

INSTRUCTIONS FOR USE

One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE

The *Multi-Drug of Abuse Urine Test* is a rapid qualitative immunoassay for screening the use of one or more drugs. The device detects any combination of the drugs or drug metabolites at or above the specified cut-off levels. It is for health care professional use only.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/ml
BAR	Barbiturates	200 ng/ml
BZD	Benzodiazepine	300 ng/ml
COC	Cocaine	300 ng/ml
MET	Methamphetamine	1000 ng/ml
MET500*	Methamphetamine	500 ng/ml
MOR	Morphine	2000 ng/ml
MOR300*	Morphine	300 ng/ml
MTD	Methadone	300 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
TCA	Tricyclics	1000 ng/ml
THC	Marijuana/Hashish	50 ng/ml
XTC	MDMA or Ecstasy	500 ng/ml

* Not SAMHSA levels.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY

Amphetamine (AMP)

The detection of amphetamines in human urine has been widely used to assess the abuse of amphetamines. Amphetamines are central nervous system stimulating drugs. They may induce alertness, wakefulness, increased energy, reduced hunger and overall feeling of well being. Overdose and extended usage of amphetamines may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. Amphetamines appear in the urine within three hours after administration (any type), and be present for about 24-48 hours after the last dose.

Barbiturates (BAR)

Barbiturates are central nervous system depressants and used as hypnotic sedatives. Overdose and extended usage of barbiturates may lead to severe and/or permanent damage to the human nervous system. Barbiturates are classified as (1) ultra-short, (2) short-intermediate, and (3) long-acting. The duration range of the ultra short-acting compounds, secobarbital, pentobarbital etc. is from fifteen (15) minutes to six (6) hours. The duration range of the intermediate acting compounds, amobarbital, etc. is from three (3) to twenty-four (24) hours. The duration range of the long-acting compounds, phenobarbital etc. is from fifteen (15) to forty-eight (48) hours.

The most commonly abused barbiturates are short- and intermediate-acting agents. The long-acting agents are rarely subject to abuse. Barbiturate derivatives are excreted into urine in varying amounts of unchanged drug and metabolites. Long-acting barbiturates are excreted with a higher percentage of unchanged drugs in the urine, while shorter-acting barbiturates, secobarbital and amobarbital, are extensively metabolized and excreted in the urine with a smaller percentage of unchanged drugs.

Benzodiazepines (BZD)

Benzodiazepines, including Alprazolam, Diazepam, Lorazepam, Triazolam, Chlordiazepoxide, Flurazepam and Temazepam are sedative, hypnotic and anti-anxiety drugs commonly used as tranquilizers. Most benzodiazepines are extensively metabolized in the liver and excreted in the urine as metabolites. The benzodiazepines have a low potential for physical or psychological dependence. However, the same as other central nervous system stimulating drugs, they may induce drowsiness and muscle relaxation. Chronic abuse of benzodiazepines may result in intoxication, similar to drunken behavior. Overdose and extended usage of benzodiazepines may lead to coma and possibly death. Benzodiazepines may remain effective for 4-8 hours. The members of the benzodiazepine family are absorbed at different rates and their effects may vary with the absorption rate. They are excreted in the urine primarily as their parent compounds or an inactive

metabolite (oxazepam glucuronide) that are only detectable for one (1) to two (2) days. Oxazepam, a common metabolite of many benzodiazepines that is also a marketed drug (Serax), may remain detectable if in urine for up to one week. That makes oxazepam a useful marker of benzodiazepines abuse.

Cocaine (COC)

Cocaine is a nervous system stimulant that can be addictive. Cocaine may appear in urine for only few hours after use, whereas the benzoylecgonine, a hydrolytic degradation product of cocaine, may be detectable in urine over 2 days after taking cocaine. Therefore the detection of benzoylecgonine in human urine is widely used to evaluate cocaine usage.

