



Healing and Ending Addiction Through Recovery and Treatment (HEART) Demonstration: Montana's Contingency Management Program

Program Manual

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Common Terms and Abbreviations

Client*

Cognitive Behavioral Therapy (CBT)

Community Reinforcement Approach (CRA)

Contingency Management (CM)

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

Contingency Management Back-up Coordinator (Back-up CM Coordinator)

Contingency Management Supervisor (CM Supervisor)

SOR Grant-Funded Member (SUPRT ID)*

Incentive Manager (IM)

MT Medicaid Member ID*

Methamphetamine (Meth)

Montana Department of Public Health and Human Services (DPHHS)

Motivational Incentives

Motivational Interviewing (MI)

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 MT HEART CM 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 MT HEART CM 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.

“Are you really paying 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 MT HEART CM 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 MT HEART CM 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 MT HEART CM 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 MT DPHHS.
 - 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 MT HEART CM Program requires UDTs twice per week for 12 weeks.

- **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 MT HEART CM Program, participating sites administer an escalating CM schedule (this will be explained in Chapter 4) for 12 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 site 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, gift card rewards are delivered in the form of an e-mail, text link, printed voucher, or other mechanism as approved by MT DPHHS. While other approaches like community reinforcement approach (CRA) do emphasize social rewards, in CM, concrete rewards should be given for the demonstration of a pre-determined, 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 E).

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 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 members 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 MT HEART CM Program and regular input was gathered from key community experts across the MT DPHHS Treatment System.

The MT HEART CM 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 E.

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 MT HEART CM 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 MT HEART CM 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 Portal 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 MT HEART CM 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 abstain from using stimulants, the more they can earn. 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 \$14 gift card for their first stimulant-negative UDT. In CM, we increase the reward (e.g., by an extra \$2) for every week of abstinence a member achieves. That means that at their first two visits they would earn \$14/visit for their stimulant-negative UDT, and by their second week, they would earn \$16/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 \$18/visit, and so on. So, by the end of 12 weeks of abstinence, a member can receive up to \$35 and \$36 for their final two stimulant-negative drug tests. The longer the member is abstinent, the bigger their rewards increase 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 MT HEART CM Program, when a member has a drug test that indicates they used stimulants, or if

they fail to show up for a scheduled visit, 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., \$14). This can be a big consequence for someone who has worked their way up to a large incentive amount. It is important to fully 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.

Return to Use 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 before a reset occurs; 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. Therefore, if a member has achieved an escalated reward amount, let’s say of \$20 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 \$14 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 4, when they would have earned \$20 for a stimulant-negative UDT, the next stimulant-negative UDT would result in a \$14 incentive, and if the next UDT after that is also negative for stimulants, they would earn \$22 (recovery of the \$20 escalation, plus the next \$2 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 use 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 some time, clinicians see 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 negative impacts 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 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 MT HEART CM Program is funded as a Medicaid benefit. Montana is the third state in the nation (following California and Washington^{29–30}) to cover CM as a Medicaid benefit under an 1115 Waiver Demonstration.

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 MT HEART CM Program protocol at 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 12 weeks.
- **CM Intervention** – 12-weeks of CM starting at \$14 for each stimulant-abstinent sample, escalating by \$2 for each week of consecutive abstinence (assessed twice-weekly); in week 12, the final two incentive amounts are \$35 and \$36/visit, respectively.

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" members 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 often experienced by members as 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 hold people accountable, though 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 validity measures 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 MT HEART CM Program. It is important to include additional validity procedures,

such as requiring the member to wash their hands before handling the testing supplies (to prevent members from putting bleach under their fingernails or urinating on them, which would contaminate the urine sample), applying bluing agent in the toilet the member will use, and/or turning off the hot water in the restroom that will be used for UDT sample collection. And if you do suspect an inaccurate test, it is important to have a conversation with the member, reminding 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, over-the-counter, and illicit 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 Montana HEART CM Sample Consent Form in Appendix A) and informed that they should talk to prescribers to see if alternatives are available and/or to avoid using these if possible during their participation in the MT HEART CM 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 to preserve the clinical relationship with a member who is very upset. Clinical judgment must be used, so we encourage you to consult your site’s CM Supervisor if this situation occurs. Also remember that reimbursement rates are based on a single test per day, 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 [MT HEART CM Program Warm Line](#).

Frequency of UDTs. In the 12-week MT HEART CM 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 may attend group/individual sessions multiple times a week. Testing shall ideally be separated by 72 hours (e.g., Monday and Thursday OR Tuesday and Friday; on rare occasions when appointment rescheduling is necessary, testing can be separated by at least 48 hours), to minimize the chance that drug metabolites from the same drug use episode shall be detected in more than one UDT.

Provider Requirements. The MT HEART CM Program may only be implemented in a state-approved and licensed SUD Outpatient Facility, a hospital with the ability to provide SUD treatment services and/or refer members to other outpatient treatment services, or a Rural Health Clinic (RHC), Federally Qualified Health Center (FQHC), or Indian Health Services (IHS) Tribal 638 Provider with SUD services in their scope of services. CM implemented in these settings consists of twice-weekly visits for the 12-week Program.

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 MT HEART CM Program. Each approved cup includes tests for amphetamine, methamphetamine, cocaine, cannabis, fentanyl/fentanyl metabolites, oxycodone, and opiates. They also test for benzodiazepines, MDMA, PCP, and several other substances, depending on the specific test kit. The purpose of testing for fentanyl, 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 refer to the MT DPHHS [Naloxone](#) web page for additional information regarding opioids and overdose, treatment for opioid use disorder, and how to find and order naloxone and fentanyl test strips.

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 a Licensed Addiction Counselor (LAC) and/or mental health professional with SUD specific scope and training (e.g., LCSW, LPC), they can complete the assessment. If the CM Coordinator is not an LAC/mental health professional (i.e., a Peer Support Specialist), the CM Coordinator shall refer the member to an LAC/mental health professional 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 non-stimulant analytes 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 MT HEART CM 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 MT HEART CM 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 MT HEART CM Program and receive reimbursement for CM services, providers must attain a Clinical Laboratory Improvement Amendments (CLIA) “waived test” certification. Additional information is available from the [Montana CLIA Program](#). Sites that already have a



CLIA Waiver in place can use these certificates for the MT HEART CM Program, even if their original application was for another test. It may take up to six months for applications to be processed once they are correctly submitted. It is therefore essential that sites submit applications as soon as possible, if needed. Agencies with multiple sites offering CM services will need one CLIA Certificate per site.

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. See [HEART Waiver Contingency Management](#) Section of the HEART Waiver Services webpage for a list 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 the MT HEART CM 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 MT HEART CM Program, please email the following information to HHSBHDDHEARTContingencyMa@mt.gov:

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

MT DPHHS 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 MT DPHHS.

UDT kits are purchased directly by each participating site according to usual procurement process. 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 7). 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 MT Medicaid benefit (see Chapter 8, Federal Law and Incentive Payments). Entering data into the IM Portal immediately and accurately and

completing clinical documentation in the EHR helps ensure that the MT HEART CM Program is compliant with state and federal laws, regulations, and MT DPHHS program requirements.

Specific Program Elements of the Montana HEART CM Program

Below is a step-by-step process for implementing the MT HEART CM 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 fentanyl, opiates, and oxycodone. 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 Montana, the following steps shall be taken for a member who tests positive for opiates, oxycodone, and/or fentanyl.

MT HEART CM Program sites shall:

- Assess and when appropriate, establish and implement a protocol to prescribe FDA-approved Opioid Overdose Reversal Medications (e.g., naloxone, nalmeferene) to all members with an opioid, sedative and/or stimulant use disorder as outlined below.
- Establish and provide an opioid overdose reversal medication distribution protocol.
- 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 MT DPHHS [Naloxone](#) web page. 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.

Monitoring and Reward Schedule. Twice-weekly during the 12-week Program, either 1) Mondays and Thursdays or 2) Tuesdays and Fridays. If it is not possible to test on an expected day, for instance in the event of an excused absence, the visit can be rescheduled on a non-consecutive day if there are **at least** 48 hours between UDTs.



Duration of Intervention. 12-weeks of CM treatment, which serves as the escalation/reset/recovery period. During the 12 weeks of CM treatment, participating members visit the treatment program twice per week for CM services as stated above. This protocol is in line with many CM interventions that were conducted as part of research studies and ended after 12 weeks (without a stabilizing period after the active intervention period). Members are encouraged to take advantage of other clinical interventions offered by sites implementing the CM benefit, such as group or individual counseling.

Reinforcement Amount, Escalation, Reset, and Recovery. The gift card values for each qualifying urine sample are at least \$14. For each week the member achieves/maintains abstinence (i.e., two consecutive stimulant-abstinent UDTs), the gift card value increases by \$2. Therefore, the maximum a member could earn if they attend every CM visit and are abstinent for the entire 12 weeks is \$599.

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 average cost of incentives in your implementation of the MT HEART CM Program will be approximately half of the maximum amount possible (\$599), or approximately \$300 per member, based on amounts earned in CM research studies.

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., \$14).

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 \$2. See Table 1 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 (SMS) link, printed voucher, or a member can choose to “bank” the incentive amount for future disbursement. 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 upon entry of stimulant-negative UDT results into the IM Portal. Restrictions are placed on the incentives so they cannot be used to purchase alcohol, tobacco, cannabis, lottery tickets or other gambling services, pornography, 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 a member's UDTs are stimulant-negative appears in Chapter 7. Remember that although you need to understand how incentives are calculated 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 = \$14, incentives escalate by \$2 for each week of continuous abstinence

Week #	Visit #	UDT Result	Incentive Earned (\$)	Week #	Visit #	UD Result	Incentive Earned (\$)
1	1	Negative	\$14.00	7	13	Missed	\$0.00
1	2	Negative	\$14.00	7	14	Positive	\$0.00
2	3	Negative	\$16.00	8	15	Negative	\$14.00
2	4	Negative	\$16.00	8	16	Negative	\$26.00
3	5	Negative	\$18.00	9	17	Negative	\$26.00
3	6	Negative	\$18.00	9	18	Negative	\$28.00
4	7	Negative	\$20.00	10	19	Negative	\$28.00
4	8	Positive	\$0.00	10	20	Negative	\$30.00
5	9	Negative	\$14.00	11	21	Excused	\$0.00
5	10	Negative	\$22.00	11	22	Negative	\$30.00
6	11	Negative	\$22.00	12	23	Negative	\$32.00
6	12	Negative	\$24.00	12	24	Negative	\$32.00
				Total			\$444.00

- **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, \$14.
- **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 (\$20) from visits 1-7. They also earned an additional escalation for another week of abstinence (visits 9 and 10), for a total of \$22 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 \$14, 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 \$26.
- 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 \$30, again because visit 21 was an excused absence.

Program Readmission. Members are discharged from the CM program if they miss eight (8) consecutive CM visits. If they return, it may be possible to readmit them if they still meet criteria. At readmission, the member must have a new/updated 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. However, medical necessity for treatment must still be documented for the readmission. 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. The IM will calculate amount earned in the calendar year for each participant and will notify provider if the member reaches the \$599 annual maximum.

A member who is readmitted to the MT HEART CM 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 MT HEART CM 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 prior to missing 8 consecutive visits, they return to the schedule of UDTs and incentives with missed session being documented as absent and program service continuing according to the expected visit number. 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 LAC, 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 MT HEART CM Program and should be transitioned to any appropriate services to ensure quality coordination of care. 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.

Chapter 5. MT HEART CM Eligibility and Billing

CM services delivered under the MT HEART CM Program are only covered when medically necessary and appropriate as determined by an initial SUD assessment showing (1) diagnosis of any of the related primary 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 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 MT Medicaid members and SOR grant recipients shall be referred to, and admitted into, treatment through a participating site's routine client admission process. The minimum age limit for an individual to receive CM services if they meet all eligibility criteria is 18 years of age. In addition, pregnant and parenting people with StimUD are eligible to receive CM services. Individuals 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.

- CM is a structured outpatient program that uses motivational incentives to support recovery from stimulant use disorder. Qualified providers, including FQHCs with SUDF (taxonomy 261QR0405X) services in their scope, may deliver CM services if all provider requirements are met

To bill for contingency management on a HCFA1500 from, you must register your agency/site with the NPPES NPI Registry and use taxonomy 261QR0405X. Your CLIA number is also required to be linked across platforms. See Appendix F for detailed MT HEART CM Provider Enrollment Step-by-Step instructions.

Information and criteria related to member eligibility and billing is separated into two sections based on site funding availability: (1) Medicaid Only Sites, and (2) SOR Sites (see Appendix G).

Medicaid-Only Sites: Establishing Member Eligibility for CM Services

MT HEART CM sites that are enrolled in MT Medicaid (and do not have SOR funding) can enroll members that meet the following conditions:

- Requires active MT Medicaid coverage. Individuals with pending MT Medicaid coverage **are not** eligible until coverage is approved. Therefore, MT Medicaid coverage must be confirmed **prior to** initiating services through the MT HEART CM Program.
- Individual meets criteria for a comprehensive, individualized course of SUD treatment with a **PRIMARY** diagnosis of moderate to severe stimulant use disorder.
- **Note:** Individuals with any **primary** diagnosis other than moderate to severe stimulant use disorder (i.e., non-stimulant substance use disorder, or a mental health disorder is primary), are **INELIGIBLE** for MT Medicaid funding for CM.
 - If SOR funding is available, they can be evaluated for services through SOR (see below).
 - Individuals who are ineligible for MT Medicaid funding and SOR funding is not available should be referred to other outpatient services to address their stimulant use disorder.
- Reside in Montana.
- Receive services in a non-residential level of care operated by a MT DPHHS-approved provider participating in the MT HEART CM Program and offering CM in accordance with MT DPHHS policies and procedures.
- CM services must be delivered and billed in accordance with MT Medicaid policy, including specimen collection, CLIA-waived urine drug testing (UDT), and administration of incentives through the approved incentive management process.

SOR Sites: Billing MT HEART CM Services

- SOR funding is intended to support individuals with stimulant or stimulant/opioid use disorder who are uninsured or underinsured.
- For SOR contracted providers, additional eligibility criteria for members are available, such as:
 - Member is **not** eligible for MT Medicaid, though receives treatment services through the SOR Grant, and meets criteria for a comprehensive, individualized course of SUD treatment with a diagnosis of moderate to severe stimulant use disorder.
- SOR funding may be used for individuals who are **NOT** Medicaid eligible. SOR funding **cannot** be used in place of Medicaid. If a member is **Medicaid eligible**:
 - For MT Medicaid eligible members with a primary StimUD diagnosis, CM services and incentives **must be** billed through Medicaid.

