CLIA Waived One Step Multi-Drug Test Cup Package Insert

Package insert for testing of any combination of the following drugs: Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Propoxyphene, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, Methadone, Marijuana and Benzodiazepines.

A rapid, one step screening test for the simultaneous, qualitative detection of Methamphetamine, Amphetamine, Cocaine, Morphine, EDDP (Methadone Metabolites), Marijuana, Propoxyphene, Benzodiazepines, Ecstasy, Oxycodone, Barbiturates, Phencyclidine, Buprenorphine, Methadone, Tricyclic Antidepressants and the metabolites in human urine.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

INTENDED USE & SUMMARY

Urine based CLIA Waived Drug tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

The **One Step Multi-Drug Screen Test Cup** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine:[1]

Test	Calibrator	Cut-off (ng/mL)
Methamphetamine (MET, mAMP)	D-Methamphetamine	1,000
Cocaine(COC)	Benzoylecgonine	300
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Morphine (MOP)	Morphine	2,000
Morphine (MOP)	Morphine	300
Benzodiazepines (BZO)	Oxazepam	300
MDMA(Ecstasy)	D,L- Methylenedioxy-methamphetamine	500
Oxycodone (OXY)	Oxycodone	100
Barbiturates (BAR)	Secobarbital	300
Buprenorphine (BUP)	Buprenorphine	10
Methadone (MTD)	Methadone	300
Phencyclidine (PCP)	Phencyclidine	25
Amphetamine (AMP)	D-Amphetamine	1,000
EDDP (Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyr rolidine (EDDP)	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Propoxyphene (PPX)	Propoxyphene	300

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

METHAMPHETAMINE (MET, mAMP)

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 has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use.

COCAINE (COC)

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

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine.1.2 Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[2]

MORPHINE (MOP)

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 central nervous system. 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.[4]

MARIJUANA (THC)

THC (Δ 9--tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it 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 smoking marijuana 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 (Δ9-THC-COOH).

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 barbiturates 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 the Benzodiazepines in the urine is 3-7 days.

OXYCODONE (OXY)

Oxycodone,[4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one,dihydrohydroxycodein one] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR®, OxyFast®(immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours).

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 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.

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. 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 Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days

Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days.

BUPRENORPHINE (BUP)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex®, and a Buprenorphine/Naloxone combination product, Suboxone®, are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

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.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.8 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.

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels. In human, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

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. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine 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 Phencyclidine. 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.5 Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system 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 test is intended for over-the-counter (OTC) use as the first step in a two step process to provide consumers with information concerning the presence or absence of the above stated drug in a urine sample. Information regarding confirmatory testing – the second step in the process, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is provided.

PRINCIPLE

The **One Step Multi-Drug Screen Test Cup** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

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 coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip.

The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test line in the test panel contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For *in vitro* diagnostic use only. It is intended for over-the-counter and for prescription use.
- Do not use after the expiration date.
- The Test Device 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 Device should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The Test Device is stable through the expiration date printed on the sealed pouch. The Test Device must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

The minimum detection time is 2-7 hours, so you may collect urine samples 2-7 hours after suspected drug use.

HOW TO COLLECT URINE?

1. Urinate directly into the provided urine cup.

2. Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap. This Labeled Vial urine sample is for shipping to the laboratory for confirmation testing. Make sure that the number on the Labeled Vial matches your personal Identification Number.

3. The residual urine sample in the urine cup is for your self-testing.

Specimen Storage

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

MATERIALS

Materials Provided

Materials Provided
• Test cup • Desiccants • Package insert •Procedure Card
• Color Chart Card for Adulterant Interpretation (when applicable)
Materials Required But Not Provided
• Timer •Disposable gloves

DIRECTIONS FOR USE

Allow the test cup to come to room temperature [15-30℃ (59-86℉)] prior to test.
1) Tear the foil bag open, remove test cup and disposable gloves provided for donor. Label the device with donor information. (Fig. 1)
2) Open test cup lid. Urinary directly into the test cup. Be sure to fill up the test cup with the urine specimen between minimum 30ml to maximum 110ml (marked on the cup). (Fig. 2)
3) After urine specimen has been collected, close the lid securely and return cup tp collection official. (Fig. 3)
4) Collection official use glove provided. Peel off label to reveal test result. Read test result at 5 minutes. DO NOT INTERPRET RESULT AFTER 10 MINUTES. (Fig.4&5)