Methamphetamine (MET and MET500)

Methamphetamine in over dosage causes restlessness, confusion, anxiety, hallucinations, cardiac arrhythmias, hypertension, hyperthermia, circulatory collapse, convulsions, and coma. Methamphetamine has been implicated in fatal poisonings following both intravenous and oral administration. Chronic abusers may develop paranoid psychosis. D-Methamphetamine (d-desoxyephedrine, Desoxyn, Methedrine) is the N-methyl derivative of amphetamine. It is utilized in the treatment of obesity. Methamphetamine is administered by oral, nasal insufflations, or intravenous injection with duration of 2-4 hours. Methamphetamine undergoes some N-demethylation to amphetamine, its major active metabolite. During normal conditions, up to 43% of a dose is eliminated with about 4-7% as amphetamine. In acidic urine, up to 76% is found as unchanged drug and 7% as amphetamine in 24 hours, whereas in alkaline urine the corresponding values are 2% and less than 0.1%. Methamphetamine urine concentrations of 0.5-4.0 mg/L are commonly observed during the first 24 hours after ingestion of 10 mg. Methamphetamine concentrations of 24-333 mg/L (average, 142) were observed in the urine of methamphetamine abusers.

Morphine (MOR and MOR300)

Morphine is a popular marketed drug (Serax) for treatment of moderate to severe pain. It is also a common metabolite of opiates [morphine, codeine (methyl-morphine), and heroin (semi-synthetic derivatives of morphine)]. The opiates are administered either by smoking, intravenous injection, intramuscular injection or oral ingestion. Adverse or toxic effects of opiates usage include papillary constriction, constipation, urinary retention, nausea, vomiting, hypothermia, drowsiness, dizziness, apathy, confusion, respiratory depression, hypotension, cold and clammy skin, coma, and pulmonary edema. Death may occur following an over dosage.

The duration of effect of morphine is 3-6 hours. Morphine is metabolized extensively, with only 2-12% excreted as unchanged morphine in the urine. Heroin is rapidly metabolized to morphine in the body; the pattern of urinary excretion of heroin is similar to that of morphine. Codeine is also extensively metabolized; 10-15% of the dose is demethylated to form morphine and norcodeine. It has been reported that the unchanged morphine may remain detectable in urine for up to one week, which make morphine a marker of opiates abuse.

Methadone (MTD)

Methadone, also called Dolophine, Methadose and Amidone, possesses many of the pharmacologic properties of morphine and is approximately equipotent as an analgesic when administered parenterally. Unlike morphine, however, methadone produces marked sedative effects with repeated administration as a result of drug accumulation. Methadone has been used as a major substitute for opiates, such as heroin, morphine, and codeine in drug maintenance treatment clinics. It is administered either orally or by intravenous or intra-muscular injection. The duration of effect of methadone is 12-24 hours. Its major urinary excretion products are methadone, EDDP (2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine), and EMDP (2-ethyl-5-methyl-3, 3-diphenylpyrrolidine). The percentage of methadone excreted unchanged in urine is 5-50%, much higher than EDDP and EMDP, of the dose in 24 hours. Large individual variations in the percentage of unchanged methadone excreted in urine have been observed due to urine pH, urine volume, dose and rate of metabolism, etc. Methadone has been found remaining in urine at levels higher than 1,000 ng/ml 24 hours after overdose. Therefore the concentration of methadone in human urine has been used as a marker of methadone abuse.

Phencyclidine (PCP)

Phencyclidine (PCP), also called Angel Dust, Hog, and Killer Weed, is a popular drug of abuse, as well as being a legitimate veterinary tranquilizer. It is self-administered either by smoking, nasal insufflations, intravenous injection or by oral ingestion. Its duration of effect is 2-4 hours, and psychosis may last for weeks. PCP has three major metabolites; however, the percentage of an intravenous dose excreted unchanged in urine is 30-50% in the 72 hours. Only 2% of a dose is excreted in feces. An average of 77% of an intravenous dose is excreted in urine and feces in 10 days. Therefore, the PCP in human urine has been used as a marker of PCP abuse. Concentrations of unchanged drug in the urine of ambulatory users of PCP are most frequently between 0.04 and 3.4mg/L.