- Requires **active** MT Medicaid coverage. Individuals with pending MT Medicaid are not eligible until coverage is approved. MT Medicaid coverage must be active at the time of enrollment for those eligible. SOR funding cannot be used for these individuals while Medicaid coverage is pending.
- Individuals who are covered by MT Medicaid **can** receive service through SOR funding if:
 - They have any **primary** diagnosis other than moderate to severe stimulant use disorder (i.e., a non-stimulant substance use disorder, or a mental health disorder is primary, though still have a stimulant use disorder diagnosis), and they are therefore **INELIGIBLE** for MT Medicaid funding for CM.
- Reside in Montana.
- Receive services in a non-residential level of care operated by a MT DPHHS-approved provider participating in the MT HEART CM Program and offering CM in accordance with MT DPHHS policies and procedures.

FQHC Billing Considerations for CM Services

For the FQHC sites participating in the MT HEART CM Program, specific billing considerations apply:

- Billing depends on whether there is a qualifying PPS encounter on the date of service:
 - If there is a qualifying FQHC encounter:
 - Bill PPS only
 - UDT is included in the PPS rate and not billed separately
 - If there is not a qualifying encounter:
 - Bill UDT and specimen collection under SUDfacility (taxonomy 261QR0405X) using a CMS-1500
- **In Practice**
 - Qualifying FQHC visit → bill PPS only (UDT included)
 - No qualifying visit → bill UDT and specimen collection under SUDfacility (taxonomy 261QR0405X)
 - Medicaid eligible → bill CM services and incentives through MT Medicaid
 - Not Medicaid eligible → SOR funding may be used, as appropriate

CLIA and Ordering Requirements

- CLIA governs who can perform a test, not who can order it
- UDT must be ordered by a qualified licensed provider (e.g., MD, DO, NP, PA), or through appropriate standing orders tied to that provider
 - Billing pathway (PPS vs. SUDfacility (taxonomy 261QR0405X)) does not change clinical ordering requirements

- Upload CLIA certificate into Optum.
 - If provider does not upload a copy of the certificate into Optum, 80305 QW, will deny.

Chapter 6. MT HEART CM Visit Flow

Starting and continuing a member in MT HEART CM services will generally follow a standard flow. It is important to remember that flexibility is important to meet the client's needs. Therefore, if changes need to be made to this standard flow, it is important that all steps are completed both during intake and during ongoing visits. This chapter describes the optimal flow through CM services.

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. Members must have an ASAM multidimensional assessment completed by an LAC or licensed behavioral health professional with SUD within their scope of practice under their specific license 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 MT Medicaid or SOR Grant eligibility, as well as their eligibility for the program before initiating the CM service. The eligibility check should be done via apply.mt.gov for Montana Medicaid.
- The member should also be asked whether they are currently enrolled in a residential SUD treatment program. Members may not be enrolled in the MT HEART CM 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 MT HEART CM Program. The orientation addresses the following:
 - The days/times that a member must visit the facility to be eligible for incentives (twice-weekly visits during weeks 1-12).
 - 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, pornography, 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 \$14 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 MT DPHHS and the program evaluation team, including all MT DPHHS-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 12), logs into the IM Portal and locates the member's record/profile.

- Conduct eligibility check – The CM Team Member checks member MT Medicaid eligibility at least monthly or more frequently if required by agency policy.
- At the same time as the monthly MT Medicaid 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 MT HEART CM Program. They may be readmitted to

the MT HEART CM 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) and other analytes included in the UDT cup.
- 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 7.
 - 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 must document the CM visit per [Policy 615](#) and [Policy 130](#) (Progress Notes) per the Montana Medicaid Manual of DPHHS. The CM Team Member shall also document StimUD on the problem list and individualized treatment plan ([Policy 120](#)). 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 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 MT HEART CM 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 H0048 with the modifier SE (\$9.15 per cup) for Specimen Collection, and 80305 QW (\$12.60) for the CLIA Waived test. CM incentive delivery can occur alongside other billable services. When incentive delivery includes support or follow-up, providers should ***bill the qualified service during that portion of the visit, such as peer support, individual therapy, or LAC services.***
- 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 7. Incentive Manager

Getting Started: OKTA System Access Setup

Important: The following instructions apply to **non-DPHHS employees only**. Please read each step carefully — each step includes guidance to help you avoid the most common issues encountered during this process. DPHHS employees can skip to page 36.

Step 1 — Navigate to the Access Request Form

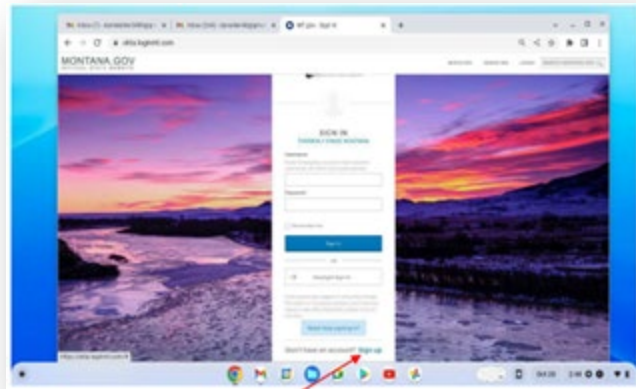
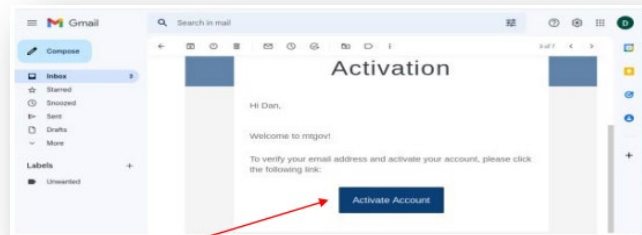
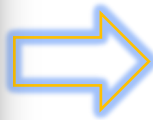
- Click the link below for the **Non-DPHHS Access Request Form**. This will take you to OKTA.
- On the OKTA screen, select "**Citizen Login**".
- **If you already have an OKTA account:** sign in and skip directly to Step 3.
- **If you do not have an OKTA account:** select "**Don't Have an Account, Sign Up**" at the bottom of the screen.
- **Citizen Workers link:** [Non-DPHHS Access Request — Montana ServiceNow](#)



Step 2 — Create Your OKTA Account

- Click "**Sign Up**" at the very bottom of the OKTA page.
- Enter the required information using your **work email and information**.
- Click "**Register**" to submit your details.
- A verification email will be sent to your work email from **noreply@okta.com** with the subject line "**Activate Account**".
- *Tip: Check your Spam or Junk folder if you do not see the email in your inbox.*

- If you do not receive the activation email, call the DPHHS Help Desk at **(406) 444-9500** for assistance.
- Once you receive the activation email, click the "**Activate Account**" button inside the email.
- This will take you to the **Okta Dashboard** — you can ignore the dashboard, as the forms are not located there.


A screenshot of the 'Sign up' form on the Montana.gov website. The form includes fields for 'First name' (filled with 'Jane'), 'Last name' (filled with 'Doe'), 'Email' (filled with 'jane@rest.com'), and 'Password' (masked with asterisks). Below the password field, there are 'Password requirements' listed: 'At least 12 characters', 'A lowercase letter', 'An uppercase letter', 'A number', 'A symbol', and 'No parts of your username'. A blue 'Sign Up' button is at the bottom.


⚠ Note: The OKTA activation email comes from noreply@okta.com with the subject "Activate Account". If you do not receive it within a few minutes, check your Spam/Junk folder before calling the Help Desk.

Step 3 — Return to the Access Request Form

- After activating your OKTA account, **go back to your email** and click the link for the Non-DPHHS Employee/File Access Request Form — OR click the citizen workers link from Step 1.
- You must be logged into OKTA for the form to load correctly.

Step 4 — Identify Your Account Type

- On the User Access Request screen, select "**I AM NOT REPRESENTING A BUSINESS**".

Step 5 — Complete the User Access Request Form

- Fill out **all fields** using your work email, phone number, and work information.
- **Phone number format is strict** — enter it exactly as: **(406) 123-4567**
(Area code in parentheses, one space after closing parenthesis, then a dash between the number groups.)
- In the "**Please list the requested System & File Accesses**" section, enter the following on separate lines:
 - **HHS APP-HEART CM Test**
 - **HHS APP-HEART CM**

⚠ Note: Both access entries above are required. Entering only one may result in incomplete access and a delay in your approval.

Step 6 — Copy Your REQ Number

- After submitting the form, you will receive a confirmation email containing a **REQ Number**.
- **Copy the full REQ Number**, including the "REQ" prefix (e.g., REQ0012345).

Step 7 — Complete the Confidentiality Agreement

- Click the **Confidentiality Agreement link** in your confirmation email — OR click here: [Non-DPHHS Employee Confidentiality Agreement — Montana](#)
- **Paste your REQ Number** into the first field — this is the first thing the form asks for.
- Complete all remaining fields in the Confidentiality Agreement.
- Note: Some questions repeat from the first form — this is expected. This is a **separate, required form** for accessing state systems.

Step 8 — Wait for Access Confirmation

- After submitting the Confidentiality Agreement, you will receive **two confirmation emails**:
- One from **DPHHS Network Security**
- One from the **data owner**
- **Wait for the email from the data owner** confirming access has been granted — this is the email that enables you to log in.
- Please allow up to **10 business days** for access requests to be processed and approved.

⚠ Note: Do not attempt to log in until you receive the data owner confirmation email. Processing can take up to 10 days — contact your supervisor if you have not received confirmation after this period.

Section 1: Member Enrollment

This section covers how to register a new member in the SIMS platform. This is performed by CM Coordinators when a new member begins their program.

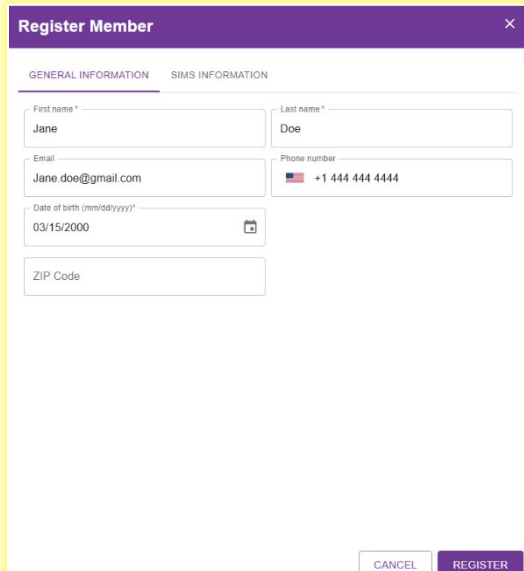
1.1 Getting Started

- Navigate to the **Members** section using the left-hand navigation panel.
- Click the purple **"Register Member"** button in the top-right corner.
- A modal dialog titled **"Register Member"** will appear with two tabs: **General Information** and **SIMS Information**.

1.2 General Information Tab

Complete all required fields marked with an asterisk (*):

- **Program Name** — Auto-populated based on your assigned program. No action needed.
- **First Name* / Last Name*** — Enter the member's full legal name.
- **Email Address** — Strongly recommended even for PRINT-only delivery members.
- **Phone Number** — Optional, for delivery of incentives by texting. Collect if available.
- **Date of Birth*** — Enter in MM/DD/YYYY format (e.g., 01/01/2000).
- **ZIP Code*** — Enter the member's current residential ZIP code.

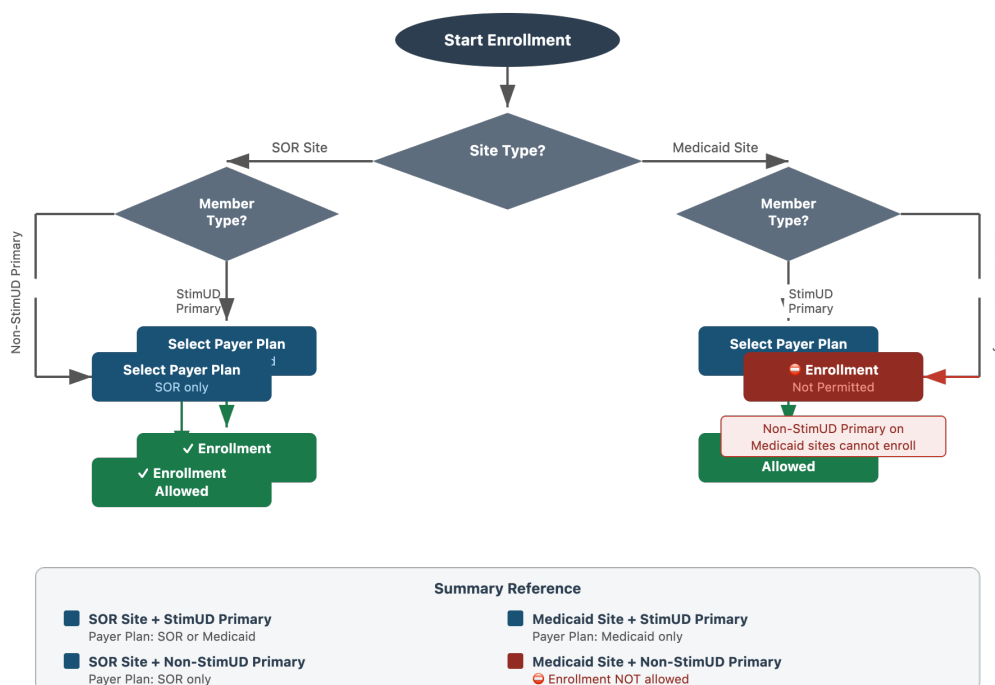


The screenshot shows a modal dialog titled "Register Member" with a close button (X) in the top right corner. It has two tabs: "GENERAL INFORMATION" (selected) and "SIMS INFORMATION". The form contains the following fields: "First name *" with the value "Jane", "Last name *" with the value "Doe", "Email" with the value "Jane.doe@gmail.com", "Phone number" with a dropdown for the US flag and the value "+1 444 444 4444", "Date of birth (mm/dd/yyyy)" with a calendar icon and the value "03/15/2000", and "ZIP Code". At the bottom right are "CANCEL" and "REGISTER" buttons.

Note: Although is not required for members participation, having an email on file allows the system to switch to electronic delivery in the future without requiring a chart update.

1.3 SIMS Information Tab

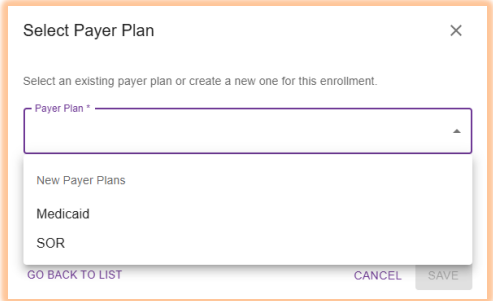
- **Program*** — Select the applicable program from the dropdown.
- **Provider Site*** — Select the site where the member will receive CM Services.
- **Provider*** — Select the CM Coordinator primarily providing services to this member.
- **Client ID Number (CIN)** — This is a randomly generated portal User ID; it carries no linkage to Medicaid, SOR, or any other member data. The Medicaid ID or SOR ID must be entered in the subsequent pop-up window, right after the CIN step (see **1.4 Payment plan** on the next page for further details).
- **CM Visit Schedule** — Select the applicable testing schedule (e.g., Monday-Thursday, Tuesday-Friday).
- **Medicaid Eligibility*** — Indicate eligibility (Yes/No).



