

One Step Drug of Abuse Test

(Strip, dipcard, cassette, cup)

Package Insert for Multi Drug Screen Test

This Instruction Sheet is for testing of any combination of the following drugs:
AMP/BAR/BZO/COC/THC/MTD/mAMP/MDMA/MOR/OPI/OXY/PCP/TCA
Including Adulterant Tests (Specimen Validity Tests) for:
Oxidants (OX), Specific Gravity (S.G) and pH.

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.
For Professional and In Vitro Diagnostic Use Only.

INTENDED USE

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:

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
Methylenedioxyamphetamine(MDMA)	D,L-Methylenedioxyamphetamine	500 ng/mL
Opiate 300 (OPI 300,MOP,MOR)	Morphine	300 ng/mL
Opiate 2000 (OPI 2000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

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

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.

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).³

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 days⁴

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.^{1,2} 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.²

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).³

MARIJUANA (THC)

THC (Δ^9 -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- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (Δ^9 -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).³

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.⁴

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)

Methylenedioxyamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.⁸ 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 Oberlander, 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 Methylenedioxyamphetamine in urine exceeds 500 ng/mL.

OPIATE (OPI 300,MOP,MOR)

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 concentration of opiate exceeds the 300 ng/mL cut-off level.

OPIATE (OPI 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.³

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).

OXYCODONE (OXY)

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one,

dihydrohydroxycodone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyLR®, OxyFast®(immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours). The One Step Drug of Abuse Test yields a positive result when the Oxycodone in urine exceeds 100 ng/mL.

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. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).⁵ 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.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for oxidants, specific gravity and pH in human urine which can help to assess the integrity of the urine specimen.

ADULTERATION

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and pH, and to detect the presence of oxidants in urine are considered to be the best ways to test for adulteration or dilution.

- Oxidants (OX): Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- Specific Gravity (S.G.): Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- pH: tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.

PRINCIPLE

The One Step Drug of Abuse Test is an immunoassay based on the principle of competitive binding. Drugs 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, Methylenedioxyamphetamine, Morphine, THC, Phencyclidine, Benzodiazepines, Methadone, Barbiturates, Tricyclic Antidepressants or Oxycodone.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.36%	99.64%
Specific Gravity (S.G.)	0.25%	99.75%
pH	0.06%	99.94%

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.
- The test is for single use.
- While urine is not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood, 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 device
- Desiccants
- Package insert
- procedure card (for cup use only)
- Color Chart Card for Adulterant Interpretation (when applicable)
- Dropper (for cassette)

Materials Required But Not Provided

- Specimen collection container (for strip, cassette, dipcard)
- Disposable gloves
- Timer

DIRECTIONS FOR USE

Allow the test device and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

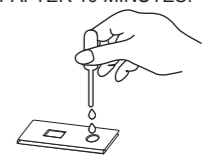
For Strip

- 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 minimum of 15 seconds in the urine and lay the strip flatly on a non-absorbent clean surface.
 - 3) Read results at 5 minutes.
- DO NOT INTERPRET RESULT AFTER 10 MINUTES.



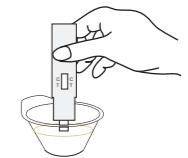
For Cassette

- 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. DO NOT INTERPRET RESULT AFTER 10 MINUTES.



For Dipcard

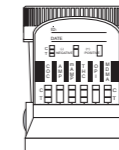
- 1) Remove the test device from the foil pouch.
- 2) Remove the cap from the test device. Label the device with patient or control identifications.
- 3) Immerse the absorbent tip into the urine sample for 5 seconds. Urine sample should not touch the plastic device.
- 4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorbent clean surface.
- 5) Read results at 5 minutes. DO NOT INTERPRET RESULT AFTER 10 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 test dipcard.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE: Two lines appear. * One color line should be in the control region (C), and another apparent color 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 color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint distinguishable color line.

POSITIVE: One color 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.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color indicator on the color chart. No instrumentation is required.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) LIMITATIONS

- The adulterant tests included with the product are meant to aid in the determination of abnormal specimens, but may not cover all the possible adulterants.
- Oxidants: Normal human urine should not contain oxidants. The presence of high level of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants pad..
- Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.

QUALITY CONTROL

A procedural control is included in the test. A color 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

- 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}
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using One Step Drug of Abuse Test and other commercially available rapid drug tests. Testing was performed on 120 samples per drug type. 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, a-OH-Alprazolam, Desalkylflurazepam
COC	Benzoyllecgonine
THC	11-nor- Δ^8 -tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	D,L-Methylenedioxyamphetamine, Methylenedioxyamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
TCA	Nortriptyline

%Agreement with GC/MS

	AMP	BAR	BZO	COC	THC	MTD	mAMP
Positive Agreement	98%	98.6%	95.7%	98%	98%	98.6%	95%
Negative Agreement	100%	98%	98%	97%	100%	96%	100%
Total Results	99%	98.3%	96.7%	97%	98%	97.5%	97.5%

	MDMA	MOP	OPI	OXY	PCP	TCA
Positive Agreement	97.1%	100%	100%	97.1%	100%	95.7%
Negative Agreement	98%	100%	100%	96%	97%	98%
Total Results	97.5%	100%	100%	96.7%	98%	96.7%

%Agreement with commercial kit

	AMP	BAR	BZO	COC	THC	MTD	mAMP
Positive Agreement	100%	99%	99%	100%	99%	99%	98%
Negative Agreement	100%	99%	98.1%	97%	100%	99%	100%
Total Results	100%	99%	99%	98%	99%	99%	99%

	MDMA	MOP	OPI	OXY	PCP	TCA
Positive Agreement	99%	100%	100%	99%	100%	98.6%
Negative Agreement	99%	100%	100%	99%	97%	99%
Total Results	99%	100%	100%	99%	98%	99.2%

Forty (40) clinical samples for each drug were run using each strip contained within 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(AMP) 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)

Benzoyllecgonine 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%
375	40	40 positive	>99%
450	40	40 positive	>99%

Marijuana(THC)

11-nor- Δ^8 -THC-9-000H 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%

Methylenedioxyamphetamine(MDMA)

Methylenedioxyamphetamine 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 (OPI 300,MOP,MOR)

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%
375	40	40 positive	>99%

Opiate 2000 (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%

Oxycodone (OXY)

Nortriptyline conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
50	40	40 negative	>99%
75	40	40 negative	>99%
100	40	40 positive	>99%
150	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	0	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		MOP	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10	0	10
+25% Cut-off	10	0	0	0	10	0	0	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10	0	10

Drug concentration Cut-off Range	n	OPI		OXY		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	0	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 One Step Drug of Abuse Test at a read time of 5 minutes

AMPHETAMINE (AMP)	ng/mL
d-amphetamine	1,000
D,l-amphetamine	1,000
l-amphetamine	20,000
Phentermine	1,250
(+/-)- Methyleneoxyamphetamine (MDA)	1,500
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butobarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINE (BZO)	
a-Hydroxyalprazolam	1,260
Alprazolam	200
Bromazepam	1,560

Chlordiazepoxide	1,565
Chlordiazepoxide HCl	780
Clobazam	100
Clonazepam	785
Clorazepate Dipotassium	195
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	385
(±) Lorazepam	1,560
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	95
Norclordiazepoxide	200
Nordiazepam	390
Oxazepam	300
Temazepam	100
Triazolam	2,500
COCAINE (COC)	
Benzoyllecgonine	300
Cocaine	300
Cocaine	300
Metoclopramide	80,000
Procaine	75,000
MARIJUANA (THC)	
11-Nor-Δ ⁹ -Tetrahydrocannabinol	50
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	5,000
11-Nor-Δ ⁹ -Tetrahydrocannabinol	50
11-Nor-Δ ⁹ -Tetrahydrocannabinol-9 Carboxylic Glucuronide	2,500
Δ ⁹ -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	500
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxyamphetamine (MDMA)	2,500
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
D,L-3,4-Methylenedioxyamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyl-amphetamine (MDEA)	300
OPIATES (OPI 300,MOP,MOR)	
6-acetylmorphine	500
Codeine	100
Eserine (Physostigmine)	15,000
Ethylmorphine	100
Heroin	500
Hydromorphone	2,000
Hydrocodone	1,250
Morphine	300
Morphine-3-glucuronide	75
Oxycodone	75,000
Thebaine	13,000

OPIATES (OPI 2000)	
6-acetylmorphine	1,000
Codeine	800
Ethylmorphine	400
Heroin	10,000
Hydromorphone	2,000
Hydrocodone	5,000
Morphine	2,000
Morphine-3-glucuronide	1,000
Oxycodone	50,000
Thebaine	26,000
OXYCODONE (OXY)	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethylmorphine	25,000
Hydrocodone	1,580
Hydromorphone	12,500
Oxymorphone	1,580
Thebaine	50,000
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxy PCP	90
PCP Morpholine	625
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Notriptyline	1,000
Amitriptyline	1,500
Clomipramine	12,500
Desipramine	200
Doxepine	2,000
Imipramine	400
Maprotiline	2,000
Nordoxepine	1,000
Promazine	1,500
Promethazine	2,500
Trimipramine	3,000

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, Methylenedioxymethamphetamine, Opiates, Oxycodone, 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 Compound

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

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
 Cannabidiol
 Chloralhydrate
 Chloramphenicol
 Chlorothiazide
 D/L-Chlorpheniramine
 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
 Fenoprofen
 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
 Sulfamethazone
 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

BIBLIOGRAPHY

1. Stewart DJ, Inaba T, Lucassen M, Kalow W. *Clin. Pharmacol. Ther.* April 1979; 25 ed: 464, 264-8.
2. Ambre J. J. *Anal. Toxicol.* 1985; 9:241.
3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.*
4. Tietz NW. *Textbook of Clinical Chemistry.* W.B. Saunders Company. 1986; 1735.
5. FDA Guidance Document: *Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.*
6. Robert DeCresce. *Drug Testing in the workplace, 114.*
7. Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA 1982; 487.*
8. OSHA, *The Bloodborne Pathogens Standard 29, Code of Federal Regulations 29 CFR 1910.1030.*
9. CDC, *Centers for Disease Control (CDC) Guidelines, Morbidity and Mortality Weekly Report, Volume 37, Number 24, 1988.*

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 EL Monte, CA 91731
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