Multi-Drug Urine Test Panel

Catalogue No. See Pouch label

Multi-Drug Urine Test Panel offers any combination from 2 to 13 drugs of abuse tests for 13 different drugs: Amphetamine (AMP), Secobarbital (BAR), Oxazepam (BZO), Cocaine (COC), Cannabinoids (THC), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP), Methadone (MTD), Morphine 2000 (OPI), Phencyclidine (PCP), Notriptyline (TCA), Oxycodone(OXY).
A rapid test for the qualitative detection of multiple drugs in human urine at specified cut off level.
For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

WHAT IS A MULTI-DRUG URINE TEST PANEL?

Multi-Drug Urine Test Panel 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 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
Secobarbital(BAR)	Secobarbital	300 ng/mL	2-4 hours	1-4 days
Oxazepam (BZO)	Oxazepam	300 ng/mL	2-7 hours	1-2 days
Cocaine /COC	Benzoylecgonine	300 ng/mL	1-4 hours	2-4 days
Cannabinoids (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
Morphine 2000 (OPI)	Morphine	2000ng/mL	2 hours	2-3 days
Phencyclidine (PCP)	Phencyclidine	25 ng/mL	4-6 hours	7-14days
Notriptyline (TCA)	Notriptyline	1000ng/mL	8-12hours	2-7 days
Oxycodone(OXY)	Oxycodone	100 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 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 only for storage purposes only, and is not used in the test procedures.
2. Urine cups.
3. Leaflet with instructions for use.

STORAGE AND STABILITY

Store at 4 ~ 30 ºC 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?

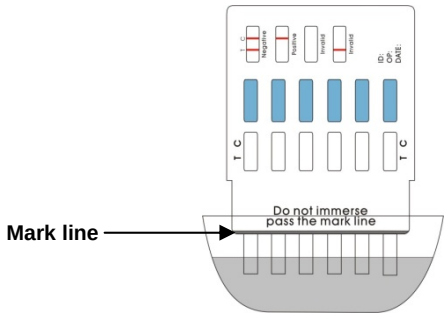
You may collect urine samples in minimum detection time later after suspected drug use. Exactly when the urine sample is collected is very important in detecting any drug of abuse. This is because each drug is cleared by the body and is detected in the urine at different times and rates. Please refer 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. Urinate directly into the provided urine cup.
2. Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds(2/3) full and tightly close the cap. This Labeled Vial urine sample is for shipping to the laboratory for confirmation testing. Make sure that the number on the Labeled Vial matches your personal Identification Number.
3. The residual urine sample in the urine cup is for your self-testing.

HOW TO DO THE TEST?

Test must be in room temperature (18ºC to 30ºC)
1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample for about 10 seconds. **Make sure that the urine level is not above the marker line printed on the front of the device.**
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result 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.*

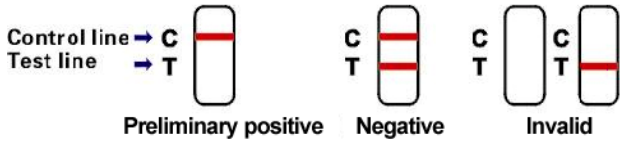
READING THE RESULTS

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 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. Certain drugs of abuse tests are more accurate than others.

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

What Is A False Positive Test?
The definition of a false positive test would be an instance where a substance is identified incorrectly by Multi-Drug Urine Test Panel. 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 Panel. 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. You can't retrieve your confirmed results without knowing your Personal Identification Number.
3. 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.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
5. For the drug tests of Notriptyline (TCA), Oxazepam (BZO), Oxycodone(OXY), and Secobarbital (BAR), the tests will yield preliminary positive results when prescription drugs Nortriptyline, Oxazepam, Oxycodone and Secobarbital are ingested, even at or above therapeutic doses.

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.

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.

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.

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 Panel 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.

Morphine 2000 (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 for Morphine 2000 (OPI) of Multi-Drug Urine Test Panel 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.

Notriptyline (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.

PRINCIPLE

Multi-Drug Urine Test Panel 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.

SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the supplied urine cup. Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).
Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well mixed before analysis. Cloudy specimens should be centrifuged before analysis. Use only clear aliquots for testing.

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

Accuracy

1040 (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	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	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%)
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%)
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	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%)
MOP	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%)
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%)

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	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	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
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
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	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
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	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
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
	200	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.

Amphetamine (AMP)	Concentration (ng/ml)	**Methamphetamine (MET)**	Concentration (ng/ml)
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)**	
Secobarbital (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	100	Thebaine	30,000
Oxazepam(BZO)		**Morphine 2000 (OPI)**	
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	σ-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	**Notriptyline (TCA)**	
Nordiazepam	400	Notriptyline	1,000
Temazepam	100	Nordoxepine	1,000
Trazolam	2,500	Trimipramiine	3,000
Cannabinoids (THC)		Amitriptyline	1,500
11-nor-Δ9-THC-9-COOH	50	Promazine	1,500
11-nor-Δ8-THC-9-COOH	30	Desipramine	200
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500	Imipramine	400

Δ8- Tetrahydrocannabinol	7,500	Clomipramine	12,500
Δ9- Tetrahydrocannabinol	10,000	Doxepine	2,000
Cannabinol	100,000	Maprotiline	2,000
Cannabidiol	100,000	Promethazine	25,000
Cocaine (COC)		**Oxycodone(OXY)**	
Benzoylecgonine	300	Oxycodone	100
Cocaine HCl	750	Dihydrocodeine	20,000
Cocaethylene	12,500	Codeine	100,000
Ecgonine	32,000	Hydromorphone	100,000
Methadone		Morphine	>100,000
Methadone	300	Acetylmorphine	>100,000
Doxylamine	50,000	Buprenorphine	>100,000
		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
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)**
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)**
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)**
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)**
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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Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
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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