Member Enrollment Decision Flow — CMI SIMS

1.4 Payment plan

Once all the information has been entered, an additional window will pop-up asking for the Payer Plan to be used for this member to which options available will show inside the dropdown menu. Please consider the flow chart above before making a selection.

A screenshot of a web application modal titled "Select Payer Plan" with a close button (X) in the top right corner. Below the title, it says "Select an existing payer plan or create a new one for this enrollment." There is a dropdown menu labeled "Payer Plan *". Below the dropdown, under the heading "New Payer Plans", are two options: "Medicaid" and "SOR". At the bottom of the modal are three buttons: "GO BACK TO LIST" (purple), "CANCEL" (purple), and "SAVE" (grey).

1.5 Completing Registration

- After completing both tabs, click the purple "**Register**" button at the bottom-right.
- The modal closes and the member appears in the Member list with status **Active**.
- To discard at any point, click "**Cancel**". No record will be created.

⚠ Note: Members are only permitted to be enrolled at one site at a time. Attempting to register a member already active at another site activates a double entry error — see Section 2.

Section 2: Double Entries

This section explains what double entry errors are, their causes, and how to resolve them during registration.

2.1 What Is a Double Entry?

A double entry error occurs when a member's **CIN or EHR MRN** already exists in SIMS. The system displays a red error beneath the CIN field: *"CIN already exists. Please contact SIMS support."* The Register button remains inactive until the conflict is resolved.

2.2 Why Does This Happen?

- A member attempting to enroll in multiple sites simultaneously.
- Accidental duplicate record creation by staff — the system automatically will block this.

2.3 How to Resolve a Double Entry

- Do **not** re-enter the same CIN/MRN or create a new record.
- Click **Cancel** to close the registration modal.
- Navigate to the **Members** pane.
- Use the **Search Member** bar to search by name or MRN.
- If found, click the member's underlined name to open their existing chart.
- If not found, **contact SIMS Support** before proceeding.

The screenshot shows the 'Register Member' modal window. At the top, it says 'DPPHS CM PROGRAM' and 'DPPHS: NORTHCARE NETWORK / PROVIDER SITE: PATHWAYS CMH'. There are two tabs: 'GENERAL INFORMATION' and 'SIMS INFORMATION'. The 'SIMS INFORMATION' tab is active. It contains several fields: 'Program' (DPPHS CM Program), 'Provider site' (Pathways CM), 'Provider' (William Swift), 'Client ID Number (CIN)*' (12345678A), 'CIN already exists. Please contact SIMS support.' (red error message), 'CM visit schedule' (Monday - Thursday), 'Medicaid eligibility' (Yes), 'Consent form' (with an 'UPLOAD' button), and 'Consent confirmation' (with a checked checkbox and text: 'I have verified the Member is eligible for CM treatment services as part of the Montana DPPHS program.'). At the bottom right, there are 'CANCEL' and 'REGISTER' buttons. The 'REGISTER' button is disabled.

⚠ Note: Never create a duplicate record to work around this error. Doing so may cause incentive tracking errors and reporting discrepancies.

Section 3: Selecting a Member

3.1 Opening the Member Pane

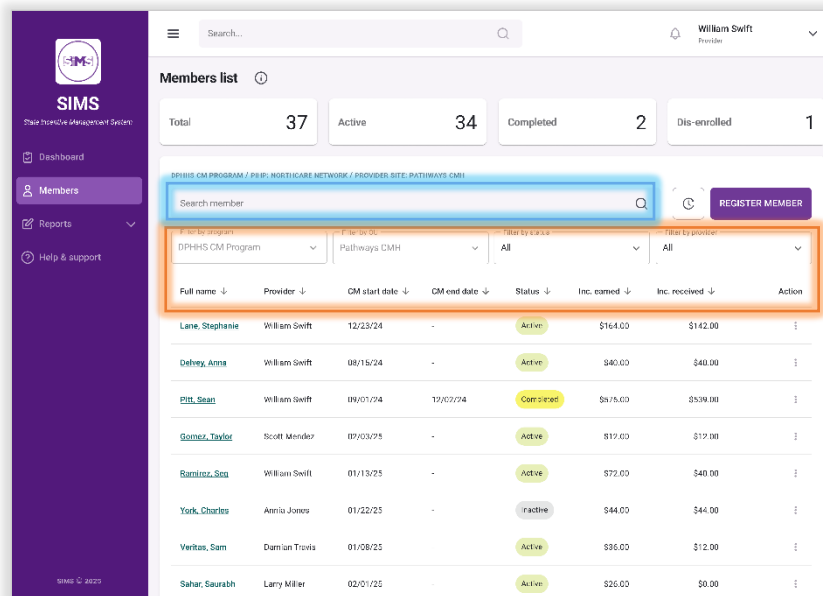
- Click "**Members**" in the left-hand navigation panel.
- The Member List loads, showing a summary bar: **Total, Active, Completed, and Dis-enrolled** counts.
- A filterable, sortable list of all assigned members appears below.

3.2 Finding a Member

- **Sorting:** Click any column header (Full Name, Provider, CM Start Date, Status, Inc. Earned, Inc. Received) to sort. Click again to reverse.
- **Searching:** Type in the "**Search Member**" field to filter by first name, last name, or MRN in real time.

3.3 Opening a Member's Chart

- Click the **underlined name** in the Full Name column to open that member's chart.
- From the chart you can enter UDS results, view incentive history, update information, and redeem balances.



Full name ↓	Provider ↓	CM start date ↓	CM end date ↓	Status ↓	Inc. earned ↓	Inc. received ↓	Action
<u>Lane, Stephanie</u>	William Swift	12/23/24	-	Active	\$164.00	\$142.00	
<u>Delvey, Anna</u>	William Swift	08/15/24	-	Active	\$40.00	\$40.00	
<u>Pitt, Sean</u>	William Swift	09/01/24	12/02/24	Completed	\$975.00	\$539.00	
<u>Gomez, Taylor</u>	Scott Mender	07/03/25	-	Active	\$12.00	\$12.00	
<u>Ramirez, Ben</u>	William Swift	01/13/25	-	Active	\$72.00	\$40.00	
<u>York, Charles</u>	Amia Jones	01/22/25	-	Inactive	\$44.00	\$44.00	
<u>Veritas, Sam</u>	Damian Travis	01/08/25	-	Active	\$36.00	\$12.00	
<u>Sahar, Saurabh</u>	Larry Miller	02/01/25	-	Active	\$26.00	\$0.00	

4: Member Information Changes

4.1 When to Edit a Member's Record

- Phone number or email address has changed — critical for uninterrupted gift card delivery.
- A typo was made during registration (name, date of birth, CIN).
- Other updates needed (Medicaid eligibility, CM visit schedule change).

4.2 How to Edit

- Open the member's chart (see Section 3).
- Click the **three-dot menu icon (:)** in the top-right of the chart header.
- Select **"Edit Member"**. The Edit Member modal will appear.

4.3 Editable Fields

- First Name / Last Name
- Email Address
- Phone Number
- Date of Birth
- Campaign
- Status (Active, Dis-enrolled, Completed)
- Client ID Number (CIN)
- CM Visit Schedule
- Medicaid Eligibility

The screenshot shows the SIMS (Site Information Management System) interface. On the left is a sidebar with navigation options: Dashboard, Members, Reports, and Help & support. The main area displays a 'Members list' table. A modal window titled 'Edit Member' is open, showing a form for editing a member's information. The form includes fields for First name (Stephanie), Last name (Lane), Email (stephanie@ggg.com), Phone number (+1 800 800 213), Date of birth (08/12/1987), Campaign (Campaign 1), Status (Active), Client ID Number (CIN) (12345678A), CM visit schedule (Monday - Thursday), and Medicaid eligibility (Yes). There are buttons for 'MOVE', 'CANCEL', and 'SAVE'. The background table shows a list of members with columns for Name, Date of Birth, Status, and Amount.

Name	Date of Birth	Status	Amount
York, Charles	01/22/75	Inactive	\$44.00
Yorlles, Sam	01/08/75	Active	\$36.00
Yorlles, Sam	01/08/75	Active	\$36.00

4.4 Saving Changes

- Click the purple **"Save"** button to confirm updates.
- Click **"Cancel"** to discard all changes.
- Updated information reflects immediately in the member's chart.

⚠ Note: The "Move" button transfers a member to a different site or provider. Consult your supervisor before using Move, as it affects enrollment records and reporting.

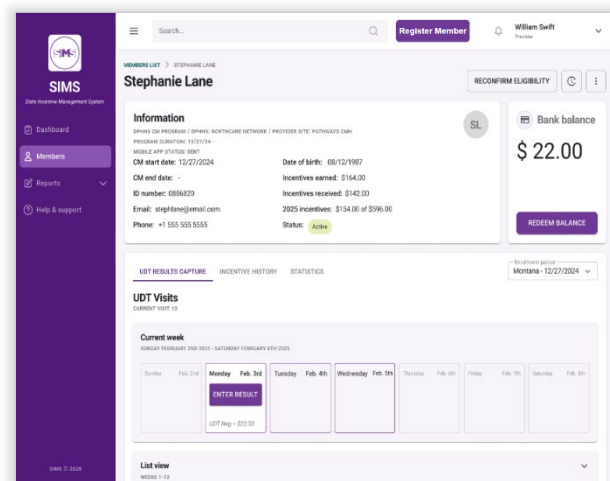
Section 5: Member Chart Overview

5.1 Chart Header

- **Member Name** — Displayed prominently as a breadcrumb from the Member list.
- **Reconfirm Eligibility** — Must be clicked once per month per active member (see Section 6).
- **Refresh Icon** — Reloads chart data.
- **Three-Dot Menu (:)** — Access to Edit Member and other actions.

5.2 Information Panel

- **CM Start / End Date** — Program enrollment dates.
- **ID Number** — Internal SIMS ID.
- **Email / Phone** — Contact details for gift card delivery.
- **Date of Birth** — Member's date of birth on file.
- **Incentives Earned / Received** — Totals to date.
- **2025 Incentives** — Year-to-date out of annual maximum (e.g., \$100.00 of \$599.00).
- **Status** — Active, Completed, or Dis-enrolled.



5.3 Bank Balance Panel

- Displays the member's current unredeemed reward balance.
- Click "**Redeem Balance**" to process a redemption and initiate gift card delivery.
- Enrollment period is shown below the balance.

5.4 Tabs

- **UDT Results Capture** — Log UDS visit results (primary day-to-day tab). See Section 8.
- **Incentive History** — Full log of all incentives. See Section 13.
- **Statistics** — Participation trends and totals for reporting.

5.5 List View

Located at the bottom of the chart — a chronological table of all UDS visits: visit number, date, result, and incentive amount.

⚠ Note: Use the enrollment period dropdown (top-right of the chart) to switch between program periods for members with multiple enrollment cycles.

Section 6: Member Pane & Eligibility Reconfirmation

Every 30 days, CM Coordinators must attest to each member's continued eligibility for the program.

6.1 How It Works

- Navigate to the **Member's Pane** (the member's individual chart).
- Locate the **"Reconfirm Eligibility"** section in the top-right of the screen.
- The system has a built-in **30-day countdown** to the next required attestation.
- The system will allow attestation starting **14 days after the last attestation**, giving a 16-calendar-day window to complete it.

6.2 Completing the Reconfirmation

Eligibility reconfirmation is required every 30 days to maintain an active enrollment. When the reconfirmation window opens (within 16 days of the due date), a Reconfirm button will appear on the member's record.

What attesting means by site type:

- **SOR Sites** — Clicking Reconfirm attests that the member remains eligible under SOR. If the member is StimUD Primary, it also attests Medicaid eligibility when applicable.
- **Medicaid Sites** — Clicking Reconfirm attests that the member remains eligible for Medicaid. Only StimUD Primary members may be enrolled and reconfirmed at these sites.

Note: Attesting reconfirmation confirms the member is eligible for Medicaid or SOR depending on their site type. For SOR-awarded sites, this attestation applies to SOR eligibility and, where applicable, Medicaid eligibility as well.

Steps to complete:

- When the Reconfirm button becomes available, click it. No additional action is required — clicking the button completes the attestation.
- If the reconfirmation window is missing or prevents you from proceeding with testing for the member, contact your supervisor or SIMS Support.

MEMBERS > JANE DOE

Jane Doe

RECONFIRM ELIGIBILITY

Information

MONTANA TRAINING PROGRAM / PROVIDER SITE: SIMS PRACTICE SITE / PROVIDER: JORGE ARRIETA
PROGRAM DURATION: 03/31/2026 -

CM start date: 03/31/2026

Date of birth: 03/15/2000

CM end date: -

ID number: 91898447

Email: Jane.doe@gmail.com

Phone: +1 4444444444

Program type:

STIM

Treatment plan:

2 CM Visit weekly for 12 weeks

Bank balance

\$ 0.00

REDEEM BALANCE

CM VISIT

INCENTIVE HISTORY

Enrollment period
Montana Training Prog...

SET VISIT DATE

Visits

CURRENT VISIT 4 - WEEK 2

⚠ Note: This must be completed for every active member on your caseload. Failure to reconfirm eligibility on time may affect the member's ability to earn incentives.

Section 7: Reward Calculator

The SIMS system automatically calculates the correct incentive award for each UDT visit based on that week's unique methodology.

7.1 How Rewards Are Calculated

- Navigate to the **Member Pane** and open the **UDT Results Capture** tab.
- Follow the instructions for inputting the appropriate result (UDT result or absence).
- The system will **automatically calculate the correct incentive award** in advance of UDT input — the amount is displayed before you confirm.
- Rewards are calculated for that particular visit given **that week's unique methodology**.

7.2 When Rewards Are Available

- If the UDT input is **negative**, the reward will be **immediately available** for dispense after entry.
- If the UDT input is positive or an absence is logged, no reward is generated for that visit.

The screenshot displays the SIMS web application interface. On the left is a purple sidebar with the SIMS logo and navigation links: Dashboard, Members (selected), Reports, and Help & support. The main content area has a top header with a search bar, a 'REGISTER MEMBER' button, and the user's name 'William Swift' with a dropdown arrow. Below the header, the 'MEMBERS LIST' section shows 'STEPHANIE LANE' selected. The member's profile for 'Stephanie Lane' is displayed, including a 'RECONFIRM ELIGIBILITY' button and a 'Bank balance' of '\$ 22.00' with a 'REDEEM BALANCE' button. The 'Information' section lists details: DPHHS CM PROGRAM / DPHHS: NORTHCARE NETWORK / PROVIDER SITE: PATHWAYS CMH, PROGRAM DURATION: 12/27/24, MOBILE APP STATUS: SENT, CM start date: 12/27/2024, CM end date: -, ID number: 0886820, Email: stephanlane@email.com, Phone: +1 555 555 5555, Date of birth: 08/12/1987, Incentives earned: \$164.00, Incentives received: \$142.00, 2025 incentives: \$154.00 of \$596.00, and Status: Active. Below this is the 'UDT RESULTS CAPTURE' section with tabs for 'UDT RESULTS CAPTURE', 'INCENTIVE HISTORY', and 'STATISTICS'. The 'UDT Results Capture' tab is active, showing 'CURRENT VISIT 13' and an 'Enrollment period' of 'Montana - 12/27/2024'. A 'Current week' calendar for 'SUNDAY FEBRUARY 2ND 2025 - SATURDAY FEBRUARY 8TH 2025' is shown, with 'Monday Feb. 3rd' highlighted and an 'ENTER RESULT' button. Below the calendar, it shows 'UDT Neg = \$22.00'. At the bottom, there is a 'List view' section for 'WEEKS 1-12'.

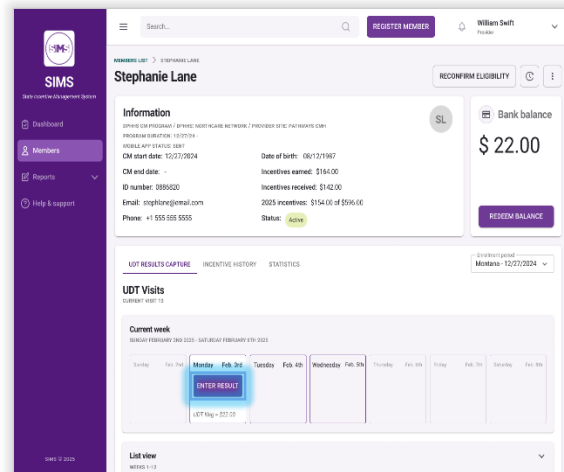
- **⚠ Note:** Reward amounts may vary by visit based on program-specific escalation or de-escalation schedules. Always refer to the system's displayed amount — do not calculate manually.

Section 8: Entering UDT Results

This section covers the full step-by-step process for logging a UDS (Urine Drug Screen) result in SIMS, including selecting the result type, UDT cup, analytes, and handling invalid samples.

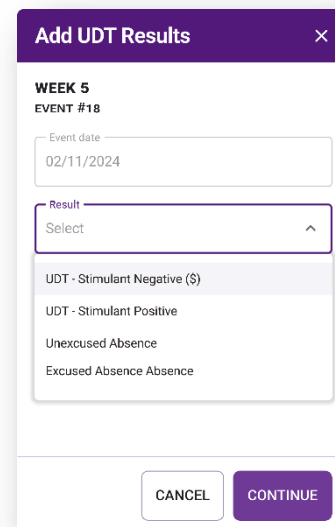
8.1 Finding the Next Available Session

- On the Member Pane, open the **UDT Results Capture** tab.
- Identify the next available session — this is the **"Enter UDT Result"** button that is **not grayed out**.
- Other session buttons will not respond when clicked as they are locked to prevent out-of-sequence entry.



8.2 Selecting the Result

- Click the active **"Enter Result"** button. Note: the text will change to the selected result after submission.
- From the dropdown list, select the relevant option:
- **UDT – Stimulant Negative (\$)** — if the UDT was negative for stimulants (generates reward)
- **UDT – Stimulant Positive** — if the UDT was positive for stimulants (no reward)
- **Excused Absence** — see Section 11
- **Unexcused Absence** — see Section 11.

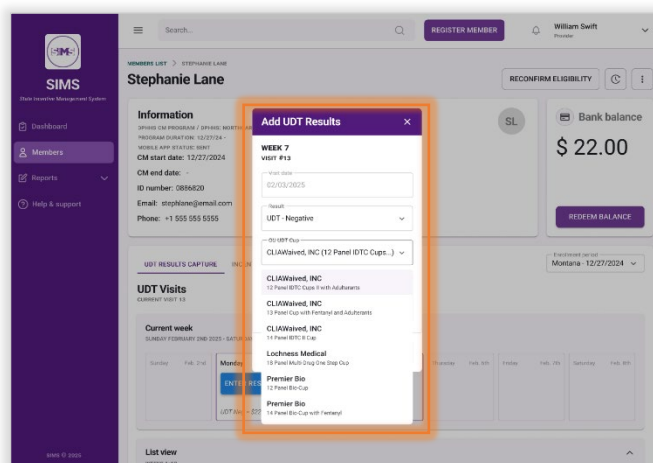


Note: UDT results can only be input at least 48 hours after the previous input. This is enforced automatically by the system.

8.3 Confirming the UDT Cup

Before submitting either a Stimulant Negative or Stimulant Positive result, you will be asked to confirm which DPHHS-approved UDT cup was used:

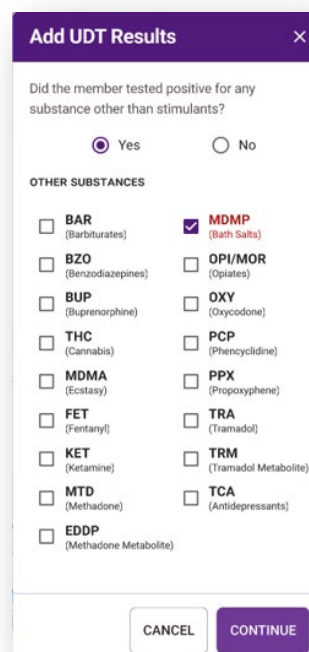
- The system defaults to your site's standard UDT cup on file.
- If you are using a different approved cup, select the correct one from the dropdown menu.
- You will be prompted to **confirm the Member's Date of Birth** — ask the member and enter it.
- Select the **Radio Button** to confirm the information is correct.
- Select **"Yes"** to proceed if certain of your input, or **"No"** to re-input your selection.



8.4 Analytes Selection

Only Stimulant Negative UDTs generate incentive rewards. After entering the result, you will be asked about other substances:

- You will be asked: *"Did the member test positive for any substance other than stimulants?"*
- If **No**: proceed directly to submission.
- If **Yes**: select which additional substances the member tested positive for from the checkboxes (BAR, BZO, BUP, THC, FET, KET, MTD, EDDP, MDMP, OPI/MOR, MDMA, OXY, PCP, PPX, TRA, TRM, TCA, etc.).
- The specific substances displayed are based on the DPHHS-approved UDT cup your site is using.



Note: Please provide appropriate praise for stimulant-negative UDT results and encouragement in the case of stimulant-positive UDT, as directed by DPHHS.

8.5 Invalid Samples

A UDT sample may be invalid for one or more of the following reasons:

- Temperature not within range
 - pH
 - Specific Gravity
 - Creatinine
 - Other (free-text explanation required)
- To mark a sample as invalid, check the **"Invalid Sample"** checkbox in the Add UDT Results modal.
 - Select the applicable reason(s) from the **Invalid Reasons** dropdown. More than one reason can be selected.
 - **Invalid UDTs are treated as Stimulant Positive UDTs** and should be documented with all associated reasons.

Add UDT Results ✕

Week 2 ☒ Invalid Sample

VISIT #4

Visit date

Result *

Cup *

Invalid Reasons

☒ Temperature ✕ ▲

Temperature

Creatinine

Specific Gravity

pH

Other (Please explain)

CANCEL **CONTINUE**

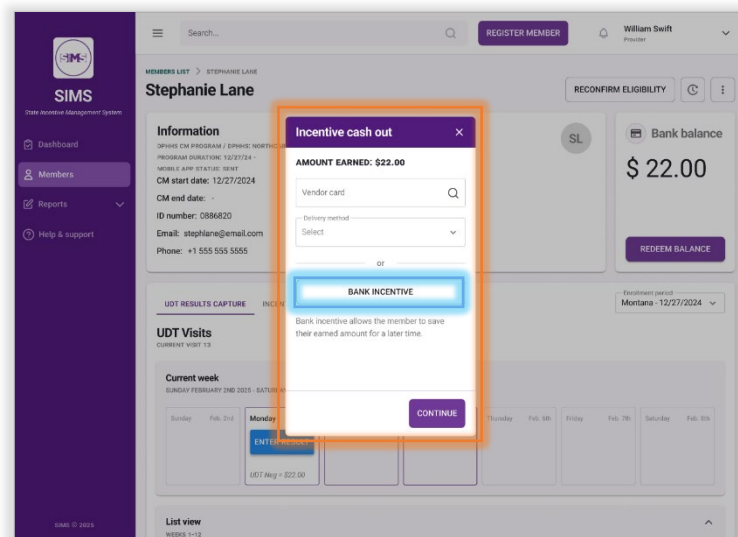
⚠ Note: Always document the specific reason for an invalid sample accurately. This information is used in program reporting and member records.

Section 9: Reward Type Selection & Rewards Bank

9.1 Reward Type Selection

Only once a Stimulant Negative UDT is input will the system offer the reward type selection:

- CM Coordinators will work with the member to select their preferred vendor.
- There are **2 options**:
 - **Gift card for a specific vendor** — Search for and select the desired vendor from the Vendor Card search field.
 - **Bank Incentive (Rewards Bank)** — Save the amount earned to the member's rewards bank for later use.
- Simply click the preferred option and proceed to the delivery type selection (see Section 10).



9.2 Rewards Bank

Rewards can be "banked" or saved if the member chooses not to redeem immediately:

- If the member chooses not to redeem the reward immediately, earnings can be saved in the rewards bank.
- To select banking, click the **"Bank Incentive"** button. This saves the amount to the member's bank balance.
- Once banked, rewards can be converted into gift cards **at any time** by clicking **"Redeem Balance"** on the member's chart.
- Clicking Redeem Balance will return you to the vendor selection screen to choose the gift card. The entire banked amount can only be redeemed for one vendor.

Note: Banked rewards accumulate in the Bank Balance panel on the Member Chart. The member can choose to redeem banked rewards at any future visit. Please remind member each time that they bank incentives that when the redeem it, it must all be applied to single reward (vendor card) type.

Section 10: Reward Delivery

10.1 Delivery Type Selection

Once a reward type (vendor card) is selected, the system will offer the delivery type option:

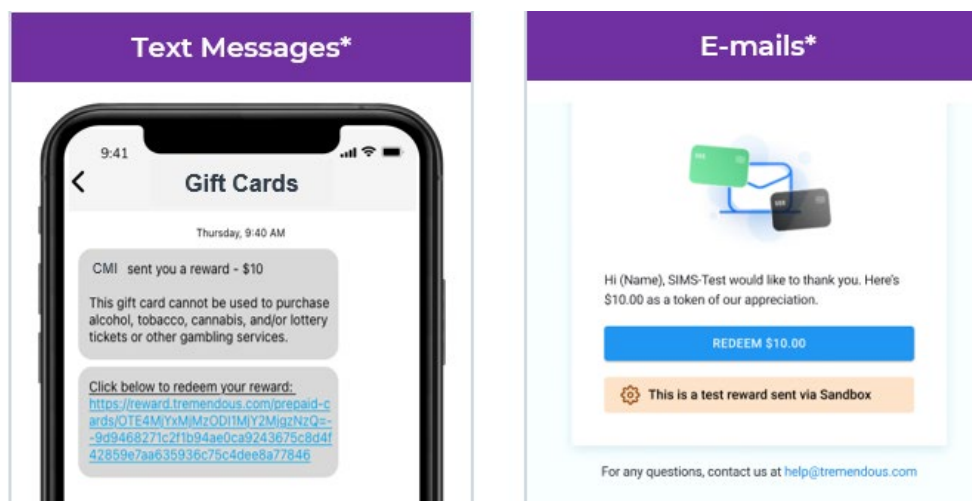
- **Email** — Gift card is sent to the member's email address on file. Member must provide email if not on file.
- **Text (SMS)** — Gift card is sent via text message. Member must provide their phone number.
- **Print** — Gift card is printed in the office immediately.
- For "**banking**" of rewards, this delivery type screen will not appear.
- Text and email gift cards can be added to Apple or Google Wallets by the member.

The screenshot displays the SIMS (State Incentive Management System) interface. On the left is a purple sidebar with the SIMS logo and navigation links: Dashboard, Members, Reports, and Help & support. The main content area shows the profile for Stephanie Lane, including her information (DOB, program duration, mobile app status, CM start/end dates, ID number, email, and phone) and a section for UDT Visits. A modal titled 'Incentive cash out' is open, showing 'AMOUNT EARNED: \$22.00'. It has a 'Vendor card' dropdown set to 'Walmart (ATF Restricted)', a 'Delivery method' dropdown with options 'Email', 'Text (SMS)', and 'Print', and a 'CONTINUE' button. On the right side of the main interface, there is a 'Bank balance' section showing '\$ 22.00' and a 'REDEEM BALANCE' button. The bottom of the screen shows a 'List view' of weeks.

10.2 Emailing and Texting Rewards

Gift cards will be delivered from the same address/number each time:

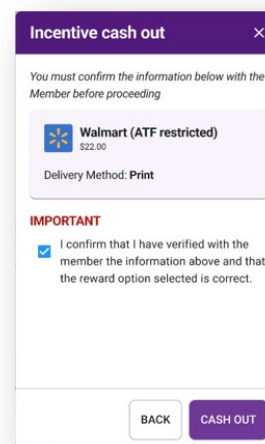
- **Text messages** come from the same number every time — recommend the member save this contact.
- **Emails** come from CMI via Tremendous (rewards@tremendous.com) — recommend the member save this contact.
- The member can use the code in the email or add it to their Apple or Google Wallet.



10.3 Printing Rewards — Confirmation

Rewards are available for printing in the office immediately after they are earned:

- Once **"Print"** is selected as the delivery method, a confirmation screen appears.
- Review the vendor (e.g., Walmart ATF restricted) and delivery method with the Member.
- Check the **confirmation checkbox**: *"I confirm that I have verified the information above and that the reward option selected is correct."*
- Click **"Cash Out"** to proceed. Click **"Back"** to go back and change the selection.



