CLIA WAIVED
Multi-Drug Urine Test Cup
Catalogue No. See Pouch Label

Multi-Drug Urine Test Cup offers any combination from 2 to 14 drugs of abuse tests for 14 different drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepine (BZO), Cocaine (COC), Marijuana(THC), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP), Methadone (MTD), Opiate (OPI2000), Phencyclidine (PCP), Tricyclic Antidepressants (TCA), Oxycodone(OXY) and Buprenorphine (BUP).

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.)

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. We refer to the labels on the pouch and the print on the test cup to identify which drugs are included in your test.

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

WHAT IS MULTI-DRUG URINE TEST CUP?

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

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 not provided.

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

Drug(Identifier)	Calibrator	Cut-off level	Minimum detection time	Maximum detection time
Amphetamine (AMP)	d-Amphetamine	1000ng/mL	2-7 hours	1-2 days
Barbiturates (BAR)	Secobarbital	300 ng/mL	2-4 hours	1-4 days
Benzodiazepine (BZO)	Oxazepam	300 ng/mL	2-7 hours	1-2 days
Cocaine (COC)	Benzoylecgonine	300 ng/mL	1-4 hours	2-4 days
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL	2 hours	Up to 5+ days
Methamphetamine (MET)	D(+)-Methamphetamine	1000ng/mL	2-7 hours	2-4 days
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine HCl (MDMA)	500 ng/mL	2-7 hours	2-4 days
Morphine (MOP)	Morphine	300 ng/mL	2 hours	2-3 days
Methadone (MTD)	Methadone	300 ng/mL	3-8 hours	1-3 days
Opiate (OPI2000)	Morphine	2000ng/mL	2 hours	2-3 days
Phencyclidine (PCP)	Phencyclidine	25 ng/mL	4-6 hours	7-14days
Tricyclic Antidepressants (TCA)	Notriptyline	1000ng/mL	8-12hours	2-7 days
Oxycodone(OXY)	Oxycodone	100 ng/mL	4 hours	1-3 days
Buprenorphine(BUP)	Buprenorphine	10 ng/mL	4 hours	1-3 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 expiration 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 cup and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Security sealed labels.
3. Adulterant color chart (Optional).
4. Leaflet with instructions for use.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

You may collect urine samples within detection time after suspected drug use. Collection time is crucial to detecting any drug of abuse. 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?" for minimum/ maximum detection time for each drug.

HOW TO COLLECT URINE?

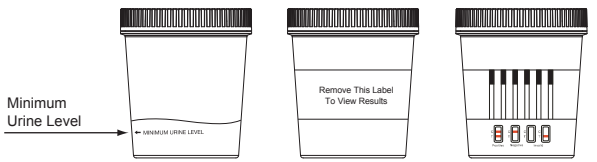
1. Remove a test cup from the foil pouch by tearing at the notch; use it as soon as possible. Open the cap of the test cup and urinate directly into the test cup. The urine sample should be above the minimum urine level scale located on the left side of cup label. Wipe of any splashes or spills that 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 to 38°C (90 ºF-100ºF) is acceptable.
3. **IMPORTANT:** The urine sample should be above the minimum urine level required for proper testing. The minimum urine level is located on the left side of the cup label.

HOW TO DO THE TEST?

Test must be in room temperature 10ºC - 30ºC (50ºF - 86ºF)..

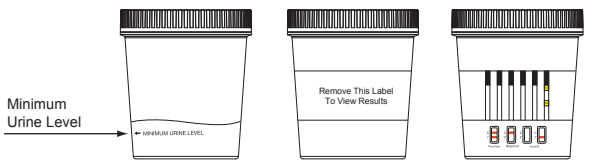
For drugs test:

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



For drugs 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.
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. **Note:** All reagent areas may be read between 1 - 2 minutes. Changes in color after 2 minutes are of no diagnostic value.
4. For the drug of abuse tests, read the results for the drugs at 5 minutes. **Do not read after 5 minutes**.



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.