Propoxyphene (PPX)

Propoxyphene is a prescription drug for the relief of pain. Propoxyphene hydrochloride (Darvon, Dolene, and others) is available in 32mg and 65mg capsules; propoxyphene napsylate (Darvon-N) is available in 100mg tablets or as a suspension. It is structurally related to methadone. Overdose of the drug can affect the brain region and cause euphoria as many opioids do. The progressive symptomatology of propoxyphene includes analgesia, stupor, respiratory depression, and coma, etc. The half-life of propoxyphene is 8-24 hours. Following oral administration, propoxyphene reaches its peak in 1 to 2 hours. There is great variability between subjects in the rate of clearance. The percentage of excreted unchanged propoxyphene in urine is less than 1%. The major metabolite of propoxyphene is norpropoxyphene. Therefore, the detection of norpropoxyphene is widely used for the testing of propoxyphene abuse. The half-life of norpropoxyphene is about 30 hours, and its accumulation with repeated doses may be responsible for some of the toxicity observed.

Tricyclics (TCA)

Tricyclic Antidepressants (TCA) are a group of antidepressant drugs that contain three fused rings in their chemical structure. TCA can be taken orally or intramuscularly (IM). The progressive symptomatology of TCA includes agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from few hours to few days. The commonly used tricyclic antidepressants are excreted with a very low percentage of unchanged drugs in the urine, less than 1%. Therefore, detecting TCA or metabolites of TCA in human urine has been used for screening the abuse of TCA. This test is able to detect amitriptyline, desipramine, imipramine and nortriptyline at a cut off level of 1,000 ng/ml.

Marijuana (THC)

Tetrahydrocannabinols (THC, Δ -9-THC, Δ -1-THC) are the most active of the principle constituents, as well as the major metabolites, of cannabinoids such as marijuana and hashish. Cannabinoids have been used as central nervous system depressants. Overdose and extended usage of cannabinoids may lead to substance abuse, which may cause severe and/or permanent damage to the human nerve system. The detection of THC in human urine is widely used to evaluate the abuse of cannabinoids.

MDMA (Ecstasy, XTC)

MDMA is an abbreviation of the chemical methylenedioxyamphetamine. It also has street names such as Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits, and Shamrocks. MDMA is a stimulant with hallucinogenic tendencies. It is described as an empathogen since it releases mood-altering chemicals, such as cartoning and L-dopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or heat stroke.

MDMA belongs to a "family" of man-made drugs; its "relatives" are MDA (methylenedioxyamphetamine), the parent drug of MDMA, and MDEA (methylenedioxyethylamphetamine), also known as EVE, the sister of MDMA. They all have the amphetamine-like effects. MDMA is administered either by oral ingestion or intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. Its clinical dose is 50-100mg; the threshold toxic dose is 500mg. The effects of the MDMA begin 30 minutes after taking. They peak in an hour and last for 2-3 hours. Sixty five percent (65%) of MDMA is excreted unchanged in urine and it is detectable in the urine for up to 3 days after use.

PRINCIPLE OF THE PROCEDURE

The Multi-Drug of Abuse Urine Test device consists of any combination between one (1) to twelve (12) individual test strip(s) for the drug(s) being tested. The assay is a one-step lateral flow chromatographic immunoassay based on the principle of competition for limited antibody binding sites between the drug or drug metabolite(s) in the sample and a drug-protein conjugate immobilized on a porous membrane support.

During test, the urine sample migrates to the testing area of the membrane by capillary action, mobilizing the colored antibody conjugates. Then the antibody conjugates move along the membrane to the testing area. In the absence of the drug or if the drug concentration is below the cutoff limit in the sample, the colored conjugates attach to the drug antigen immobilized in the test line region, forming a burgundy-colored band (T line). When the drug is present in the sample, the drug or drug metabolite(s) compete for the limited antibody binding sites. If the drug concentration is at or above the cutoff limit, the drug will saturate all the binding sites of the antibody, preventing the attachment of the colored conjugates to the antigen in the test line area of the membrane. Therefore the colored line will not form.

The control line (C line) serves as an internal quality control of the system. It should always appear as a burgundy-colored band regardless of the presence of the drug.

REAGENTS AND MATERIALS SUPPLIED

- 25 test devices, each sealed in a foil pouch with a desiccant and a dropper pipette (20 devices for 7-12 test panel)
- 1 package insert (Instructions for Use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

PRECAUTIONS

1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially bio-hazardous.
5. Do not use the test if you are colored-blind.

STORAGE AND STABILITY

- Store the product at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.
- Do not freeze and / or expose this kit to temperatures over 30°C (86°F).

SPECIMEN COLLECTION

- Each urine specimen must be collected in a clean container. Do not combine specimens.
- Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

ASSAY PROCEDURE

IMPORTANT: REFRIGERATED SPECIMENS AND OTHER TEST MATERIALS, INCLUDING DEVICES, MUST BE EQUILIBRATED TO ROOM TEMPERATURE BEFORE TESTING.

1. Bring the pouch to room temperature before opening.
2. Remove the test device from the sealed pouch and label it with specimen identification.
3. Remove the cap from the device, add urine sample to the device using either "Dip Method (I)" or "Dropper Method (II)" as follows:

I. DIP METHOD

- a) Dip the sample well end of the device into the specimen.
Note: The sample well must be completely immersed in the urine sample and the tip of the arrows in the device's window must be above the sample surface.
- b) Start the timer.
- c) Remove the device from the specimen after 10 seconds.
- d) Replace the cap back onto the device. Set the device on a clean and level surface.
- e) Read results between 4-7 minutes.

II. DROPPER METHOD (Recommended for small sample volumes.)

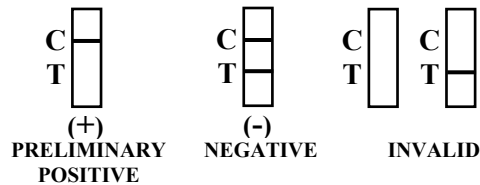
- a) Set the device on a clean and level surface.
- b) Use the provided dropper to pick up the urine sample, fill the sample to the mark.
- c) Transfer all of the urine sample in the dropper to the sample well of the device. Avoid trapping air bubbles in the sample well.
- d) For a 2-sided panel (7-12 tests), turn the device over to the other side and add a full dropper of urine sample (up to the mark on the dropper) to the sample well on side 2.
- e) Start the timer.
- f) Read results between 4-7 minutes.

INSTANT-VIEW® Multi-Drug Screen Urine Test



INTERPRETATION OF RESULTS

IMPORTANT: Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line. Do not compare color intensity of one test to another.



Preliminary Positive:

If the C line appears and there is no T line, the test indicates a positive result for that particular drug.

Note: Samples with preliminary positive results should be confirmed with a more specific method before a positive determination is made.

Negative:

If the C line and the T line both appear, the test indicates that the level for the corresponding drug or its metabolites is below the cutoff level.

Note: A very faint T line should be considered negative.

Invalid:

If no C line develops within 4 minutes on any test strip, the test is invalid. In this case repeat the assay with a new test device. If the result is still invalid, stop using the test device and contact the manufacturer.

QUALITY CONTROL

Built-in Control Features

This test contains a built-in control feature, the C line. The appearance of the burgundy C line indicates an adequate volume of specimen has been absorbed and the capillary flow has occurred. The C line should always appear. If the Control line does not develop within 5 minutes, review the entire procedure and repeat test with a new device.

External Quality Control

Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

LIMITATIONS

1. This kit is for professional *in vitro* diagnostic use only.
2. Results obtained by this device provide only a preliminary qualitative analytical test result. A more specific alternate method must be used in order to obtain a confirmed analytical result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results. When suspected, collect a fresh specimen and repeat the test with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results.

EXPECTED VALUES

This test is capable of detecting each drug and/or drug metabolite specified in human urine at or above its specific cutoff concentration indicated in the intended use section on page 1.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study was performed at three different Physician's Office Laboratories (POL) and a Reference Laboratory. Clinical samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested at each site, with the multi-drug of abuse urine test device, and compared to GC/MS or HPLC/MS results. The test results are grouped into drug free, below 75% cutoff (Negative), above 125% cutoff (Positive), between 75% cutoff and

cutoff, between cutoff and 125% cutoff according to the analyte concentrations from GC/MS for all analytes except TCA, which was tested with HPLC/MS. Overall, this device agrees with the results from the selected analytical method more than 90% for each analyte. The test results are tabulated below.

