One Step Drug of Abuse Test

(Strip, Dip card, Cassette, Cup)

Package Insert for Multi Drug Screen Test

This Instruction Sheet is for testing of any combination of the following drugs:

AMP/BARB/BZO/BUP/COC/GAB/HYD/THC/MTD/mAMP/MDMA/MOR/OPI/OXY/PCP/PGB/PPX/TCA
/EDDP/6-ACM/COT/K2/K3/K4/KET/KRA/FEN/TRA/ETG/MDPV/ALCO

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 Amphetamine (AMP 1000)	Calibrator D-Amphetamine	Cut-off 1,000 ng/mL
Amphetamine (AMP 500)	D-Amphetamine	500 ng/mL
Amphetamine (AMP 300)	D-Amphetamine	300 ng/mL
Barbiturates (BARB)	Butalbital	300 ng/mL
Benzodiazepines (BZO 300)	Oxazepam	300 ng/mL
Benzodiazepines (BZO 200)	Oxazepam	200 ng/mL
Buprenorphine (BUP 10)	Buprenorphine	10 ng/mL
Buprenorphine (BUP 5)	Buprenorphine	5 ng/mL
Cocaine (COC 300)	Benzoylecgonine	300 ng/mL
Cocaine (COC 150)	Benzoylecgonine	150 ng/mL
Gabapentin (GAB1000)	Gabapentin	1,000 ng/mL
Gabapentin (GAB 2000)	Gabapentin	2,000 ng/mL
Hydrocodone (HYD)	Hydrocodone	300 ng/mL
Marijuana (THC 50)	11-nor-Δ%-THC-9-COOH	50 ng/mL
Marijuana (THC 20)	11-nor-∆°-THC-9-COOH	20 ng/mL
Marijuana (THC 15)	11-nor-∆°-THC-9-COOH	15 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (mAMP 1000)	D-Methamphetamine	1,000 ng/mL
Methamphetamine (mAMP 500)	D-Methamphetamine	500 ng/mL
Methamphetamine (mAMP 300)	D-Methamphetamine	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L-Methylenedioxymethamphetamine	500 ng/mL
Opiate (OPI 300, MOP, MOR)	Morphine	300 ng/mL
Opiate (OPI 2000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Pregabalin (PGB)	Pregabalin	2,000 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL
2-Ethylidene-1 5-dimethyl-3 3-diphenylpyrrolidine (EDDP 300)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine	300 ng/mL
2-Ethylidene-1 5-dimethyl-3 3-diphenylpyrrolidine (EDDP 100)	2-Ethylidene-1 5-dimethyl-3 3-dipheylpyrrolidine	100 ng/mL
6-Acetylmorphine (6-ACM)	6-Acetylmorphine	10 ng/mL
Cotinine (COT)	Cotinine	200 ng/mL
Synthetic Cannabinoid (K2 50)	JWH-018 Pantanoic Acid / JWH-073 Butanoic Acid	50 ng/mL
Synthetic Cannabinoid (K2 20)	JWH-018 Pantanoic Acid / JWH-073 Butanoic Acid	20 ng/mL
AB-Pinaca (K3)	AB-Pinaca 5-Pentanoic Acid	10 ng/mL
UR-144 (K4)	UR-144 5-Pentanoic Acid	25 ng/mL
Ketamine (KET)	Ketamine	1,000 ng/mL
Kratom (KRA)	Mitragynine	100 ng/mL
Fentanyl (FEN)	Fentanyl	10 ng/mL
Tramadol (TRA 50)	Tramadol	50 ng/mL
Tramadol (TRA 100)	Tramadol	100 ng/mL
Tramadol (TRA 200)	Tramadol	200 ng/mL

Ethyl Glucuronide (ETG 500)	Ethyl Glucuronide	500 ng/mL
Ethyl Glucuronide (ETG 300)	Ethyl Glucuronide	300 ng/mL
Methylenedioxypyrovalerone (MDPV)	Methylenedioxypyrovalerone	1,000 ng/mL
Alcohol (ALCO)	Alcohol	>0.04%

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.' 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 AMP 1000 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Amphetamine in urine exceeds 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).³

AMPHETAMINE (AMP 500)

See AMPHETAMINE (AMP 1000) for the summary.

The AMP 500 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Amphetamine in urine exceeds 500 ng/mL.

AMPHETAMINE (AMP 300)

See AMPHETAMINE (AMP 1000) for the summary.

The AMP 300 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Amphetamine in urine exceeds 300 ng/mL.

BARBITURATES (BARB)

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 BARB assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of Butalbital in urine exceed 300 ng/mL.

BENZODIAZEPINES (BZO 300)

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 with 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 BZO 300 assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of Oxazepam in urine exceeds 300 ng/mL.

BENZODIAZEPINES (BZO 200)

See BENZODIAZEPINES (BZO 300) for the summary

The BZO 200 assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of Oxazepam in urine exceeds 200 ng/mL.

BUPRENORPHINE (BUP 10)

Buprenorphine is a semisynthetic opioid analgesic derived from thebaine, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, perioperative 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 BUP 10 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Buprenorphine in urine exceeds 10 ng/mL.

BUPRENORPHINE (BUP5)

See BUPRENORPHINE (BUP 10) for the summary.

The BUP 5 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Buprenorphine in urine exceeds 5 ng/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. 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 COC 300 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Benzoylecgonine in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).³

COCAINE (COC 150)

See COCAINE (COC 300) for the summary.

The COC 150 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Benzoylecgonine in urine exceeds 150 ng/mL.

GABAPENTIN (GAB 1000)

Gabapentin, developed under the brand name Neurontin, is used to treat epilepsy, neuralgia, hot flashes, and sleep pediculitis. This drug is generally used for the treatment of local epilepsy. Gabapentin is also the first choice for the treatment of neuropathic pain in diseases such as diabetic neuritis, severe pain after herpes, and central neuropathic pain. About 14% of patients with neuropathic pain can be improved.

Side effects include drowsiness and dizziness. Serious side effects may include increased risk of suicide, agitation, eosinophilia, and systemic symptoms. Whether it is harmful to pregnancy or breastfeeding is unclear. Patients with renal failure should use a lower dose.

The GAB1000 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Gabapentin in urine exceeds 1000 ng/mL.

GABAPENTIN (GAB 2000)

See GABAPENTIN (GAB 1000) for the summary

The GAB 2000 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Gabapentin in urine exceeds 2000 ng/mL.

HYDROCODONE (HYD)

Hydrocodone is in a class of medications called opiate analgesics. Hydrocodone relieves pain by changing the way the brain and nervous system respond to pain. Hydrocodone relieves cough by decreasing activity in the part of the brain that causes coughing.

Hydrocodone is the most frequently prescribed opioid and hydrocodone is associated with more drug abuse and diversion than any other licit or illicit opioid. Hydrocodone is an orally active narcotic analgesic (pain reliever) and antitussive (cough suppressant). It is commonly available in tablet, capsule and syrup form and is often compounded with other, generally less effective non-opioid compounds such as paracetamol (also known as acetaminophen) or ibuprofen, often added both to discourage recreational use and to provide a possible synergy of analgesic effects between hydrocodone and the non-opioid compounds present.

The HYD assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Hydrocodone in urine exceeds 300 ng/mL.

MARIJUANA (THC 50)

THC (Δ° -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° -tetrahydrocannabinol-9-carboxylic acid (11-nor- Δ° -THC-9-COOH).

The THC 50 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of 11-nor- Δ^{0} -THC-9-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).³

MARIJUANA (THC 20)

See MARIJUANA (THC 50) for the summary.

The THC 20 assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of 11-nor-Δ^α-THC-9-COOH in urine exceeds 20 ng/mL.

MARIJUANA (THC 15)

See MARIJUANA (THC 50) for the summary.

The THC 15 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of 11-nor-Δ⁰-THC-9-COOH in urine exceeds 15 ng/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 MTD assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of Methadone in urine exceeds 300 ng/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 mAMP 1000 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Methamphetamine in urine exceeds 1,000 ng/mL.

METHAMPHETAMINE (mAMP 500)

See METHAMPHETAMINE (mAMP 1000) for the summary.

The mAMP 500 assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of Methamphetamine in urine exceeds 500 ng/mL.

METHAMPHETAMINE (mAMP 300)

See METHAMPHETAMINE (mAMP 1000) for the summary.

The mAMP 300 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Methamphetamine in urine exceeds 300 ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. 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 MDMA assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/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 semisynthetic 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 OPI 300 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Morphine in urine exceeds the 300 ng/mL.

OPIATE (OPI 2000)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semisynthetic 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 OPI 2000 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of 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).³

OXYCODONE (OXY)

 $\label{eq:controlled} Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] is a semisynthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR®, OxyFast® (immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours).$

The OXY assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of 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 PCP assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Phencyclidine 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) ³

PREGABALIN (PGB)

Pregabalin, sold under the trade name Lyrica[®], an analog of the inhibitory neurotransmitter gamma-aminobutyric acid and also of gabapentin, has been used clinically since 2002 as an analgesic, anticonvulsant and anxiolytic agent. It is supplied as the free drug in 25-300mg capsules for oral administration. Adult dose are normally within a range of 50-200mg thricedaily. A single oral labeled dose of pregabalin in humans was eliminated in urine (92%) and feces (<0.1%) over a 4 days period. Urinary excretion products included unchanged drug (90% of the dose), N-Methylpregabalin (0.9%) and others. Single oral 75 or 150mg doses given to a healthy human yielded peak urinary pregabalin concentrations of 151 or 214 μg/mL, respectively, in the first 8 hours specimen. Pregabalin urine levels in 57,542 specimens from chronic pain patients averaged 184 μg/mL ^{27,28} The PGB assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Pregabalin in urine exceeds 2000 ng/mL.

PROPOXYPHENE (PPX)

Propoxyphene 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 PPX assay contained within 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 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 TCA assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Nortriptyline in urine exceeds 1,000 ng/mL.

2-ETHYLIDENE-1.5-DIMETHYL-3.3-DIPHEYLPYRROLIDINE (EDDP 300)

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 300 ng/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 300 ng/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 EDDP 300 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of 2-Ethylidene-1,5-Dimethyl-3,3-Dipheylpyrrolidine in urine exceeds 300 ng/mL.

2-ETHYLIDENE-1.5-DIMETHYL-3.3-DIPHEYLPYRROLIDINE (EDDP 100)

See 2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHEYLPYRROLIDINE (EDDP300) for the summary. The EDDP 100 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of 2-Ethylidene-1, 5-Dimethyl-3, 3-Dipheylpyrrolidine in urine exceeds 100 ng/mL.

6-ACETYLMORPHINE (6-ACM)

6-Acetylmorphine (6-ACM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-acetylmorphine (3-ACM). 6-ACM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. Since 6-ACM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opioid used. This is significant because on a urine immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulphate, and heroin. 6-ACM remains in the urine for no more than 24 hours so a urine specimen must be collected soon after the last heroin use, but the presence of 6-ACM guarantees that heroin was in fact used as recently as within the last day.

The 6-ACM assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of 6-Acetylmorphine in urine exceeds 10 ng/mL.

COTININE (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as theactive ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

The COT assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Cotinine in urine exceeds 200 ng/mL.

SYNTHETIC CANNABINOIDS (K2 50)

Since 2004, herbal mixtures such as "Spice" have been sold in Switzerland, Austria, Germany and other European countries mainly via Internet shops. Although declared as incense, they are smoked as "bio-drugs" by the consumers. In corresponding blogs, drug users reported cannabis-like effects after smoking. These products enjoy great popularity particularly among younger people, as up to now the mixtures are sold in head shops and via internet in many countries without age restriction.¹⁰

JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors.¹¹ JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", and "K3".¹² These products may be smoked for their psychoactive effects.

The K2 50 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Synthetic Cannabinoid compounds in urine exceeds 50 ng/mL.

SYNTHETIC CANNABINOIDS (K2 20)

See SYNTHETIC CANNABINOIDS (K250) for the summary.

The K2 20 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Synthetic Cannabinoid compounds in urine exceeds 20 ng/mL.

AB-PINACA (K3)

See SYNTHETIC CANNABINOIDS (K250) for the summary.

The K3 assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of AB-Pinaca 5-Pentanoic Acid in urine exceeds 10 ng/mL.

UR-144 (K4)

See SYNTHETIC CANNABINOIDS (K2 50) for the summary.

The K4 assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of UR-144 5-Pentanoic Acid in urine exceeds 25 ng/mL.

KETAMINE (KET)

Ketamine is a short-acting "dissociative" anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very

different ways. Ketamine is chemically related to PCP (Angel Dust). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is most often diverted in liquid form from vets' offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately an 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours.

The KET assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Ketamine in urine exceeds 1,000 ng/mL.

KRATOM (KRA)

Kratom is from a leaf of the kratom plant, it's a natural narcotic produced mainly in southern Thailand, containing mitragynine and 7-Hydroxymitragynine. It is often used to relieve chronic diseases, alcohol, etc., and relieve the pain caused by withdrawal of opium. A pain-eating cocktail made from the pain bearing leaves is the most common and readily available drug drink in southern Thailand. It can cause drowsiness and paralysis.

The KRA assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of Mitragynine in urine exceeds 100 ng/mL.

FENTANYL (FEN)

Fentanyl is a potent, synthetic opioid analgesic with a rapid onset and short duration of action. ¹³ It is a strong agonist at the µ-opioid receptors. Historically, it has been used to treat breakthrough pain and is commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with a benzodiazepine. Fentanyl is approximately 80 to 100 times more potent than morphine and roughly 15 to 20 times more potent than heroin. ^{14,15} Fentanyl and its derivatives are used recreationally. Deaths have resulted from both recreational and improper medical use. ¹⁸

The FEN assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Fentanyl in urine exceeds 10 ng/mL.

TRAMADOL (TRA 50

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. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites.

The TRA 50 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Tramadol in urine exceeds 50 ng/mL.

TRAMADOL (TRA 100)

See TRAMADOL (TRA 50) for the summary.

The TRA 100 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Tramadol in urine exceeds 100 ng/mL.

TRAMADOL (TRA 200)

See TRAMADOL (TRA 50) for the summary.

The TRA 200 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Tramadol in urine exceeds 200 ng/ml.

ETHYL GLUCURONIDE (ETG 500)

Ethyl Glucuronide (ETG) is a direct metabolite of ethanol, which is formed by enzymatic conjugation of ethanol with glucuronic acid. 17,18 Alcohol in urine is normally detected for only a few hours, whereas ETG can be detected up to several days even after complete elimination of alcohol from the body. 19 Therefore, ETG can be a useful diagnostic biomarker for determining recent alcohol use and in monitoring abstinence in alcoholics in alcohol withdrawal treatment programs. 20-23 Ethanol can be produced *in vitro* due to fermentation of urine samples containing sugars, bacteria or yeast when samples are exposed to warm temperatures. 24 In such cases, ETG test can be used, as a confirmatory test to determine if the alcohol in the sample is due to consumption of alcohol or it is formed *in vitro* as a result of fermentation. Currently ETG is monitor by GC/MS and LC/MS/MS. 25.28

Ethyl glucuronide (ETG) is a minor non-oxidative metabolite of ethyl alcohol formed by the in vivo conjugation of ethanol with glucuronic acid with UDP glucuronosyltransferase. ETG is a product of metabolic process of ingested alcohol (ethanol) rapidly metabolized in the body, which is excrete in the blood, hair and urine. By using, the *One Step Drug of Abuse Test* ETG can be detect in urine, confirming the consumption of alcohol. The ETG metabolite remains in the body longer and therefore has a more useful window of detection of 8 to 80 hours. ETG testing is an excellent option for zero-tolerance alcohol consumption or for rehabilitation programs.

The ETG 500 assay contained within the **One Step Drug of Abuse Test** yields a positive result when the concentration of Ethyl Glucuronide in urine exceeds 500 ng/mL.

ETHYL GLUCURONIDE (ETG 300)

See ETHYL GLUCURONIDE (ETG 500) for the summary.

The ETG 300 assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Ethyl Glucuronide in urine exceeds 300 ng/mL.

METHYLENEDIOXYPYROVALERONE (MDPV)

"Bath salts", a form of designer drugs, also promoted as "plant food" or "research chemicals", is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised as "legal" highs. The technical term for "bath salts" is substituted cathinone. Substituted cathinones are synthetic, concentrated versions of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. It has a stimulant effect on the user and can be quite dangerous. The white crystals resemble legal bathing salts, thus the name of "bath salts". In 2009 and 2010 there was a significant rise in the abuse of synthetic cathinones, initially in the United Kingdom and the rest of Europe, and subsequently in the US and Canada.

Established as one of the main ingredients for "bath salts", among other synthetic stimulants like Mephedrone, Methylone, Butylone and Methadrone, MDPV started appearing around 2004 when it was popularized as a club drug, often used in combination with alcohol, GHB, cannabis and other abused drugs, for its desired effects such as euphoria, alertness, talkativeness, and sexual arousal. There are currently no prescribed used for the synthetic stimulants.

While synthetic stimulants appear to affect users in ways similar to amphetamines, ecstasy and cocaine, reports concerning aggression, tachycardia, paranoia and suicide suggest that they may be more acutely toxic. These negative effects have resulted in an increase of ER visits and hospitalizations, severe psychotic and violent episodes, self-inflicted wounds, suicide and an alarming increase in abuse-related deaths. U.S. Poison Control and National Drug Intelligence have all issued health warnings, noting nationwide emergency room visits related to these drugs. In October 2011, the DEA announced an emergency ban on MDPV, Methylone and Mephedrone, making testing for these substances more vital than ever.

The MDPV assay contained within the *One Step Drug of Abuse Test* yields a positive result when the concentration of Methylenedioxypyrovalerone in urine exceeds 1,000 ng/mL.

ALCOHOL (ALCO)

Excess or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributory factor to many accidents, injuries and medical conditions. Urine alcohol test is intended for use as a rapid method to detect the presence of alcohol in urine greater than 0.04%. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.

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

(1) 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, ndicating that proper volume of specimen has been added and membrane wicking has occurred.

(2) Alcohol test is based on the high specifity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:

The distinct color on reactive pad could be observed in less than 60 seconds after the reaction pad was wetted with urine specimens with the ethyl alcohol concentration greater than 0.04%. It should be pointed out that other alcohols such as methyl, propanyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in human urine.

REAGENTS

- (1) 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 individual drug on the list in the "Intended Use" section.
- (2) The alcohol pad contains tetramethylbenzidine, alcohol oxidaze, peroxidase, buffer and stabilizing proteins.

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.36%	99.64%
Specific Gravity (S.G.)	0.25%	99.75%
pH	0.06%	99.94%
Nitrite (NIT)	0.07%	99.93%
Glutaraldehyde (GLU)	0.02%	99.98%
Creatinine (CRE)	0.04%	99.96%

PRECAUTIONS

- · 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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at $4-30^{\circ}$ C (39-86°F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

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

SPECIMEN STORAGE

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

MATERIALS

Materials Provided

- Test device
 Desiccants
 Package insert
 Procedure card (for test cup use only)
- · Color chart card for adulterant and alcohol interpretation (when applicable)
- Disposable specimen droppers (for test cassette only)

Materials Required But Not Provided

• Specimen collection container (for strip, cassette, dip card) • Disposable gloves • Timer

DIRECTIONS FOR USE

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

- Remove the strip from the foil pouch 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 strip with 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 result at 5 minutes. DO NOT READ RESULT AFTER 5 MINUTES. (Fig. 1)

[For Cassette

- Remove the test cassette from its foil pouch by tearing along the slice. Label the cassette with patient or control identifications.
- 2) Using the specimen dropper, withdraw the urine sample from the specimen container and slowly dispense 3 drops (approximately 120mL) into the circular sample well, being careful not to overfill the absorbent pad.
- Read results of alcohol test at 2 minutes, and drug tests at 5 minutes. DO NOT READ ALCOHOL TEST AND DRUG TESTS RESULTS AFTER 5 MINUTES. (Fig. 2)





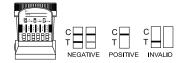
[For Dip card]

- 1) Remove the test dip card from the foil pouch.
- 2) Remove the cap from the test dip card. Label the dip card with patient or control identifications.
- 3) Immerse the absorbent tip into the urine sample for 1 minute. Urine sample should not touch the plastic device.
- 4) Replace the cap over the absorbent tip and lay the dip card flatly on a non-absorptive clean surface.
- 5) Read results of alcohol test at 2 minutes, adulterant tests at 3 minutes, and drug tests at 5 minutes. DO NOT READ ALCOHOL, ADULTERANT AND DRUG TESTS RESULTS AFTER 5 MINUTES. (Fig. 3)



[For Multi-Drug Screen Test Cup]

Please follow the instructions on the Procedure Card. Read results of alcohol test at 2 minutes, adulterant test at 3 minutes, and drug tests at 5 minutes. DO NOT READ ALCOHOL, ADULTERANT AND DRUG TESTS RESULTS AFTER 5 MINUTES. (Fig. 4)



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

(Fig. 4)

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

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

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

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

ALCOHOL TEST RESULTS

(Please refer to the alcohol color chart)

NEGATIVE: Almost no color change by comparing with the background. The negative result indicates that the alcohol concentration is less than 0.04%.

POSITIVE: A distinct color developed all over the pad. The positive result indicates that the urine alcohol concentration is 0.04% or higher.

INVALID: The test should be considered invalid if only the edge of the reactive pad turned color that might be attributed to insufficient sampling. The subject should be retested.

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: 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 > 20mg/dL may produce false positive glutaraldehyde results.
- Glutaraldehyde: 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: Tests for the specimen for dilution and flushing. Normal creatinine levels are between 20 and 350mg/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 (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

- The One Step Drug of Abuse Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. 34.7
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen and a new test device.
- A positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- 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.
- Alcohol test is designed for use with human urine only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.
- 9. There is a possibility that technical or procedure error for alcohol test as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to "Analytical Specificity" section for alcohol test list of substances that will interfere the test results.

10.Alcohol test is a semi-quantitative assay. It identifies alcohol in human urine specimens at a concentration of 0.04% or higher.

PERFORMANCE CHARACTERISTICS

Accuracy

In the comparison study, the *One Step Drug of Abuse Test* was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for each of the drug types list on the following table. Clinical specimens were quantified by GC/MS analysis before testing.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BARB	Butalbital
BZO	Oxazepam, Nordiazepam, a -OH-Alprazolam, Desalkylflurazepam
BUP	Buprenorphine
COC	Benzoylecgonine
GAB	Gabapentin
HYD	Hydrocodone
THC	11-nor-∆⁰-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
mAMP	Methamphetamine
MDMA	D,L-Methylenedioxymethamphetamine, Methylenedioxyamphetamine
OPI, MOR	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PGB	Pregabalin
PPX	Propoxyphene
TCA	Nortriptyline
EDDP	2-Ethylidene-1,5-Dimethyl-3,3-Dipheylpyrrolidine
6_ACM	6-Acetylmorphine
COT	Cotinine
K2	JWH-018 Pentanoic Acid / JWH-073 Butanoic Acid
K3	AB-Pinaca 5-Pentanoic Acid
K4	UR-144 5-Pentanoic Acid
KET	Ketamine
KRA	Mitragynine
FEN	Fentanyl
TRA	Tramadol
ETG	Ethyl Glucuronide
MDPV	Methylenedioxypyrovalerone

The following results are tabulated from these clinical studies:

[%] Agreement with GC/MS (HPLC for TCA, Predicate Device for COT and KET)

	mAMP1000	mAMP500	mAMP300	OPI 2000	MOR	COC 300	COC150	GAB 1000	GAB 2000	HYD	PCP	AMP 1000	AMP500	AMP300	BARB
Positive Agreement	96%	>99%	96%	>99%	96%	96%	>99%	100%	100%	>97%	95%	95%	>99%	>99%	100%
Negative Agreement	>99%	>99%	>99%	97%	>99%	>99%	>99%	100%	100%	100%	>99%	>99%	95%	98%	97.5%
Overa ll Agreement	98%	>99%	98%	98%	98%	98%	>99%	100%	100%	>98%	95%	98%	98%	99%	98.8%

	TRA50	TRA100	TRA 200	MDMA	BZO300	BZO200	MTD	OXY	EDDP300	EDDP100	THC 50	THC20	THC15	PPX	PGB
Positive Agreement	98%	97.5%	97.5%	93%	96%	96%	94%	95%	98%	95%	96%	>99%	97.5%	95%	100%
Negative Agreement	95%	97.5%	97.5%	>99%	>99%	>99%	98%	>99%	95%	97.5%	>99%	>99%	100%	98%	97.5%
Overall Agreement	96%	97.5%	97.5%	96%	98%	98%	96%	98%	96%	96%	98%	>99%	98.8%	96%	98.8%

	FEN	BUP 10	BUP 5	6-ACM	COT	K2 50	K2 20	K3	K4	KET	KRA	ETG500	ETG300	MDPV
Positive Agreement	97.5%	93%	100%	98%	98%	>97%	>97%	97.5%	100%	>99%	97.5%	>99%	>99%	>99%
Negative Agreement	100%	95%	95%	>99%	98%	>99%	>99%	97.5%	97.5%	>99%	97.5%	>99%	>99%	95%
Overall Agreement	99%	94%	97.5%	99%	98%	98%	98%	97.5%	98.8%	>99%	97.5%	>99%	>99%	≥90%

Analyte	BA	RB	GAB	1000	GAB	2000	H	D	MD	MA	BZC	300	BZC	200	M.	TD	OX	Ϋ́	TC	:A	TH	C 50	THO	20	THO	15
Analyte	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	5	0	5	0	5	0	4	0	5	0	5	0	3	0	4	0	4	0	0	0	40	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	0	18	0	18	0	18	0	36	0	28	0	28	1	44	0	36	0	36	0	15	0	3	0	20
Near Cut-off Positive Samples [between cut- off and 150% of cut-off]	20	0	19	0	19	0	18	1	33	3	27	2	27	2	27	2	34	2	35	1	23	1	3	0	19	1
Positive Samples [>150% of cut-off]	20	0	18	0	18	0	18	0	4	0	18	0	18	0	3	0	4	0	4	0	1	0	47	0	20	0
Agreement with GC/MS	100%	97.5%	100%	100%	100%	100%	>97%	100%	93%	>99%	96%	>99%	96%	>99%	94%	98%	95%	>99%	98%	>99%	96%	>99%	>99%	>99%	97.5%	100%

Amalida	FE				AMF	1000	AMF	500	AMF	300	mAM	P1000	mAM	P500	mAN	IP300	M	OR	OPI	2000	PF	PΧ	PC	βB	CO	T	COC	300
Analyte	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	1	0	1	0	20	0	42	0	4	0	42	0	4	0	3	0	17	0	20	0	20	0	20	0	0
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	0	0	0	19	2	18	1	6	0	10	0	6	0	10	0	11	1	13	1	1	0	19	1	19	0	13
Near Cut-off Positive Samples [between cut- off and 150% of cut-off]	20	0	7	2	7	1	20	0	3	0	3	1	11	0	3	1	18	1	3	0	18	2	20	1	19	1	26	1
Positive Samples [>150% of cut-off]	20	0	28	0	13	0	20	0	40	0	22	0	31	0	22	0	7	0	6	0	20	0	20	0	20	0	0	0
Agreement with GC/MS	97.5%	100%	95%	>99%	95%	>99%	>99%	95%	>99%	98%	96%	>99%	>99%	99%	96%	99%	96%	>99%	>99%	97%	95%	98%	100%	97.5%	98%	98%	96%	>99%

Analyte	CO					P100			BUI			\CM	ETG	500	ETG	300	TRA	150	TRA	100	TRA	200	MD	PV	K	3	K	4	KF	₹A
Analyte	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	40	0	20	0	20	0	20	0	20	0	20	0	70	0	70	0	20	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]	0	6	2	18	1	19	2	18	0	20	0	20	0	70	0	70	2	18	1	19	1	19	2	18	1	19	0	19	1	19
Near Cut-off Positive Samples [between cut- off and 150% of cut-off]	4	0	19	1	18	2	17	3	18	2	19	1	70	0	70	0	19	1	19	1	19	1	20	0	19	1	20	1	19	1
Positive Samples [>150% of cut-off]	51	0	20	0	20	0	20	0	20	0	20	0	70	0	70	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	>99%	>99%	98%	95%	95%	97.5%	93%	95%	100%	95%	98%	>99%	>99%	>99%	>99%	>99%	98%	95%	97.5%	97.5%	97.5%	97.5%	>99%	95%	97.5%	97.5%	100%	97.5%	97.5%	97.5%

Analyte		KET	K2	20	K2	50
Analyte	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples						
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	0	270	1	22	1	20
Near Cut-off Positive Samples [between cut- off and 150% of cut-off]	274	1	37	0	39	0
Positive Samples [>150% of cut-off]						
Agreement with GC/MS	>99%	>99%	>97%	>99%	>97%	>99%

Reproducibility

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

AMPHETAMINE (AMP 1000)

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%

AMPHETAMINE (AMP 500)

•	,		
Amphetamine 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%
1,000	40	40 positive	>99%

AMPHETAMINE (AMP 300)

Amphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
150	30	30 negative	>99%
225	15	15 negative	>99%
375	15	15 positive	>99%
450	30	30 positive	>99%
600	30	30 positive	>99%

BARBITURATES (BARB)

Butalbital 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%

BENZODIAZEPINES (BZO 300)

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%

BENZODIAZEPINES (BZO 200)

Oxazepam conc.(ng/mL)	Total number of Determinations	Result	Precision	
No drug present	40	40 negative	>99%	
100	40	40 negative	>99%	
300	40	40 positive	>99%	

COCAINE (COC 300)

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

COCAINE (COC 150)

Benzoylecgonine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
75	30	30 negative	>99%
112.5	15	15 negative	>99%
187.5	15	11 positive	>73%
225	30	29 positive	>96%
300	30	30 positive	>99%

GABAPENTIN (GAB 1000)

Gabapentin conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
500	60	60 negative	>99%
1500	60	60 positive	>99%

GABAPENTIN (GAB 2000)

Gabapentin conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
1000	60	60 negative	>99%
3000	60	60 positive	>99%

HYDROCODONE (HYD)

Total number of Determinations	Result	Precision
30	30 negative	>99%
30	30 negative	>99%
30	27 negative	90%
30	30 positive	>99%
30	30 positive	>99%
30	30 positive	>99%
	Determinations	Determinations Result 30 30 negative 30 30 negative 30 27 negative 30 30 positive 30 30 positive

MARIJUANA (THC 50)

11-nor-Δ*-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%

MARIJUANA (THC 20)

11-nor-∆∿-THC-9-COOH conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
10	30	29 negative	97%
15	15	9 negative	60%
25	15	12 positive	>80%
30	30	29 positive	97%
40	30	30 positive	>99%

MARIJUANA (THC 15)

11-nor-∆⁴-THC-9-COOH conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
7.5	40	40 negative	>99%
22.5	40	40 positive	>99%
30	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%

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymeth- amphetamine 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%

METHAMPHETAMINE (mAMP 1000)

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%

METHAMPHETAMINE (mAMP 500)

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
250	30	30 negative	>99%
375	15	15 negative	>99%
625	15	12 positive	>80%
750	30	30 positive	>99%
1000	30	30 positive	>99%

METHAMPHETAMINE (mAMP 300)

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%

OPIATE (OPI 300, MOP, MOR)

Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
375	40	40 positive	>99%

OPIATE (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%

TRICYCLIC ANTIDEPRESSANTS (TCA)

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

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHEYLPYRROLIDINE (EDDP 300)

EDDP conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
150	60	60 negative	>99%
450	60	60 positive	>99%
600	60	60 positive	>99%

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHEYLPYRROLIDINE (EDDP 100)

EDDP conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
50	60	60 negative	>99%
150	60	60 positive	>99%

6-ACETYLMORPHINE (6-ACM)

6-Acetylmorphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
5	40	40 negative	>99%
15	40	40 positive	>99%
20	40	40 positive	>99%

BUPRENORPHINE (BUP 10)

Buprenorphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
5	60	60 negative	>99%
15	60	60 positive	>99%
20	60	60 positive	>99%

BUPRENORPHINE (BUP 5)

Buprenorphine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
2.5	60	60 negative	>99%
7.5	60	60 positive	>99%

PREGABALIN (PGB)

Pregabalin conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
1000	60	60 negative	>99%
3000	60	60 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	60	60 negative	>99%
150	60	60 negative	>99%
450	60	60 positive	>99%
600	60	60 positive	>99%

KETAMINE (KET)

Ketamine conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	24	24 negative	>99%
500	24	24 negative	>99%
1,000	24	24 positive	>99%
1,500	24	24 positive	>99%

KRATOM (KRA)

Kratom conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
50	60	60 negative	>99%
150	60	60 positive	>99%

COTININE (COT)

Cotinine conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
100	60	60 negative	>99%
400	60	60 positive	>99%

SYNTHETIC CANNABINOID (K2 50)

JWH-018 Pentanoic Acid/ JWH-073 Butanoic Acid conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
25	60	60 negative	>99%
75	60	60 positive	>99%

SYNTHETIC CANNABINOID (K2 20)

JWH-018 Pentanoic Acid/ JWH-073 Butanoic Acid conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
10	60	60 negative	>99%
30	60	60 positive	>99%

AB-PINACA (K3)

AB-Pinaca 5-Pentanoic Acid conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
5	60	60 negative	>99%
15	60	60 positive	>99%

UR-144 (K4)

UR-144 5-Pentanoic Acid conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
12.5	60	60 negative	>99%
37.5	60	60 positive	>99%

FENTANYL (FEN)

Fentanyl conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
5	60	60 negative	>99%
15	60	60 positive	>99%

ETHYL GLUCURONIDE (ETG 500)

Ethyl Glucuronide 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%

ETHYL GLUCURONIDE (ETG 300)

Ethyl Glucuronide conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	70	70 negative	>99%
150	70	70 negative	>99%
450	70	70 positive	>99%
600	70	70 positive	>99%

TRAMADOL (TRA 50)

Tramadol conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
25	60	60 negative	>99%
75	60	60 positive	>99%

TRAMADOL (TRA100)

Tramadol conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
50	60	60 negative	>99%
150	60	60 positive	>99%

TRAMADOL (TRA 200)

Tramadol conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
100	60	60 negative	>99%
300	60	60 positive	>99%

METHYLENEDIOXYPYROVALERONE (MDPV)

Methylenedioxypyrovalerone conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	60	60 negative	>99%
500	60	60 negative	>99%
1500	60	60 positive	>99%

Analytical Sensitivity

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

Drug concentration	n	AMP	1000	BZC	300	BZC	200	coc	300	Нλ	/D	TH	C 50	mAM	P 300	K2	50
Cut-off Range		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+25% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10

_																				
ſ	Drug concentration	n	K2	20	M.	TD	mAMF	21000	MD	MA	М	OR	0	ΡI	0)	ΧY	Р	СР	TC	A
	Cut-off Range		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
	0% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
	-50% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
	-25% Cut-off	10	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0
	Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
	+25% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10
	+50% Cut-off	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10	0	10

Drug concentration	n	AMP	300	COC	150	THO	20	mAM	P500
Cut-off Range		-	+	-	+	-	+	-	+
0% Cut-off	25	25	0	25	0	25	0	25	0
-50% Cut-off	25	25	0	25	0	25	0	25	0
-25% Cut-off	25	25	0	25	0	25	0	25	0
Cut-off	25	1	24	3	22	2	23	2	23
+25% Cut-off	25	0	25	0	25	0	25	0	25
+50% Cut-off	25	0	25	0	25	0	25	0	25

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Drug concentration	n	BUI	P 10	P	PPX		EDDP300		6-ACM AMP 500		COT		n	ETG 500		ETG30		
Cut-off Range	''	-	+	-	+	-	+	-	+	-	+	-	+	"	-	+	-	+
0% Cut-off	90	90	0	90	0	90	0	90	0	90	0	90	0	30	30	0	30	0
-50% Cut-off	90	90	0	90	0	90	0	90	0	90	0	90	0	30	30	0	30	0
-25% Cut-off	90	81	9	81	9	78	12	80	10	81	9	90	0	30	30	0	30	0
Cut-off	90	48	42	44	46	41	49	46	44	45	45	63	27	30	3	27	3	27
+25% Cut-off	90	11	79	12	78	15	75	12	78	10	80	40	50	30	1	29	1	29
+50% Cut-off	90	0	90	0	90	0	90	0	90	0	90	16	74	30	0	30	0	30
2X Cut-off	90	0	90	0	90	0	90	0	90	0	90	0	90	30	0	30	0	30

Drug concentration	n	EDD	P100	FE	ΕN	TRA	A 50	TRA	100	TRA	A 200	ME	PV	THO	C15	BU	P5	К	3	K	4	KF	RA	P	ЗB	ВА	RB	GAB	1000	GAE	3 2000
Cut-off Range		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	30	0	29	1	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
Cut-off	30	1	29	4	26	2	28	0	30	0	29	2	28	3	27	3	28	3	27	3	27	3	27	2	28	1	29	0	30	0	30
+25% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	1	29	1	29	0	30	0	30	0	30	0	30	0	30	0	30	0	30
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug concentration	n	KET		
Cut-off Range		-	+	
0% Cut-off	30	30	0	
-50% Cut-off	30	30	0	
Cut-off	30	0	30	
+50% Cut-off	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.

AMPHETAMINE (AMP 1000)	Result
D-Amphetamine, Cutoff = 1,000ng/mL)	Positive at 1,000ng/mL
-Amphetamine	Positive at 100,000ng/mL
D,L-Amphetamine	Positive at 500ng/mL
+/-)-3,4-Methylenedioxyamphetamine (MDA)	Positive at 1,300ng/mL
Phentermine	Positive at 100,000ng/mL
Apomorphine	Positive at 50,000ng/mL
3-Phenylethylamine	Positive at 25,000ng/mL
Tyramine	Positive at 10,000ng/mL
Tryptamine	Positive at 25,000ng/mL
D-Methamphetamine	Negative at ≤ 100,000ng/mL
L-Methamphetamine	Negative at ≤ 100,000ng/mL
Ephedrine	Negative at ≤ 100,000ng/mL
3,4-Methylenedioxyethylamphetamine (MDEA)	Negative at ≤ 100,000ng/mL
AMPHETAMINE (AMP 500)	Result
(D-Amphetamine, Cutoff = 500ng/mL)	Positive at 500ng/mL
L-Amphetamine	Positive at 60,000ng/mL
D,L- Amphetamine	Positive at 1,000ng/mL
Methylenedioxyamphetamine (MDA)	Positive at 600ng/mL
R-(-)-Apomorphine	Positive at 13,000ng/mL
3-Phenylethylamine	Positive at 8,000ng/mL
Tyramine	Positive at 5,000ng/mL
Tryptamine	Positive at 100,000ng/mL
Hydroxyamphetamine	Positive at 600ng/mL
D-Pseudoephedrine	Negative at ≤ 100,000ng/mL
D-Methamphetamine	Negative at ≤ 100,000ng/mL
L-Methamphetamine	Negative at ≤ 100,000ng/mL
(±)-Methamphetamine	Negative at ≤ 100,000ng/mL
Ephedrine	Negative at ≤ 100,000ng/mL
Methylenedioxyethylamphetamine (MDEA)	Negative at ≤ 100,000ng/mL
3,4–Methylenedioxymethamphetamine (MDMA)	Negative at ≤ 100,000ng/mL
Phentermine	Negative at ≤ 100,000ng/mL
AMPHETAMINE (AMP 300)	Result
(D-Amphetamine, Cutoff = 300ng/mL)	Positive at 300ng/mL
D,I-amphetamine	Positive at 500ng/mL
I-amphetamine	Positive at 10,000ng/mL
Phentermine	Positive at 400ng/mL

	Positive at 500ng/m
BUTALBITAL (BARB)	Resu
(Butalbital, Cutoff = 300ng/mL)	Positive at 300ng/m
Secobarbital	Positive at 1,500ng/m
Amobarbital	Positive at 3,000ng/m
Alphenal	Positive at 250ng/m
Aprobarbital	Positive at 200ng/m
Allobarbital	Positive at 500ng/m
Butabarbital	Positive at 1,000ng/m
Butethal	Positive at 500ng/m
Cyclopentobarbital	Positive at 300ng/m
Pentobarbital	Positive at 1,300ng/m
Phenobarbital	Positive at 1,900ng/m
	Tooling at 1,000 ig.
BENZODIAZEPINES (BZO 300)	Resi
(Oxazepam, Cutoff = 300ng/mL)	Positive at 300ng/r
Alprazolam	Positive at 125ng/r
α-Hydroxyalprazolam	Positive at 2,500ng/r
Bromazepam	Positive at 1,565ng/r
Chlordiazepoxide	Positive at 1,560ng/r
Clobazam	Positive at 65ng/r
Clonazepam	Positive at 10,000ng/r
Clorazepate Dipotassium	Positive at 195ng/r
Delorazepam	Positive at 1,560ng/r
Desalkylflurazepam	Positive at 1,560ng/r
Diazepam	Positive at 115ng/r
Estazolam	Positive at 165ng/r
Flunitrazepam	Positive at 166ng/r
Midazolam	Positive at 6,500ng/r
Nitrazepam	Positive at 300ng/r
Norchlordiazepoxide	Positive at 250ng/r
Nordiazepam	Positive at 400ng/r
Temazepam	Positive at 100ng/r
Triazolam	Positive at 2,500ng/r
DL-Lorazepam	Negative at ≤ 100,000ng/r
Methamphetamine	Negative at ≤ 100,000ng/r
Morphine	Negative at ≤ 100,000ng/r
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BENZODIAZEPINES (BZO 200)	Resi
(Oxazepam, Cutoff = 200ng/mL)	Positive at 200ng/r
a-Hydroxyalprazolam	Positive at 400ng/r
Alprazolam	Positive at 75ng/r
Bromazepam	Positive at 5,000ng/r
Chlordiazepoxide HCI	Positive at 15ng/r
Clobazam	Positive at 30ng/r
Clonazepam	Positive at 20,000ng/r
Clorazepate Dipotassium	Positive at 2,000ng/r
Delorazepam	Positive at 1,000ng/r
Desalkylflurazepam	Positive at 260ng/r
Diazepam	Positive at 75ng/r
Estazolam	Positive at 50ng/r
Flunitrazepam	Positive at 200ng/r
(±) Lorazepam/ RS-Lorazepam glucuronide	Positive at 1,000ng/r
Midazolam	Positive at 10,000ng/r
Norchlordiazepoxide	Positive at 750ng/r
Nordiazepoxide	Positive at 150ng/r
	i ositive at 1501lg/l

Triazolam	Positive at 3,000ng/mL
BUPRENORPHINE (BUP 10)	Result
(Buprenorphine, Cutoff = 10ng/mL)	Positive at 10ng/mL
Buprenorphine-3-D-Glucuronide	Positive at 15ng/mL
Norbuprenorphine	Positive at 40ng/mL
Norbuprenorphine-3-D-Glucuronide	Positive at 500ng/mL
Morphine	Negative at ≤ 100,000ng/mL
Oxymorphone	Negative at ≤ 100,000ng/mL
Hydromorphone	Negative at ≤ 100,000ng/mL
BUPRENORPHINE (BUP 5)	Result
(Buprenorphine, Cutoff = 5ng/mL)	Positive at 5ng/mL
Buprenorphine-3-D-Glucuronide	Positive at 15ng/mL
Norbuprenorphine	Positive at 40ng/mL
Norbuprenorphine-3-D-Glucuronide	Positive at 500ng/mL
Morphine	Negative at ≤ 100,000ng/mL
Oxymorphone	Negative at ≤ 100,000ng/mL
Hydromorphone	Negative at ≤ 100,000ng/mL
COCAINE (COC 300)	Result
(Benzoylecgonine, Cutoff = 300ng/mL)	Positive at 300ng/mL
Cocaine HCL	Positive at 5,000ng/mL
Cocaethylene	Negative at ≤ 100,000ng/mL
Ecgonine	Negative at ≤ 100,000ng/mL
COCAINE (COC 150)	Result
(Benzoylecgonine, Cutoff = 150ng/mL)	Positive at 150ng/mL
Cocaine HCL	Positive at 3,000ng/mL
Norcocaine	Negative at ≤ 100,000ng/mL
Cocaethylene	Negative at ≤ 100,000ng/mL
Ecgonine	Negative at ≤ 100,000ng/mL
GABAPENTIN (GAB 1000)	Result
(Gabapentin, Cutoff = 1,000ng/mL)	Positive at 1,000ng/mL
Diffunisal	Positive at 80,000ng/mL
GABAPENTIN (GAB 2000)	Result
(Gabapentin, Cutoff = 2,000ng/ml)	Positive at 2,000ng/mL
Diflunisal	Positive at 100,000ng/mL
HYDROCODONE (HYD)	Result
(Hydrocodone, Cutoff = 300ng/mL)	Positive at 300ng/mL
Norhydrocodone HCI	Positive at 12,500ng/mL
MARIJUANA (THC 50)	Result
(11-nor- Δ ⁹ -THC-9-COOH, Cutoff = 50ng/mL)	Positive at 50ng/mL
11-hydroxy-Δ ⁹ -Tetrahydrocannabinol	Positive at 15,000ng/mL
Δ ⁸ -Tetrahydrocannabinol	Positive at 8,000ng/mL
Δº-Tetrahydrocannabinol	Positive at 7,000ng/mL
Cannabinol	Negative at ≤200,000ng/mL
Cannabidiol	Negative at ≤200,000ng/mL
MARIJUANA (THC 20)	Result
(11-Nor-Δ ⁹ - Tetrahydrocannabinol-9-COOH, Cutoff = 20ng/mL)	Positive at 20ng/mL
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	Positive at 8,000ng/mL
Δ ⁸ -Tetrahydrocannabinol	Positive at 5,000ng/mL
Δº-Tetrahydrocannabinol	Positive at 3,000ng/mL

11-Nor-∆ ⁸ - Tetrahydrocannabinol-9-COOH	Positive at 30ng/mL
11-Nor-∆ ⁹ -THC-carboxy glucuronide	Positive at 5,000ng/mL
Cannabinol	Negative at ≤ 100,000ng/mL
Cannabidiol	Negative at ≤ 100,000ng/mL
MARIJUANA (THC 15)	Result
(11-Nor-Δ ⁹ - Tetrahydrocannabinol-9-COOH, Cutoff = 15ng/mL)	Positive at 15ng/mL
11-Hydroxy-∆ ⁹ -Tetrahydrocannabinol	Positive at 8,000ng/mL
Δ ⁸ -Tetrahydrocannabinol	Positive at 5,000ng/mL
Δ ⁹ -Tetrahydrocannabinol	Positive at 3,000ng/mL
11-Nor-∆ ⁸ - Tetrahydrocannabinol-9-COOH	Positive at 30ng/mL
11-Nor-Δ ⁹ -THC-carboxy glucuronide	Positive at 5,000ng/mL
Cannabinol	Negative at ≤ 100,000ng/mL
Cannabidiol	Negative at ≤ 100,000ng/mL
METHAMPHETAMINE (mAMP 1000)	Result
(D-Methamphetamine, Cutoff = 1,000ng/mL)	Positive at 1,000ng/mL
(+/-)-3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 41,600ng/mL
DL-Methamphetamine	Positive at 1,000ng/mL
p-Hydroxymethamphetamine	Positive at 27,000ng/mL
(+/-)-3,4-Methylenedioxymethamphetamine (MDMA)	Positive at 8,000ng/mL
L-Methamphetamine	Positive at 10,000ng/mL
Trimethobenzamide	Negative at ≤ 100,000ng/mL
Chloroquine	Negative at ≤ 100,000ng/mL
Ephedrine	Negative at ≤ 100,000ng/mL
Fenfluramine	Negative at ≤ 100,000ng/mL
Procaine (Novocaine)	Negative at ≤ 100,000ng/mL
Ranitidine (Zantac)	Negative at ≤ 100,000ng/mL
D-Amphetamine	Negative at ≤ 100,000ng/mL
L-Amphetamine	Negative at ≤ 100,000ng/mL
Oxazepam	Negative at ≤ 100,000ng/mL
Morphine	Negative at ≤ 100,000ng/mL
METHAMPHETAMINE (mAMP 500)	Result
(D-Methamphetamine, Cutoff = 500ng/mL)	Positive at 500ng/mL
(±)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 20,000ng/mL
(±)-Methamphetamine	Positive at 1,000ng/mL
P-Hydroxymethamphetamine	Positive at 16,000ng/mL
(±)3,4-MDMA	Positive at 2,000ng/mL
L-Methamphetamine	Positive at 5,000ng/mL
Fenfluramine	Positive at 40,000ng/mL
L-Amphetamine	Positive at 60,000ng/mL
D-Pseudoephedrine	Negative at ≤ 100,000ng/mL
Trimethobenzamide	Negative at ≤ 100,000ng/mL
Chloroquine	Negative at ≤ 100,000ng/mL
Ephedrine	Negative at ≤ 100,000ng/mL
Procaine (Novocaine)	Negative at ≤ 100,000ng/mL
Ranitidine (Zantac)	Negative at ≤ 100,000ng/mL
D-Amphetamine	Negative at ≤ 100,000ng/mL
Oxazepam	Negative at ≤ 100,000ng/mL
Morphine	Negative at ≤ 100,000ng/mL
(+/-) 3,4-MDA	Negative at ≤ 100,000ng/mL
METHAMPHETAMINE (mAMP 300)	Result
(D-Methamphetamine, Cutoff = 300ng/mL)	Positive at 300ng/mL
(±)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 20,000ng/mL
(±)-Methamphetamine	Positive at 1,000ng/mL
P-Hydroxymethamphetamine	Positive at 16000ng/mL
г-пучгохуппециалириеталине	FUSILIVE AL TOUUUTIG/ML

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(±)3,4-MDMA	Positive at 5,000mg/mL
L-Methamphetamine	Positive at 5,000ng/mL
Fenfluramine	Positive at 40,000ng/mL
L-Amphetamine	Positive at 60,000ng/mL
D-Pseudoephedrine	Negative at ≤ 100,000ng/mL
Trimethobenzamide	Negative at ≤ 100,000ng/mL
Chloroquine	Negative at ≤ 100,000ng/mL
Ephedrine	Negative at ≤ 100,000ng/mL
Procaine (Novocaine)	Negative at ≤ 100,000ng/mL
Ranitidine (Zantac)	Negative at ≤ 100,000ng/mL
D-Amphetamine	Negative at ≤ 100,000ng/mL
Oxazepam	Negative at ≤ 100,000ng/mL
Morphine	Negative at ≤ 100,000ng/mL
(+/-) 3,4-MDA	Negative at ≤ 100,000ng/mL
OPIATE (OPI 2000)	Result
(Morphine, Cutoff = 2,000ng/mL)	Positive at 2,000ng/mL
Codeine	Positive at 1,000ng/mL
Ethylmorphine	Positive at 560ng/mL
Hydrocodone	Positive at 5,000ng/mL
Hydromorphone	Positive at 7,315ng/mL
Levorphanol	Positive at 16,000ng/mL
6-Monoacetylmorphine	Positive at 1,000ng/mL
Morphine 3-β-D-Glucuronide	Positive at 1,300ng/mL
Thebaine	Negative at ≤ 100,000ng/mL
Norcodeine	Negative at ≤ 100,000ng/mL
Normorphine	Negative at ≤ 100,000ng/mL
Oxycodone	Negative at ≤ 100,000ng/mL
Oxymorphone	Negative at ≤ 100,000ng/mL
Procaine	Negative at ≤ 100,000ng/mL
Oxazepam	Negative at ≤ 100,000ng/mL
Methamphetamine	Negative at ≤ 100,000ng/mL
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OPIATE (OPI 300)	Result
(Morphine, Cutoff = 300ng/mL)	Positive at 300ng/mL
6-Acetylmorphine	Positive at 750ng/mL
Codeine	Positive at 300ng/mL
Ethylmorphine	Positive at 200ng/mL
Heroin	Positive at 700ng/mL
Hydromorphone	Positive at 4,000ng/mL
Hydrocodone	Positive at 2,000ng/mL
Levorphanol	Positive at 12,000ng/mL
Thebaine	Positive at 90,000ng/mL
Morphine-3-β-Glucuronide	Positive at 450ng/mL
Oxycodone	Negative at ≤ 100,000ng/mL
Procaine	Negative at ≤ 100,000ng/mL
METHADONE (MTD)	Result
(Methadone, Cutoff = 300ng/mL)	Positive at 300ng/mL
Levo-α-Acetylmethadol	Positive at 10,000ng/mL
Alphamethadol	Negative at ≤ 100,000ng/mL
Doxylamine	Negative at ≤ 100,000ng/mL
2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine	Negative at ≤ 100,000ng/mL
2-Ethyl-5-Methyl-3,3-Diphenylpyrroline	Negative at ≤ 100,000ng/mL
OXYCODONE (OXY)	Result
(Oxycodone, Cutoff = 100ng/mL)	Positive at 100ng/mL
Dihydrocodeine	Positive at 50,000ng/mL

Alphamethadol Doxylamine 2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 100)	Negative at ≤ 100,000ng/m
Alphamethadol	
J J \ \	Negative at ≤ 100,000ng/m
Levo-α-Acetylmethadol Hydrochloride (LAAM)	Negative at ≤ 100,000ng/m
Methadone	Negative at ≤ 100,000ng/m
Disopyramide	Negative at ≤ 100,000ng/m
(2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine, Cutoff = 300ng/mL) 2-Ethyl-5-Methyl-3,3-Diphenylpyrroline (EMDP)	Positive at 300ng/m Negative at ≤ 100,000ng/m
	Resul
2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 300)	-
D-Norpropoxyphene	Positive at 1,500ng/m
(Propoxyphene, Cutoff = 300ng/mL)	Positive at 300ng/m
PROPOXYPHENE (PPX)	Resul
Norclomipramine	Negative at ≤ 100,000ng/m
Promethazine	Negative at ≤ 100,000ng/m
Maprotiline	Negative at ≤ 100,000ng/m
Cyclobenzaprine Hydrochloride	Positive at 1,500ng/m
Trimipramine	Positive at 4,000ng/m
Promazine	Positive at 24,000ng/m
Nordoxepin	Positive at 1,000ng/m
Imipramine	Positive at 600ng/m
Doxepin	Positive at 2,000ng/m
Desipramine	Positive at 1,000ng/m
Clomipramine	Positive at 15,000ng/m
Amitriptyline	Positive at 5,000ng/m
(Nortriptyline, Cutoff = 1,000ng/mL)	Positive at 1,000ng/m
TRICYCLIC ANTIDEPRESSANTS (TCA)	Resu
L-Methamphetamine	Negative at ≤ 100,000ng/m
L-Amphetamine	Negative at ≤ 100,000ng/m
D-Amphetamine	Negative at ≤ 100,000ng/m
D-Methamphetamine	Negative at ≤ 100,000ng/m
(-)-Ψ-Ephedrine	Positive at 40,000ng/m
3,4-Methylenedioxyethylamphetamine (MDEA)	Positive at 1,000ng/m
3,4-Methylenedioxyamphetamine HCI (MDA)	Positive at 8,000ng/m
(Methylenedioxymethamphetamine, Cutoff = 500ng/mL)	Positive at 500ng/m
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	Resu
(Pregabalin, Cutoff = 2,000 ng/mL)	Positive at 2,000 ng/ml
PREGABALIN (PGB)	Resu
•	
4-Hydroxyphencyclidine	Positive at 250ng/m
Phencyclidine Morpholine	Positive at 625ng/m
(Phencyclidine, Cutoff = 25ng/mL)	Positive at 25ng/m
PHENCYCLIDINE (PCP)	Resu
Ethylmorphine	Negative at ≤ 100,000ng/m
Buprenorphine	Negative at ≤ 100,000ng/m
Acetylmorphine	Negative at ≤ 100,000ng/m
Morphine	Negative at ≤ 100,000ng/m
Hydromorphone	Negative at ≤ 100,000ng/m
Codeine	Negative at ≤ 100,000ng/m
Morphine 3-β-D-Glucuronide	Negative at ≤ 100,000ng/m
Heroin	Negative at ≤ 100,000ng/m
Hydrocodone	Positive at 10,000ng/m

Disopyramide	Negative at ≤ 15,000ng/mL
Mianserin	Negative at ≤ 25,000ng/mL
Tramadol	Negative at ≤ 60,000ng/mL
Venlafaxine hydrochloride	Negative at ≤ 30,000ng/mL
6-ACETYLMORPHINE (6-ACM)	Result
(6-Acetylmorphine, Cutoff = 10ng/mL)	Positive at 10ng/mL
Heroin	Positive at 37.5 ng/mL
Morphine	Negative at 100,000ng/mL
COTININE (COT)	Result
((-)-Cotinine, Cutoff = 200ng/mL)	Positive at 200ng/mL
(-)-Nicotine	Positive at 6,250 ng/mL
CVAITHETIC CANNADINOID (V2 50)	Result
SYNTHETIC CANNABINOID (K2 50)	Positive at 50ng/mL
(Synthetic Cannabinoid, Cutoff = 50ng/mL)	
JWH-018 Pentanoic Acid	Positive at 50ng/mL
JWH-073 Butanoic Acid	Positive at 50ng/mL
MAM2201 N-pentanoic acid metabolite	Positive at 200ng/mL
JWH-398 N-pentanoic acid metabolite	Positive at 400ng/mL
JWH-210 N-(5-carboxypentyl) metabolite	Positive at 2,500ng/mL
JWH-073 3-hydroxybutyl metabolite	Positive at 2,500ng/mL
JWH-018 N-4-hydroxypentyl	Positive at 8,000ng/mL
JWH-073 4-hydroxybutyl metabolite	Positive at 40,000ng/mL
JWH-019 5-hydroxyhexyl metabolite	Positive at 40,000ng/mL
JWH-018 5-hydroxypentyl metabolite	Positive at 45,000ng/mL
JWH-122 5-hydroxypentyl metabolite	Positive at 50,000ng/mL
JWH-122 4-hydroxypentyl metabolite	Positive at 50,000ng/mL
JWH-019 6-hydroxyhexyl metabolite	Positive at 50,000ng/mL
RCS-4 N-(5-carboxypentyl) metabolite	Positive at 50,000ng/mL
Trifluoperazine dihydrochloride	Positive at 50,000ng/mL
Trifluoperazine hydrochloride	Positive at 70,000ng/mL
2,4,6-Trimethylbenzamide	Positive at 100,000ng/mL
SYNTHETIC CANNABINOID (K2 20)	Result
(Synthetic Cannabinoid, Cutoff = 20ng/mL)	Positive at 20ng/mL
JWH-018 5 pentanoic acid metabolite	Positive at 20ng/mL
JWH-073 4-butanoic acid metabolite	Positive at 20ng/mL
MAM2201 N-pentanoic acid metabolite	Positive at 200ng/mL
JWH-398 N-pentanoic acid metabolite	Positive at 400ng/mL
JWH-210 N-(5-carboxypentyl) metabolite	Positive at 2,500ng/mL
JWH-073 3-hydroxybutyl metabolite	Positive at 2,500ng/mL
JWH-018 N-4-hydroxypentyl	Positive at 8,000ng/mL
JWH-073 4-hydroxybutyl metabolite	Positive at 40,000ng/mL
JWH-019 5-hydroxyhexyl metabolite	Positive at 40,000ng/mL
JWH 018 5 hydroxypentyl metabolite	Positive at 45,000ng/mL
JWH-122 5-hydroxypentyl metabolite	Positive at 50,000ng/mL
JWH-122 4-hydroxypentyl metabolite	Positive at 50,000ng/mL
JWH-019 6-hydroxyhexyl metabolite	Positive at 50,000ng/mL
RCS-4 N-(5-carboxypentyl) metabolite	Positive at 50,000ng/mL
Trifluoperazine dihydrochloride	Positive at 50,000ng/mL
Trifluoperazine hydrochloride	Positive at 70,000ng/mL
24,6-Trimethylbenzamide	Positive at 100,000ng/mL
AB-PINACA (K3)	Result
(AB-Pinaca 5-Pentanoic Acid, Cutoff = 10ng/mL)	Positive at 10ng/mL
AB-FUBINACA	Positive at 200ng/mL
AB-Pinaca	Positive at 100ng/mL

AB-Pinaca 4-Hydroxypentyl Metabolite	Positive at 15ng/mL
AB-Pinaca 5-Hydroxypentyl Metabolite	Positive at 15ng/mL
AB-Pinaca 5-Pentanoic Acid Metabolite	Positive at 10ng/mL
ADB-Pinaca 5-Pentanoic Acid Metabolite	Positive at 25ng/mL
UR-144	Negative at 10,000ng/mL
UR-144 5- Hydroxypentyl Metabolite	Negative at 10,000ng/mL
UR-144 5- Pentanoic Acid Metabolite	Negative at 10,000ng/mL
APinaca 5- Hydroxypentyl Metabolite	Negative at 10,000ng/mL
UR-144 (K4)	Result
(UR-144 5-Pentanoic Acid, Cutoff = 25ng/mL)	Positive at 25ng/mL
UR-144 5-Hydroxypentyl Metabolite	Positive at 300ng/mL
UR-144	Negative at 10,000ng/mL
AB-Fubinaca	Negative at 10,000ng/mL
AB-Pinaca	Negative at 10,000ng/mL
AB-Pinaca 4-Hydroxypentyl Metabolite	Negative at 10,000ng/mL
AB-Pinaca 5-Hydroxypentyl Metabolite	Negative at 10,000ng/mL
AB-Pinaca 5-Pentanoic Acid Metabolite	Negative at 10,000ng/mL
APinaca 5- Hydroxypentyl Metabolite	Negative at 10,000ng/mL
ADB-Pinaca 5-Pentanoic Acid Metabolite	Negative at 10,000ng/mL
KETAMINE (KET)	Result
(Ketamine , Cutoff = 1,000ng/mL)	Positive at 1,000ng/mL
Methadone	Positive at 100,000ng/mL
Meperidine	Positive at 30,000ng/mL
Methamphetamine	Positive at 40,000ng/mL
Methoxyphenamine	Positive at 20,000ng/mL
D-methamphetamine	Positive at 40,000ng/mL
Promethazine	Positive at 50,000ng/mL
Phencyclidine	Positive at 10,000ng/mL
Bupivacaine	Positive at 20,000ng/mL
Disopyramide	Positive at 100,000ng/ml
Eserine	Positive at 70,000ng/ml
Glutathione reduced	Positive at 50,000ng/ml
Mianserin	Positive at 30,000ng/ml
Naphazoline hydrochloride	Positive at 20,000ng/mL
Nomifensine	Positive at 100,000ng/mL
Prilocaine	Positive at 50,000ng/ml
Promazine	Positive at 100,000ng/ml
Pyrilamine	Positive at 50,000ng/ml
Thioridazine hydrochloride	Positive at 100,000ng/ml
Benzthiazide	Positive at 100,000ng/mL
Picrotoxin	Positive at 10,000ng/mL
Phenyltoloxamine	Positive at 100,000ng/mL
2,4,6-Trimethylbenzamide	Positive at 100,000ng/mL
Nordiazepam	Positive at 390ng/ml
Oxazepam	Positive at 390ng/ml
Temazepam	Positive at 100ng/ml
Triazolam	Positive at 2,500ng/mL
WDATOM (VDA)	
KRATOM (KRA)	Result
(Mitragynine, Cutoff = 100ng/mL)	Positive at 100ng/mL
7-Hydroxymitragynine	Negative at 10,000ng/mL
FENTANYL (FEN)	Result
(Fentanyl, Cutoff = 10ng/mL)	Positive at 10ng/mL
Valeryl fentanyl HCI	Positive at 5,000ng/mL

Butyryl fentanyl	Positive at 50ng/mL
Furanyl fentanyl HCl	Positive at 250ng/mL
Norfentanyl oxalate	Positive at 25ng/mL
Ocfentanil	Positive at 5,000ng/mL
Para-Fluorofentanyl	Positive at 25ng/mL
(±) ⁻ cis ⁻ 3 ⁻ Methylfentanyl HCL	Positive at 250ng/mL
Acetyl fentanyl	Positive at 1,000ng/mL
TRAMADOL (TRA 50)	Result
(Tramadol, Cutoff = 50ng/mL)	Positive at 50ng/mL
TRAMADOL (TRA 100)	Result
(Tramadol, Cutoff = 100ng/mL)	Positive at 100ng/mL
TRAMADOL (TRA 200)	Result
(Tramadol, Cutoff = 200ng/mL)	Positive at 200ng/mL
ETHYL GLUCURONIDE (ETG 500)	Result
(Ethyl-β-D-glucuronide, Cutoff = 500ng/mL)	Positive at 500ng/mL
ETHYL GLUCURONIDE (ETG 300)	Result
(Ethyl-β-D-glucuronide, Cutoff = 300ng/mL)	Positive at 300ng/mL
METHYLENEDIOXYPYROVALERONE (MDPV)	Result
(Methylenedioxypyrovalerone, Cutoff = 1,000ng/mL)	Positive at 1,000ng/mL
Butylone	Positive at 1,000ng/mL
Ethylone	Positive at 1,000ng/mL
Methylone	Positive at 10,000ng/mL
Mephedrone	Positive at 10,000ng/mL
Methedrone	Positive at 10,000ng/mL
Pyrovalerone	Positive at 4,000ng/mL
Naphyrone	Positive at >100,000ng/mL
Flephedrone	Positive at >100,000ng/mL
Brompheniramine	Positive at >100,000ng/mL
Methyprylon	Positive at >100,000ng/mL
Zomepirac	Positive at >100,000ng/mL

The following substances may interfere with the alcohol test: strong oxidizers, ascorbic acid, tannic acid, polyphenolic compounds, mercaptans, uric acid, bilirubin, oxalic acid and so on, but these compounds are not normally present in sufficient amount in urine to interfere with the test

EFFECT OF URINARY SPECIFIC GRAVITY

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

EFFECT OF THE URINARY PH

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

INTERFERENCE

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Gabapentin, Hydrocodone, Marjuana, Methadone, Methamphetamine,

Methylenedioxymethamphetamine, Opiate, Oxycodone, Phencyclidine, Pregabalin, Propoxyphene, Tricyclic Antidepressants, 2-Elhylidene-1, 5-dimethy-3, 3-dipheypyrolidine, 6-Acetylmorphine, Cotinine, Synthetic Cannabinoid, AB-Pinaca, UR-144, Ketamine, Kratom, Fentanyl, Tramadol, Ethyl Glucuronide, Methylenedioxypyrovalerone. The following compounds show no cross-reactivity when tested with the One Step Drug of Abuse Test at concentrations of 100 µg/mL.

Amphetamine, Buprenorphine, Barbiturates, Benzodiazepines, Cocaine, 2-Ethylidene-1,5-dimethvI-3.3-diphenylpyrrolidine. Methamphetamine, Methylenedioxymethamphetamine, Morphine. Methadone, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressant and Marijuana Non-Cross-Reacting Compounds

Acetaminophen β-Estradio Oxalic acid Acetophenetidin Oxolinic acid Erythromycin N-Acetylprocainamide Ethanol (1%) Oxymetazoline Acetylsalicylic acid Fenoprofen Papaverine Albumin (100mg/dL) Furosemide Penicillin G Aminopyrine Gentisic acid Perphenazine Amoxicillin Hemoglobin Phenelzine Ampicillin Hydralazine Prednisone Apomorphine Hydrochlorothiazide (±)-Propranolol Ascorbic acid Hydrocortisone Pseudoephedrine Aspartame O-Hydroxyhippuric acid Quinine Atropine 3-Hydroxytyramine Ranitidine Benzilic acid buprofen Salicylic acid Benzoic acid Isoproterenol Serotonin (5- Hydroxytyramine) Bilirubin Isoxsuprine Sulfamethazine

Ketamine Sulindac

Chloral hydrate Chloramphenicol Ketoprofen Tetrahydrocortisone 3-(β-Dglucuronide)

Chlorothiazide Labetalol Tetrahydrocortisone 3-acetate Chlorpromazine Loperamide Tetrahydrozoline Cholesterol Meperidine Thiamine Clonidine Meprobamate Thioridazine Cortisone Methoxyphenamine Triamterene (-)-Cotinine Nalidixic acid Trifluoperazine Creatinine Naloxone Trimethoprim Deoxycorticosterone Naltrexone DL-Tryptophan Dextromethorphan Naproxen Tyramine Diclofenac Niacinamide DL-Tyrosine Diflunisal Nifedipine Uric acid

Norethindrone

Noscapine

Ecgonine methyl ester (±)-Octopamine

Digoxin

Aspartame

Diphenhydramine

Gabapentin, Hydrocodone, Pregabalin, 6-Acetylmorphine, Cotinine, Synthetic Cannabinoid, AB-Pinaca, UR-144, Ketamine, Kratom, Fentanyl, Tramadol, Ethyl Glucuronide, Methylenedioxypyrovalerone, Non Cross-Reacting Compounds

Verapamil

Zomepirac

Propranolol Hydrochloride

PCP Acebutolol Hydrochloride **EthylMorphine** Pentobarbital Acepromazine-d6 hydrochloride Fenoprofen Acetaminophen Furosemide Pentazocine N-Acetylprocainamide Gentisic acid Perphenazine Acetophenetidin D-Glucuronic acid Penicillin G Sodium salt Alprazolam Glutethimide Phenelzine sulfate salt Alphenal Phenobarbital Guaifenesin Amoxici**l**in Hemoglobin porcine Phentermine HCL Ampici**ll**in Heroin hydrochloride Phenylethylamine Amitriptyline Hydrochloride Tablets Hippuric Acid L-phenylephrine

S(+)Amphetamine Hydralazine hydrochloride Phenylpropanolamine hydrochloride

R(-)-Amphetamine Hydromorphone Prednisolone

Amobarbital Hydrocodone Prednisone Acetate Tablets

(±)Amphetamine Procaine HCL α-Hydroxyhippuric acid

R-(-)-Apomorphine Hydrochloride 21-Hydroxy progesterone Promazine hydrochloride p-Hydroxymethamphetamine Aprobarbital Promethazine Aspirin Hydrocortisone Propoxyphene,d-

Hydrochlorothiazide -4-Hydroxyamphetamine HCL L-Ascorbic Acid Pseudoephedrine
 Atropine
 Ibuprofen
 Phendimetrazine

 6-Acetylmorphine
 Imipramine
 Phenytoin

 Acetylsalicylic acid
 Iprazid
 Quinine

 Benzphetamine
 Isoxsuprine hydrochloride
 Quinidine

 Benzilic acid
 Isoproterenol Hydrochloride Injection
 Quinacrine

Ranitidine Hydrochloride Tablets

Nortriptyline Hydrochloride

Sertraline HCI

Tetracycline

Tryptamine

(-)-delta-9-THC)

Tetrahydrocortisone 3-(β-D-glucuronide

Benzoylecgonine Ketamine hydrochloride

SS Benzoic Acid Ketoprofen

Bilirubin, Mixed Isomers Emetine dihydrochloride hydrate Salicylic Acid
Brompheniramine maleate Ephedrine (+/-) hydrochloride Secobarbital
Buprenorphine (-)-Ephedrine HCL Serotonin

[1R,2S] (-) Ephedrine Buspirone hydrochloride Noroxymorphone HCL Butalbita Erythromycin Nylidrin hydrochloride Butabarbital Eserine Norfentany Cannabidiol Estazolam (±)-Octopamine HCL Cannabinol β-Estradiol Oxalic Acid Caffeine (±)-EDDP Oxolinic Acid Cetirizine Hvdrochloride Ethyl-p-aminobenzoate Oxycodone Chlordiazepoxide HCL JWH-018 pantanoic acid Oxymetazoline Chlorothiazide JWH-073 butanoic acid Papaverine Chloroquine Labetalol Hydrochloride (±)-Octopamine HCL

 Chlorpromazine Hydrochloride Tablets
 Loperamide Hydrochloride
 Sulfamethazine,min 99%

 Chloramphenicol
 Lorazepam
 Sulindac

 ChloralHydrate
 Maprotiline hydrochloride
 Temazepam

 Cholesterol
 (±)MDEA
 Terfenadine

 Chlorothiazide
 (±)MDA
 Terbutaline

Levorphanol

Chlorothiazide (±)-MDA Terbutaline
Clomipramine Meperidine Tetraethytthiuram disulfide

Clonazepam Meprobamate Tetrahydrocannabinol, Delta-8-((-)-delta-8-THC)

Clonidine hydrochloride Methamphetamine hydrochloride
Clozapine (±)Methadone

Chlorpheniramine Maleate

(-) Cotinine S(+)D-methamphetamine

 Cocaethylene
 L-methamphetamine
 (+/-)11-Hydroxy-delta-9-THC

 Cocaine Hydrochloride
 Methylphenidate
 (-)-11-nor-9-Carboxy-delta9-THC

 Codeine
 (±)MDMA
 Thebaine

 Cortisone
 (±)MDPV
 Theophylline

 Creatinine
 Methyprylon
 Thioridazine

 Cyclopentobarbital
 Morphine
 Thiamine, (Vitamin B1 Tablets)HCL

Cyclopentobarbital Morphine Thiamine, (V/
Citalopram hydrobromide Morphine-3β-D-glucuronide DL-Thyroxine

Dextromethorohan Morphine sulfate salt solution Tolbutamide

Naloxone

 Dextromethorphan
 Morphine sulfate salt solution
 Tolbutamide

 Desipramine
 Nalidixic acid
 Tramadol

 Diazepam
 Nalorphine hydrochloride
 Triamterene

 Didofenac Sodium salt
 Naproxen
 Trimipramine

Digoxin Naltrexone hydrochloride Trifluoperazine dihydrochloride

4-Dimethylaminoantipyrine Nicotinamide (vitamin B3) DL-Tryptophan
Dihvdrocodeine HCL Nimesulide Triazolam

5,5-Diphenylhydantoin Nifedipine Trans-2-phenylcyclo-propylamine hydrochloride

 Diphenhydramine
 Norcodeine
 D/L-Tyrosine

 Dopamine
 Nordoxepin hydrochloride
 Tyramine

 Doxylamine
 Norfloxacin Capsule
 Uric Acid

Ecgonine methylester Norethisterone Tablets Verapamil Hydrochloride

 Ecgonine HCL
 d-Norpropoxyphene maleate salt
 Valproic acid

 Efavirenz
 Noscapine
 Zomepirac

Ethylone

Dicyclomine

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