

Accutest® 13 Drug Test Cup

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

INTENDED USE

The **Accutest 13 Drug Test Cup** is a rapid qualitative immunoassay for screening potential abuse 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
AMP300*	Amphetamine	300 ng/ml
BAR****	Barbiturates	200 ng/ml
BUP/NBUP	Buprenorphine/Norbuprenorphine	10 ng/ml**
BZD****	Benzodiazepine	300 ng/ml
COC	Cocaine	300 ng/ml
COC150*	Cocaine	150 ng/ml
MET	Methamphetamine	1000 ng/ml
MET500*	Methamphetamine	500 ng/ml
MET300*	Methamphetamine	300 ng/ml
MOR	Morphine (a drug in the Opiates class)	2000 ng/ml
MOR300*	Morphine (a drug in the Opiates class)	300 ng/ml
MTD	Methadone	300 ng/ml
OXY***	Oxycodone	100 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. **Combined concentrations of Buprenorphine (BUP) and Norbuprenorphine (NBUP). ***SAMHSA has not recommended the screening cutoff levels for positive specimens. ****The BAR, BZD, TCA test will yield preliminary positive results when BAR, BZD, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant in urine. The Accutest 13 Drug Test Cup shows the drug was or was not present at the cutoff level.

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 and AMP300)

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 drug 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.

Buprenorphine/Norbuprenorphine (BUP/NBUP)

Buprenorphine is an analgesic drug. It is also used in heroin substitution and detoxification treatment. With this increased medical use, it also occurs on the black market as an illicit drug; and fatalities have occurred when used in combination with other drugs.

Buprenorphine is administered clinically by intravenous, intramuscular or sublingual routes. Buprenorphine is metabolized by N-dealkylation to form the pharmacologically active Norbuprenorphine. Both buprenorphine and norbuprenorphine are also glucuronidated to the clinically inactive conjugates buprenorphine-3-beta-D-glucuronide and norbuprenorphine-3-beta-D-glucuronide. Buprenorphine and its metabolite norbuprenorphine (along with the glucuronide forms) are both excreted in urine during the course of several days. Buprenorphine and its metabolites are eliminated mainly in the feces (68%), with a small proportion excreted in urine (27%). It was reported that urine samples taken from patients who had received treatment for 2 weeks with 4 mg of buprenorphine daily (sublingually) showed buprenorphine concentrations ranging from 54 to 260 ng/ml 24 hours after the dose. It was found in another study that the concentrations

of the unconjugated buprenorphine and unconjugated norbuprenorphine in the urine samples collected 10 hours after a single dose intramuscular injection of 0.3 mg buprenorphine were 500 pg/ml and 2 ng/ml, respectively.

The concentration of the metabolite norbuprenorphine is usually higher than buprenorphine. The median ratio of buprenorphine to norbuprenorphine is dependent on the time between sampling and dose intake. It was reported that in suspected abusers, the ranges were 2.3 to 796 ng/ml for unconjugated buprenorphine and 5 to 2580 ng/mL for unconjugated norbuprenorphine. It was also found that the concentration of free buprenorphine and norbuprenorphine in urine may be relatively small (<1 ng/mL) if taken in clinically administered doses, but can reach up to 20 ng/mL if abused.

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 and COC150)

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, MET500 and MET300)

Methamphetamine in overdose 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 insufflation, 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/Opiates (MOR/OPI2000 and MOR/OPI300)

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 pupillary 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 overdose.

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, Methadone 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 intramuscular 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.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structure similar to codeine. It is prescribed for the relief of moderate to severe pain. Like all opiate agonists, oxycodone provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. 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 respirator depression, hypotension, and striptic arrest.

Oxycodone is metabolized by demethylation into oxymorphone and noroxycodone. After a single 5 mg oral dose, 13-19% of the oxycodone is excreted as unchanged in a 24-hour urine collection. The time window for detection of oxycodone in urine is expected to be similar to that of other opioids such as morphine.

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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 insufflation, 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 Accutest 13 Drug Test Cup 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 cups with built-in test strips & desiccants; each cup sealed in a foil pouch
- 1 package insert (Instructions for Use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- External positive and negative controls

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

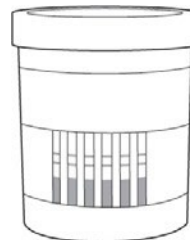
IMPORTANT: Do not open pouch until ready to perform the test.