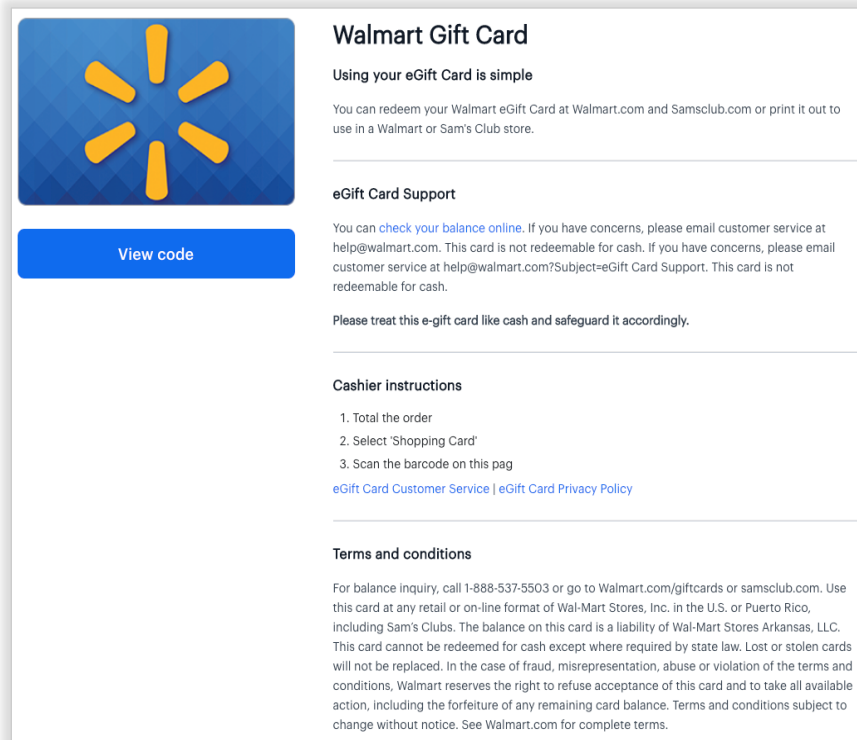
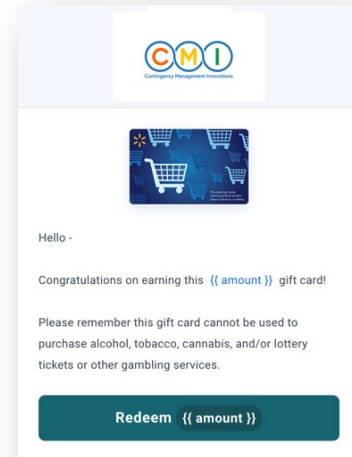
⚠ Note: Printed cards CANNOT be re-printed within the system. Once generated, the member must keep track of these rewards. It is highly recommended that all members provide an email address, as they will receive a copy of any printed card they earn.

[Screenshot: CMI redeem screen with "Redeem" button, and Walmart gift card page with "View code" and cashier instructions]

10.4 Printing Rewards — Redeem Process

The portal will route you to a new tab in your browser:

- Click the **"Redeem"** button on the CMI screen.
- Click **"View code"** on the subsequent screen.
- Click **"Open redemption page"** to access the full printable version.
- Print the resulting screen for the member to use at the vendor.



Section 11: Managing Absences

In addition to logging UDT results, CM Coordinators can log absences — excused or unexcused — for sessions where a member did not provide a sample.

11.1 Types of Absences

- **Unexcused Absence** — Activates a program "reset" (escalation/de-escalation counter resets).
- **Excused Absence** — Does NOT activate a reset, but has strict eligibility criteria.

11.2 Criteria for an Excused Absence

Excused absences can only be logged if ALL of the following are true:

- The member informed you **in advance** of the absence.
- There is a **valid reason** for the absence.
- The member presents **valid documentation** supporting the absence at the next visit.

Note: The member can miss a **maximum of 2 CM visits in a row before a reset occurs.**

11.3 Logging an Absence

- Selections are made in the same way as UDT results — click the **"Enter Result"** button on the appropriate session.
- From the dropdown, select either **"Excused Absence"** or **"Unexcused Absence"**.
- Click **"Continue"** to proceed.

The screenshot shows the SIMS (State Inmate Management System) interface. A modal titled "Add UDT Results" is open, displaying "WEEK 7 VISIT #13". The modal includes a "Visit date" field set to "02/03/2025" and a "Result" dropdown menu. The dropdown menu is open, showing four options: "UDT - Negative", "UDT - Positive", "Excused Absence", and "Unexcused Absence". Below the dropdown are "CANCEL" and "CONTINUE" buttons. The background interface shows the member's information for Stephanie Lane, including her ID number (0886820), email (stephane@email.com), and phone number (+1 555 555 5555). It also displays a calendar for February 2025, a bank balance of \$22.00, and a "REDEEM BALANCE" button.

11.4 Submitting Excused Absences — Adding a Note

- After selecting Excused Absence and clicking Continue, you will be asked to **input a note**.
- The note should capture the **reasoning behind the excused absence** (up to 100 characters).
- On the **subsequent visit**, you will be asked to confirm that documentation was provided to support the reasoning.
- **You must also track this information in your EHR.**

The screenshot shows a mobile application interface for adding visit results. The title bar is purple with the text 'Add CM Visit Results' and a close icon. The form is titled 'Week 1 VISIT #2'. It has a 'Visit date' field with the value '04/23/2026'. Below that is a 'Result*' dropdown menu with 'Excused Absence' selected. At the bottom of the form is a 'Notes*' text area containing the text 'Member called ahead requesting an excused absence due to a medical appointment, unable to reschedule'. A character count '100/100' is visible at the bottom right of the text area. At the very bottom of the form are two buttons: 'CANCEL' and 'CONTINUE'.

11.5 Confirming Excused Absences at the Next Visit

At the next visit after an excused absence, the system will prompt you to confirm:

- If the member **provides adequate documentation**: confirm by leaving the "Change to Unexcused Absence" box unchecked and click "**Submit**".
- If the member **does not provide documentation**: check "**Change to Unexcused Absence**" and click Submit. This will convert the prior entry to an unexcused absence and activate a reset.

The screenshot shows a mobile application interface for confirming an excused absence. The title bar is purple with the text 'Confirm excused absence' and a close icon. The form is titled 'WEEK 5 VISIT #18' with a date of '06/13/2024'. It asks the user to 'Please add the confirmation of the previous excused absence.' Below this is a 'Notes' text area with a character count '0/100'. A message states: 'If you select "Unexcused Absence" the prior result will be changed to "Unexcused Absence"'. Below this message is a checkbox labeled 'Change to Unexcused Absence', which is currently unchecked. At the bottom of the form are two buttons: 'CANCEL' and 'SUBMIT'.

⚠ Note: Only 2 excused absences are allowed in a row before a 3rd incurs a reset. Unexcused absences always activate a reset.

Section 12: Missed Entries & Corrections

12.1 Missed Entries — Weeks 1–12

- CM Coordinators must make **2 entries per week per member** (for M-W or W-S visits). You must log unexcused absences on the day the absence occurred.
- If you do not do this, the system will **automatically create an absence entry** for that visit.
- On the subsequent visit, the system will prompt you with the same screen as confirming absence type (excused or unexcused).
- If no entries are made in a week, they will be assumed as **unexcused absences**.

⚠ Note: Document visits and absences actively daily. This automatic entry is necessary to ensure that the portal calculates visits and incentives accurately. Good clinical practice mandates that providers complete documentation in a timely manner on the day that a visit or absence occurs.

12.2 Incorrect Entries — How to Correct

- **Entered Positive UDT when intended Negative:**
 - Keep the member in the office
 - Call the call center immediately
 - Ideally corrected within minutes; worst case within 24–48 hours
 - The reward will be placed in the rewards bank if corrected after dispense
- **Entered Negative UDT when intended Positive:**
 - Keep the member in the office
 - Do NOT generate a gift card
 - Call the call center
 - Ideally corrected within minutes; worst case 24–48 hours
- **Entered wrong type of absence:**
 - Correct upon the subsequent visit using the Confirm Excused/Unexcused absence screen (see Chapter 11.5)
 - If already confirmed in error, call the call center.
 - Ideally corrected within minutes; worst case 24–48 hours
- **Entered unexcused absence because client no-showed, but they call afterward and asked to reschedule for an allowable contiguous day:**
 - Keep the member in the office
 - Call the call center immediately
 - Ideally corrected within minutes; worst case within 24–48 hours
 - The reward will be placed in the rewards bank if corrected after dispensing

⚠ Note: When in doubt about an incorrect entry, contact the call help desk immediately and keep the member present if possible. Do not generate a gift card until the correction is confirmed.

Section 13: Rewards History

13.1 Accessing Rewards History

- Open the member's chart (see Chapter 3).
- Click the **"Incentive History"** tab at the top of the UDT/Incentive section.

The screenshot displays the SIMS (State Incentive Management System) interface. The sidebar on the left contains navigation links: Dashboard, Members, Reports, and Help & support. The main content area shows the member's profile for William Swift, including ID number, email, phone, and status (Active). A summary of incentives received is shown: \$142.00 total, with 2025 incentives totaling \$154.00 of \$596.00. A 'REDEEM BALANCE' button is visible. Below this, the 'INCENTIVE HISTORY' tab is selected, displaying a table of transactions. The table has columns for Timestamp, Transaction, Value, and Provider. The transactions include Bank redeem, Earned & banked, Visit cashed out, and Full redeem, with values ranging from -\$10.00 to +\$11.50. A 'GIFT CARD LINK' button is present next to the 'Visit cashed out' transaction. The footer indicates 'Rows per page: 10' and '1.5 of 13'.

Timestamp	Transaction	Value	Provider
01/04/2025 09:01h	Bank redeem	-\$17.50	William Swift
01/03/2025 09:01h	Earned & banked	+\$13.00	William Swift
01/02/2025 10:01h	Earned & banked	+\$11.50	William Swift
01/02/2025 09:02h	Visit cashed out GIFT CARD LINK	-\$10.00	William Swift
01/02/2025 09:01h	Earned	+\$10.00	William Swift
12/20/2024 09:01h	Earned & banked	+\$10.00	William Swift
12/18/2024 09:01h	Full redeem	-\$23.50	William Swift
12/09/2025 09:01h	Visit cashed out	-\$10.00	William Swift
12/04/2025 09:01h	Earned	+\$10.00	Jane Doe
12/01/2025 09:01h	Reverse	+\$10.00	William Swift

13.2 What History Shows

Rewards history can be seen in two ways:

- **Comprehensive list of every reward earned:**
- Timestamp — when the transaction occurred
- Transaction — type of event (Earned, Earned & Banked, Bank Redeemed, Full Redeem, Gift Card Link, Reverse)
- Value — dollar amount (green = credit, red = debit)
- Provider — who processed the transaction
- **Summary of results earned in total:**
- Total earnings across the program period
- Percentages of sessions with negative UDT

Section 14: Appropriate Disclaimers

CM Coordinators must be aware of and communicate the following restrictions regarding incentive rewards.

14.1 Restricted Uses for Incentive Rewards

Incentive rewards **cannot** be used for the following:

- Intoxicants (e.g., alcohol)
- Tobacco/nicotine products
- Over-the-counter preparations containing possible intoxicants (e.g., dextromethorphan)
- Gambling-related items (e.g., lottery tickets)
- Pornographic materials
- Cannabis
- Pornographic Materials
- Weapons

14.2 Vendor Card Restrictions

- Vendor-specific gift cards are either for vendors who do not offer these restricted items, OR have inherent system restrictions built in.
- Incentive rewards **cannot be re-distributed** once already delivered.
- The required verbal disclaimer to members when delivering a gift card: *"Please remember this gift card cannot be used to purchase alcohol, tobacco, cannabis, and/or lottery tickets, weapons, or other gambling services including lottery tickets."*
- Walmart gift cards additionally restrict the purchase of **firearms or ammunition**.

⚠ Note: Always read the appropriate disclaimer to the member at the time of reward delivery. This is a required step in the reward distribution process.

Section 15: Reports Pane

15.1 Accessing Reports

- Click "**Reports**" in the left-hand navigation panel.
- Two report types are available: **Provider report** and **Member's report**. Select via the sub-menu.
- Reports are available at all levels applicable to your role (see access rights).

15.2 Provider Report

- Provides data at the **provider/coordinator level**.
- Filterable by: Program, Site, Provider, Provider NPI, and Date of Service range.
- Columns include: Provider NPI, Role, Start Date, PDHP, Provider Site, # of Visits, # of Neg, Total Pos, Total Neg, Total Exc., Total Unex., Missed Entries, Incentives Generated, Incentives Disbursed.

15.3 Member Report

- Provides data at the **individual member level** across your caseload.
- Filterable by: Program, Site, Provider, Provider NPI, Member CIN, and Date of Service range.
- Columns include: Name, CIN, Site, Provider, Enrollment NPI, Enrollment Period, Status, Total Neg, Total Pos, Absences, Incentives Earned, Incentives Received, Bank Balance.

SIMS
State Insurance Management System

Dashboard
Members
Reports
Provider report
Member's report
Help & support

Search... REGISTER MEMBER William Swift Provider

Provider report

DOWNLOAD EXCEL DOWNLOAD PDF

Program: Program 1 Site: Pathways CMH Provider: Provider NPI: Date of service from: Select

Date of service to: Select RUN REPORT

Provider name	NPI	Role	Start date	PDHP	Provider site	# of benef	# of visits	Total Neg	Total Pos	Total Exc.	Total Unex.	Missed entries	Incentives generated	Incentives disbursed
William Swift	939203456A	Provider	03/15/23	Northern Pathways Network	CMH	22	143	104	22	3	17	3	\$1,231.00	\$1,612.00
John Smith	2010302720	CM coordinator	12/01/23	Northern Pathways Network	CMH	23	145	105	23	4	16	3	\$1,235.00	\$1,615.00
Jane Wilson	944080293C	CM supervisor	06/01/23	Northern Gogebic Network	CMH	1	2	2	0	0	0	0	\$98.00	-
Jane Wilson	962402593F	CM supervisor	11/01/23	Northern Pathways Network	CMH	2	4	3	1	0	0	0	\$99.00	\$276.50
Jane Doe	412839289G	Provider	05/01/23	Northern Pathways Network	CMH	2	5	2	1	0	0	0	\$185.00	\$276.50

Rows per page: 10 1-5 of 5

15.4 Running and Downloading a Report

- Set the desired filters using the dropdown menus.
- Click "**Run Report**" to generate the data.
- Click "**Download Excel**" to export as an .xlsx file, or "**Download PDF**" to export as a .pdf.
- Once downloaded, open the file in Excel or your PDF viewer to review the contents.

⚠ Note: Reports are compiled automatically by the system and are always current. Run reports regularly to monitor member engagement, incentive disbursement, and missed entries.

Quick Reference Guide

Use the table below as a fast reference for the most common CM Coordinator tasks in SIMS.

Task	Where to Go	Key Action
Register a new member	Members → Register Member	Complete General Info + SIMS Info tabs, click Register
Resolve a double entry error	Members → Search bar	Search name/MRN → open existing chart; contact Support if needed
Find an existing member	Members → search or sort list	Click the underlined member name to open their chart
Edit member information	Member Chart → : → Edit Member	Update fields and click Save
Reconfirm member eligibility	Member Chart → Reconfirm Eligibility button	Click once per month per active member (within 16-day window)
Enter a UDT result	Member Chart → UDT Results Capture tab	Click "Enter Result" on active session, select result type
Select reward type	After entering Neg UDT → Incentive cash out modal	Choose vendor card or Bank Incentive
Bank a reward	Incentive cash out modal → Bank Incentive	Click Bank Incentive to save to rewards bank

Task	Where to Go	Key Action
Redeem banked rewards	Member Chart → Redeem Balance	Click Redeem Balance and select vendor
Select delivery method	Incentive cash out → Delivery method	Choose Email, Text (SMS), or Print
Print a reward	Delivery method: Print → Confirmation → Cash Out	Confirm details, check box, click Cash Out, then Redeem on browser tab
Log an excused absence	Member Chart → UDT Results Capture → Enter Result	Select Excused Absence, add note on next screen
Log an unexcused absence	Member Chart → UDT Results Capture → Enter Result	Select Unexcused Absence
Correct an incorrect entry	Call center immediately	Call center; keep member present; correction made within 24–48 hrs
View incentive history	Member Chart → Incentive History tab	Review transaction log: date, type, value, provider
Run a provider report	Reports → Provider report	Set filters, click Run Report, Download Excel or PDF
Run a member report	Reports → Member's report	Set filters, click Run Report, Download Excel or PDF

Chapter 8. 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 MT HEART CM Program, it is important to follow established criteria to identify eligible members. These criteria can be found in the [HEART Waiver – Contingency Management \(CM\) Policy 615](#) (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.

Program Roles, Supervision, Fidelity, and Evaluation

Once you have set up your CM Program using the instructions provided in this Manual, MT DPHHS policy documents ([HEART Waiver – Contingency Management \(CM\) Policy 615](#), 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 MT DPHHS 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, MT DPHHS 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 pursuant to Montana Medicaid Manual by DPHHS Policy 615. For the MT HEART CM 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. Other staff involved with CM protocols should have their roles clearly defined, as well. UCLA has also set up a [website](#) for consultation and questions.

- The only staff members who can administer CM are the CM Coordinator, the Back-up CM Coordinator, and the CM Supervisor. A CM Team Member may be a Licensed Addiction Counselor (LAC) and/or Mental Health professionals with SUD specific scope and training (ex: LCSW, LPC); or trained staff with appropriate supervision by licensed behavioral health professionals.

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 3-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 D for a visual flow chart of the CM Team Requirements for completing all training required by the Program.
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 [HEART Waiver – Contingency Management \(CM\) Policy 615](#) (Appendix D) 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 MT HEART CM 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 MT HEART CM 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 MT HEART CM 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). The specific documentation required should be negotiated before the absence when the member calls to inform staff of the upcoming absence.

- **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 the visit occurs at least 48 hours after their last test was entered. 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 at the 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 do they get to ‘make up’ the missed appointment, though their previously earned 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 Healing and Ending Addiction through Recovery and Treatment (HEART) Demonstration: Montana’s Contingency Management Program 2-Part 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 the required 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 MT DPHHS standards and the rules and

regulations of the MT HEART CM 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, as is completion of three practice cases in the IM Portal Sandbox environment. The Readiness Assessment process includes:

- Entering practice cases into the IM Portal to demonstrate proficiency with these tools.
- Interactive demonstration of procedures and site-specific implementation goals.
- 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 D for a visual flow chart of the CM Team Requirements for completing the Readiness Assessment process.

Evaluation

The MT HEART CM Program is being evaluated by The Rural Institute at the University of Montana. Questions can be directed to Patrick Boise, MA, Health Economist (patrick.boise@mso.umt.edu).

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.

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 MT DPHHS-approved CM protocol. For the purpose of the MT DPHHS contingency management benefit authorized under the 1115 HEART Waiver demonstration:

For purposes of this demonstration, these motivational incentives are a covered item or service and are used to reinforce objectively verified recovery behaviors using a clinically

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

² Ibid.

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 (CMP) provision prohibiting inducements to beneficiaries (42 U.S.C. 1320a-7a(a)(5), “Beneficiary Inducements CMP”) would be implicated.

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

Chapter 9. Communicating with Members about the MT HEART CM Program

Member Outreach

MT DPHHS recognizes that effective outreach and marketing strategies will increase the likelihood that eligible members will learn about the MT HEART CM Program. MT DPHHS' goal in offering CM is to ensure that eligible MT Medicaid and SOR Grant 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 MT HEART CM 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 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 per Policy 615	✗ 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 MT DPHHS' CM protocol	✗ Suggest that CM incentives are conditioned on members receiving services beyond those required under MT DPHHS' CM protocol

DO	DON'T
✓ Emphasize that CM is a new and exciting option under the MT HEART Waiver 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 if all communications are accurate and are not misleading or coercive. As a component of the 2-part Implementation Training, CM Teams will discuss outreach strategies.

Additional Resources

MT DPHHS Contingency Management Policy Website:

<https://dphhs.mt.gov/HeartInitiative/ContingencyManagement>

UCLA MT HEART CM Program Training and Implementation Support Website:

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

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Date Last Updated: July 27, 2026.

Appendix A

Sample Member Consent Form

Appendix A

Healing and Ending Addiction through Recovery and Treatment (HEART) Demonstration: Montana's Contingency Management Program (MT HEART CM Program) Sample Member Consent Form/Agreement

NOTE: This template is provided as a guide to counties and treatment provider sites participating in the Healing and Ending Addiction through Recovery and Treatment (HEART) Demonstration: Montana's Contingency Management Program. This consent form is specific to the MT HEART CM Program and is not meant to replace existing consent forms in place for the member's enrollment/participation in other non-CM treatment services. Agencies should adapt this content to fit within the parameters of existing member consent forms/agreements, including state/agency-specific branding, logos, and letterheads, and larger font size and spacing to meet accessibility standards.

I understand that the goal of the MT HEART CM 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 MT HEART CM Program, I may only be enrolled in ONE stimulant-specific contingency management program.

I have participated in a CM program previously? Yes/No

If yes, when did you participate? _____

If yes, what provider were you working with? _____

If yes and the date was within the current calendar year, your current CM provider will need to confirm the amount that you received during the previous protocol and note that here. _____ This may impact the amount you are eligible to receive during this CM protocol cycle.

2. I confirm that I am not currently enrolled in a residential treatment program, adult foster care (AFC), acute inpatient hospital, or behavioral health group home (BHGH).
3. During my enrollment in the MT HEART CM Program, I will notify the program site if I am admitted into a residential treatment program, adult foster care (AFC), acute inpatient hospital, or behavioral health group home (BHGH).
4. I understand that I am ineligible to participate in the MT HEART CM Program while I am enrolled in a residential treatment program, adult foster care (AFC), acute inpatient hospital, or behavioral health group home (BHGH). However, I may be eligible to resume participation in the MT HEART CM Program on the same date that I am discharged from a residential treatment program, adult foster care (AFC), or behavioral health group home (BHGH).
5. I can start the MT HEART CM Program at any time. 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).
6. I may come to the clinic more often to participate in other treatment services, and these visits will not involve submitting a urine sample for a MT HEART CM Program UDT.

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7. Participation in the MT HEART CM Program is voluntary, and I can discontinue at any time. Leaving the MT HEART CM 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 MT HEART CM 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 following the provision of a stimulant-negative UDT.
10. For the first two stimulant-negative UDTs, the incentive payment will be worth \$14. If I provide two stimulant-negative UDTs in a row, the incentive payment will increase to \$16. The value of the incentive payment will keep increasing by \$2 for every two times I provide stimulant-negative UDTs. The highest amount an incentive payment can reach for an individual test is \$36.
11. If all tests are stimulant-negative over 12 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 MT HEART CM Program.
12. 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 MT HEART CM Program staff even if I disagree with the results.
13. If I submit a stimulant-positive UDT, the incentive payment will return to \$14 the next time I provide a stimulant-negative UDT. After the second stimulant-negative UDT I provide following a stimulant-positive UDT result, I will return to the incentive payment amount I achieved prior to the stimulant-positive UDT result and I will continue to earn increases each time I test negative for stimulants two times in a row.
14. 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 even if they are a result of one of these medications and no incentive will be given. 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.
15. I agree to inform MT HEART CM staff if I am taking a prescription stimulant medication. Taking prescription stimulant medications will cause my UDTs to always be positive for stimulants. I understand that UDTs with stimulant-positive results caused by prescription stimulant medication are not eligible for incentive payment and that taking a prescription stimulant medication will make me ineligible for the MT HEART CM Program.
16. 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.
17. For unavoidable absences (e.g., a doctor appointment, illness, funeral, etc.), I will reschedule my UDT visit on a contiguous day if 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

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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 \$14.

18. 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 an unexcused absence.
19. If I do not submit a urine sample or have an unexcused absence from the clinic, it will be treated the same as a stimulant-positive UDT result, as outlined in paragraphs 12 and 13, above. It will not negatively affect any other treatment services I am receiving or are eligible to receive.
20. I understand that I will be considered to have dropped out of the contingency management program if I am absent from contingency management services for eight or more consecutive unexcused absences.
21. I agree that I will give my own urine for all urine drug tests. I will not tamper with the urine sample. I commit to following the rules and procedures of the MT HEART CM Program.
22. I agree to use the earned incentive payments for my own personal use only. I will not sell or trade any incentive payments. I agree that I will not use incentive payments to purchase alcohol, tobacco, cannabis, gambling products, firearms, or ammunition.
23. I will not enroll in the MT HEART CM Program with more than one treatment provider at a time. I understand that if I am registered with more than one MT HEART CM Program provider, the providers must meet to determine which provider will assume responsibility to continue my treatment.
24. During my enrollment in the MT HEART CM Program, I will not participate in any other contingency management services for treatment of stimulant use disorder.
25. The clinic will collect information about me throughout my participation in the MT HEART CM Program for evaluation and incentive tracking purposes.
26. MT HEART CM Program staff will record my attendance, UDT results, and any incentive payments distributed in an electronic database.
27. My personal and medical information will be protected according to required state and federal privacy and confidentiality regulations (including the Health Insurance Portability and Accountability Act (HIPAA); 42 CFR Part 2; the Montana Government Health Care Information Act; and 50-16-801, MCA, et seq. or the Montana Uniform Health Care Information Act) and will only be shared when medically necessary or with the provider organization; the County; the Department of Public Health and Human Services; UCLA-affiliated staff; CMI-affiliated staff for program payment, monitoring, oversight, auditing, or evaluation purposes; and when required by law.
28. I will be able to submit any feedback about the MT HEART CM Program by emailing HHSBHDDHEARTContingencyMa@mt.gov and Jill.Richards@mt.gov.

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29. I agree to complete evaluation surveys and forms related to my participation in the MT HEART CM Program to help program staff understand how this program helped me and others.

Member Name (Print)

Member Signature

Date

MT HEART CM Program
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 MT HEART CM 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 MT HEART CM Program.

Appendix B
Instructions for Administering Approved UDT Kits

NOTE:

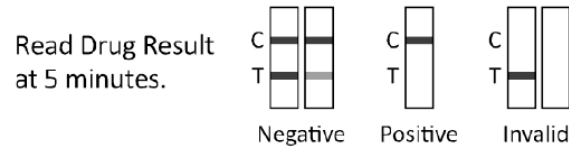
Enclosed files include:

- Tip Sheet for Interpreting UDT Results
- Abbott UDT Package Insert
- CLIAWaived, Inc. 13-Panel UDT Package Insert
- CLIAWaived, Inc. Rapid Test Cup RTC + Fentanyl Package Insert and Procedure Card
- Lochness Medical UDT Package Insert
- Premier Biotech 14-Panel UDT Package Insert

Tip Sheet for Interpreting UDT Results

How to interpret the results for the approved UDT products for the MT HEART CM Program. Additional guidance can be found in the individual package inserts for each product.

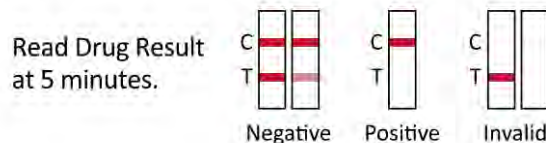
1) Abbott iScreen Urine Test DX Drug Screen Tox Cup [14-panel]



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



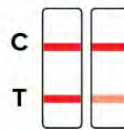
3) CLIAWaived, Inc. Rapid Test Cup “RTC” + Fentanyl [14-panel]



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

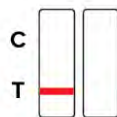


POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.



***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 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.

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



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

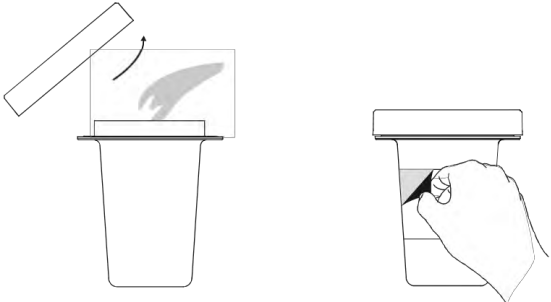
【DIRECTIONS FOR USE】

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).

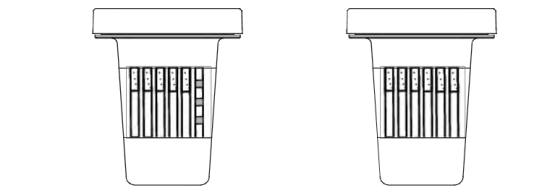
5. Technician dates and initials the security seal and attaches the security seal over the cup cap.
6. Technician peels off label to reveal adulteration strip(s), if applicable.
7. Technician peels off the label on the multi-drug test cup to view results.
8. The adulteration strip(s), if applicable, 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



1. Open the cap and add specimen. Specimen volume must exceed the minimum line.

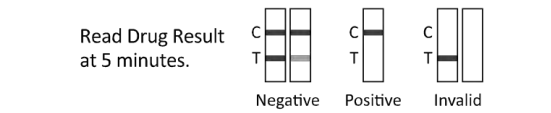
2. Peel off the label to view results



Cup with adulteration

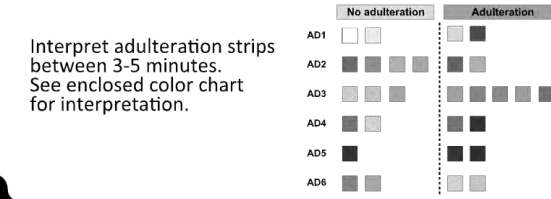
Cup without adulteration

Read Drug Result at 5 minutes.



Negative Positive Invalid

Interpret adulteration strips between 3-5 minutes. See enclosed color chart for interpretation.



AD1 AD2 AD3 AD4 AD5 AD6

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 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)

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%
	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

	BZO 300	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
		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
	COC 150	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
		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
	FTY1	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
		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
	MDMA 500	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
		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
	MET 500	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
		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
	MOP /OPI 300	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
		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
	MTD 300	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	26	24	26	24	25	25

	OXY 100	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
		25ng/ml	50	0	50	0	50	0	50
	PCP 25	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
	TCA 1000	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
		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
	THC 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
		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

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

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Made in China

Number 14602416900
Revision date: 2024-07-24

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-Hydroxylalprazolam	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
Hydroxylalprazolam	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
Dextrometorphan	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!

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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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“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/BUP/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, Methyleneiodoxymethamphetamine, 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
Methylenedioxyamphetamin (MDMA)	d,l-Methylenedioxyamphetamin	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 detectable 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 detectable 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 detectable 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 benzoylcegonine. Benzoylcegonine, 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 detectable 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 detectable 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 detectable 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 detectable level.

Methylenedioxyamphetamin (MDMA)

Methylenedioxyamphetamin (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 Methylenedioxyamphetamin in urine exceeds detectable 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 detectable 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 detectable 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 detectable 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 have 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】

- Immunosay 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

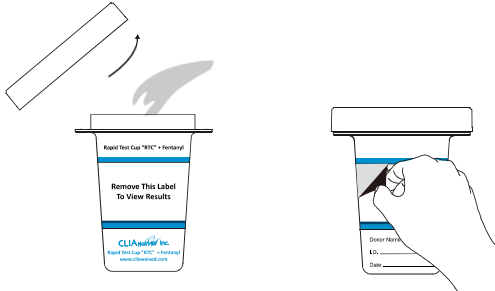
- Specimen Collection Containers
- Timer

【DIRECTIONS FOR USE】

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

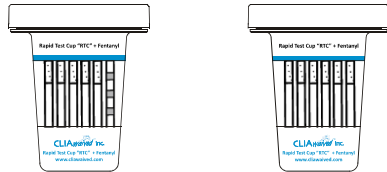
- Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch.
- Donor provides specimen.
- Technician replaces and secures cap while the cup is on a flat surface.
- Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100°F (32-38°C).
- Technician dates and initials the security seal and attaches the security seal over the cup cap.
- Technician peels off label to reveal adulteration strip(s), if applicable.
- Technician peels off the label on the multi-drug test cup to view results.
- 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.
- If results do not indicate adulteration, read the drug test result at **5 minutes**. Do not interpret the result after 10 minutes.
- If preliminary positive results are observed, please send the cup to the laboratory for confirmation.

TEST PROCEDURE Cup



- Open the cap and add specimen.
- Specimen volume must exceed the minimum line.
- Peel off the label to view results

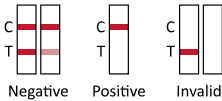
1



Cup with adulteration

Cup without adulteration

Read Drug Result at 5 minutes.

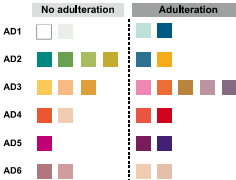


Negative

Positive

Invalid

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】

- 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.
- There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- 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.
- This test does not distinguish between drugs of abuse and certain medications.
- 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%
(+/-)-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- Methylene-dioxymethamphetamine (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%
Cocaoethylene	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-isobutryl fentanyl	50	2%
Para-fluorobutryl 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
MDMA 500	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	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
OXY 100	0ng/ml	50	0	50	0	50	0	50
	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
PCP 25	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
	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
COC 150	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
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
MTD 300	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
	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
BAR 300	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	1	49	0	50
	300ng/ml	50	28	22	25	25	26	24
BZO 300	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
	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	0	50	0	50	0	50
	375ng/ml	50	0	50	0	50	0	50
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
MET 500	1000ng/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	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
	0ng/ml	50	0	50	0	50	0	50
THC 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
FYL1	20ng/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
	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】

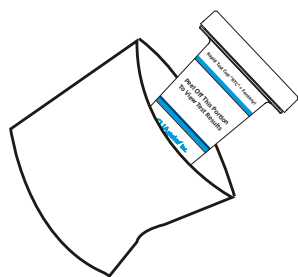
Index of Symbols					
	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Store between 35.6-86°F (2-30°C)
	In vitro diagnostic medical device		Batch code		Catalogue number
	Unique device identifier		Use-by date		Do not re-use
	Do not use if package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

Manufactured for:
CLIAwaived, Inc.
2721 Loker Ave W
Carlsbad CA 92010
www.cliawaived.com

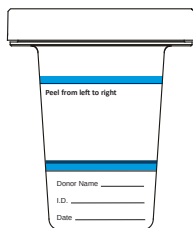
Toll-free number:
1-888-882-7739

Number 14602420900
Revison date: 2024-07-03

Rapid Test Cup "RTC" + Fentanyl Procedure Card



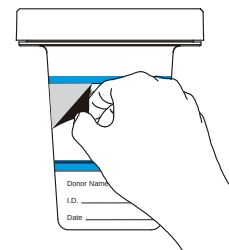
1. Remove the cup from the foil pouch.



2. Write donor ID and date on the label.



3. Collect specimen in the cup.



4. Peel off the label and read results. The adulteration strip(s), if applicable, should be read between 3-5 minutes. Read the drug test result at 5 minutes. Do not read after 10 minutes.

INTERPRETATION OF RESULT

Each strip contains one drug test. C region shows validity of a test result. T region shows result for this test.

For C region:

The appearance of a line indicates a valid result.

No line means an Invalid result.

If a test strip does not have a line in the C region, test results are Invalid for this strip.

For T region:

The appearance of a line indicates a Negative result.

Note: Any test line, even a very faint test line, is considered a negative result.

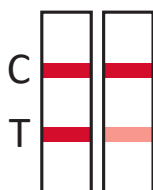


← C region: show validity for each strip

← T region: shows results for Test on each strip

No line indicates a Preliminary Positive result.

Note: Any urine with preliminary positive results should be sent to a laboratory for confirmation.



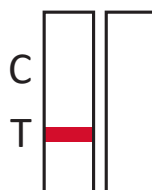
(Negative Result)

A red or pink line next to the "T"(drug test line) under the drug name indicates a negative result for that drug. Certain lines may appear lighter or thinner than other lines.



(Preliminary Positive Result)

If NO red or pink line appears next to the "T" under the drug name, the sample may contain that drug.



(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.

	No adulteration	Adulteration
AD1 (OX)		
AD2 (S.G.)		
AD3 (pH)		
AD4 (NIT)		
AD5 (GLU)		
AD6 (CRE)		

Read adulteration test results at 3 - 5 min. 143026902

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

CLIAwaived,™ Inc. Rapid Test Cup "RTC" + Fentanyl



DETECTS UP TO 14 DRUGS

Amphetamine (AMP)
Buprenorphine (BUP)
Secobarbital (BAR)
Oxazepam (BZO)
Cocaine (COC)
Methamphetamine (MET)
Methylenedioxymethamphetamine (MDMA)
Morphine (OPI 300)
Methadone (MTD)
Oxycodone (OXY)
Phencyclidine (PCP)
Nortriptyline (TCA)
Marijuana (THC)
Fentanyl (FYL)



adulteration
(CRE/OX/pH)

- Fast, dark test lines
- FDA-cleared and CLIA-waived
- Non-negative results in five minutes
- Donor-friendly cup opening
- Results can be photocopied
- Optional tests for adulterants
- Remarkable pricing and quality

Call your sales representative now at 1-888- 882-7739

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

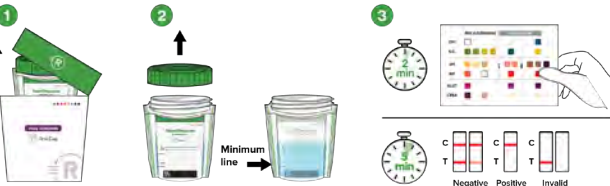
- Stored at 36-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch or closed canister until use.
- DO NOT FREEZE.
- Keep away from direct sunlight, moisture and heat

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:

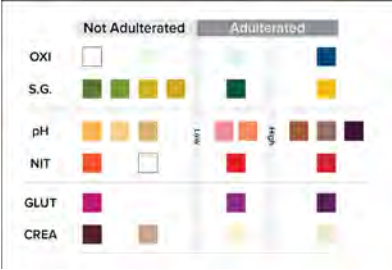
- The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in 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.



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 94.3%

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-Methylenedioxyamthamphetamine(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-methylenedioxymethamphetamine(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%
Temazepam	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
Methylenedioxmthamphetamine (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%
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^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 -D-glucuronide	>100,000	<0.01%
Tapentadol HCl	>100,000	<0.01%
Tramadol	>100,000	<0.01%

C. Precision

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-

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+/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	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+/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	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+/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	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+/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	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+/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	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+	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	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+/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	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+/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	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+/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	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+/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 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+/6-	23+/7-	23+/7-
+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-

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 Biotech Cup

Catalogue No.: See Box Label

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

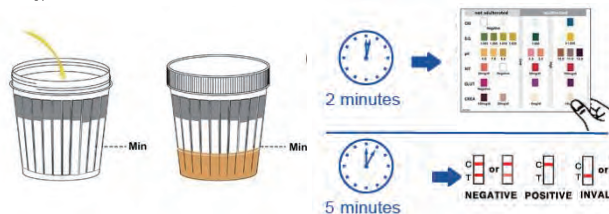
- Remove the Cup from the sealed pouch and use it within the first hour after opening
- Collect urine above the Minimum level on the label into the cup.
- Screw the cap onto the cup and immediately start the timer.

Reading Result:

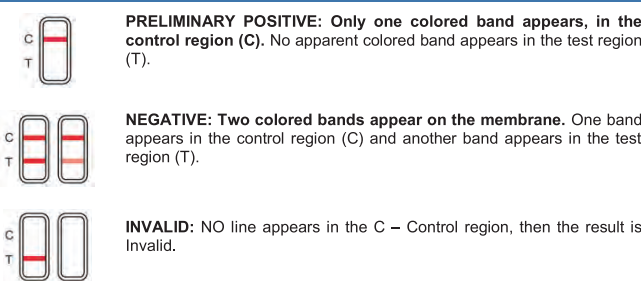
- The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

- 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



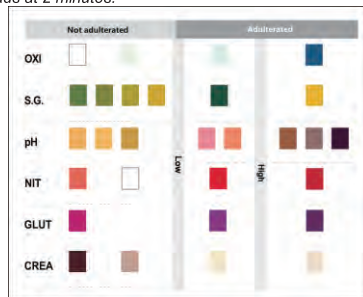
NOTE:

- 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

Operator C	Positive	0	0	1	15	25
	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 A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator C	Positive	0	0	2	14	25
	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)
Operator A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator B	Positive	0	0	2	14	25
	Negative	10	20	8	1	0
Operator C	Positive	0	0	1	15	25
	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 A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator B	Positive	0	0	1	15	25
	Negative	10	20	9	0	0
Operator C	Positive	0	0	1	15	25
	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 A	Positive	0	0	1	14	25
	Negative	10	20	9	1	0
Operator B	Positive	0	0	0	14	25
	Negative	10	20	10	1	0
Operator C	Positive	0	0	1	14	25
	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 A	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Operator B	Positive	0	0	0	15	25
	Negative	10	20	10	0	0
Operator C	Positive	0	0	0	15	25
	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

Labeltol 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 Fentnail	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%
1-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(PM MA)	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-Methylenedioxymethamphetamine(M DMA)	>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
Benzoyllecgonine	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-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+/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-

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+/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-

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+/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-

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+/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-

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+/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-

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+/3-	48+/2-	48+/2-	39+/11-	40+/10-	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-

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+/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-

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+/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-

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+/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-

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+/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-

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+/6-	23+/7-	23+/7-
+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

Montana Heart CM Policy Documents

[BHDD Medicaid Services Provider Manual, Section 5, Policy Number 505: Specimen Collection for SUD Drug Testing](#)

[BHDD Medicaid Services Provider Manual, Section 6, Policy Number 615: HEART Waiver – Contingency Management \(CM\)](#)

[BHDD Medicaid Service Provider Manual, Policy Number 120: Individualized Treatment Plans for Behavioral Health Treatment](#)

[BHDD Medicaid Services Provider Manual, Policy Number 130: Progress Notes](#)

Appendix D

CM Team Requirements Flow Chart

MT HEART CM Program: CM Team Requirements Flow Chart

Individuals serving as CM Supervisor, CM Coordinator, and Back-up CM Coordinator must complete all steps prior to initiating services at their site. More information about the MT HEART CM Program, including Implementation training slides and handouts, upcoming training dates/times, contact information, and warmline assistance can be found here:

<https://uclaisap.org/montanaheartcm/index.html>

STEP 1

Completion of Healing and Ending Addiction through Recovery and Training (HEART) Demonstration: Montana's Contingency Management Program 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. Upcoming dates and times for trainings can be found [here](#). Completion of the post-test following the Part 2 training with an 80% (16/20) or higher is required for all participants.

STEP 4

Entry of 3 practice cases into the IM Portal Sandbox by all CM team members. The login for the IM Portal Sandbox can be found All CM Team members, including those who join later, must successfully enter the practice cases into the IM Portal Sandbox prior to delivering CM Services.

STEP 3

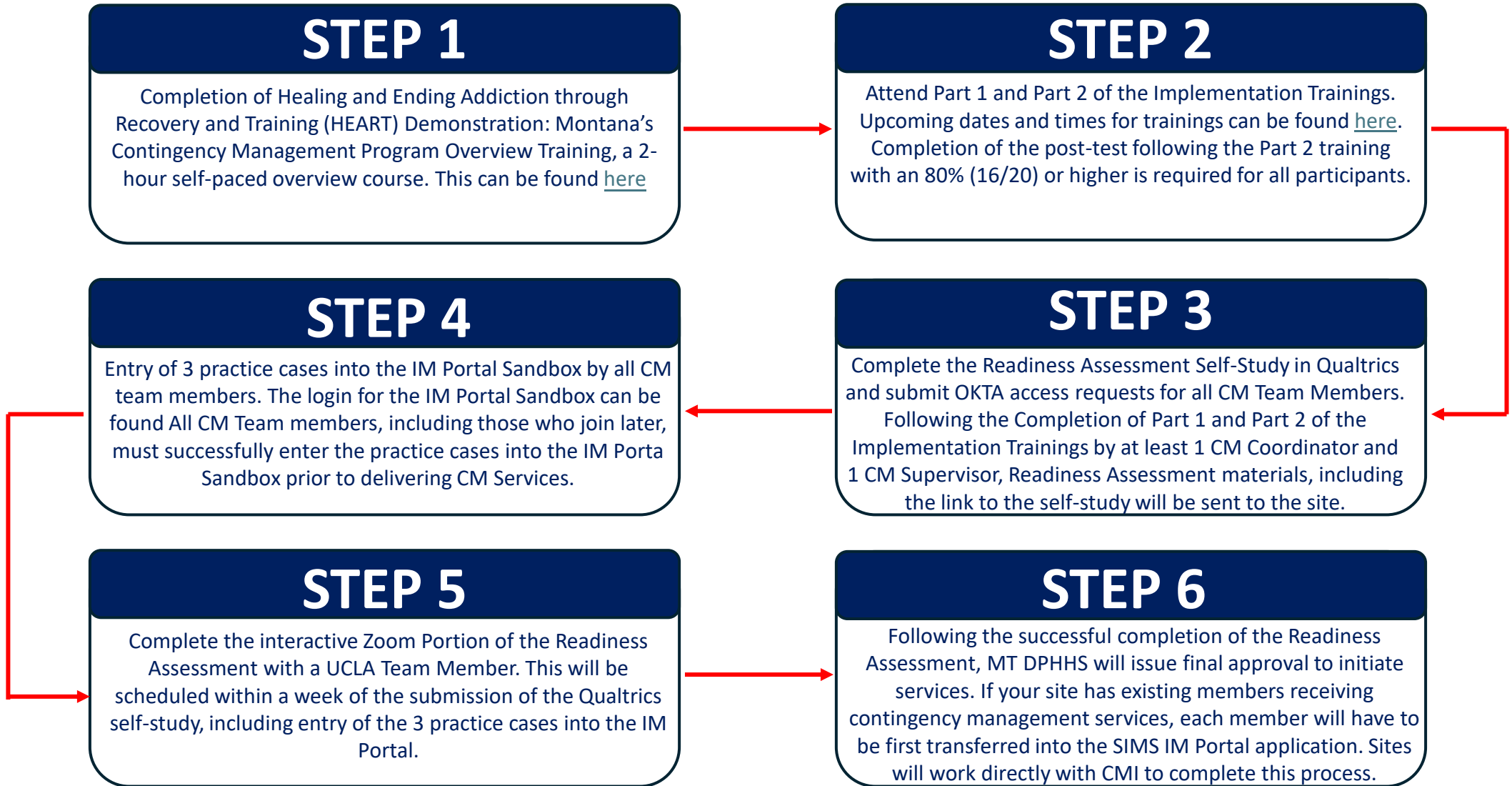
Complete the Readiness Assessment Self-Study in Qualtrics and submit OKTA access requests for all CM Team Members. Following the Completion of Part 1 and Part 2 of the Implementation Trainings by at least 1 CM Coordinator and 1 CM Supervisor, Readiness Assessment materials, including the link to the 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, MT DPHHS will issue final approval to initiate services. If your site has existing members receiving contingency management services, each member will have to be first transferred into the SIMS IM Portal application. Sites will work directly with CMI to complete this process.



Appendix E

OIG Rules Applying to Non-Medicaid-Funded Contingency Management Programs

Appendix E

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 MT DPHHS-approved CM protocol. For the purpose of the MT DPHHS contingency management benefit authorized under the 1115 HEART Waiver demonstration:

For the purposes of this demonstration, these motivational incentives are a 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.

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

² Ibid.

Appendix F

MT HEART CM Program Provider Enrollment Step-by-Step Instructions

MT HEART CM Program – Provider Enrollment Step-by-Step Instructions

This document provides step-by-step instructions regarding updating provider enrollment to participate as a site in the MT HEART CM Program. You will likely need to notify your financial or administrative team to complete updates to your agency's NPI and/or enrollment.

If your team has questions regarding enrollment, please reach out to Conduent (contact information is listed below). If your team has questions regarding Medicaid CM, please reach out to Jill Richards (Jill.Richards@mt.gov) and Emily Munn (Emily.Munn@mt.gov). If your team has questions regarding SOR CM, please reach out to Nikki Campbell (NCampbell@mt.gov) and Meaghan Kolar (Meaghan.Kolar@mt.gov).

To bill for Contingency Management on a HCFA1500 form, you must use taxonomy [261QR0405X](#). Your CLIA number is also required to be linked across platforms.

NPPES NPI REGISTRY

<https://npiregistry.cms.hhs.gov/registry/>

- Search for the NPI
- Verifying all information shown under the NPI is correct.
 - Name
 - Address
 - Phone number
 - **Taxonomy**
- Note the taxonomy needed for the current application.
 - <https://taxonomy.nucc.org>

If the correct taxonomy does not display under your NPI, you must log into your [NPPES](#) account and add this taxonomy.

Code	261QR0405X
Name	Rehabilitation, Substance Use Disorder

Once you have registered this taxonomy, please wait 10-14 business days for the update to link across platforms.

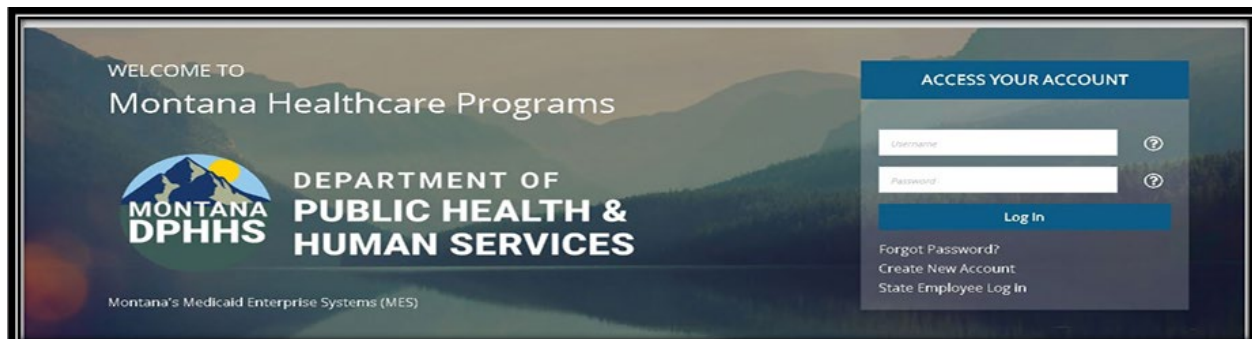
SIGN INTO THE PROVIDER SERVICES PORTAL

- Go to the MT Medicaid website – <https://medicaidprovider.mt.gov/>
Click the Provider Services Portal Link. It will take you to the ICAP Login



Direct link – <https://portal.mt.healthinteractive.net/icapPortal/>

- Sign into the ICAP Portal
 - Your Username is the email you are registered with on the Provider Services Portal!



UPDATES

1. Search your NPI
2. Select the Radio button for the NPI
3. Click the Update button on left menu

4. A new Update line will appear at the end of your list, click the pencil icon.

Enrollment Workbench

Select "Search By" Column: Select One Search Criteria: Search Search Clear

Actions	Type	Status	Submission Date	Confirmation #	Tax ID	NPI/Atypical ID	Provider ID	Provider Name
  	Enrollment	Enrolled	12-09-2021	20086035	XX-XXX1234	0002089504	200002447	Deb Braga
  	Update	In Progress	20087591	XX-XXX1234	0002089504	200002447	Deb Braga	

5. Answer the question regarding laboratory services provided at this location.
 - a. Provide the required Clinical Laboratory Improvement Amendments (CLIA) number, Type, and Effective date information, then either upload the pertinent document or choose the mail or fax option.

Questions:

1) Do you provide laboratory services at this location? * ☒ Yes ☐ No

CLIA NUMBER (format: 99A9999999) * Upload Document ☒ Other (Mail or Fax)

Type: * Select One ▼ Effective Date: * MM/DD/YYYY 📅

Terminate Date: MM/DD/YYYY 📅

SPECIALTY

To add the taxonomy to the Agency provider type:

Select add, then select the taxonomy and enter your effective date

Specialties: * Add 📌

Type of Provider	Specialty	Taxonomy	Primary	Effective Date	Terminate Date	Actions
Montana Medicaid (RMK Plus)	Clinic/Center; Rehabilitation, Substance Use Disorder	261QR0405X	☐	07/01/2024		 

SUB-PARTS

Under your existing NPI, if you need to add the approved taxonomy but do not already have the provider type.

Answering “YES” will make the Type of Provider section option to add available again and you can then follow the steps to select the type of provider you need to add.

Do you have Subparts of the organization sharing this NPI, which are a different Provider Type than the Primary one selected? * ⓘ

☒ Yes ☐ No

ENROLLMENT UNITS

Select the blue pencil to complete the Enrollment Units

The screenshot shows a table titled "Enrollment Units" with the following columns: Enrollment Unit ↑, Program, Specialty, Service Location, Team Name, Team Number, Effective Date, Terminate Date, System Status, and Actions. A single row is displayed with the following data: Enrollment Unit 0001866358, Program Tenancy Support, Specialty Case Management, Service Location 001-Helena Location 1, Team Name Helena-1, Team Number, Effective Date 01/09/2025, Terminate Date, System Status Pending, and an Actions column containing a blue pencil icon. Above the table is a search bar with "Show Filter", "Select 'Search By'", "Select One", "Search Criteria", "Search", and "Clear" buttons. Below the table are pagination controls: "Items per page 50", "1 - 1 of 1", and navigation arrows. At the bottom are buttons for "Save and Exit", "Cancel", "Previous", and "Save and Continue".

Enrollment Unit ↑	Program	Specialty	Service Location	Team Name	Team Number	Effective Date	Terminate Date	System Status	Actions
0001866358	Tenancy Support	Case Management	001-Helena Location 1	Helena-1		01/09/2025		Pending	

- Select the attestation Box.
- Save and continue To move forward.

The screenshot shows the "Licensing, Certifications & Accreditations" section. It includes a "Please see below for the Licensing, Certification and Accreditations specific to this Enrollment Unit." instruction, a note that a primary license must be selected, and a requirement that fields marked with an asterisk (*) are required. A checkbox "I have reviewed the information on this screen as presented" is checked. Below this is a "Licenses" section with a "Select Available Licenses" dropdown. A table lists available licenses with columns: License #, Specialty, State, Effective Date, Expiration Date, Issuing Party Identifier, Primary, and Action. One license is listed: License # abc-med-lic-124, Specialty Case Management, State MT, Effective Date 01/01/2025, Expiration Date 12/31/2026, Issuing Party Identifier Board of Behavioral Health, Primary (indicated by a blue circle), and an Action column with a blue pencil icon.

Licensing, Certifications & Accreditations ⓘ Address ⓘ Communications ⓘ Managing Employees ⓘ

Please see below for the Licensing, Certification and Accreditations specific to this Enrollment Unit.
A primary license must be selected at the Enrollment Unit. If you have multiple licenses select MT as the primary.
Required fields are marked with an asterisk (*).

☒ I have reviewed the information on this screen as presented * ⓘ

Licenses ⓘ

Licenses Available: Select Available Licenses ⓘ

License #	Specialty	State	Effective Date	Expiration Date	Issuing Party Identifier	Primary	Action
abc-med-lic-124	Case Management	MT	01/01/2025	12/31/2026	Board of Behavioral Health		

- Only the billing address has to be a physical location, cannot be a PO Box.

Licensing, Certifications & Accreditations **Address** Communications Managing Employees

Please see below for the Address information specific to this Enrollment Unit.

Required fields are marked with an asterisk (*).

Type	Address Line 1	Address Line 2	City	State	Zip Code
Billing*	Select				
Mailing*	Select				
Remittance*	Select				
Other	Select				

Cancel Previous Save and Continue Save

- Select a primary contact and Information and save

Add Contact

Required fields are marked with an asterisk (*).

Contact Type: * Office Manager Terminate Date: MM/DD/YYYY

Set Contact as Primary

☒ Primary Contact

First Name: * M.I.: Last Name: *

Phone Number: * Ext: Fax Number: Ext:

Contact Email Address: * Re-enter Email Address: *

Save Cancel

After Enrollment Units are complete, save and continue to Final Submission.

Enrollment Units

Final Submission

Summary

Demographic Maintenance

Information from previous sections will populate within the Enrollment Unit. This workbench will display all enrollment units for this enrollment application, please complete each as applicable.

Show Filter Select "Search By" Select One Search Criteria Search - + Search Clear

Enrollment Unit	Program	Specialty	Service Location	Team Name	Team Number	Effective Date	Terminate Date	System Status	Actions
0001866358	Tenancy Support	Case Management	001-Helena Location 1	Helena-1		01/09/2025		Complete	

Items per page 50 1 - 1 of 1 |< < > >|

Save and Exit Cancel Previous Save and Continue

Need Help?

At the top of each screen is a **User Guide** icon.

When you click on the icon, the user guide will open to the section matching the screen you are on.



Provider Information Website:

<https://medicaidprovider.mt.gov>

- [Provider Enrollment Page](#)
- Provider Services Module User Guides
- [Claim Jumper Newsletters](#)
- Previous training presentations and videos

Provider Relations Call Center: (800) 624-3958

Monday through Friday 8am to 5pm MST

General, Claims, TPL, and EDI questions:

MTPRHelpdesk@conduent.com

Enrollment Questions and documents: MTEnrollment@conduent.com

Note: The Conduent helpdesks cannot accept secured emails or PHI.

Email Assistance MTPRHelpdesk@conduent.com

When emailing the help desk please provide the following so we can research & submit a help ticket to our Tech Team.

GovID: Name: Email registered: NPI attempting/registered: Phone number: A screen shot of the error:

Please allow 2 - 5 business days for a response

Appendix G

MT HEART CM Program Eligibility and Billing Guidance

MT HEART CM Program Eligibility and Billing Guidance

The following guidance clarifies how Contingency Management (CM) services and incentives should be funded and billed across Medicaid, State Opioid Response (SOR) funding, and Federally Qualified Health Centers (FQHCs). The MT DPHHS team has received several questions in this area and this guidance ensures a consistent understanding across providers.

Contingency Management (CM) Eligibility

- SOR:
 - SOR funding is intended to support individuals with stimulant or stimulant/opioid use disorder who are uninsured or underinsured
- Medicaid HEART:
 - Requires active Medicaid coverage. Individuals with pending Medicaid are not eligible until coverage is approved.

Contingency Management (CM) – Medicaid Benefit

- CM is a covered Medicaid service for eligible members and is defined in the Medicaid Services Provider Manual (Policy 615).
- CM is a structured outpatient program that uses motivational incentives to support recovery from stimulant use disorder
- Qualified providers, including FQHCs with SUD services in their scope, may deliver CM services if all provider requirements are met

How Funding Works

- Medicaid is the primary payer for CM services
- For Medicaid-enrolled members:
- CM services must be delivered and billed in accordance with Medicaid policy
- This includes specimen collection, CLIA-waived urine drug testing (UDT), and administration of incentives through the approved incentive management process

SOR Funding

- SOR funding is intended to support individuals with stimulant or stimulant/opioid use disorder who are uninsured or underinsured

- SOR funding may be used for:
- Individuals who are not Medicaid eligible
- SOR funding cannot be used in place of Medicaid
- If a member is Medicaid eligible, CM services and incentives must be billed through Medicaid

FQHC Billing Considerations

- FQHCs may provide CM services if they meet provider requirements
- Billing depends on whether there is a qualifying PPS encounter on the date of service:
 - If there is a qualifying FQHC encounter:
 - Bill PPS only
 - UDT is included in the PPS rate and not billed separately
 - If there is not a qualifying encounter:
 - Bill UDT and specimen collection under PT32 using a CMS-1500

CLIA and Ordering Requirements

- CLIA governs who can perform a test, not who can order it
- UDT must be ordered by a qualified licensed provider (e.g., MD, DO, NP, PA), or through appropriate standing orders tied to that provider
- Billing pathway (PPS vs. PT32) does not change clinical ordering requirements

In Practice

- Qualifying FQHC visit → bill PPS only (UDT included)
- No qualifying visit → bill UDT and specimen collection under PT32
- Medicaid eligible → bill CM services and incentives through Medicaid
- Not Medicaid eligible → SOR funding may be used, as appropriate

Our shared goal is to ensure CM services are delivered consistently, billed correctly, and available to members without unnecessary delays.

If you have questions about how this applies to your organization, please feel free to reach out.

Thank you for all the work you do to support Montanans.



Nikki Campbell MS

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