Multi-Drug Urine Test Cup

Catalogue No. See Box label

The Multi-Drug Urine Test Cup is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, Ethyl Glucuronide, Fentanyl,Synthetic Cannabis,Methylenedioxymethamphetamine, Methamphetamine, Morphine, Methadone, Opiate, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, Cannabinoids and Tramadolin human urine at specified cutoff level.

Configurations of the Multi-Drug Urine Test Cup can consist of any combination of the above listed drug analytes.

The test provides only preliminary test results. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

The test may yield positive results for the prescription drugs buprenorphine, oxazepam, oxycodone, and secobarbital 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 exercised with any drug of abuse test result, particularly when the preliminary result is positive.

The multi-drug device may be combined with the adulteration control (Creatinine (CR),Glutaraldehyde (GLU), Nitrite (NI), pH, Specific Gravity (S.G.), Oxidants (OXI), and/or Pyridium Chlorochromate (PCC)) for the determination of diluted or adulterated urine specimens. The adulteration control is an important pre-screening test for drug-testing. (The adulteration tests are optional, customers can distinguish them from the pouch label).

This package insert applies to both multi-drug Cups with and without the adulteration. Therefore, some information on the performance characteristics of the product may not be relevant to your test. Please refer to the labels on the pouch and the printing on the test to identify which drugs are included in your test.

For in vitro diagnostic use only. It is intended for prescription use only.
Note: Any combination tests with Tramadol(TRA) or/and Synthetic Cannabis*(K2) or/and Ethyl Glucuronide*(EtG) or/and Fentanyl*(FTY) are intended for forensic use only.*

WHAT IS MULTI-DRUG URINE TEST CUP?

The Multi-Drug Urine Test Cup is an immunochromatographic assay for the qualitative determination of multiple drugs in human urine. *It is intended for prescription use only.*

WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

Drug(Identifier)	Calibrator	Cut-off level	Minimum detection time	Maximum detection time
Amphetamine (AMP 500)	d-Amphetamine	500 ng/mL	2-7 hours	1-2 days
Amphetamine (AMP1000)	d-Amphetamine	1000 ng/mL	2-7 hours	1-2 days
Secobarbital (BAR)	Secobarbital	300 ng/mL	2-4 hours	1-4 days
Buprenorphine(BUP)	Buprenorphine	10 ng/mL	4 hours	1-3 days
Oxazepam (BZO)	Oxazepam	300 ng/mL	2-7 hours	1-2 days
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL	1-4 hours	2-4 days
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL	1-4 hours	2-4 days
Ethyl Glucuronide (EtG)	Ethyl Glucuronide	500 ng/ml	1-2 hours	Up to 3+ days
Fentanyl (FTY)	Norfentanyl	20 ng/mL	1-4 hours	1-3 days
Synthetic Cannabis (K2)	JWH-018 Pentanoic Acid JWH-073 Butanoic Acid	50 ng/mL 25 ng/mL	8-12hours	Up to 5+ days
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine HCl(MDMA)	500 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET500/mAMP500)	D(+)-Methamphetamine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET1000/mAMP1000)	D(+)-Methamphetamine	1000 ng/mL	2-7 hours	2-4 days
Morphine (MOP/OPI300)	Morphine	300 ng/mL	2 hours	2-3 days
Methadone (MTD)	Methadone	300 ng/mL	3-8 hours	1-3 days
Opiate (OPI)	Morphine	2000ng/mL	2 hours	2-3 days
Oxycodone (OXY)	Oxycodone	100 ng/mL	4 hours	1-3 days
Phencyclidine (PCP)	Phencyclidine	25 ng/mL	4-6 hours	7-14days
Propoxyphene (PPX)	Propoxyphene	300 ng/mL	8-12hours	5-10days
Nortriptyline (TCA)	Nortriptyline	1000ng/mL	8-12hours	2-7 days
Cannabinoids (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL	2 hours	Up to 5+ days
Tramadol (TRA)	Tramadol	200 ng/mL	8-12hours	3-7 days

WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes.
7. This kit is for in vitro diagnostic use.

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch containing a test and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Security sealed labels.
3. Leaflet with instructions for use.
4. Adulteration & Adulteration Color Chart. (Provided with Kits including Adulterants.)

MATERIAL REQUIRED BUT NOT PROVIDED

Timer or clock

STORAGE AND STABILITY

Store at 4ºC-30ºC (40ºF-86ºF) in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION

WHEN TO COLLECT URINE FOR THE TEST?

Collect the urine sample for the test in the minimum detection time after the suspected drug use. Exactly when the urine sample is collected is very important in detecting any drug of abuse. This is because each drug is cleared by the body and is detected in the urine at different times and rates. Please refer to the section "WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?" in this instruction for use for the minimum/maximum detection time for each drug.

HOW TO COLLECT URINE?

1. Remove the test cup from the foil pouch by tearing at the notch and use it as soon as possible. Open the cap of the test cup and urinate directly into the test cup. Fill the cup to above 25mL mark. It's acceptable to have some extra sample. Wipe off any splashes or spills that may be on the outside of this cup.

2. You may observe the temperature strip affixed on the test cup between 2 to 4 minutes to see if the urine is diluted by water or liquid other than urine. The temperature range from 32°C-38°C (90ºF-100ºF) is acceptable.

IMPORTANT: The residual urine sample in the test cup should be enough to reach the 25mL (see the Minimum Fill Volume scale on the cup label). The residual urine sample in the test cup is for your self-testing.

TEST PROCEDURE

Test should be in room temperature 18ºC-30ºC (65ºF-86ºF)

<u>For Drug Test:</u>

1. After the urine has been collected, re-cap the cup and place the test cup on a flat surface.
2. Start the timer. Peel the label from right to left and read the result with in 5 minutes. **Do not read results after 5 minutes.**

For Drug and Adulteration Test:

1. After the urine has been collected, re-cap the cup and place the test cup on a flat surface.
2. Start the timer. Peel the label from right to left and read the result within 5 minutes. **Do not read results after 5minutes.**
3. For the adulteration strip(s),compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results. If the results indicate adulteration, do not read the drug test results, obtain a new sample.
   Note: All reagent areas may be read between 1 - 2 minutes. Changes in color after 2 minutes are of no diagnostic value.

Note: *Results after more than 5 minutes may be not accurate and should not be read.*

READING THE RESULTS

ADULTERATION CONTROL:

Semi-quantitative results are obtained by visually comparing the color of each pad with the corresponding color blocks on the enclosed color chart.

DRUGS-OF-ABUSE TESTS:

Preliminary positive (+)

A rose-pink band is visible in each control region. No color band appears in the appropriate test region. It indicates a preliminary positive result for the corresponding drug of that specific test zone.

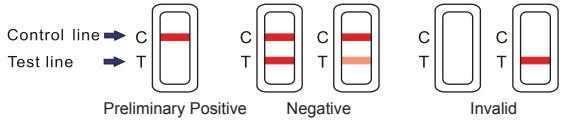
Negative (-)

A rose-pink band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Invalid

If a color band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor or the store,where you bought the product,with the lot number.

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 should be tested by a 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 the Multi-Drug Urine Test Cup. 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 drugis present but isn't detected by theMulti-Drug Urine Test Cup. If the sample is diluted, or the sample is adulterated that may cause false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test anything but urine.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

Note: The test provides only preliminary test results. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. GC/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.

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. These tests detect the presence of drugs such as marijuana, cocaine, opiates, methamphetamine, amphetamines, PCP, benzodiazepine, barbiturates, methadone, tricyclic antidepressants, ecstasy, and oxycodone.

   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 drugs and are accurate. These tests, however, 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. *If the test results are negative, can the conclusion be that the person isfree of drugs?*
   This means that if the sample was collected properly and if the test was performed according to direction, then probably none of the drug screened were present in the sample.

6. *Does a preliminary positive screen test mean that drugs of abuse have been found?*
   This means that the test has reacted with something in the sample and the sample should be sent to the lab for a more accurate test.

7. *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.

SUMMARY

Amphetamine (AMP)
Amphetamine and the structurally related “designer” drugs are sympathomimetic amines whose biological effects include potent central nervous system (CNS) stimulation, anorectic, hyperthemic, and cardiovascular properties. They are usually taken orally, intravenously, or by smoking. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or excreted unchanged in the urine with a half life of about 12 hours. It can be detected in the urine for 1 to 2 days after use. Amphetamine is metabolized to deaminated (hippuric and benzoic acids) and hydroxylated metabolites. Methamphetamine is partially metabolized to amphetamine and its major active metabolite. Amphetamines increase the heart rate and blood pressure, and suppress the appetite. Some studies indicate that heavy abuse may result in permanent damage to certain essential nerve structural in the brain.

Secobarbital (BAR)
Barbiturates are a class of central nervous system depressions. They have a wide range of half-life of 2 to 40 hours and can be detected in the urine for 1 to 4 days after use. Phenobarbital is a long acting barbiturate derivative that has been used as a daytime sedative and very extensively as an anticonvulsant. Pentobarbital and secobarbital are two examples of a short acting barbiturate sedative. Abuse of barbiturates can lead not only to impaired motor coordination and mental disorder, but also to respiratory collapse, coma and even death. Barbiturates are taken orally, rectally, or by intravenous and intramuscular injections. Short-acting barbiturates will generally be excreted in urine as metabolites, while the long-acting barbiturates will primarily appear unchanged.

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™; all of which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. A 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. 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 detection window for the parent drug in urine is thought to be approximately 3 days.

Oxazepam (BZO)
Benzodiazepines are the most widely used anxiolytic drugs. They are used extensively as anti-anxiety agents, hypnotics, muscle relaxants and anti-convulsants. They are taken orally or sometimes by injection and have a wide range of half-life from 2 to 40 hours. They can generally be detected for 1 to 2 days after Benzodiazepines use. Benzodiazepines are metabolized in the liver. Some Benzodiazepines and their metabolites are excreted in the urine. Their use can result in drowsiness and/or confusion. Benzodiazepines potentiate alcohol and other CNS depressants. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period.

Cocaine(COC)
Cocaine derived from leaves of coca plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in urine primarily as benzoylecgonine in a short period of time.

Ethyl Glucuronide (EtG)
Ethyl Glucuronideis a direct metabolite of alcohol. Presence in urine may be used to detect recent alcohol intake, even after alcohol is no longer measurable. Traditional laboratory methods detect the actual alcohol in the body, which reflects current intake within the past few hours (depending on how much was consumed). The presence of EtG in urine is a definitive indicator that it can be detected in the urine for 3 to 4 days after drinking alcohol, even alcohol is eliminated from the body. Therefore, EtG is a more accurate indicator of the recent intake of alcohol than measuring for the presence of alcohol itself. The EtG test can aid in the diagnosis of drunk driving and alcoholism, which has important significance in the forensic identification and medical examination.

Fentanyl (FTY)
Fentanyl is a potent, synthetic narcotic analgesic with a rapid onset and short duration of action. It was first synthesized by Janssen Pharmaceutica (Belgium) in the late 1950s, and It is approximately 100 times more potent than morphine. Fentanyl is a strong agonist at the μ-opioid receptors. Historically it has been used to treat breakthrough pain and is commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with a benzodiazepine. Fentanyl is frequently given intrathecally as part of spinal anesthesia or epidurally for epidural anesthesia and analgesia.

Synthetic cannabis (K2)
Synthetic cannabis is a psychoactive designer drug derived of natural herbs sprayed with synthetic chemicals that, when consumed, allegedly mimic the effects of cannabis, It is best known by the brand names K2 and Spice. Synthetic cannabis act on the body in a similar way to cannabinoids naturally found in cannabis, such as THC. A large and complex variety of synthetic cannabis most often cannabicyclohexanol, JWH-018, JWH-073, or HU-210, are used in an attempt to avoid the laws that make cannabis illegal, making synthetic cannabis a designer drug Although synthetic cannabis does not produce positive results in drug tests for cannabis, it is possible to detect its metabolites in human urine.

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.

Methamphetamine (MET/mAMP)
Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at half-life of about 15 hours and is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

Morphine (MOP/OPI300)
The opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. The principal metabolites of opiates are morphine, morphine-3-glucuronide normorphine and codeine with a half-life of about 3 hours. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might both be found in the urine of a person who has taken only heroin. The body also changes codeine to morphine. Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the urine indicates heroin, morphine and/or codeine use.
The test for Morphine (MOP/OPI300)of the Multi-Drug Urine Test Cup yields a positive result when themorphine in urine exceeds 300ng/mL.

Methadone (MTD)
Methadone is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver and excreted in urine as methadone, EDDP, EMDA and methadol. The kidneys are a major route of methadone excretion. Methadone has a biological half-life of 15 to 60 hours.

Opiate (OPI)
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.
The test forMorphine 2000 (OPI) of the Multi-Drug Urine Test Cup yields a positive result when themorphine in urine exceeds 2000 ng/mL.

Oxycodone (OXY)
Oxycodone is known as Oxycontin and Roxicodone. It is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiates derived from opium. Like other opiates, Oxycodone is characterized by its analegestic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analgesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of Oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and cardiac arrest.
Oxycodone is metabolized by N- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% of a single dose of Oxycodone is excreted in a 24 hour urine collection and consists of 13-19% free Oxycodone, 7-29% glucuronide conjugated Oxycodone, 13-14% glucuronide conjugated oxymorphone and an unknown amount of noroxycodone. The detection time window of Oxycodone is 1-3 days following use.

Phencyclidine (PCP)
Phencyclidine is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilizer. Phencyclidine can produce hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It has many street names, such as “angel dust” and “crystal cyclone,” etc. phencyclidine can be administered orally, by nasal ingestion, smoking, or by intravenous injection. It is metabolized in the liver and excreted through the kidneys in urine in unchanged form and oxidized metabolites with a half life of about 12 hours. Suction and urinary acidification in the treatment of overdose typically reduces its half-life from three days to one day.

Propoxyphene (PPX)
Propoxyphene, a synthetic opiate agonist, is structurally similar to methadone. Propoxyphene is a narcotic analgesic used to relieve mild to moderate pain. The principal metabolites are nordextropropoxyphene. The combination usage of propoxyphene, aspirin, acetaminophen or other sedatives can lead cooperative interaction. Abuse of propoxyphene can lead nausea, vomit, astriction, illusion, hallucination, heart poisoning, lung dropsy and even death. Propoxyphene is metabolized in the liver and excreted in urine as nordextropropoxyphene. Thus the presence of the propoxyphene or its metabolites in the urine indicates propoxyphene use.

Nortriptyline (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.

Cannabinoids (THC)
Cannabinoids is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC&Cannabinol can be metabolized and excreted as 11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. It can be detected for 1 to 5 days after use. Smoking is the primary method of use of Cannabinoids/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

Tramadol (TRA)
Tramadol [2-(dimethylaminomethyl)-1-(3-methoxyphenyl)cyclohexanol] is used similarly to codeine, to treat moderate to moderately severe pain. It is a synthetic analog of the phenanthrene alkaloid codeine and, as such, is an opioid and also a prodrug (codeine is metabolized to morphine, tramadol is converted to O-desmethyltramadol). Tramadol and its metabolites are excreted primarily in the urine with observed plasma half-lives of 6.3 and 7.4 hours for tramadol and O-desmethyltramadol(denoted M1), respectively. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% of the dose is excreted as metabolites.

PRINCIPLE

The Multi-Drug Urine Test Cup is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs in a sample competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end is immersed into urine specimen, the urine is absorbed into the device by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), respective drug monoclonal antibody conjugate binds to the respective drug-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the respective drug monoclonal antibody conjugate preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials.

Even though there is an internal procedural control line in the test device in the Control Region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment, each new operator and monthly to determine that tests are working properly. This will ensure that the end user has clear understanding of when to perform quality control testing.

PERFORMANCE CHARACTERISTICS

Accuracy

1760 (eighty of each drug)clinical urine specimens were analyzed by GC-MS and by each corresponding drug of abuse Test. Each test was read by three viewers. 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:

Drug test	Result		Drug-free	Less than half the cutoff concentration by GC/MS analysis	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)	%Agreement with GC/MS (95%CI)
AMP (500)	Viewer A	+	0	0	1	10	29	97.5% (84.5% - 100%)
		-	10	18	11	1	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	9	29	95% (84.5% - 100%)
		-	10	18	10	2	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	10	29	97.5% (84.5% - 100%)
		-	10	18	11	1	0	97.5% (79.5% - 100%)
AMP (1000)	Viewer A	+	0	0	1	11	29	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	11	29	100% (84.5% -100%)
		-	10	18	10	0	0	95%(79.5% - 100%)
	Viewer C	+	0	0	2	11	29	100% (84.5% -100%)
		-	10	18	10	0	0	95%(79.5% - 100%)
BAR	Viewer A	+	0	0	2	20	20	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
	Viewer C	+	0	0	2	20	20	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
BZO	Viewer A	+	0	0	2	20	20	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
	Viewer C	+	0	0	2	20	20	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
COC (150)	Viewer A	+	0	0	1	11	29	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
COC (300)	Viewer A	+	0	0	2	11	29	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
	Viewer B	+	0	0	1	11	29	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
EtG	Viewer A	+	0	0	0	17	21	95% (79.5% - 100%)
		-	10	12	18	2	0	100% (84.5% - 100%)
	Viewer B	+	0	0	0	18	21	97.5% (82% - 100%)
		-	10	12	18	1	0	100% (84.5% - 100%)
	Viewer C	+	0	0	0	18	21	97.5% (82% - 100%)
		-	10	12	18	1	0	100% (84.5% - 100%)
FTY	Viewer A	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
MET (mAMP) (500)	Viewer A	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	16	13	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	20	20	100% (l84.5% - 100%)
		-	10	16	12	0	0	95% (79.5% - 100%)

	Viewer C	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	16	13	0	0	97.5% (82% - 100%)
MET (mAMP) (1000)	Viewer A	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	16	13	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	20	20	100% (I84.5% - 100%)
		-	10	16	12	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	16	12	0	0	95% (79.5% - 100%)
MDMA	Viewer A	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
BUP	Viewer A	+	0	0	1	16	24	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	16	24	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	2	16	24	100% (84.5% - 100%)
		-	10	18	10	0	0	95% (79.5% - 100%)
MOP /OPI300	Viewer A	+	0	0	2	20	20	100% 84.5% - 100%)
		-	10	19	9	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	19	9	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
MTD	Viewer A	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
OPI	Viewer A	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
PCP	Viewer A	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	13	16	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	13	15	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	13	16	0	0	97.5% (82% - 100%)
TCA	Viewer A	+	0	0	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	10	30	100% (84.5% - 100%)
		-	10	19	9	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
THC	Viewer A	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
OXY	Viewer A	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
PPX	Viewer A	+	0	0	2	20	20	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
	Viewer C	+	0	0	2	20	20	100% (84.5% -100%)
		-	10	10	18	0	0	95%(79.5% - 100%)
K2	Viewer A	+	0	0	1	18	22	100% (84.5% -100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	0	17	22	97.5% (82% - 100%)
		-	10	12	18	1	0	100% (84.5% - 100%)
	Viewer C	+	0	0	0	15	22	92.5% (77% - 100%)
		-	10	12	18	3	0	100% (84.5% - 100%)
TRA	Viewer A	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	20	8	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	20	8	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)

Precision and Sensitivity

To investigate the precision and sensitivity, each drug samples was analyzed at the following concentrations: cutoff - 100%, cutoff - 75%, cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, cutoff + 50%, cutoff + 75%and the cutoff + 100%. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots of the corresponding drug of abuse test. Totally 3 operators participated in the study of the corresponding drug of abuse test. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day), for a total of 50 determinations per concentration per lot of the corresponding drug of abuse test.

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Results Negative/ Positive		
			Lot 1	Lot 2	Lot 3
AMP (500)	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	6/44	5/45	4/46
	625	50	50/0	50/0	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
AMP (1000)	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
	1000	50	5/45	6/44	6/44
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
BAR	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	5/45	5/45	6/44
	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
BZO	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	6/44	5/45	6/44
	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
COC (150)	0	50	0/50	0/50	0/50
	37.5	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	112.5	50	50/0	50/0	50/0
	150	50	5/45	5/45	5/45
	187.5	50	0/50	0/50	0/50
	225	50	0/50	0/50	0/50
	262.5	50	0/50	0/50	0/50

	300	50	0/50	0/50	0/50
COC (300)	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	6/44	5/45	5/45
	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
EtG	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	5/45	4/46	5/45
	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
FTY	0	50	50/0	50/0	50/0
	5	50	50/0	50/0	50/0
	10	50	50/0	50/0	50/0
	15	50	50/0	50/0	50/0
	20	50	4/46	5/45	5/45
	25	50	0/50	0/50	0/50
	30	50	0/50	0/50	0/50
	35	50	0/50	0/50	0/50
	40	50	0/50	0/50	0/50
MET (mAMP) (500)	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	4/46	5/45	5/45
	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
MET (mAMP) (1000)	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
	1000	50	5/45	6/44	4/46
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
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	7/43	6/44	5/45
	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
BUP	0	50	50/0	50/0	50/0
	2.5	50	50/0	50/0	50/0
	5.0	50	50/0	50/0	50/0
	7.5	50	50/0	50/0	50/0
	10.0	50	5/45	5/45	6/44
	12.5	50	0/50	0/50	0/50
	15.0	50	0/50	0/50	0/50
	17.5	50	0/50	0/50	0/50
	20.0	50	0/50	0/50	0/50
MOP/OPI300	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	7/43	5/45	6/44