Method			HPLC/MS					Overall
Multi-Drug of Abuse Urine Test			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	
Drug	Cutoff (ng/ml)							
TCA	1000	Positive	0	0	2	8	12	/
		Negative	40	10	8	0	0	/
		Total	40	10	10	8	12	80
		Agreement	100%	100%	80%	100%	100%	97.5%

Method			GC/MS					Overall
Multi-Drug of Abuse Urine Test			Drug-free	Negative <75% Cutoff	75% Cutoff to Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff	
Drug	Cutoff (ng/ml)							
AMP	1000	Positive	0	0	37	15	148	/
		Negative	176	76	23	1	0	/
		Total	176	76	60	16	148	476
		Agreement	100%	100%	38.3%	93.8%	100%	92%
BAR	200	Positive	0	0	0	27	140	/
		Negative	200	12	20	1	0	/
		Total	200	12	20	28	140	400
		Agreement	100%	100%	100%	96.4%	100%	99.8%
BZD	300	Positive	0	0	7	32	144	/
		Negative	168	24	25	0	0	/
		Total	168	24	32	32	144	400
		Agreement	100%	100%	78%	100%	100%	98.3%
COC	300	Positive	0	0	9	24	164	/
		Negative	188	4	11	0	0	/
		Total	188	4	20	24	164	400
		Agreement	100%	100%	55%	100%	100%	97.8%
MET500	500	Positive	0	0	6	24	152	/
		Negative	220	36	22	16	0	/
		Total	220	36	28	40	152	476
		Agreement	100%	100%	78.6%	60%	100%	95.4%
MET	1000	Positive	0	0	12	24	136	/
		Negative	200	16	12	0	0	/
		Total	200	16	24	24	136	400
		Agreement	100%	100%	50%	100%	100%	97%
MOR300	300	Positive	0	0	13	24	136	/
		Negative	180	12	11	0	0	/
		Total	180	12	24	24	136	376
		Agreement	100%	100%	45.8%	100%	100%	96.5%
MOR	2000	Positive	0	0	2	28	144	/
		Negative	132	64	30	0	0	/
		Total	132	64	32	28	144	400
		Agreement	100%	100%	93.8%	100%	100%	99.5%
MTD	300	Positive	/	0	10	36	144	/
		Negative	/	192	18	0	0	/
		Total	/	192	28	36	144	400
		Agreement	/	100%	64.3%	100%	100%	97.5%
PCP	25	Positive	/	0	8	32	160	/
		Negative	/	184	16	0	0	/
		Total	/	184	24	32	160	400
		Agreement	/	100%	66.7%	100%	100%	98%
PPX	300	Positive	0	0	0	8	30	/
		Negative	40	10	10	2	0	/
		Total	40	10	10	10	30	100
		Agreement	100%	100%	100%	80%	100%	98%
THC	50	Positive	0	0	11	17	156	/
		Negative	160	36	13	3	0	/
		Total	160	36	24	20	156	396
		Agreement	100%	100%	54.2%	85%	100%	96.5%
MDMA	500	Positive	0	0	2	9	10	/
		Negative	40	10	9	0	0	/
		Total	40	10	11	9	10	80
		Agreement	100%	100%	82%	100%	100%	97.5%

Reproducibility

Reproducibility of each test was evaluated on replicate assays of three production lots with spiked samples at four levels: drug-free, 75% cutoff, 125% cutoff and 200% cutoff. For AMP, COC, MET500, MOR300, THC and MDMA tests, the devices were tested for three consecutive days, six replicates per day, for a total of eighteen tests for each control. For BAR, BZD, MET, MOR, MTD, PCP, PPX and TCA tests, the devices were tested for five consecutive days, five times per day, for a total of 25 assays for each control. The results indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation across the three different lots of devices.

Cross Reactivity

The cross reactivity of the test was evaluated by spiking drug free samples with structurally related compounds. Compounds producing positive response are listed below.

