-Cal members who are enrolled in a comprehensive treatment program that offers Recovery Incentives and meet other eligibility requirements. All Medi-Cal members participating in CM must be assessed and determined to have a moderate or severe StimUD as defined by the clinical criteria in the Diagnostic and Statistical Manual (current edition i.e., DSM-5-TR). The assessing clinician must determine that in addition to the diagnosis, outpatient, intensive outpatient, or partial hospitalization treatment is appropriate per the American Society of Addiction Medicine (ASAM) criteria, and the CM benefit is medically necessary based on existing medical necessity criteria. Each treatment program must also maintain fidelity to the evidence-based CM practice. SUD treatment providers will collaborate with eligible members to develop and document an individualized treatment plan that includes CM as one component of that plan. Each CM visit will be documented consistent with existing DHCS policy.

Additional details related to state documentation requirements and other CM protocols are available in BHIN #23-040.