One Step Drug of Abuse Test
(Strip, dipcard, cassette)

Package Insert for Multi-Drug Screen Test

This Instruction Sheet is for testing of any combination of the following drugs: AMP/BAR/BZO/BUP/COC/THC/MTD/mAMP/MDMA/MOR/OPI/OXY/PCP/PPX /TCA/EDDP/TRA.

Including Adulterant Tests (Specimen Validity Tests) for:
Oxidants (OX), Specific Gravity (S.G), pH, Creatinine (CRE), Nitrite (NIT) and Glutaraldehyde (GLU).

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

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 1000)	D-Amphetamine	1,000ng/mL
Amphetamine (AMP 500)	D-Amphetamine	500ng/mL
Amphetamine (AMP 300)	D-Amphetamine	300ng/mL
Barbiturates (BAR)	Secobarbital	300ng/mL
Benzodiazepines (BZO)	Oxazepam	300ng/mL
Benzodiazepines (BZO)	Oxazepam	200ng/mL
Cocaine (COC 300)	Benzoylecgonine	300ng/mL
Cocaine (COC 150)	Benzoylecgonine	150ng/mL
Marijuana (THC 50)	11-nor-Δ^9-THC-9 COOH	50ng/mL
Marijuana (THC 20)	11-nor-Δ^9-THC-9 COOH	20ng/mL
Methadone (MTD)	Methadone	300ng/mL
Methamphetamine (mAMP 1000)	D-Methamphetamine	1,000ng/mL
Methamphetamine (mAMP 500)	D-Methamphetamine	500ng/mL
Methamphetamine (mAMP 300)	D-Methamphetamine	300ng/mL
MDMA(Ecstasy)	D,L-Methylenedioxy-methamphetamine	500ng/mL
Morphine 300 (OPI 300, MOP, MOR)	Morphine	300ng/mL
Opiate 2000 (OPI 2000)	Morphine	2,000ng/mL
Oxycodone (OXY)	Oxycodone	100ng/mL
Phencyclidine (PCP)	Phencyclidine	25ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000ng/mL
EDDP(Methadone Metabolites)	2-Ethylidene-1,5-dimethyl-3,3-diph eylpyrrolidine (EDDP)	300ng/mL
Buprenorphine (BUP)	Buprenorphine	10ng/mL
Propoxyphene (PPX)	Propoxyphene	300ng/mL
Tramadol (TRA)	Tramadol	200ng/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 without the use of an instrument.

AMPHETAMINE(AMP 1000)

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 1,000ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA,USA).[3]

AMPHETAMINE (AMP 500)

See AMPHETAMINE (AMP 1000) for the summary.
The **One Step Drug of Abuse Test** yields a positive result when Amphetamines in urine exceeds 500ng/mL.

AMPHETAMINE (AMP 300)

See AMPHETAMINE (AMP 1000) for the summary.
The **One Step Drug of Abuse Test** yields a positive result when Amphetamines in urine exceeds 300ng/mL.

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 days[4]
The **One Step Drug of Abuse Test** yields a positive result when the Barbiturates in urine exceed 300ng/mL.

BENZODIAZEPINES (BZO300)

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 300ng/mL.

BENZODIAZEPINES (BZO200)

See **BENZODIAZEPINES (BZO300)** for the summary.
The **One Step Drug of Abuse Test** yields a positive result when Benzodiazepines in urine exceeds 200ng/mL.

BUPRENORPHINE (BUP)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex®, and a Buprenorphine/Naloxone combination product, Suboxone®, are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.
The **One Step Drug of Abuse Test** yields a positive result when the Buprenorphine in urine exceeds 10ng/mL.

COCAINE (COC 300)

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.[1,2] 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.[2]
The **One Step Drug of Abuse Test** yields a positive result when the cocaine metabolite in urine exceeds 300ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). [3]

COCAINE (COC 150)

See COCAINE (COC 300) for the summary.
The **One Step Drug of Abuse Test** yields a positive result when the concentration of Benzoylecgonine in urine exceeds 150ng/mL.

MARIJUANA (THC 50)

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 50ng/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 20)

See MARIJUANA (THC 50) for the summary.
The **One Step Drug of Abuse Test** yields a positive result when the concentration of THC-COOH in urine exceeds 20ng/mL.

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 300ng/mL.

METHAMPHETAMINE (mAMP 1000)
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 1,000ng/mL.

METHAMPHETAMINE (mAMP 500)
See METHAMPHETAMINE (mAMP 1000) for the summary.
The **One Step Drug of Abuse Test** yields a positive result when the concentration of Methamphetamine in urine exceeds 500ng/mL.

METHAMPHETAMINE (mAMP 300)
See METHAMPHETAMINE (mAMP 1000) for the summary.
The **One Step Drug of Abuse Test** yields a positive result when the concentration of Methamphetamine in urine exceeds 300ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)
Methylenedioxymethamphetamine (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 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 500ng/mL.

OPIATE (OPI 300, MOR, MOP)
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 300ng/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, 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 100ng/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 25ng/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 300ng/mL.

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 1,000ng/mL.

2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)

One Step Drug of Abuse Test EDDP is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a urine specimen migrates upward by capillary action. EDDP, if present in the urine specimen below 300ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody-coated particles will then be captured by immobilized EDDP conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the EDDP level exceeds 300ng/mL because it will saturate all the binding sites of anti-EDDP antibodies. A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. 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.
The **One Step Drug of Abuse Test** EDDP yields a positive result when the EDDP in urine exceed 300ng/mL.

TRAMADOL(TRA)
Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.[2] Large doses of Tramadol could develop tolerances and physiological dependency and lead to its abuse. Both Δ (d) and L forms of the isomers are controlled substances. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucoronidation or sulfation in the liver.
The **One Step Drug of Abuse Test** yields a positive result when the Tramadol in urine exceeds 200ng/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, pH, Creatinine, Nitrite and Glutaraldehyde 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, Nitrite, Glutaraldehyde and Creatinine 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.
- Nitrite(NIT) : Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- Glutaraldehyde(GLU): Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- Creatinine(CRE): Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

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 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, Buprenorphine, Morphine, Marijuana, Phencyclidine, Benzodiazepines, Methadone, Barbiturates, Tramadol, Oxycodone, Propoxyphene, Tricyclic Antidepressants or EDDP.

ADULTERANT TESTS(SPECIMEN VALIDITY TEST) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.30%	99.70%
Specific Gravity (S.G.)	0.21%	99.79%
Ph	0.06%	99.94%
Nitrite（NIT）	0.06%	99.94%
Glutaraldehyde（GLU）	0.02%	99.98%
Creatinine（CRE）	0.03%	99.97%

PRECAUTIONS

For medical and other professional *in vitro* diagnostic use only.
Do not use after the expiration date.
The test device 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[8,9], the use of gloves is recommended to avoid unnecessary contact with the specimen. The used test device and urine specimen should be discarded according to federal, state and local regulations.

STORAGTE 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

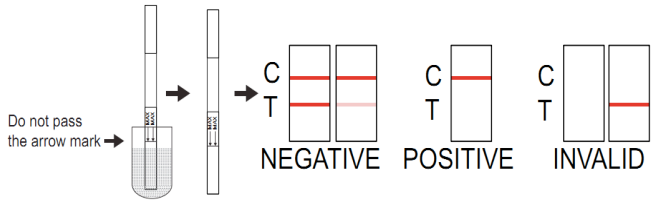
Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

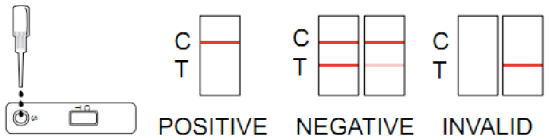
Materials Provided
• Test device • Desiccants • Package insert
• Color Chart Card for Adulterant Interpretation (when applicable)
• Disposable specimen droppers (for test cassette only)
Materials Required But Not Provided
• Specimen collection container (for strip, cassette, dipcard) • Disposable gloves • Timer
• Dropper (for strip, cassette)

DIRECTIONS FOR USE

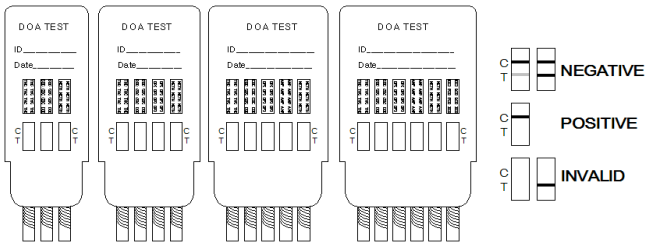
Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.
[For Strip]
1) Remove the strip from the foil wrapper or the desiccated container (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label 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-absorptive 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 overfill 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 about 10 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.
DO NOT INTERPRET RESULT AFTER 10 MINUTES.



PERFORMANCE CHARACTERISTICSINTERPRETATION OF RESULTS

(Please refer to the previous illustration)
NEGATIVE: Two lines appear. * One color line should be in the control region ©, 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

1. 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.
2. 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.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite (NIT) : Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/Dl may produce false positive glutaraldehyde results.
5. Glutaraldehyde(GLU): Is not normally found in a urine specimen. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
6. Creatinine(CRE): Tests for the specimen for dilution and flushing. Normal creatinine levels are between 20 and 350 mg/Dl. Under rare conditions, certain kidney diseases may show dilute urine.

QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region © 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

In the Comparison Study, the **One Step Drug of Abuse Test**s were compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for each of the drug types of Cocaine, Benzodiazepine, Morphine, Oxycodone, Methadone, EDDP, Amphetamine, Barbiturates, Marijuana, Methamphetamine, MDMA, Opiate 2000, Phencyclidine, Buprenorphine and Tricyclic Antidepressants. Clinical specimens were quantified by GC/MS analysis before testing.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital
BZO	Oxazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
Mamp	Methamphetamine
MDMA	D,L Methylenedioxymethamphetamine, Methylenedioxyamphetamine
OPI,	Morphine, Codeine
OXY	Oxycodone

PCP	Phencyclidine
TCA	Nortriptyline
EDDP	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine
BUP	Buprenorphine
PPX	Propoxyphene
TRA	Tramadol

The following results are tabulated from these clinical studies.

	AMP 1000	AMP 500	AMP 300	MTD	OPI 2000	BAR	TCA	MDMA
Positive Agreement	98%	98%	95%	98%	95%	95%	98%	93%
Negative Agreement	98%	98%	95%	95%	98%	98%	95%	95%
Overall Agreement	98%	98%	95%	96%	96%	96%	96%	94%

	EDDP	THC	PCP	COC	TRA	BUP	BZO300	OXY
Positive Agreement	98%	95%	93%	93%	93%	93%	98%	95%
Negative Agreement	95%	98%	95%	95%	95%	95%	93%	95%
Overall Agreement	96%	96%	94%	94%	94%	94%	95%	95%

	mAMP 1000	mAMP 500	mAMP 300	THC20	BZO200	COC150	MOP300	PPX
Positive Agreement	93%	95%	98%	98%	95%	98%	98%	95%
Negative Agreement	95%	98%	95%	95%	98%	98%	95%	98%
Overall Agreement	94%	96%	96%	96%	96%	98%	96%	96%

Analyte	THC		BZO300		PPX		OXY		MTD		EDDP	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	3	17	1	19	2	18	2	18	2	18
Near Cut-off Positive Samples [between cutoff and 150% of cut-off]	18	2	19	1	18	2	18	2	19	1	19	1
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	95%	98%	98%	93%	95%	98%	95%	95%	98%	95%	98%	95%

Analyte	BAR		COC		OPI2000		MDMA		mAMP		BUP	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	2	18	1	19	2	18	2	18	2	18
Near Cut-off Positive Samples [between cutoff and 150% of cut-off]	18	2	17	3	18	2	17	3	17	3	17	3
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	95%	98%	93%	95%	95%	98%	93%	95%	93%	95%	93%	95%

Analyte	mAMP500		AMP300		MOP300		THC20		COC150		TRA	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	2	18	2	18	1	19	1	19	2	18
Near Cut-off Positive Samples [between cutoff and 150% of cut-off]	18	2	18	2	19	1	18	2	19	1	17	3
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	95%	98%	95%	95%	98%	95%	95%	98%	98%	98%	93%	95%

Analyte	TCA		AMP1000		PCP		AMP500		BZO200		mAMP300	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	2	18	1	19	2	18	1	19	1	19	2	18
Near Cut-off Positive Samples [between cutoff and 150% of cut-off]	19	1	19	1	17	3	19	1	18	2	19	1
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	98%	95%	98%	98%	93%	95%	98%	98%	95%	98%	98%	95%

Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

Amphetamine (AMP1000)

Amphetamine (AMP) conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

Amphetamine (AMP500)

Amphetamine (AMP) conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
250	40	40 negative	>99%
750	40	40 positive	>99%
1000	40	40 positive	>99%

Amphetamine (AMP300)

Amphetamine (AMP) conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Barbiturates (BAR)

Secobarbital conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Benzodiazepines (BZO300)

Oxazepam conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Benzodiazepines (BZO200)

Oxazepam conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
100	40	40 negative	>99%
300	40	40 positive	>99%
400	40	40 positive	>99%

Cocaine (COC300)

Benzoylecgonine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Cocaine (COC150)

Benzoylecgonine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
75	40	40 negative	>99%
225	40	40 positive	>99%
300	40	40 positive	>99%

Marijuana (THC50)

11-nor-Δ^9-THC-9-COOH conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
25	40	40 negative	>99%
75	40	40 positive	>99%
100	40	40 positive	>99%

Marijuana (THC20)

11-nor-Δ^9-THC-9-COOH conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
10	40	40 negative	>99%
30	40	40 positive	>99%
40	40	40 positive	>99%

Methadone (MTD)

Methadone conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Methamphetamine (mAMP1000)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

Methamphetamine (mAMP500)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
250	40	40 negative	>99%
750	40	40 positive	>99%
1000	40	40 positive	>99%

Methamphetamine (mAMP300)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

MDMA (Ecstasy)

Methylenedioxymetham phetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
250	40	40 negative	>99%
750	40	40 positive	>99%
1000	40	40 positive	>99%

Opiate 300 (OPI 300, MOP, MOR)

Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Opiate 2000 (OPI 2000)

Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
1000	40	40 negative	>99%
3000	40	40 positive	>99%
4000	40	40 positive	>99%

Oxycodone (OXY)

Oxycodone conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
50	40	40 negative	>99%
150	40	40 positive	>99%
200	40	40 positive	>99%

Phencyclidine (PCP)

Phencyclidine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
12.5	40	40 negative	>99%
37.5	40	40 positive	>99%
50	40	40 positive	>99%

Tricyc antidepressants (TCA)

Nortiptyline conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

EDDP(Methadone Metabolites)

EDDP 2-Ethylidene-1,5-dimeth yl-3,3-dipheylpyrrolidine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Buprenorphine (BUP)

Buprenorphine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
5	40	40 negative	>99%
15	40	40 positive	>99%
20	40	40 positive	>99%

Propoxyphene (PPX)

Propoxyphene conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Tramadol (TRA)

TRA Tramadol	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

Drug concentration Cut-off Range	n	AMP1000		BAR		BZO		COC300		THC50	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	27	3	28	2	30	0	20	10
Cut-off	30	17	13	15	15	16	14	9	21	13	17
+25% Cut-off	30	6	24	4	26	3	27	7	23	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	MTD		AMP500		mAMP1000		MDMA		MOP300	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	27	3	24	6	28	2	28	2
Cut-off	30	16	14	16	14	14	16	19	11	20	10
+25% Cut-off	30	3	27	3	27	7	23	2	28	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	OXY		PCP		TRA		TCA		EDDP	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	23	7	27	3	26	4	20	10	27	3
Cut-off	30	10	20	19	11	16	14	14	16	16	14
+25% Cut-off	30	1	29	1	29	3	27	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	OPI2000		BUP		AMP500		mAMP500		mAMP300	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	28	2	26	4	27	3	27	3
Cut-off	30	14	16	16	14	19	11	20	10	14	16
+25% Cut-off	30	4	26	5	25	3	27	6	24	29	1
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	AMP 300		COC150		THC 20		BZO200	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	26	4	25	5	26	4	25	5
Cut-off	30	14	16	13	17	18	12	14	16
+25% Cut-off	30	5	25	2	28	4	26	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30

Analytical Specificity

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

Drug	**Concentration (ng/ml)**
AMPHETAMINE (AMP1000)	
d-amphetamine	1,000
D,l-amphetamine	1,000
l-amphetamine	20,000
Phentermine	1,250
(+/-)-Methylenedioxyamphetamine (MDA)	1,500
(+/-)-4-Hydroxyamphetamine HCL	600
AMPHETAMINE (AMP500)	
d-amphetamine	500
D,l-amphetamine	750
l-amphetamine	16,000
Phentermine	650

Drug	Concentration (ng/ml)
(+/-)-Methylenedioxyamphetamine (MDA)	800
AMPHETAMINE (AMP300)	
d-amphetamine	300
D,l-amphetamine	500
l-amphetamine	10,000
Phentermine	400
(+/-)-Methylenedioxyamphetamine (MDA)	500
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	750
Aprobarbital	250
Butabarbital	6,000
Butalbital	2,500
Butethal	2,500
Cyclopentobarbital	500
Pentobarbital	2,500
Phenobarbital	25,000
BENZODIAZEPINES (BZO300)	
a-Hydroxyalprazolam	1,260
Alprazalam	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
Norchlordiazepoxide	200
Nordiazepam	390
Oxazepam	300
Temazepam	100
Triazolam	2,500
BENZODIAZEPINES (BZO200)	
a-Hydroxyalprazolam	840
Alprazalam	150
Bromazepam	1,040
Chlordiazepoxide	1,040
Chlordiazepoxide HCl	520
Clobazam	70
Clonazepam	560
Clorazepate Dipotassium	160
Delorazepam	1,040
Desalkylflurazepam	260
Diazepam	150
Estazolam	1,500
Flunitrazepam	260
(±) Lorazepam	1,040
RS-Lorazepam glucuronide	100
Midazolam	12,500
Nitrazepam	70
Norchlordiazepoxide	150
Nordiazepam	260

Drug	Concentration (ng/ml)
Oxazepam	200
Temazepam	70
Triazolam	1,500
Flunitrazepam	150
(±) Lorazepam	7,000
RS-Lorazepam glucuronide	100
Midazolam	3,500
Nitrazepam	500
Norchlordiazepoxide	150
Nordazepam	700
Temazepam	35,000
Triazolam	1,500
COCAINE (COC300)	
Benzoylecogonine	300
Cocaethylene	300
Cocaine	300
Metoclopromide	80,000
Procaine	75,000
Riboflavin	25,000
Norcocaine	50,000
COCAINE (COC150)	
Benzoylecogonine	150
Cocaethylene	2,500
Cocaine	1000
MARIJUANA (THC50)	
11-Nor-Δ^9-Tetrahydrocannabinol	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	5,000
11-Nor-Δ^8-Tetrahydrocannabinol	50
11-Nor-Δ^9-Tetrahydrocannabinol-9 Carboxylic Glucuronid	2,500
Δ^8-Tetrahydrocannabinol	20,000
Δ^9 -Tetrahydrocannabinol	50,000
MARIJUANA (THC20)	
11-Nor-Δ^9-COOH	20
Cannabinol	10,000
11-Nor-Δ^8-COOH	20
11-Nor-Δ^9-Tetrahydrocannabinol-9 Carboxylic Glucuronid	2,500
Δ^8-THC	10,000
Δ^9 -THC	10,000
METHAMPHETAMINE (mAMP 1000)	
+methamphetamine	1,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+/-methamphetamine	1,000
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2,500
Chloroquine	50,000
Ephedrine	100,000
Fenfluramine	50,000
p-Hydroxymethamphetamine	10,000
METHAMPHETAMINE (mAMP 500)	
+methamphetamine	500
D,l-amphetamine	750
l-amphetamine	16,000
Phentermine	650
(+/-)-Methylenedioxyamphetamine (MDA)	800
METHAMPHETAMINE (mAMP 300)	
+methamphetamine	300
D,l-amphetamine	450

Drug	Concentration (ng/ml)
l-amphetamine	9,600
Phentermine	400
(+/-)-Methylenedioxyamphetamine (MDA)	480
METHYLENEDIOXYMETHAMPHETAMINE （MDMA）	
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300
Labetalol	50,000
MORPHINE (OPI 300,MOP,MOR)	
Morphine	300
6-acetylmorphine	500
Codeine	100
Eserine (Physosotigmine)	15,000
Ethylmorphine	100
Heroin	500
Hydromorphone	2,000
Hydrocodone	1,250
Morphine-3-glucuronide	75
Oxycodone	75,000
Thebaine	13,000
OPIATES (OPI 2000)	
Morphine	2,000
6-acetylmorphine	2,500
Codeine	1,000
Ethyl Morphine	250
Heroin	5,000
Hydromorphine	2,500
Hydrocodone	5,000
Morphine-3-glucuronide	75
Oxycodone	75,000
Thebaine	13,000
Levorphanol	25,000
Eserine	50,000
OXYCODONE (OXY)	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethyl Morphine	75,000
Hydrocodone	1,580
Hydromorphone	100,000
Oxymorphone	750
Thebaine	50,000
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxy PCP	90
PCP Morpholine Anolog	625
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	50,000
Desipramine	5,000
Doxepine	10,000
Imipramine	10,000
Maprotiline	100,000
Nordoxepin	10,000
Promazine	50,000
Promethazine	2,500
Trimipramine	50,000
Cyclobenzaprine Hydrochloride	5,000
Norclomipramine	50,000
Buprenorphine (BUP)	

Drug	Concentration (ng/ml)
Buprenorphine	10
Norbuprenorphine	20
Methadone (MTD)	
Methadone	300
Doxylamine	50,000
Propoxyphene (PPX)	
Norpropoxyphene	300
Propoxyphene,d-	300
EDDP(Methadone Metabolites)	
EDDP	300
Disopyramide	50,000
Tramadol	100,000
Venlafaxine hydrochloride	100,000
TRAMADOL (TRA)	
Tramadol	200
N-desmethyl-tramadol	500
O-desmethyl-tramadol	20,000

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 in either drug-free urine or drug positive urine containing Cocaine, Barbiturates, Benzodiazepines, Amphetamine , Methamphetamine, Marijuana, Methadone, MDMA(Ecstasy), Opiate , Oxycodone, Phencyclidine, EDDP(Methadone Metabolites), Buprenorphine, Tramadol, 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-REACTIVITY COMPOUNDS

Acetophenetidin	l-Cotinine	Ketoprofen	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Labetalol	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Loperamide	Quinine
Aminopyrine	Dextromethorphan	Meprobamate	Salicylic acid
Amoxicillin	Diclofenac	Methoxyphenamine	Serotonin
Ampicillin	Diflunisal	Methylphenidate	Sulfamethazine
l-Ascorbic acid	Digoxin	Nalidixic acid	Sulindac
Apomorphine	Diphenhydramine	Naproxen	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Niacinamide	Tetrahydrocortisone,
Atropine	β-Estradiol	Nifedipine	3-Acetate
Benzilic acid	Estrone-3-sulfate	Norethindrone	Tetrahydrocortisone
Benzoic acid	Erythromycin	Noscapine	Tetrahydrozoline
Bilirubin	Fenoprofen	d,l-Octopamine	Thiamine
d,l-Brompheniramine	Furosemide	Oxalic acid	Thioridazine
Caffeine	Gentisic acid	Oxolinic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxymetazoline	Tolbutamide
Chloralhydrate	Hydralazine	Papaverine	Triamterene
Chloramphenicol	Hydrochlorothiazide	Penicillin-G	Trifluoperazine
Chlorothiazide	Hydrocortisone	Perphenazine	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Phenelzine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Prednisone	Uric acid
Cholesterol	d,l-Isoproterenol	d,l-Propanolol	Verapamil
Clonidine	Isoxsuprine	Cortisone	Zomepirac

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