Drug	Related Compounds	Concentration (ng/ml)	Related Compounds	Concentration (ng/ml)
AMP	d-Amphetamine	1000	d,l-Amphetamine	1000
	l-Amphetamine	20,000	3,4-methylenedioxyamphetamine (MDA)	3000
BAR	Amobarbital	250	Phenobarbital	200
	Barbital	250	Pentobarbital	250
	Butobarbital	300	Secobarbital	200
	Butalbital	200		
BZD	Alprazolam	300	Lormetazepam	300
	Bromazepam	500	Medazepam	300
	Clobazem	1500	Nitrazepam	250
	Chlonezepam	500	Nordiazepam	400
	Diazepam	200	Prazepam	250
	Desmethyldiazepam	300	Triazolam	300
	Flurazepam	300	Oxazepam	300
	Lorazepam	450		
COC	Cocaine	300	Isoxsuprine	1500
	Benzoylcegonine	300		
MET500	d-Methamphetamine	500	l-Amphetamine	10,000
	l-Methamphetamine	25,000	3,4-methylenedioxyamphetamine (MDA)	50,000
	d-Amphetamine	50,000	3,4-methylenedioxyamphetamine (MDA)	50,000
MET	d-Amphetamine	50,000	3,4-methylenedioxyamphetamine (MDA)	50,000
	l-Amphetamine	10,000		
MOR300	Morphine	300	Morphine-glucuronide	500
	Codeine	300	Meperidine	30000
	Ethyl Morphine	300	Oxycodone	1000
	Hydromorphone	400		
MOR	Codeine	2000	Morphine-glucuronide	3000
	Ethyl Morphine	2000	Meperidine	30,000
	Hydro morphine	2500		
MTD	(-)-a-Methadol	800	(-)-a-Acetylmethadol (LAAM)	1000
PCP	Methylphenidate	25,000	Tenocyclidine	2,000
	Pheniramine	25,000		
PPX	Propoxyphene	300	2-ethyl-1,5-dimethyl-3,3-diphenylpyrroline (EDDP, Methadone Metabolite)	200,000
	Norpropoxyphene	300		
	Methadone	1,350,000		
TCA	Nortriptyline	1,000	Clomipramine	5,000
	Amitriptyline	1,000	Doxepin	3,000
	Imipramine	800	Protriptyline	2,000
	Desipramine	800	Perphenazine	75,000
	Nordoxepine	1,000	Promazine	15,000
	Cyclobenzaprine	1,500	Trimipramine	2,000
THC	11-nor-D-8-THC-9-COOH	50	11-hydroxy-D-9-THC	100
	11-nor-D-9-THC-9-COOH	50	9-Tetrahydrocannabinol	10,000
	Cannabonol	10,000		
MDMA	methylenedioxyamphetamine (MDA)	2000	Methylenedioxyamphetamine (MDEA)	1000

Interference

To determine the interference of structurally unrelated analytes, each test analyte was evaluated, using the analyte specific urine test device, in both drug free urine pools and urine pools spiked with the cutoff level of each analyte.

Common substances listed in this table were found not to interfere with the test results at the concentration of 100 µg/ml		
Acetaminophen	Oxalic Acid	Ethanol
Acetylsalicylic Acid	Caffeine	Lidocaine
Amikacin	(+)-Chlorpheniramine	Penicillin-G
Amitriptyline	Cocaine	Phenylpropanolamine
Ampicillin	Codeine	Ranitidine
Arterenal	Cortisone	Salicylic Acid
Aspirin	Methadone	Thioridazine
Atropine	Methanol	Trifluoperazine
Benzoic Acid		

Biological Analytes	Concentration	Biological Analytes	Concentration
Albumin	200 µg/ml	pH	5.0 – 9.0
Bilirubin	100 µg/ml	Specific Gravity	1.002 – 1.035 g/ml
Creatine	100 µg/ml	Uric Acid	100 µg/ml
Glucose	200 µg/ml	Vitamin C	100 µg/ml
Hemoglobin	100 µg/ml	(L-Ascorbic Acid)	

There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results. (e.g., technical or procedural errors)

REFERENCES

- FDA Guidance for Labeling Urine Drugs of Abuse Screening Testing, Kshit Mohan, 7/21.
- Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, 4th ED., Biomedical Publ., Davis, CA; p713-715, 1995.
- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register. (69): 11970 (1988).
- Wilson, John, Abused Drugs II, a Laboratory Pocket Guide, AACC Press. Washington, DC; 1994.
- Gilman AG, Rall TW, Nies AS, Taylor P eds., Goodman and Gilman's the Pharmacological Basis of Therapeutics, 8th ed., New York, Pergamon Press, 1990.
- Dorland's Illustrated Medical Dictionary, 26th Edition, W.B. Saunders Company, Philadelphia, PA, pp89, 1981. 4Urine Testing for Drugs of Abuse, National Institute on Drug Abuse (NIDA): Research Monograph 73, 1986.
- S-J. Peroutka ed. Ecstasy: The clinical, pharmacological and neurotoxicological effects of the drug MDMA. Kluwer Academic Publishers, 1990.



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