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for Oxidants, Specific Gravity, pH, Creatinine, Nitrite and Glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.
Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and pH, and to detect the presence of oxidants, Nitrite, Glutaraldehyde and Creatinine in urine are considered to be the best ways to test for adulteration or dilution.
• **Oxidants (OXI)**: Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
• **Specific Gravity (S.G.)**: Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
• **pH**: tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.
• **Nitrite(NIT)**: Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
• **Glutaraldehyde(GLUT):** Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
• **Creatinine(CRE):** Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

ADULTERANT TESTS(SPECIMEN VALIDITY TEST) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OXI)	0.30%	99.70%
Specific Gravity (S.G.)	0.21%	99.79%
pH	0.06%	99.94%
Nitrite（NIT）	0.06%	99.94%
Glutaraldehyde（GLUT）	0.02%	99.98%
Creatinine（CRE）	0.03%	99.97%

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.
*NOTE: The shade of red in the test line region (Drug/T) will vary, but it should be considered negative whenever there is even a faint pink line.
POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

Note: There is no meaning attributed to line color intensity or width.

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by One Step Multi-Drug Screen Urine Test. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial Methamphetamine is present but isn't detected by One Step Multi-Drug Screen Urine Test. If the sample is diluted, or the sample is adulterated that may cause false negative result.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line 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. Please contact our Technical Support at 1-866-982-3818 for controls that work with the device.

LIMITATIONS

1. The One Step Multi-Drug Screen Test Cup provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

QUESTIONS AND ANSWERS

1. What does the Drug of Abuse Urine Test do?
These tests indicate if one or more prescription or illegal drugs are present in urine. The testing is done in two steps. First, you do a quick at-home test. Second, if the test suggests that drugs may be present, you send the sample to a laboratory for additional testing.
2. What is "cut-off level"?
The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test is called positive, and below that concentration it is called negative.
3. What are drugs of abuse?
Drugs of abuse are illegal or prescription medicines (for example, Oxycodone or Valium) that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed it for or for a purpose other than what the doctor prescribed it for.
4. How accurate is the test?
The tests are sensitive to the presence of drugs in urine sample. These tests are not as accurate as lab tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug-testing kits..
5. Does a preliminary positive screen test mean that you have found of abuse?
This means that the test has reacted with something in the sample and the sample must be sent to the lab for a more accurate test.
6. What should I do, if the lab test confirms a positive result?
If you have received a confirmed positive result, please consult with our staff on a proper course of action. We will help you identify counselors who can help you. It is important that you remain calm and do not react in a negative way to the situation. If you do not believe the test result, please consult with your physician. They will have your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

MAILING A URINE SAMPLE TO THE LABORATORY FOR CONFIRMATION TESTING

1. Ensure that the Labeled Vial is about two third (2/3) full and that the cap is tightly closed.
2. Check the label identifying the drug that was a preliminary positive result.
3. Be sure to write your Cell Phone Number on the mailing box that the laboratory can send you the message with the confirmed results along with the Personal Identification Number.
4. Place the Labeled Vial in the plastic bag and seal the plastic bag.
5. Place the sealed plastic bag in the mailing box. Close the mailing box and secure it with packing tape. The mailing address for the laboratory is already on the mailing box. ***Please note that the mailing box isn't pre-paid. You must attach the proper postage to have a carrier service deliver it.***
6. Place the mailing box in any US Postal Service Office.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Technical Support Number 1-866-982-3818 (9:00 a.m. to 5 p.m. CDT).

PERFORMANCE CHARACTERISTICS

Accuracy

80 clinical urine specimens were analyzed by GC-MS and by the **One Step Multi-Drug Screen Test Cup**. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Methamphetamine (mAMP)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Operator B	Positive	0	0	0	12	27
	Negative	10	19	15	1	0
Operator C	Positive	0	0	0	11	27
	Negative	10	19	15	2	0

% agreement among positives is 96.7%
% agreement among negatives is 100%

Cocaine (COC)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	15	24
	Negative	10	17	13	1	0
Operator B	Positive	0	0	0	16	24
	Negative	10	17	13	0	0
Operator C	Positive	0	0	0	14	24
	Negative	10	17	13	2	0

% agreement among positives is 92.5%
% agreement among negatives is 100%

Morphine (MOP300)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	14	25
	Negative	10	15	15	1	0
Operator B	Positive	0	0	1	15	25
	Negative	10	15	15	0	0
Operator C	Positive	0	0	0	15	25
	Negative	10	15	15	0	0

% agreement among positives is 97.5%
% agreement among negatives is 100%

Morphine (MOP2000)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Operator B	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Operator C	Positive	0	0	0	13	23
	Negative	10	16	14	4	0

% agreement among positives is 92.5%
% agreement among negatives is 100%

Benzodiazepines (BZO)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 95%
% agreement among negatives is 100%

Marijuana (THC)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	12	26
	Negative	10	16	16	2	0
Operator B	Positive	0	0	0	11	26
	Negative	10	16	16	3	0
Operator C	Positive	0	0	0	12	26
	Negative	10	16	16	2	0

% agreement among positives is 94.2%
% agreement among negatives is 100%

Phencyclidine (PCP)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 92.5%
% agreement among negatives is 100%

Ecstasy (MDMA)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	12	24
	Negative	10	15	15	4	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 91.7%
% agreement among negatives is 100%

Oxycodone (OXY)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

% agreement among positives is 93%
% agreement among negatives is 100%

Amphetamine (AMP)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Operator B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Operator C	Positive	0	0	0	15	23
	Negative	10	16	14	2	0

% agreement among positives is 93%
% agreement among negatives is 100%

Barbiturates (BAR)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 93.3%
% agreement among negatives is 100%

Buprenorphine (BUP)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 94.2%

% agreement among negatives is 100%

Methadone (MTD)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 94.2%

% agreement among negatives is 100%

EDDP (Methadone Metabolites)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 94.2%

% agreement among negatives is 100%

Propoxyphene (PPX)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 95%

% agreement among negatives is 100%

Tricyclic Antidepressants (TCA)

Test		Drug-free	Low Negative (Less than half the cutoff concentration)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Operator A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

% agreement among positives is 95%

% agreement among negatives is 100%

ANALYTICAL SENSITIVITY

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Methamphetamine, Amphetamine, Cocaine, Morphine, Propoxyphene, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, Methadone, Marijuana and Benzodiazepines. The cut-off value for the device is verified.

ANALYTICAL SPECIFICITY

The following table lists compounds that are positively detected in urine by the **One Step Multi-Drug Screen Test Cup** at 5 minutes.

Drug	Concentration (ng/ml)	% Cross-Reactivity
METHAMPHETAMINE (mAMP)		
D-Methamphetamine	1,000	100%
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000	5%
Procaine (Novocaine)	60,000	1.7%
Trimethobenzamide	20,000	5%
Methamphetamine	1,000	100%
Ranitidine (Zantac)	50,000	2%
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2,500	40%
Chloroquine	50,000	2%
Ephedrine	100,000	1%
Fenfluramine	50,000	2%
p-Hydroxymethamphetamine	10,000	10%
COCAINE (COC)		
Benzoylecogonine	300	100%
Cocaethylene	300	100%
CocaineHCl	300	100%
MARIJUANA (THC)		
Delta-9-Tetrahydrocannabinol	50,000	0.1%
11-nor-delta-9-THC-carboxyglucuronide	75	67%
(-)-11-nor-9-carboxy-delta9-THC	75	67%
11-Nor-Δ9-Tetrahydrocannabinol	50	100%
11-Hydroxy-Δ9-Tetrahydrocannabinol	5,000	1%
11-Nor-Δ8-Tetrahydrocannabinol	50	100%
Δ8-THC-COOH	50,000	0.1%
MORPHINE(MOP300)		
Morphine	300	100%
O6-Acetylmorphine	400	75%
Codeine	300	100%
EthylMorphine	100	300%
Heroin	600	50%
Hydromorphone	500	60%
Hydrocodone	625	48%
Levorphanol	1,500	20%
Oxycodone	30,000	1%
Procaine	15,000	2%
Thebaine	6,240	5%
MORPHINE(MOP2000)		
Morphine	2,000	100%
O6-Acetylmorphine	2,500	80%
Codeine	1,000	50%
EthylMorphine	250	800%
Heroin	5,000	40%
Hydromorphone	2,500	80%
Hydrocodone	5,000	50%
Oxycodone	75,000	3%
Thebaine	13,000	15%
BENZODIAZEPINES (BZO)		
Alprazolam	200	150%
Bromazepam	1,560	19%
Chlordiazepoxide HCL	1,560	19%
Clobazam	100	300%
Clonazepam	780	38%
Clorazepate Dipotassium	200	150%
Delorazepam	1,560	19%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	2,500	12%
Flunitrazepam	400	75%
a-Hydroxyalprazolam	1260	24%
(±) Lorazepam	1,560	19%
RS-Lorazepam glucuronide	160	188%
Midazolam	12,500	2%
Nitrazepam	100	300%
Norchlordiazepoxide	200	150%
Nordiazepam	400	75%
Oxazepam	300	100%
Temazepam	100	300%
Triazolam	2,500	12%
OXYCODONE (OXY)		
Oxycodone	100	100%
Codeine	50,000	0.2%
Ethyl Oxycodone	75,000	0.1%
Thebaine	50,000	0.2%
BARBITURATES (BAR)		
Secobarbital	300	100%
Amobarbital	300	100%
Alphenal	750	40%
Aprobarbital	250	120%
Butabarbital	2,500	12%
Butethal	2,500	12%
Butalbital	2,500	12%
Cyclopentobarbital	500	60%
Pentobarbital	2,500	12%
Phenobarbital	25,000	1.2%
BUPRENORPHINE (BUP)		
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	20	50%
Morphine	Negative at 100000	Not detected
Oxymorphone	Negative at 100000	Not detected
Hydromorphone	Negative at 100000	Not detected
METHADONE (MTD)		
Methadone	300	100%
Doxylamine	5,000	6%
EDDP	Negative at 100,000	Not Detected
EMDP	Negative at 100,000	Not Detected
LAAM HCl	Negative at 100,000	Not Detected
Alpha Methadol	Negative at 100,000	Not Detected
EDDP(Methadone Metabolites)		
EDDP	300	100%
Disopyramide	50,000	0.6%
Methadone	>100,000	<1%
EMDP	500	60%
PHENCYCLIDINE (PCP)		
Phencyclidine	25	100%
4-Hydroxy Phencyclidine	90	28%