	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
MTD	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	5/45	7/43	5/45
	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
OPI	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	5/45	5/45	6/44
	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
PCP	0	50	50/0	50/0	50/0
	6.25	50	50/0	50/0	50/0
	12.5	50	50/0	50/0	50/0
	18.75	50	50/0	50/0	50/0
	25	50	6/44	4/46	5/45
	31.25	50	0/50	0/50	0/50
	37.5	50	0/50	0/50	0/50
	43.75	50	0/50	0/50	0/50
	50	50	0/50	0/50	0/50
TCA	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
	1000	50	6/44	5/45	4/46
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
THC	0	50	50/0	50/0	50/0
	12.5	50	50/0	50/0	50/0
	25.0	50	50/0	50/0	50/0
	37.5	50	50/0	50/0	50/0
	50.0	50	4/46	4/46	5/45
	62.5	50	0/50	0/50	0/50
	75.0	50	0/50	0/50	0/50
	87.5	50	0/50	0/50	0/50
	100.0	50	0/50	0/50	0/50
OXY	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	4/46	4/46	5/45
	125	50	0/50	0/50	0/50
	150	50	0/50	0/50	0/50
	175	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
K2 JWH-018 Pentanoic Acid	0	50	50/0	50/0	50/0
	12.5	50	50/0	50/0	50/0
	25.0	50	50/0	50/0	50/0
	37.5	50	50/0	50/0	50/0
	50.0	50	5/45	6/44	5/45
	62.5	50	0/50	0/50	0/50
	75.0	50	0/50	0/50	0/50
	87.5	50	0/50	0/50	0/50
	100.0	50	0/50	0/50	0/50
K2 JWH-073	0	50	50/0	50/0	50/0
	6.25	50	50/0	50/0	50/0

Butanoic Acid	12.5	50	50/0	50/0	50/0
	18.75	50	50/0	50/0	50/0
	25	50	5/45	6/44	6/44
	31.25	50	0/50	0/50	0/50
	37.5	50	0/50	0/50	0/50
	43.75	50	0/50	0/50	0/50
	50	50	0/50	0/50	0/50
PPX	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	6/44	5/45	5/45
	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
TRA	0	50	50/0	50/0	50/0
	50	50	50/0	50/0	50/0
	100	50	50/0	50/0	50/0
	150	50	50/0	50/0	50/0
	200	50	4/46	6/44	5/45
	250	50	0/50	0/50	0/50
	300	50	0/50	0/50	0/50
	350	50	0/50	0/50	0/50
	400	50	0/50	0/50	0/50

Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally relatedcompounds produced positive results with the test when tested at levels equal to or greater than theconcentrations listed below.

Items	Concentration (ng/mL)	Items	Concentration (ng/mL)
Amphetamine (AMP500)		**Methamphetamine (MET500/mAMP500)**	
d-Amphetamine	500	D(+)-Methamphetamine	500
d.l-Amphetamine	1500	MDMA	10,000
1-Amphetamine	25,000	MDEA	100,000
(+/-) 3,4-methylenedioxyamphetamine (MDA)	2500	**Methamphetamine (MET1000/mAMP1000)**	
Phentermine	1500	D(+)-Methamphetamine	1,000
Phenylpropanolamine	1500	D-Amphetamine	50,000
d-methamphetamine	>50,000	Chloroquine	50,000
l-methamphetamine	>50,000	(+/-)-Ephedrine	50,000
3,4-Methylenedioxyethylamphetamine(MDE)	50,000	(-)-Methamphetamine	25,000
(+/-)3,4-methylenedioxumethamphetam ine (MDMA)	50,000	(+/-)3,4-methylenedioxumethamphetam ine(MDMA)	2,000
Amphetamine (AMP1000)		β-Phenylethylamine	50,000
d-Amphetamine	1,000	Trimethobenzamide	10,000
d.l-Amphetamine	3,000	l-Methamphetamine	8,000
1-Amphetamine	50,000	3,4-Methylenedioxyamphetamine (MDA)	3,000
(+/-) 3,4-methylenedioxyamphetamine (MDA)	5,000	3,4-Methylenedioxyethylamphetamine(MDE)	600
Phentermine	3,000	**Methylenedioxymethamphetamine (MDMA)**	
Phenylpropanolamine	3,000	3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
d-methamphetamine	>100,000	3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
l-methamphetamine	>100,000	3,4-Methylenedioxyethylamphetamine (MDE)	300
3,4-Methylenedioxyethylamphetamine(MDE)	100,000	D-Methamphetamine	8,000
(+/-)3,4-methylenedioxumethamphetam ine(MDMA)	100,000	L–Methamphetamine	10,000
Barbiturates (BAR)		**Morphine (MOP/OPI300)**	
Secobarbital	300	Morphine	300
Amobarbital	300	Codeine	300
Alphenol	150	Ethyl Morphine	300
Aprobarbital	200	Heroin	300
Butabarbital	75	Hydrocodone	5,000
Butathal	100	Hydromorphone	5,000
Butalbital	5,000	Morphine-3-β-d-glucuronide	1,000
Cyclopentobarbital	600	σ-Monoacetylmorphine	400
Pentobarbital	5,000	Oxycodone	25,000
Phenobarbital	10,000	Oxymorphone	10,000
Benzodiazepines (BZO)		Thebaine	30,000
Oxazepam	300	**Opiate (OPI)**	
Alprazolam	200	Morphine	2,000
a-Hydroxyalprazolam	1,500	Codeine	2,000
Benzodiazepine	100	Ethylmorphine	5,000
Bromazepam	1,500	Heroin	2,000
Chlordiazepam	10,000	Hydrocodone	12,500
Chlordiazepoxide	1,500	Hydromorphine	5,000
Clonazepam HCl	800	Levorphanol	75,000
Clobazam	100	σ-Monoacetylmorphine	5,000
Clonazepam	5,000	Morphine 3-b-D-glucuronide	2,000
Clorazepate dipotassium	200	s-Monoacetylmorphine	5,000
Delorazepam	1,500	Norcodeine	12,500
Desalkylflurazepam	400	Normorphone	50,000
Diazepam	200	Oxycodone	25,000
Estazolam	2,500	Oxymorphine	25,000
Flunitrazepam	400	Procaine	150,000
Hydroxyalprazolam	1,500	Thebaine	100,000
D,L-Lorazepam	1,500	**Oxycodone(OXY)**	
Lorazepam	2,000	Oxycodone	100
Midazolam	12,500	Dihydrocodeine	20,000
Nitrazepam	100	Codeine	100,000
Norchlordiazepoxide	200	Hydromorphone	100,000
Nordiazepam	400	Morphine	>100,000
Temazepam	100	Acetylmorphine	>100,000
Triazolam	1,000	Buprenorphine	>100,000
Buprenorphine(BUP)		Ethylmorphine	>100,000
Buprenorphine	10	**Phencyclidine (PCP)**	
Buprenorphine -3-D-Glucuronide	15	Phencyclidine	25
Norbuprenorphine	20	4-Hydroxyphencyclidine	12,500
Norbuprenorphine 3-D-Glucuronide	200	Phencyclidine morpholine	50
Cannabinoids (THC)		**Propoxyphene (PPX)**	
11-nor-Δ9-THC-9-COOH	50	d-Norpropoxyphene	300
11-nor-Δ8-THC-9-COOH	30	**Synthetic Cannabis (K2)**	
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500	JWH-018 Pentanoic Acid	50
Δ8- Tetrahydrocannabinol	7,500	JWH-073 Butanoic Acid	25
Δ9- Tetrahydrocannabinol	10,000	JWH-018 N-4-hydroxypentyl	2,000
Cannabinol	100,000	JWH-018 (Spice Cannabinoid)	1,000
Cannabidiol	100,000	JWH-018 4-Hydroxypentyl metabolite-D5 (indole-D5)	1,000
Cocaine (COC150)		JWH-073 (Spice Cannabinoid)	2,000
Benzoylecgonine	150	JWH-073 3-Hydroxybutyl metabolite	1,000
Cocaine HCl	375	JWH-073 3-Hydroxybutyl metabolite-D5 (indole-D5)	1,000
Cocaethylene	6250	JWH-019 6-hydroxypentyl	1,000
Ecgonine	16,000	JWH-122 N-4-hydroxypentyl	2,000
Cocaine (COC300)		JWH-210 5-Hydroxypentyl metabolite	5,000
Benzoylecgonine	300	AM2201 4-Hydroxypentyl metabolite	1,000
Cocaine HCl	750	**Nortriptyline (TCA)**	
Cocaethylene	12,500	Nortriptyline	1,000
Ecgonine	32,000	Nordoxepin	1,000
Ethyl Glucuronide (EtG)		Trimipramine	3,000
Ethyl Glucuronide	500	Amitriptyline	1,500
Fentanyl (FTY)		Promazine	1,500
Norfentanyl	20	Desipramine	200
Methadone (MTD)		Imipramine	400
Methadone	300	Clomipramine	12,500
Doxylamine	50,000	Doxepin	2,000
EDDP	300	Maprotiline	2,000

		Promethazine	25,000
		Tramadol (TRA)	
		Tramadol	200

Effect of Urinary Specific Gravity

12 urine samples with density ranges (1.005-1.025) are collected and spiked with each drug at 25% below and 25% above cutoff level. Each sample was tested by three batches of the corresponding drug of abuse test. Three laboratory assistants read the result per batch of the corresponding drug of abuse test. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary PH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with each drug at 25% below and 25% above cutoff levels. Each sample was tested by three batches of the corresponding drug of abuse test. Three laboratory assistants read the result per batchof the corresponding drug of abuse test. The result demonstrates that varying range of PH do not interfere with the performance of the test.

Interfering Substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff for the corresponding drug of abuse test. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

Acetominophen
Acetophenetidin
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
Apomorphine
Aspartame
Aspirin
Atropine
Benadryl
Benzilic acid
Benzoic acid
Benzoylecgonine **(except COC test)**
Bilirubin
Cannabidiol **(except THC, OXY tests)**
Captopril
Chloralhydrate
Chloramphenicol
Chlorothiazide
Chlorpromazine
Chlorquine
Cholesterol
Clarithromycin
Clonidine
Codeine **(except MOP/OPI300, OPI tests)**
(-) Cotinine
Cortisone
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam**(except BZO test)**
Dopamine HCl**(except AMP test)**
Doxepin **(except TCA test)**
Doxylamine**(except KET,MTD, TRA tests)**
Ecgonine methyl ester
β-Estradiol **(except BZO test)**
Ephedrine HCl**(except MET/mAMP test)**
Erythromycin **(except BZO test)**
Estrogen
Fenoprofen
Fentanyl citrate**(except MDMA test)**
Furosemide
Gentisic acid
Hydralazine **(except BZO test)**
Hydrochlorothiazide
Hydrocodone **(except BZO, MOP/OPI300, OPI, OXY tests)**
3-Hydroxytyramine
Hydrocortisone
I Caps
Ibuprofen **(except OXY test)**
Isoxsuprine
Ketamine **(except OXY test)**
Ketoprofen
Labetalol
Lamotrigine
Levonorgestrel
Lofexidine **(except OXY test)**
Loperamide **(except MTD test)**
Maprotiline **(except TCA, OXY tests)**
Meperidine
Meprobamate
Methadone **(except MTD test)**
Methamphetamine **(except MDMA,MET/mAMP, TCA tests)**
Methoxyphenamine **(except MDMA, MET/mAMP,TCA tests)**
Morphine-3-b-d-glucuronide **(except BZO, MOP/OPI300, OPI tests)**
N-Acetylprocainamide**(except OXY test)**
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Nitroglycerin
Norcodein **(except MOP/OPI300, OPI, BZO, OXY tests)**
Norethindrone
Noscapine
O-Hydroxyhippuric acid
Omeprazole
Oxalic acid
Oxazepam **(except BZO test)**
Oxolinic acid
Oxycodone acetaminophen **(except MOP/OPI300,OPI,OXY tests)**
Oxymetazoline
Papaverine
Penicillin V Potassium
Penicillin-G
Pentobarbital**(except BAR, OXY tests)**
Perphenazine
Pethidine HCl
Phencyclidine**(except PCP, OXY tests)**
Phenylephrine**(except MET/mAMP test)**
Phenelzine
Phenytoin **(except BAR test)**
Pholcodine**(except MOP/OPI300,OPI tests)**
Prednisone
Procaine **(except COC test)**
Propranolol HCl
Quinine
Ranitidine
Ranitidine HCl
Salicylic acid
Secobarbital **(except MET/mAMP, BAR tests)**
Serotonin (5- Hydroxytyramine)
Sinus&Allergy**(except BZO, MET/mAMP tests)**
Sulfamethazine
Sulindac
Tetrahydrocortisone3-(β-Dglucuronide) **(except AMP, BAR, OXY tests)**
Tetrahydrocortisone, 3-acetate **(except AMP, BAR, OXY tests)**
Tetrahydrozoline
Thiamine
Thioridazine
Triamterene
Trifluoperazine
Trimethoprim
Tyramine **(except AMP, BAR tests)**
Uric acid
Venlafaxine HCl**(except TRA test)**
Verapamil
Zoloft
Zomepirac
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
D L-Tryptophan **(except AMP, BAR tests)**
D,L-Isoproterenol**(except AMP, BAR tests)**
D,L-Octopamine
DL-Propranolol
DL-Tyrosine
D-Norpropoxyphene
D-Propoxyphene **(except OXY test)**
D-Pseudoephedrine

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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 Treatmentwww.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


Keep away from sunlight

Store between 4ºC - 30ºC (40ºF - 86ºF)


Keep dry


Do not re-use

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