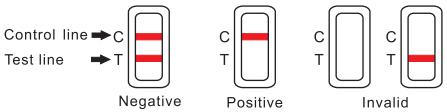
DRUGS-OF-ABUSE TESTS:

Preliminary positive (+)
A rose-pink band is visible in each control region. No color band appears in the appropriate test region. This 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. This indicates that the concentration of the corresponding drug of that specific test zone is below zero or 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.

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 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 drug is present but isn't detected by **Multi-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. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If these adulterants are suspected, the test should be repeated with another urine specimen.
4. There is a possibility that technical or procedural errors may cause erroneous results.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when a drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. The adulteration assays are for screening purposes only; all abnormal results should be confirmed by an alternative methodology.

The test is also intended for prescription use. The below sections are for the reference of prescription users. The above sections of WARNINGS AND PRECAUTIONS, CONTENT OF THE KIT, STORAGE AND STABILITY, HOW TO DO THE TEST, READING THE RESULTS, and TEST LIMITATIONS also apply to the prescription users.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a conformed 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.

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, intraveneously, 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.

Barbiturates (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.

Benzodiazepine (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.

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- Δ 9-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.

Methamphetamine (MET)
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.

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.

Morphine (MOP)
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) of **Multi-Drug Urine Test Cup** yields a positive result when the morphine 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 kinneys are a major route of methadone excretion. Methadone has a biological half-life of 15 to 60 hours.

Opiate (OPI2000)
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 for Morphine 2000 (OPI) of **Multi-Drug Urine Test Cup** yields a positive result when the morphine in urine exceeds 2,000 ng/mL..

Phencyclidine (PCP)
Phencyclidine is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilzer. 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.

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.

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 analegesics 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.

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.

PRINCIPLE

Multi-Drug Urine Test Cup is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. This is a 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 test is activate, 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.

SPECIMEN COLLECTION AND PREPARATION

1. Remove a 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. The urine sample should be above the **Minimum Urine Level** scale on the cup label.
2. The technician replaces the cap and tightens the seal. Check the cap for a tight seal.
3. The technician observes 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 32ºC to 38ºC (90 ºF-100ºF) is acceptable.
4. Technician dates and signs the name of the donor and the operator on the security seal label.
5. Technician dates and initials the security seal and attaches the security seal over the cup cap.

QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials. Though there is an internal procedural control line in the test device of 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 control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

PERFORMANCE CHARACTERISTICS

ADULTERATION CONTROL:

Expected Results

Creatinine: Daily creatinine excretion, related to muscle mass of the human body, is usually constant. The DOT guideline states that urine specimens with creatinine levels of less than 20 mg/dl are indications of adulteration. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution2, sample with creatinine level of lower than 20 mg/dl should be considered adulterated.

Glutaraldehyde: Glutaraldehyde is not a natural component of human urine and it should not be present in normal urine. The presence of glutaraldehyde in the urine sample indicates the possibility of adulteration. However, false positive may result when ketone bodies are presence in urine. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolic abnormalities.

Nitrite: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. In this adulteration control, nitrite level above 7.5 mg/dl is considered abnormal.

Oxidants: The presence of Bleach and other oxidizing reagents in the urine is indicative of adulteration since oxidizing reagents are not normal constituents of urine. Other oxidizing reagents include Hydrogen Peroxide, Ferricyanide, Persulfate, Pyridinium Chlorochromate…etc.

pH: Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

Specific Gravity: Random urine may vary in specific gravity from 1.003 - 1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016 - 1.022. Elevated urine specific gravity value may be obtained in the presence of moderate quantities of protein. DOT guidelines state that a urine specimen with specific gravity level of less than 1.003 is an indication of adulteration. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is adulterated.

Pyridium Chlorochromate: The presence of any chromate in urine is indicative of adulteration as chromate is not a normal constituent of urine.

DRUGS-OF-ABUSE TESTS:

Accuracy

1120 (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	Viewer A	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	18	10	0	0	95% (79.5% - 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	1	11	29	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 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	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
BZO	Viewer A	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
COC	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%)
THC	Viewer A	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 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	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%)

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	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
MOP	Viewer A	+	0	0	1	20	20	100% 84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 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	2	19	21	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 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	2	18	22	100% (84.5% - 100%)
		-	10	13	15	0	0	95% (79.5% - 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	2	18	22	100% (84.5% - 100%)
		-	10	13	15	0	0	95% (79.5% - 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	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
OXY	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%)
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	1	16	24	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)

Precision and Sensitivity

To investigate the precision and sensitivity, each drug samples were 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	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	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
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	7/43	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
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	7/43	6/44	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
COC	0	50	0/50	0/50	0/50
	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	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
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	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
MET	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	4/46	5/45	5/45
	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	6/44	5/45	6/44
	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
MOP	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	6/44	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
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	6/44	4/46	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	6/44	4/46	4/46
	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	5/45	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	5/45	6/44	5/45
	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
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	6/44	6/44	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
	200	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	6/44	4/46	4/46
	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

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 related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Items	Concentration (ng/ml)	Items	Concentration (ng/ml)
Amphetamine (AMP)		**Methamphetamine (MET)**	
d-Amphetamin	1,000	D(+)-Methamphetamine	1,000
d,l-Amphetamine	3,000	D-Amphetamine	50,000
l-Amphetamine	50,000	Chloroquine	50,000
(+/-) 3,4-methylenedioxyamphetamine (MDA)	5,000	(+/-)-Ephedrine	50,000
Phentermine	3,000	(-)-Methamphetamine	25,000
d-methamphetamine	>100,000	(+/-)3,4-methylenedioxumethamphetamine(MDMA)	2,000
l-methamphetamine	>100,000	β-Phenylethylamine	50,000
3,4-Methylenedioxyethylamphetamine(MDE)	100,000	Trimethobenzamide	10,000
(+/-)3,4-methylenedioxumethamphetamine (MDMA)	100,000	**Methylenedioxymethamphetamine (MDMA)**	
Barbiturates (BAR)		3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
Secobarbital	300	3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
Amobarbital	300	3,4-Methylenedioxyethylamphetamine (MDE)	300
Alphenol	150	**Morphine (MOP)**	
Aprobarbital	200	Morphine	300
Butabarbital	75	Codeine	300
Butathal	100	Ethyl Morphine	300
Butalbital	2,500	Hydrocodone	5,000
Cyclopentobarbital	600	Hydromorphone	5,000
Pentobarbital	300	Morphinie-3-β-d-glucuronide	1,000
Phenobarbital	10000	Thebaine	30,000
Benzodiazepine (BZO)		**Opiate (OPI2000)**	
Oxazepam	300	Morphine	2,000
Alprazolam	200	Codeine	2,000
a-Hydroxyalprazolam	1,500	Ethylmorphine	5,000
Bromazepam	1,500	Hydrocodone	12,500
Chlordiazepoxide	1,500	Hydromorphine	5,000
Clonazepam HCl	800	Levorphanol	75,000
Clobazam	100	α-Monoacetylmorphine	5,000
Clonazepam	800	Morphine 3-b-D-glucuronide	2,000
Clorazepate dipotassium	200	Norcodeine	12,500
Delorazepam	1,500	Normorphone	50,000
Desalkylflurazepam	400	Oxycodone	25,000
Diazepam	200	Oxymorphine	25,000
Estazolam	2,500	Procaine	150,000
Flunitrazepam	400	Thebaine	100,000
D,L-Lorazepam	1,500	**Phencyclidine (PCP)**	
Midazolam	12,500	Phencyclidine	25
Nitrazepam	100	4-Hydroxyphencyclidine	12500
Norchlordiazepoxide	200		
Nordiazepam	400		
Temazepam	100		
Trazolam	2,500		

Cannabinoids (THC)		**Tricyclic Antidepressants (TCA)**	
11-nor-Δ9-THC-9-COOH	50	Notriptyline	1,000
11-nor-Δ8-THC-9-COOH	30	Nordoxepine	1,000
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500	Trimipramiine	3,000
Δ8- Tetrahydrocannabinol	7,500	Amitriptyline	1,500
Δ9- Tetrahydrocannabinol	10,000	Promazine	1,500
Cannabinol	100,000	Desipramine	200
Cannabidiol	100,000	Imipramine	400
Cocaine (COC)		Clomipramine	12,500
Benzoylecgonine	300	Doxepine	2,000
Cocaine HCl	750	Maprotiline	2,000
Cocaethylene	12,500	Promethazine	25,000
Ecgonine	32,000	**Oxycodone(OXY)**	
Methadone		Oxycodone	100
Methadone	300	Dihydrocodeine	20,000
Doxylamine	50,000	Codeine	100,000
Buprenorphine(BUP)		Hydromorphone	100,000
Buprenorphine	10	Morphine	>100,000
Buprenorphine -3-D-Glucuronide	15	Acetylmorphine	>100,000
Norbuprenorphine	20	Buprenorphine	>100,000
Norbuprenorphine 3-D-Glucuronide	200	Ethylmorphine	>100,000

Effect of Urinary Specific Gravity

12 urine samples with density ranges (1.000-1.035) 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 batch of the corresponding drug of abuse test. The result demonstrate that varying ranged 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 (4-Acetamidophenol) **(except OXY test)**
Acetophenetidin
N-Acetylprocainamide **(except OXY test)**
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
Apomorphine
Aspartame
Atropine **(except BAR test)**
Benzilic acid
Benzoic acid
Benzoylecgonine **(except COC,OXY tests)**
Bilirubin
Cannabidiol **(except THC, OXY tests)**
Chloralhydrate
Chloramphenicol
Chlorothiazide
Chlorpromazine
Chlorquine
Cholesterol
Clonidine
Codeine **(except MOP, OPI, BZO, OXY tests)**
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Ecgonine methyl ester
Erythromycin **(except BZO test)**
β-Estradiol **(except BZO test)**
Fenoprofen
Furosemide
Gentisic acid
Hydralazine **(except BZO test)**
Hydrochlorothiazide **(except BZO test)**
Hydrocodone **(except BZO, MOP, OPI, OXY tests)**
Hydrocortisone
O-Hydroxyhippuric acid
3-Hydroxytyramine
Ibuprofen **(except OXY test)**
D,L-Isoproterenol **(except AMP, BAR test)**
Isoxsuprine
Ketamine **(except OXY test)**
Ketoprofen
Labetalol
Loperamide
Maprotiline **(except TCA, OXY tests)**
Meperidine **(except THC, OXY tests)**
Meprobamate
Methadone **(except MTD, OXY tests)**
Methoxyphenamine **(except AMP, BAR tests)**
Morphinie-3-β-d-glucuronide **(except BZO, MOP, OPI tests)**
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein **(except MOP, OPI, BZO, OXY tests)**
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam **(except BZO, OXY tests)**
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentobarbital **(except BZR, OXY test)**
Perphenazine
Phenelzine
Phencyclidine**(except PCP, OXY tests)**
Prednisone
Procaine **(except BZO, MOP, OPI, OXY tests)**
DL-Propranolol
D-Propoxyphene **(except OXY, test)**
D-Pseudoephedrine **(except AMP, BAR tests)**
Quinine
Ranitidine
Salicylic acid
Secobarbital **(except BAR, OXY tests)**
Serotonin (5- Hydroxytyramine)
Sulfamethazine
Sulindac
Tetrahydrocortisone, 3-acetate **(except AMP, BAR, OXY tests)**
Tetrahydrocortisone 3-(β-Dglucuronide) **(except AMP, BAR, OXY tests)**
Tetrahydrozoline
Thiamine
Thioridazine
Triamterene
DL-Tyrosine
Trifluoperazine
Trimethoprim
D L-Tryptophan **(except AMP, BAR tests)**
Tyramine **(except AMP, BAR tests)**
Uric acid
Verapamil
Zomepirac

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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 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


Keep away from sunlight

Store between 4°C and 30°C


Keep dry


Do not re-use

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