Drug	Concentration (ng/ml)	% Cross-Reactivity
AMPHETAMINE (AMP)		
D-Amphetamine	1,000	100%
D,L - Amphetamine (Amphetamine Sulfate)	1,000	100%
Phentermine	1,250	80%
(+/-)-4-Hydroxyamphetamine HCL	600	167%
L-Amphetamine	20,000	5%
(+/-)-Methylenedioxyamphetamine(MDA)	1,500	67%
d-Methamphetamine	>100000 ng/mL	<1%
1-Methamphetamine	>100000 ng/mL	<1%
ephedrine	>100000 ng/mL	<1%
3,4-Methylenedioxyethylamphetamine (MDE)	>100000 ng/mL	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	>100000 ng/mL	<1%
ECSTASY (MDMA)		
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000	17%
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300	167%
d-methamphetamine	2500	20%
d-amphetamine	>100000	Not detected
l-amphetamine	>100000	Not detected
l-methamphetamine	>100000	Not detected
TRICYCLIC ANTIDEPRESSANTS (TCA)		
Nortriptyline	1,000	100%
Amitriptyline	1,500	67%
Clomipramine	50,000	2%
Desipramine	5,000	20%
Doxepine	10,000	10%
Imipramine	10,000	10%
Maprotiline	100,000	1%
Nordoxepin	10,000	10%
Promazine	50,000	2%
Promethazine	2,500	40%
Trimipramine	50,000	2%
Cyclobenzaprine Hydrochloride	5,000	20%
Norclomipramine	50,000	2%
PROPOXYPHENE (PPX)		
Norpropoxyphene	300	100%
Propoxyphene,d-	300	100%

PRECISION

This study is performed 2 runs/day and lasts 25 days for each format with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