1. Remove the test cup from the pouch.
2. Label the cup with patient or control number identification and the date.
3. Have the patient remove the lid and urinate directly into the cup to at least the Min (minimum) level marked on the cup, up to the Max (maximum) level. Do not over fill. Put the lid back onto the cup. Wipe any splashes or spills that may be on the outside of the cup.
4. Immediately check the temperature strip on the cup. The temperature should be between 32-38 °C (90-100 °F). If the temperature is not in this range, the sample may be altered and another sample should be collected.
5. Make sure the cup is closed tightly with the lid.
6. Specimens may be kept at 15-30 °C (59-86 °F) for 8 hours or at 2-8 °C for up to 3 days. **Do not freeze the cup.**

ASSAY PROCEDURE

IMPORTANT: Refrigerated specimens and other test materials, including cups, must be equilibrated to room temperature before testing.

1. Remove the test cup from the sealed pouch.



2. Issue the cup to the individual to be tested.
3. Collect the urine into the cup. Ensure the specimen is above the minimum level.
4. The cup must be returned immediately to the collector. Authorized personnel should remove the tear-off label. Immediately check the temperature strip on the cup. The temperature should be in between 32-38°C (90-100 °F). If the temperature is not in this range, the sample may be altered and another sample should be collected.
5. Read results of drugs of abuse tests in 4-7 minutes.

INTERPRETATION OF RESULTS

Each test strip is labeled with abbreviations for a test. For example, "COC" is for cocaine test. A complete list for each test can be found in the intended use section on Page 1.

IMPORTANT:

- **Read each test independently.**
- **Do not compare color intensity of one test to another.**
- **Do not compare color intensity of the T line to the C line.**
- **Do not interpret the results after 7 minutes.**

ADULTERATION ASSAY

Between 1-2 minutes after sample addition, compare the color of each pad with that of the corresponding pad in the color chart attached to the back of this insert. Changes in color after 2 minutes are of no value to interpretation. The 6 pads, as read from left to right in the sample well, assess the following parameters: CR NI GL pH SG OX

CR (Creatinine): Creatinine is used to test for sample dilution. Daily creatinine excretion,

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related to muscle mass of the human body, is usually constant. The DOT guideline states that creatinine levels less than 20 mg/dl in urine specimens indicate adulteration, regardless of factors such as age, sex, diet, muscle mass and local population distribution.

NI (Nitrite): Nitrite is not a normal component of urine. Nitrite levels less up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. A nitrite level above 7.5 mg/dl is considered abnormal.

GL (Glutaraldehyde): Glutaraldehyde is not a natural component of human urine and its presence indicates adulteration. False positive results may arise when ketone bodies are present. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolically abnormal conditions.

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.

SG (Specific Gravity): Random urine samples 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 may be obtained in the presence of moderate quantities of protein. DOT guidelines state that a urine specimen with specific gravity level 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.

OX (Oxidants): The presence of oxidizing reagents in the urine is indicative of adulteration since oxidizing reagent are not normal constituents of urine. Oxidizing reagents include bleach, hydrogen peroxide, pyridinium chlorochromate, etc.

If the test pads indicate an invalid sample for the assays, note this information on the sample record.

DRUG ASSAY

Preliminary Positive:

If the C line appears and there is no T line, the test is positive for that drug. More than one test may be Preliminary Positive.

Note: Preliminary positive results should be confirmed with a more specific method. GC/MS or HPLC is a preferred confirmatory method.

1 2 3 4 5 6



**Preliminary Positive
for test 2 and test 3**

Negative:

If both C line and T line appear on a test, the test is negative for that drug. If both C line and T line appear for all tests, the urine specimen is negative for all the drugs tested.

1 2 3 4 5 6



**Negative for all 6 drugs
tested**

Note: Even a very faint T line is negative.

Invalid:

If no C line develops within 4 minutes on any test strip, the test is invalid. In this case, do not report test results. Repeat the assay with a new test device. If the result is still invalid, stop using the test device. Contact the manufacturer.

1 2 3 4 5 6



**Invalid for test 4 and
test 5**

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 4 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 two Physician's Office Laboratories (POL) and a Reference Laboratory. 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 BUP/NBUP and 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		GC/MS					Overall	
Multi-Drug of Abuse Urine Test		Drug-free	Negative <75% Cutoff	75% Cutoff to 125% Cutoff	Cutoff to 125% Cutoff	Positive >125% Cutoff		
AMP	1000	Positive	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%
AMP300	300	Positive	0	0	39	75		
		Negative	30	45	45	6	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	100%	86.7%	100%	97.5%
BAR	200	Positive	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	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	9	24	164		
		Negative	188	4	11	0	0	
		Total	188	4	20	24	164	400
		Agreement	100%	100%	55%	100%	100%	97.8%
COC150	150	Positive	0	2	42	75		
		Negative	30	45	43	3	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	95.6%	93.3%	100%	97.9%
MET	1000	Positive	0	12	24	136		
		Negative	200	16	12	0	0	
		Total	200	16	24	24	136	400
		Agreement	100%	100%	50%	100%	100%	97%
MET500	500	Positive	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%
MET300	300	Positive	0	0	38	75		
		Negative	30	45	45	7	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	100%	84.4	100%	97.1
MOR300	300	Positive	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	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	0	
		Total	192	28	36	144	400	
		Agreement	100%	64.3%	100%	100%	100%	97.5%
OXY	100	Positive	0	3	40	75		
		Negative	30	45	42	5	0	
		Total	30	45	45	45	75	240
		Agreement	100%	100%	93.3%	88.9%	100%	96.7%
PCP	25	Positive	0	8	32	160		
		Negative	184	16	0	0	0	
		Total	184	24	32	160	400	
		Agreement	100%	100%	66.7%	100%	100%	98%

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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)							
PPX	300	Positive	0	0	0	8	30	
		Negative	40	10	10	2	0	
		Total	40	10	10	10	30	
		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	
		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	
		Agreement	100%	100%	82%	100%	100%	97.5%

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)							
BUP/NBUP	10	Positive	0	1	18	19		
		Negative	49	5	2	0		
		Total	49	6	20	19	94	
		Agreement	100%	100%	83.3%	90%	100%	96.8%
TCA	1000	Positive	0	0	2	8	12	
		Negative	40	10	8	0	0	
		Total	40	10	10	8	12	
		Agreement	100%	100%	80%	100%	100%	97.5%

Reproducibility

Reproducibility of each test was determined by replicate assays of three different production lots with four levels of samples: drug-free, 75% cutoff, 125% cutoff and 300% cutoff. For AMP, AMP300, BUP/NBUP, COC, COC150, MET500, MET300, MOR300, OXY, 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-methylenedioxy-amphetamine (MDA)	3000
AMP300	d-Amphetamine	300	d-,l-Amphetamine	300
	l-Amphetamine	20,000	3,4-methylenedioxy-amphetamine (MDA)	3000
BAR	Amobarbital	250	Phenobarbital	200
	Barbital	250	Pentobarbital	250
	Butobarbital	300	Secobarbital	200
	Butalbital	200		
BUP/NBUP	Buprenorphine-3-β-D-glucuronide	750	Norbuprenorphine-3-β-D-glucuronide	30,000
	Nalorphine	100,000		
BZD	Alprazolam	300	Lormetazepam	300
	Bromazepam	500	Medazepam	300
	Clobazem	1500	Nitrazepam	250
	Chlonazepam	500	Nordiazepam	400
	Diazepam	200	Prazepam	250
	Desmethyldiazepam	300	Triazolam	300
	Flurazepam	300	Oxazepam	300
COC	Cocaine	300	Isoxsuprine	1500
	Benzoylcegonine	300		
COC150	Cocaine	150	Isoxsuprine	1500
	Benzoylcegonine	150		
MET	d-Amphetamine	50,000	3,4-methylenedioxy-amphetamine (MDA)	50,000
	l-Amphetamine	10,000		
MET500	d-Methamphetamine	500	l-Amphetamine	10,000
	l-Methamphetamine	25,000	3,4-methylenedioxy-amphetamine (MDA)	50,000
	d-Amphetamine	50,000		
MET300	d-Methamphetamine	300	l-Amphetamine	10,000
	l-Methamphetamine	25,000	3,4-methylenedioxy-amphetamine (MDA)	50,000
	d-Amphetamine	50,000		
MOR	Codeine	2000	Morphine- glucuronide	3000
	Ethyl Morphine	2000	Meperidine	30,000
	Hydro morphine	2500	6-Acetylmorphine	2,000
MOR300	Morphine	300	Morphine- glucuronide	500
	Codeine	300	Meperidine	30000
	Ethyl Morphine	300	Oxycodone	1000
	Hydromorphine	400	6-Acetylmorphine	300
MTD	(-)-a-Methadol	800	(-)-a-Acetylmethadol (LAAM)	1000

Drug	Related Compounds	Concentration (ng/ml)	Related Compounds	Concentration (ng/ml)
OXY	Oxycodone	100	Hydrocodone	100,000
	Morphine	20,000	Ethyl morphine	100,000
PCP	Methylphenidate	25,000	Tenocyclidine	2,000
	Pheniramine	25,000		
PPX	Propoxyphene	300	2-ethyl-1,5-dimethyl-3,3-diphenylpyrrolone (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	methylenedioxyamphetamin e (MDA)	2000	Methylenedioxyethylamphetam ine (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
Arterenol	Cortisone	Salicylic Acid
Aspirin	Methadone	Thioridazine
Atropine	Methanol	Trifluoperazine
Benzocic 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 (L-Ascorbic Acid)	100 µg/ml
Hemoglobin	100 µg/ml		

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)

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Made in USA

Manufactured for:

Jant Pharmacal Corporation
Encino, California 91436, USA

Tel: (818)986-8530

Email: info@jantdx.com

Website: www.jantdx.com