

One Step Drug of Abuse Tests

A One Step Drug of Abuse Test kit, showing the cassette, dipcard, and multi-drug screen test cup.

Package Insert for Single and Multi-drug Screening Test Strip, Cassette, Dipcard, and Multi-Drug Screen Test Cup.

A One Step Drug of Abuse Test kit, showing the cassette, dipcard, and multi-drug screen test cup.

This Instruction Sheet is for testing of any combination of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine and Tricyclic Antidepressants.

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

<i>For Professional and In Vitro Diagnostic Use Only.</i>
INTENDED USE
<p>The One Step Drug of Abuse Test is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:</p>

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoyllecgonine	300 ng/mL
Marijuana (THC)	11-nor-Δ ⁹ -THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	1,000 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxy-methamphetamine	500 ng/mL
Morphine (MOP 300)	Morphine	300 ng/mL
Opiates (OPI 2000)	Morphine	2,000 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the One Step Drug of Abuse Test can consist of any combination of the above listed drug analytes. This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.¹ Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST
<p>The One Step Drug of Abuse Test is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of multiple drugs and drug metabolites in human urine. The One Step Drug of Abuse Test is a rapid urine screening test that utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine without the use of an instrument.</p>

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AMPHETAMINE (AMP)
Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body’s natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives. The One Step Drug of Abuse Test yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).²

BARBITURATES (BAR)
Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics,

and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:
Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days
Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days¹

The One Step Drug of Abuse Test yields a positive result when the Barbiturates in urine exceed 300 ng/mL.

BENZODIAZEPINES (BZO)
Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

The One Step Drug of Abuse Test yields a positive result when the Benzodiazepines in urine exceed 300 ng/mL.

COCAINE (COC)
Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoyllecgonine.^{2,4} Benzoyllecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.⁴

The One Step Drug of Abuse Test yields a positive result when the cocaine metabolite in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).²

MARIJUANA (THC)
THC (Δ⁹-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ⁹-tetrahydrocannabinol-9-carboxylic acid (Δ⁹-THC-COOH). The One Step Drug of Abuse Test yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).²

METHADONE (MTD)
Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.¹³ The One Step Drug of Abuse Test yields a positive result when the Methadone in urine exceeds 300 ng/mL.

METHAMPHETAMINE (mAMP)
Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased

blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level. The One Step Drug of Abuse Test yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)
Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.³ 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. The One Step Drug of Abuse Test yields a positive result when the Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

OPIATE (MOP 300 or OPI 300)
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.¹ The One Step Drug of Abuse Test yields a positive result when the concentration of opiate exceeds the 300 ng/mL cut-off level.

OPIATE (2000)
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.⁴ The One Step Drug of Abuse Test yields a positive result when the morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PHENCYCLIDINE (PCP)
Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950’s. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user’s age, weight, activity, and diet.³ Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).⁶ The One Step Drug of Abuse Test yields a positive result when the phencyclidine level in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

TRICYCLIC ANTIDEPRESSANTS (TCA)
TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days. The One Step Drug of Abuse Test yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000 ng/mL.

PRINCIPLE
<p>The One Step Drug of Abuse Test is an immunoassay based on the principle of competitive binding. Drugs</p>

^[1] Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained

which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, THC, Phencyclidine, Benzodiazepines, Methadone, Barbiturates or Tricyclic Antidepressants.

PRECAUTIONS

- For Professional Use Only.
- For *In Vitro* Diagnostic Use Only.
- Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- While urine is not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood^{8,9}, the use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test card and urine specimen should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- Test devices
- Desiccant
- Package insert
- Specimen dropper (for test cassette only)
- Procedure Card (for Multi-Drug Screen Test Cup only)

Materials Required But Not Provided

- Specimen collection container
- Disposable gloves
- Timer

DIRECTIONS FOR USE

Allow the test card, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing. DO NOT INTERPRET RESULT AFTER 10 MINUTES.

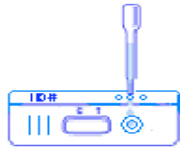
[For Strip]

- 1) Remove the strip from the foil wrapper or the desiccated container (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the strip with patient or control identifications.
- 2) Immerse the strip into the urine with the arrow end pointing toward the urine. Do not cover the urine over the MAX (maximum) line. You may leave the strip in the urine or you may take the strip out after a maximum of 15 seconds in the urine and lay the strip flatly on a non-absorptive clean surface.
- 3) Read results at 5 minutes.



[For Cassette]

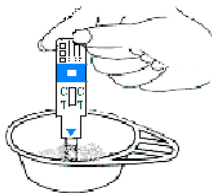
- 1) Remove the test device from its foil wrapper by tearing along the slice (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the device with patient or control identifications.
- 2) Using the specimen dropper, withdraw the urine sample from the specimen cup and slowly dispense 3 drops (approximately 120uL) into the circular sample well, being careful not to overflow the absorbent pad.
- 3) Read results at 5 minutes.



Add 3 drops of urine

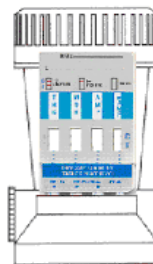
[For Dipcard]

- 1) Remove the test device from the foil pouch.
- 2) Remove the cap from the test device. Label the device with patient or control identifications.
- 3) Immerse the absorbent tip into the urine sample for 5 seconds. Urine sample should not touch the plastic device.
- 4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.
- 5) Read results at 5 minutes.



[For Multi-Drug Screen Test Cup]

Please follow the instructions on the Procedure Card.



This illustration shows a multi-drug screen test cup with a built-in 4 panel test dipcard.



NEGATIVE



POSITIVE



INVALID

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE: Two lines appear. * One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of red in the test line region (T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your supplier.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The One Step Drug of Abuse Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.^{3,4,7}
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen and a new test device.
4. A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using The One Step Drug of Abuse Test and other commercially available rapid drug tests. Testing was performed on 120 specimens per drug type previously collected from subjects presenting for drug screen testing. All the presumptive positive and negative results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, α -OH-Alprazolam, Desalkylflurazepam
COC	Benzoyllecgonine
THC	11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	D,L Methylenedioxymethamphetamine, Methylenedioxyamphetamine
OPI	Morphine, Codeine
PCP	Phencyclidine
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

%Agreement with Commercial Kit

	AMP	BAR	BZO	COC	THC	MTD
Positive Agreement	98%	100%	100%	98%	98%	100%
Negative Agreement	100%	100%	98%	100%	100%	100%
Total Results	99%	100%	99%	99%	99%	100%

	mAMP	MDMA	MOP	OPI	PCP	TCA
Positive Agreement	98%	100%	98%	98%	98%	97%
Negative Agreement	100%	100%	100%	100%	100%	98%
Total Results	99%	100%	99%	99%	99%	97.5%

%Agreement with GC/MS

	AMP	BAR	BZO	COC	THC	MTD
Positive Agreement	95%	98.5%	95.7%	95%	95%	98.5%
Negative Agreement	100%	98%	98%	100%	100%	96%
Total Results	97.5%	98.2%	96.8%	97.5%	97.5%	97%

	mAMP	MDMA	MOP	OPI	PCP	TCA
Positive Agreement	95%	97.1%	95%	95%	95%	95.7%
Negative Agreement	100%	98%	100%	100%	100%	98%
Total Results	97.5%	97.5%	97.5%	97.5%	97.5%	96.8%

Forty (40) clinical samples for each drug were run using each strip contained within The One Step Drug of Abuse Test by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the untrained operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained laboratory personnel.
*Note: TCA was based on HPLC data.

Reproducibility

Reproducibility studies were carried out using commercially available standards. Each standard was diluted in normal, drug-free urine to give the appropriate concentration. Each specimen, at each concentration of analyte, was tested four times daily, in duplicate, for five consecutive days. A total of 40 determinations were made at each concentration. The results are given below:

AMPHETAMINE (AMP)

Amphetamine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

BARBITURATES (BAR)

Secobarbital Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

BENZODIAZEPINES (BZO)

Oxazepam Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

COCAINE (COC)

Benzoylcegonine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%

150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

MARIJUANA (THC)

11-nor- Δ^9 -THC-9 COOH Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
25	40	40 negative	>99%
37.5	40	40 negative	>99%
50	40	40 positive	>99%
75	40	40 positive	>99%

METHADONE (MTD)

Methadone Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

METHAMPHETAMINE (mAMP)

Methamphetamine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxy-methamphetamine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
250	40	40 negative	>99%
375	40	40 negative	>99%
500	40	40 positive	>99%
750	40	40 positive	>99%

OPIATE 300 (MOP 300)

Morphine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

OPIATES (OPI 2000)

Morphine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
1,000	40	40 negative	>99%
1,500	40	40 negative	>99%
2,000	40	40 positive	>99%
3,000	40	40 positive	>99%

PHENCYCLIDINE (PCP)

Phencyclidine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
12.5	40	40 negative	>99%
19	40	40 negative	>99%
25	40	40 positive	>99%
37.5	40	40 positive	>99%

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortriptyline Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	AMP		BAR		BZO		COC	
		-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10
+25% Cut-off	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10

Drug concentration Cut-off Range	n	THC		MTD		mAMP		MDMA	
		-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10
+25% Cut-off	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10

Drug concentration Cut-off Range	n	MOP		OPI		PCP		TCA	
		-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10
+25% Cut-off	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by First Sign™ One Step Drug of Abuse Test at a read time of 5 minutes.

Drug	Concentration (ng/mL)
Amphetamine (AMP)	
d-amphetamine	1,000
D,l-amphetamine	1,000
l-amphetamine	20,000
Phentermine	1,250
(+/-)- Methylenedioxyamphetamine (MDA)	1,500
BARBITURATES(BAR)	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES(BZO)	
Oxazepam	300
Alprazolam	196
α -Hydroxyalprazolam	1,262
Bromazepam	1,562

Chlordiazepoxide	1,562
Chlordiazepoxide HCl	781
Clobazam	98
Clonazepam	781
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500

COCAINE (COC)	
Benzoylcocaine	300
Cocaine	300
Cocaine	300

MARIJUANA (THC)	
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	5,000
11-Nor-Δ ⁸ -Tetrahydrocannabinol	50
11-Nor-Δ ⁹ -Tetrahydrocannabinol	50
11-Nor-Δ ⁹ -Tetrahydrocannabinol-9 Carboxylic Glucuronide	2,500
Δ ⁸ -Tetrahydrocannabinol	20,000
Δ ⁹ -Tetrahydrocannabinol	20,000

METHADONE (MTD)	
Methadone	300
Doxylamine	50,000

Methamphetamine (mAMP)	
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+/-methamphetamine	1,000
+methamphetamine	1,000
Ranitidine (Zantac)	500,000
(+/-) 3,4-Methylenedioxyamphetamine (MDMA)	2,500
MDA	100,000

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
D,L-3,4-Methylenedioxyamphetamine HCl (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethylamphetamin (MDEA)	300

OPIATES (MOP 300)	
6-acetylmorphine	500
Codeine	300
Ethylmorphine	15,00
Heroin	300
Hydromorphone	2,000
Hydrocodone	1,250
Meperidine	300,000
Morphine	300
Morphine-3-glucuronide	300
Oxycodone	negative at 100,000

OPIATES (OPI 2000)	
Codeine	2,000
Hydromorphone	5,000

Oxycodone	negative at 100,000
Morphine Sulfate	2,000
Morphine-3-b-D-glucuronide	2,000
Morphine-6-b-D-glucuronide	2,000
Methadone	negative at 100,000
Nalorphine	negative at 100,000
Heroin	2,000
Ethylmorphine	5,000
Meperidine	5,000,000

Phencyclidine (PCP)	
Phencyclidine	25
Phencyclidine-d5	10000

TCA	
Notriptyline	1,000
Nordoxepine	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.03) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Drug of Abuse Test was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the One Step Drug of Abuse Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Cocaine, Barbiturates, Benzodiazepines, Amphetamine, Methamphetamine, Marijuana, Methadone, Methylenedioxyamphetamine, Opiates, Phencyclidine or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with The One Step Drug of Abuse Test at concentrations of 100 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Acetophenetidin
N-Acetylprocainamide	Acetylsalicylic acid
Aminopyrine	Amoxicillin
Ampicillin	L-Ascorbic acid
Apomorphine	Aspartame
Atropine	Benzilic acid
Benzoic acid	Benzphetamine*
Bilirubin	D/L-Brompheniramine
Caffeine	Cannabidol
Chloralhydrate	Chloramphenicol
Chlorothiazide	D/L-Chloropheniramine
Chlorpromazine	Chloroquine
Cholesterol	Clonidine
Cortisone	L-Cotinine
Creatinine	Deoxycorticosterone
Dextromethorphan	Diclofenac
Diflunisal	Digoxin
Diphenhydramine	Ecgonine methyl ester
L -Ψ -Ephedrine	b-Estradiol
Estrone-3-sulfate	Ethyl-p-aminobenzoate
[1R,2S] (-) Ephedrine	L(-)-Epinephrine

Erythromycin	Fenopifen
Furosemide	Gentisic acid
Hemoglobin	Hydralazine
Hydrochlorothiazide	Hydrocortisone
O-Hydroxyhippuric acid	p-Hydroxyamphetamine
p-Hydroxytyramine	Ibuprofen
Iproniazid	D/L-Isoproterenol
Isoxsuprine	Ketamine
Ketoprofen	Labetalol
Loperamide	Meperidine
Meprobamate	Methoxyphenamine
Methylphenidate	Nalidixic acid
Naloxone	Naltrexone
Naproxen	Niacinamide
Nifedipine	Norethindrone
D-Norpropoxyphene	Noscapine
D/L-Octopamine	Oxalic acid
Oxolinic acid	Oxymetazoline
Papaverine	Penicillin-G
Pentazocine hydrochloride	Perphenazine
Phenelzine	Trans-2-phenylcyclo-propylamine hydrochloride
L-Phenylephrine	β-Phenylethylamine
Phenylpropanolamine	Prednisolone
Prednisone	D/L-Propranolol
D-Propoxyphene	D-Pseudoephedrine
Quinacrine	Quinine
Quindine	Ranitidine
Salicylic acid	Serotonin
Sulfamethazine	Sulindac
Tetracycline	Tetrahydrocortisone 3-acetate
Tetrahydrocortisone 3 (b-D-glucuronide)	Tetrahydrozoline
Thiamine	Thioridazine
D/L-Tyrosine	Tolbutamide
Triamterene	Trifluoperazine
Trimethoprim	Tryptamine
D/L-Tryptophan	Tyramine
Uric acid	Verapamil
Zomepirac	

*Parent compound only; metabolizes into amphetamine and methamphetamine in the body.

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