Drugs	Concentration (ng/mL)	n	Lot1		Lot2		Lot3	
			-	+	-	+	-	+
Methamphetamine	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	22	28	22	28	22	28
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
Benzoylecogonine	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	18	32	18	32	18	32
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Methadone	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	22	28	25	25	22	28
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
11-nor-Δ9-THC-9-COOH	0	50	50	0	50	0	50	0
	12.5	50	50	0	50	0	50	0
	25	50	50	0	50	0	50	0
	37.5	50	50	0	50	0	50	0
	50	50	14	36	14	36	14	36
	62.5	50	0	50	0	50	0	50
	75	50	0	50	0	50	0	50
	87.5	50	0	50	0	50	0	50
	100	50	0	50	0	50	0	50
Oxazepam	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	20	30	20	30	20	30
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Morphine	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	20	30	20	30	20	30
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Ecstasy(MDMA)	0	50	50	0	50	0	50	0
	125	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	375	50	50	0	50	0	50	0
	500	50	30	20	30	20	30	20
	625	50	0	50	0	50	0	50
	750	50	0	50	0	50	0	50
	875	50	0	50	0	50	0	50
	1000	50	0	50	0	50	0	50
Oxycodone	0	50	50	0	50	0	50	0
	25	50	50	0	50	0	50	0
	50	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	100	50	16	34	16	34	16	34
	125	50	0	50	0	50	0	50
	150	50	0	50	0	50	0	50
	175	50	0	50	0	50	0	50
	200	50	0	50	0	50	0	50
Secobarbital	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	27	23	25	25	22	28
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Buprenorphine	0	50	50	0	50	0	50	0
	2.5	50	50	0	50	0	50	0
	5	50	50	0	50	0	50	0
	7.5	50	50	0	50	0	50	0
	10	50	26	24	24	26	25	25
	12.5	50	0	50	0	50	0	50
	15	50	0	50	0	50	0	50
	17.5	50	0	50	0	50	0	50
	20	50	0	50	0	50	0	50
D-Amphetamine	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	18	32	18	32	18	32
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
Phencyclidine	0	50	50	0	50	0	50	0
	6	50	50	0	50	0	50	0
	12.5	50	50	0	50	0	50	0
	19	50	50	0	50	0	50	0
	25	50	16	34	16	34	16	34
	31	50	0	50	0	50	0	50
	37.5	50	0	50	0	50	0	50
	44	50	0	50	0	50	0	50
	50	50	0	50	0	50	0	50
EDDP	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	21	29	26	24	22	28
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
Nortriptyline	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	22	28	26	24	18	32
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
Morphine (OPI,MOP2000)	0	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	1000	50	50	0	50	0	50	0
	1500	50	50	0	50	0	50	0
	2000	50	22	28	22	28	22	28
	2500	50	0	50	0	50	0	50
	3000	50	0	50	0	50	0	50
	3500	50	0	50	0	50	0	50
	4000	50	0	50	0	50	0	50
Propoxyphene	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	25	25	21	29	29	21
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **One Step Multi-Drug Screen Test Cup** was tested in duplicate using ten drug-free urine and spiked urine samples. 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 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The **One Step Multi-Drug Screen Test Cup**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Propoxyphene, Buprenorphine, Phencyclidine, Methadone, Marijuana and Benzodiazepines positive urine. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Test Cup** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Cotinine(-)	Cortisone	Pseudoephedrine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinidine
Acetylsalicylic acid	Dexamethasone	Labetalol	Quinine
Amiloride	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Desipramine	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Droperidol	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrozoline
Atropine	Ethopropazine	Niacinamide	Theobromine
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tolazamide
p-Aminobenzoic Acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
Beclomethasone	Furosemide	Octopamine	Thioridazine Hydrochloride
Caffeine	Gentisic acid	Oxalic acid	D/L-Tyrosine
Cannabidiol	Hemoglobin	Oxyphenbutazone	Tolbutamide
Carbamazepine	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Paclitaxel	Trimethoprim
Chlorpheniramine	a -Hydroxyhippuric acid	Perphenazine	D,L-Tryptophan
Chlorpromazine	Hydroxyprogesterone	Phenelzine	Uric acid
Cholesterol	Isoproterenol-(+/-)	Prednisone	Verapamil
Clonidine	Isoxsuprine	Prilocaine	Zomepirac

Lay User Study

A lay user study was performed at three intended user sites with 140 lay persons. For a Cup device study, participants were tested the Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, Methadone, Marijuana and Benzodiazepines. sample. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled samples and a device. The typical results are summarized below.

Drugs	% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		The percentage agreement (%)
				No. of Positive	No. of Negative	
mAMP /MET	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	250	0	20	100%
	-50% Cutoff	20	500	0	20	100%
	-25% Cutoff	20	750	1	19	95%
	+25% Cutoff	20	1250	20	0	100%
	+50% Cutoff	20	1500	20	0	100%
	+75% Cutoff	20	1750	20	0	100%
COC	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	75	0	20	100%
	-50% Cutoff	20	150	0	20	100%
	-25% Cutoff	20	225	1	19	90%
	+25% Cutoff	20	375	20	0	100%
	+50% Cutoff	20	450	20	0	100%
	+75% Cutoff	20	525	20	0	100%
MTD	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	75	0	20	100%
	-50% Cutoff	20	150	0	20	100%
	-25% Cutoff	20	225	2	18	90%
	+25% Cutoff	20	375	19	1	95%
	+50% Cutoff	20	450	20	0	100%
	+75% Cutoff	20	525	20	0	100%
THC	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	12.5	0	20	100%
	-50% Cutoff	20	25	0	20	100%
	-25% Cutoff	20	37.5	3	17	85%
	+25% Cutoff	20	62.5	20	0	100%
	+50% Cutoff	20	75	20	0	100%
	+75% Cutoff	20	87.5	20	0	100%
MOP200	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	500	0	20	100%
	-50% Cutoff	20	1000	0	20	100%
	-25% Cutoff	20	1500	2	18	90%
	+25% Cutoff	20	2500	19	1	95%
	+50% Cutoff	20	3000	20	0	100%
	+75% Cutoff	20	3500	20	0	100%
BZO	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	75	0	20	100%
	-50% Cutoff	20	150	0	20	100%
	-25% Cutoff	20	225	2	18	90%
	+25% Cutoff	20	375	19	1	95%
	+50% Cutoff	20	450	20	0	100%
	+75% Cutoff	20	525	20	0	100%
TCA	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	125	0	20	100%
	-50% Cutoff	20	250	0	20	100%
	-25% Cutoff	20	375	1	19	95%
	+25% Cutoff	20	625	19	1	95%
	+50% Cutoff	20	750	20	0	100%
	+75% Cutoff	20	875	20	0	100%
OXY	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	25	0	20	100%
	-50% Cutoff	20	50	0	20	100%
	-25% Cutoff	20	75	1	19	95%
	+25% Cutoff	20	125	19	1	95%
	+50% Cutoff	20	150	20	0	100%
	+75% Cutoff	20	175	20	0	100%
BAR	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	75	0	20	100%
	-50% Cutoff	20	150	0	20	100%
	-25% Cutoff	20	225	1	19	95%
	+25% Cutoff	20	375	19	1	95%
	+50% Cutoff	20	450	20	0	100%
	+75% Cutoff	20	525	20	0	100%
BUP	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	2.5	0	20	100%
	-50% Cutoff	20	5	0	20	100%
	-25% Cutoff	20	7.5	2	18	90%
	+25% Cutoff	20	12.5	18	2	90%
	+50% Cutoff	20	15	20	0	100%
	+75% Cutoff	20	17.5	20	0	100%
PCP	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	6	0	20	100%
	-50% Cutoff	20	12.5	0	20	100%
	-25% Cutoff	20	19	2	18	90%
	+25% Cutoff	20	31	19	1	95%
	+50% Cutoff	20	37.5	20	0	100%
	+75% Cutoff	20	44	20	0	100%
AMP	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	250	0	20	100%
	-50% Cutoff	20	500	0	20	100%
	-25% Cutoff	20	750	1	19	95%
	+25% Cutoff	20	1,250	20	0	100%
	+50% Cutoff	20	1,500	20	0	100%
	+75% Cutoff	20	1,750	20	0	100%
MOP300	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	75	0	20	100%
	-50% Cutoff	20	150	0	20	100%
	-25% Cutoff	20	225	1	19	95%
	+25% Cutoff	20	375	20	0	100%
	+50% Cutoff	20	450	20	0	100%
	+75% Cutoff	20	525	20	0	100%
EDDP	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	75	0	20	100%
	-50% Cutoff	20	150	0	20	100%
	-25% Cutoff	20	225	1	19	95%
	+25% Cutoff	20	375	19	1	95%
	+50% Cutoff	20	450	20	0	100%
	+75% Cutoff	20	525	20	0	100%
TCA	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	250	0	20	100%
	-50% Cutoff	20	500	0	20	100%
	-25% Cutoff	20	750	2	18	90%
	+25% Cutoff	20	1,250	18	2	90%
	+50% Cutoff	20	1,500	20	0	100%
	+75% Cutoff	20	1,750	20	0	100%
PPX	-100%Cutoff	20	0	0	20	100%
	-75%Cutoff	20	75	0	20	100%
	-50% Cutoff	20	150	0	20	100%
	-25% Cutoff	20	225	1	19	95%
	+25% Cutoff	20	375	19	1	95%
	+50% Cutoff	20	450	20	0	100%
	+75% Cutoff	20	525	20	0	100%

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4. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.

5. FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

Center for Substance Abuse Treatment www.health.org 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS