RAPID DETECT DIP CARD
One Step Drug of Abuse Tests

Package Insert for Single and Multi-drug Screening Test Strip, 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 (Opiates), Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants.

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)	Benzoylecgonine	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
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 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

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). [2]

BARBITURATES (BAR)

Barbiturates produce a wide spectrum of central nervous system depression, from mild sedation to coma, and have been used as sedatives, hypnotics, anesthetics, and anticonvulsants. Barbiturates are classified as ultrashort, short, intermediate, and long-acting. These drugs are primarily used for insomnia and preoperative sedation daytime sedation and the treatment of seizure disorders. Veterinarians use pentobarbital, a long-acting barbiturate, for anesthesia and euthanasia.

Barbiturates are common drugs of abuse taken orally or intravenously. They produce symptoms similar to intoxication. Chronic use will develop tolerance, physical dependence and psychological dependence on barbiturates. Overdoses can cause profound shock, coma, or death.

Shorter acting barbiturates (Allobarbital, Alphenal, Amobarbital, Aprobarbital, Butabarbital, Butalbital, Butethal, Pentobarbital, Secobarbital) can be detected for only 1 to 4 days, while long-acting barbiturates (Barbital, Phenobarbital) can be detected for 2 to 3 weeks. Normally the suggested detection period for the Barbiturates in urine is 4 to 7 days.

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

BENZODIAZEPINES (BZO)

Benzodiazepines are frequently prescribed sedative and hypnotic drug for the symptomatic treatment of anxiety, insomnia, sleep and seizure disorders. Most Benzodiazepines are extensively metabolized in the liver and excreted in the urine as metabolites. Chronic abuse may increase the risk of physical dependence and may result in intoxication, drowsiness and muscle relaxation. Benzodiazepines may remain effective for 4 to 8 hours. However, oxazepam, a major metabolite of Benzodiazepines may remain detectable in urine for up to 7 days.

The One Step Drug of Abuse Test yields a positive result when the Benzodiazepines (Oxazepam) 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 Benzoylecgonine.[2,4] Benzoylecgonine, 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 (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). [2]

METHADONE (MTD)

Methadone was synthesized by German scientists during World War II due to a shortage of morphine. Methadone produces many of the same effects as morphine and heroin, and is primarily used for the treatment of narcotic addiction.[1] Methadone is administered orally, or by intravenous or intra-muscular injection.[2] Its duration of effect is 12 to 24 hours.[3] Chronic administration of methadone results in physical dependence. Although the substitution of methadone is an acceptable method of detoxification for patients and therapists, the withdrawal syndrome develops more slowly and prolonged than that associated with heroin withdrawal.[6] 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)

MDMA, ECSTASY; 3,4-METHYLENEDIOXY-N-METHYLAMPHETAMINE was first identified by a DEA Lab in 1972. MDMA is a Schedule 1 synthetic, psychoactive drug possessing stimulant and hallucinogenic properties. MDMA possesses chemical variations of the stimulant amphetamine or methamphetamine and a hallucinogen, most often mescaline.

Ecstasy is said to produce empathy, decreased anxiety, relaxation and heightened senses. MDMA also suppresses appetite, thirst and the need to sleep. Because of this in combination with dancing and increased activity can cause severe dehydration and exhaustion. Adverse effects may include nausea, cold sweats, chills, hallucinations, increased body temperature, tremors, teeth clenching, tremors, double vision and muscle cramps. Long term after-effects of MDMA include anxiety, paranoia and depression. This is most likely attributed to the decreased serotonin levels found in the brain for up to three weeks after their last dose. The National Institute of Mental Health conducted a study in 1998 to support this. It was found that the use of MDMA severely damaged the neurons in the brain that transmit serotonin. Serotonin is the chemical that is used in learning, sleep, and integration of emotion. The study concluded that even recreational users of the drug might be at risk of developing permanent damage that can manifest depression, anxiety, memory loss, and neuropsychotic disorders.

In addition to these troubling facts, recent research is pointing to the real cause of the long term effects of MDMA. The drug acts primarily on the serotonin receptor

sites in the brain, enabling them to take in large quantities of serotonin. It also enables them to take in other chemicals in the brain. Namely, it takes in dopamine and as the serotonin receptor sites attempt to break the dopamine down, it produces hydrogen peroxide. Which many researches believe is the cause of long term damage to serotonin receptors.
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).

OXYCODONE (OXY)

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] 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), OxyIR®, 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.[5] 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).

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels. In human, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.
The One Step Drug of Abuse Test yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL.

TRICYCLIC ANTIDEPRESSANTS (TCA)

Tricyclic Antidepressants (TCA) are commonly used to relieve mental depression and can be taken orally or by injection. Tricyclic Antidepressants are a group of antidepressant drugs that contain three fused rings in their chemical structure.[1] Symptoms of TCA overdose include confusion; convulsions (seizures); disturbed concentration; severe drowsiness; enlarged pupils; fast, slow, or irregular heartbeat; fever; hallucinations; restlessness and agitation; shortness of breath or troubled breathing; unusual tiredness or weakness (severe); vomiting.[2] 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, so detecting the metabolites of TCA in human urine has been used for screening the abuse of TCA.[3,4]
The One Step Drug of Abuse Test yields a positive result when the concentration of Tricyclic Antidepressants (Nortriptyline) in urine exceeds 1,000 ng/mL.

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, Barbiturates (Secobarbital), Benzodiazepines (Oxazepam), Cocaine, Marijuana (THC), Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine (Opiates), Oxycodone, Phencyclidine, Propoxyphene, or Tricyclic Antidepressants (Nortriptyline).

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 · Desiccants · Package insert
· Disposable specimen droppers (for test cassette only)
· Procedure Card (for Multi-Drug Screen Test Cup only)

Materials Required But Not Provided

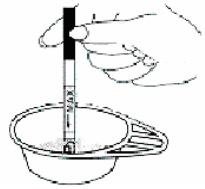
· Specimen collection container · Disposable gloves
· Timer

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 minimum of 15 seconds in the urine and lay the strip flatly on a non-absorptive clean surface.
3) Read results at 5 minutes.

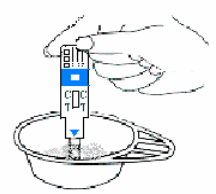


[For Cassette]

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 overfill the absorbent pad.
3) Read results at 5 minutes.

[For Dipcard]

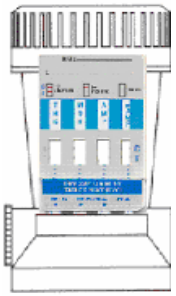
1) Remove the test device from the foil pouch.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 5 seconds. Urine sample should not touch the plastic device.
4) Replace the cap over the absorbent tip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

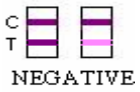


[For Multi-Drug Screen Test Cup]

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	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	D,L Methylenedioxymethamphetamine, Methylenedioxyamphetamine
OPI, MOP	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
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	OXY	PCP
Positive Agreement	98%	100%	98%	98%	100%	98%
Negative Agreement	100%	100%	100%	100%	100%	100%
Total Results	99%	100%	99%	99%	100%	99%
	PPX	TCA				
Positive Agreement	98%	98.5%				
Negative Agreement	100%	100%				
Total Results	99%	99%				

%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	OXY	PCP
Positive Agreement	95%	97.1%	95%	95%	97%	95%
Negative Agreement	100%	98%	100%	100%	96%	100%
Total Results	97.5%	97.5%	97.5%	97.5%	96.5%	97.5%

	PPX	TCA
Positive Agreement	97.1%	95.7%
Negative Agreement	98%	98%
Total Results	97.5%	96.8%

Either forty (40) or eighty (80) 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 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.

%Agreement with GC/MS

	AMP	BAR	BZO	COC	THC	MTD
Positive Agreement	95%	97.4%	95.7%	96%	96%	93.7%
Negative Agreement	100%	97.6%	100%	100%	100%	97.9%
Total Results	97.5%	97.5%	97.5%	98%	98%	96.2%
	mAMP	MDMA	MOP	OPI	OXY	PCP
Positive Agreement	96%	92.5%	96%	100%	95%	95%
Negative Agreement	100%	100%	100%	96%	100%	100%

Total Results	98%	96.2%	98%	98%	97.5%	97.5%

	PPX	TCA
Positive Agreement	95%	97.5%
Negative Agreement	100%	100%
Total Results	97.5%	98.7%

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)

Benzoylecgonine 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%

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)

Oxycodone 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%

PROPOXYPHENE (PPX)

Propoxyphene 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%

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortiptyline 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	
		-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10
+25% Cut-off	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10

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

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

Drug concentration Cut-off Range	n	PPX		TCA	
		-	-	-	+
0% Cut-off	10	10	10	10	0
-50% Cut-off	10	10	10	10	0
-25% Cut-off	10	10	10	10	0
Cut-off	10	0	0	0	10
+25% Cut-off	10	0	0	0	10
+50% Cut-off	10	0	0	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	
D,l-amphetamine	
l-amphetamine	
Phentermine	
(+/-)- Methylenedioxyamphetamine (MDA)	
BARBITURATES (BAR)	
Secobarbital	
Amobarbital	
Alphenol	
Aprobarbital	
Butabarbital	
Butalbital	
Butethal	
Cyclopentobarbital	
Pentobarbital	
Phenobarbital	
BENZODIAZEPINES (BZO)	

Oxazepam	300
Alprazolam	300
α-Hydroxyalprazolam	negative at 100,000
Bromazepam	negative at 100,000
Chlordiazepoxide	negative at 100,000
Chlordiazepoxide HCl	negative at 100,000
Clobazam	negative at 100,000
Clonazepam	negative at 100,000
Clorazepate dipotassium	negative at 100,000
Delorazepam	negative at 100,000
Desalkylflurazepam	negative at 100,000
Diazepam	negative at 100,000
Estazolam	negative at 100,000
Flunitrazepam	negative at 100,000
(±) Lorazepam	negative at 100,000
RS-Lorazepam glucuronide	negative at 100,000
Midazolam	negative at 100,000
Nitrazepam	negative at 100,000
Norchlordiazepoxide	negative at 100,000
Nordiazepam	negative at 100,000
Temazepam	negative at 100,000
Triazolam	negative at 100,000
COCAINE (COC)	
Benzoylecogonine	300
Cocaethylene	300
Cocaine	300
MARIJUANA (THC)	
11-Hydroxy-Δ^9-Tetrahydrocannabinol	50
11-Nor-Δ^8-Tetrahydrocannabinol	50
11-Nor-Δ^9-Tetrahydrocannabinol	50
11-Nor-Δ^9-Tetrahydrocannabinol-9 Carboxylic Glucuronide	50
Δ^8-Tetrahydrocannabinol	50
Δ^9–Tetrahydrocannabinol	50
METHADONE (MTD)	
Methadone	300
Doxylamine	20,000
Methamphetamine (mAMP)	
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	500
Procaine (Novocaine)	3,000
Trimethobenzamide	300
+/-methamphetamine	500
+methamphetamine	1,000
Ranitidine (Zantac)	500,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	1,000
MDA	500
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
D,L-3,4-Methylenedioxymethamphetamine HClI (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300
OPIATES (MOP 300)	
6-acetylmorphine	300
Codeine	300
Ethylmorphine	15,000
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	1,562
Hydromorphone	1,562
Oxycodone	1,562
Morphine Sulfate	781
Morphine-3β-D-glucuronide	781
Morphine-6β-D-glucuronide	781
Methadone	195
Nalorphine	1,562
Heroin	390
Ethylmorphine	195
Meperidine	2,500
	390
Oxycodone (OXY)	500
Oxycodone	156
Codeine	12,500
Dihydrocodeine	98
Ethylmorphine	195
Hydrocodone	390
Hydromorphone	98
Oxymorphone	2,500
Thebaine	1,000
Phencyclidine (PCP)	300
Phencyclidine	500
Phencyclidine-d5	800
Propoxyphene (PPX)	
D-Propoxyphene	5,000
D-Norpropoxyphene	20,000
	50
Tricyclic Antidepressants (TCA)	1,500
Notriptyline	5,000
Nordoxepine	40,000
Trimipramine	1,000
Amitriptyline	300
Promazine	20,000
Desipramine	1,000
Imipramine	300
Clomipramine	20,000
Doxepin	60,000
Maprotiline	20,000
Promethazine	1,000

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) 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 other than drug-free urine positive urine containing Cocaine, Barbiturates, Benzodiazepines, Amphetamine, Methamphetamine, Marijuana, Methadone, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene 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-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
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.

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.

Manufactured for: