



Drug of Abuse Test Cup

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

AMP/BARB/BZO/BUP/COC/GAB/HYD/THC/MTD/mAMP/MDMA/MQL/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.

For Forensic Use Only

INTENDED USE

The *MEGACup® Drug of Abuse Test Cup* is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP 1000)	D-Amphetamine	1,000 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)	Benzoylcegonine	300 ng/mL
Cocaine (COC 150)	Benzoylcegonine	150 ng/mL
Gabapentin (GAB 1000)	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^9 -THC-9-COOH	50 ng/mL
Marijuana (THC 20)	11-nor- Δ^9 -THC-9-COOH	20 ng/mL
Marijuana (THC 15)	11-nor- Δ^9 -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
Methaqualone (MQL)	Methaqualone	300 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-diphenylpyrrolidine	300 ng/mL
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP 100)	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100 ng/mL
6-Acetylmorphine (6-ACM)	6-Acetylmorphine	10 ng/mL
Cotinine (COT)	Cotinine	200 ng/mL
Synthetic Cannabinoid (K2 50)	JWH-018 Pentanoic Acid / JWH-073 Butanoic Acid	50 ng/mL
Synthetic Cannabinoid (K2 20)	JWH-018 Pentanoic 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
Methylenedioxypropyvalerone (MDPV)	Methylenedioxypropyvalerone	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 *MEGACup® Drug of Abuse Test Cup* 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 an unchanged form, while the remainder stays as hydroxylated and deaminated derivatives.

The AMP 1000 assay contained within the *MEGACup® Drug of Abuse Test Cup* yields a positive result when the concentration of Amphetamine in urine exceeds 1,000 ng/mL.

AMPHETAMINE (AMP 500)

See AMPHETAMINE (AMP 1000) for the summary.

The AMP 500 assay contained within the *MEGACup® Drug of Abuse Test Cup* yields a positive result when the concentration of Amphetamine in urine exceeds 500 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 300)

See AMPHETAMINE (AMP 1000) for the summary.

The AMP 300 assay contained within the *MEGACup® Drug of Abuse Test Cup* 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 *MEGACup® Drug of Abuse Test Cup* yields a positive result when the concentration of Butalbital in urine exceeds 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 symptoms such 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 Benzodiazepines in the urine is 3-7 days.

The BZO 300 assay contained within the *MEGACup® Drug of Abuse Test Cup* 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 *MEGACup® Drug of Abuse Test Cup* 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 of Buprenorphine produce a sufficient agonistic 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." This means it no longer continues 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 a Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

The BUP 10 assay contained within the *MEGACup® Drug of Abuse Test Cup* yields a positive result when the concentration of Buprenorphine in urine exceeds 10 ng/mL.

BUPRENORPHINE (BUP 5)

See BUPRENORPHINE (BUP 10) for the summary.

The BUP 5 assay contained within the *MEGACup® Drug of Abuse Test Cup* 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 or free-base smoking. It is excreted in the urine in a short time primarily as Benzoylcegonine.^{1,2} Benzoylcegonine, 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 *MEGACup® Drug of Abuse Test Cup* yields a positive result when the concentration of Benzoylcegonine in urine exceeds 300 ng/mL.

COCAINE (COC 150)

See COCAINE (COC 300) for the summary.

The COC 150 assay contained within the *MEGACup® Drug of Abuse Test Cup* yields a positive result when the concentration of Benzoylcegonine in urine exceeds 150 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

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 GAB 1000 assay contained within the *MEGACup® Drug of Abuse Test Cup* yields a positive result when the concentration of Gabapentin in urine exceeds 1,000 ng/mL.

GABAPENTIN (GAB 2000)

See GABAPENTIN (GAB 1000) for the summary

The GAB 2000 assay contained within the *MEGACup® Drug of Abuse Test Cup* yields a positive result when the concentration of Gabapentin in urine exceeds 2,000 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. 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. Hydrocodone is often compounded with other, generally less effective non-opioid compounds such as paracetamol (also known as acetaminophen) or ibuprofen. It is 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 *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of Hydrocodone in urine exceeds 300 ng/mL.

MARIJUANA (THC 50)

THC (Δ⁹-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ⁹-tetrahydrocannabinol-9-carboxylic acid (11-nor-Δ⁹-THC-9-COOH).

The THC 50 assay contained within the *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of 11-nor-Δ⁹-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 *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of 11-nor-Δ⁹-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 *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of 11-nor-Δ⁹-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, inducing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal Heroin, the dangers of injection, and 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 *MEGACup*[®] *Drug of Abuse Test Cup* 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 *MEGACup*[®] *Drug of Abuse Test Cup* 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 *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of Methamphetamine in urine exceeds 500 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

METHAMPHETAMINE (mAMP 300)

See METHAMPHETAMINE (mAMP 1000) for the summary.

The mAMP 300 assay contained within the *MEGACup*[®] *Drug of Abuse Test Cup* 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.⁸ Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with Amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug was to produce a clenching of the jaws.

The MDMA assay contained within the *MEGACup*[®] *Drug of Abuse Test Cup*yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 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

METHAQUALONE (MQL)

Methaqualone (Quaalude, Sopor) is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956. It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form, and is also available in Europeon countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule. At least 12 metabolites have been identified in the urine.

The MQL assay contained within the *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of methaqualone in urine exceeds 300 ng/mL.

OPIATE (OPI 300, MOR, MOP)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine, 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 it is also the major metabolic product of Codeine and Heroin. Morphine is detectable in the urine for several days after an opiate dose !

The OPI 300 assay contained within the *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of Morphine in urine exceeds the 300 ng/mL.

OPIATE (OPI 2000)

See OPIATE(OPI 300,MOR,MOP) for the summary.

The OPI 2000 assay contained within the *MEGACup*[®] *Drug of Abuse Test Cup* 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)

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); these 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 *MEGACup*[®] *Drug of Abuse Test Cup* 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, or 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 *MEGACup*[®] *Drug of Abuse Test Cup* 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 doses are normally within a range of 50-200mg thricedaily. A single oral labeled dose of pregabalin in humans is eliminated in urine (92%) and feces (<0.1%) over a 4 day period. Urinary excretion products included unchanged drug (90% of the dose), N-Methylpregabalin (0.9%) and others. A single oral 75 or 150mg dose given to a healthy human yielded peak urinary pregabalin concentrations of 151 or 214 µg/mL, respectively, within the first 8 hours. Pregabalin urine levels in 57,542 specimens from chronic pain patients averaged 184 µg/mL ^{27,28} The PGB assay contained within the *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of Pregabalin in urine exceeds 2,000 ng/mL.

PROPOXYPHENE (PPX)

Propoxyphene is a mild narcotic analgesic found in various pharmaceutical preparations, usually as 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 humans, 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 *MEGACup*[®] *Drug of Abuse Test Cup* 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. A 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 *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of Nortriptyline in urine exceeds 1,000 ng/mL.

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (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 *MEGACup*[®] *Drug of Abuse Test Cup* yields a positive result when the concentration of 2-Ethylidene-1,5-Dimethyl-3,3-diphenylpyrrolidine in urine exceeds 300 ng/mL.

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

See 2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP300) for the summary. The EDDP 100 assay contained within the *MEGACup*® *Drug of Abuse Test Cup* yields a positive result when the concentration of 2-Ethylidene-1, 5-Dimethyl-3, 3-diphenylpyrrolidine 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 *MEGACup*® *Drug of Abuse Test Cup* yields a positive result when the concentration of 6-Acetylmorphine in urine exceeds 10 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

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 the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine sample , approximately 5% of a nicotine dose is excreted as an unchanged drug with 10% as Cotinine and 35% as Hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%¹. While Cotinine is thought to be an inactive metabolite, its 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 administration² 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 *MEGACup*® *Drug of Abuse Test Cup* yields a positive result when the concentration of Cotinine in urine exceeds 200 ng/mL.

SYNTHETIC CANNABINOID (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 restrictions.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 *MEGACup*® *Drug of Abuse Test Cup* yields a positive result when the concentration of Synthetic Cannabinoid compounds in urine exceeds 50 ng/mL.

SYNTHETIC CANNABINOID (K2 20)

See SYNTHETIC CANNABINOID (K2 50) for the summary.

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

AB-PINACA (K3)

See SYNTHETIC CANNABINOID (K2 50) for the summary.

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

UR-144 (K4)

See SYNTHETIC CANNABINOID (K2 50) for the summary.

The K4 assay contained within the *MEGACup*® *Drug of Abuse Test Cup* 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 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 *MEGACup*® *Drug of Abuse Test Cup* 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 is 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 pain caused by the withdrawal of opium. A pain-relieving 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 *MEGACup*® *Drug of Abuse Test Cup* 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.¹⁶ The FEN assay contained within the *MEGACup*® *Drug of Abuse Test Cup* 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 an unchanged drug, whereas 60% is excreted as metabolites.

The TRA 50 assay contained within the *MEGACup*® *Drug of Abuse Test Cup* 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 *MEGACup*® *Drug of Abuse Test Cup* 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 *MEGACup*® *Drug of Abuse Test Cup* 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, an 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 monitored by GC/MS and LC/MS/MS.^{25,26}

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 excreted in the blood, hair and urine. By using the *MEGACup*® *Drug of Abuse Test Cup* ETG, can be detected 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 *MEGACup*® *Drug of Abuse Test Cup* 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 *MEGACup*® *Drug of Abuse Test Cup* 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,” are 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; they 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 Methadone, MDPV started appearing around 2004 when it was popularized as a club drug. It is 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 uses for the synthetic stimulants.

While synthetic stimulants appear to affect users in ways similar to Amphetamines, users of ecstasy and cocaine are reported having aggression, tachycardia, paranoia, and suicide. This suggests that synthetic stimulants 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 *MEGACup*® *Drug of Abuse Test Cup* yields a positive result when the concentration of Methylenedioxypropyrolvalerone 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. A 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 diluted urine.

PRINCIPLE

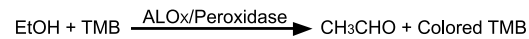
(1) The **MEGACup® Drug of Abuse Test Cup** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

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

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

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

(2) An alcohol test is based on the high specificity 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 a 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, Propyl and allyl alcohol can develop a 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 oxidase, 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

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

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°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)

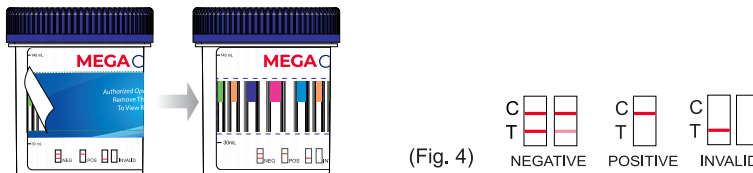
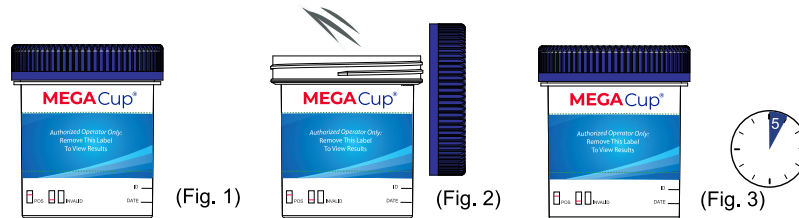
Materials Required But Not Provided

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

DIRECTIONS FOR USE

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

- 1) Tear the foil pouch open, remove test cup, and donor needs to obtain their own disposable gloves. Label the test cup with donor information (Fig. 1).
- 2) Wear disposable gloves to collect urine specimen. Open test cup lid. Urinate directly into the test cup. Be sure to fill up the test cup with the urine specimen between minimum 30mL to maximum 140 mL (marked on the cup) (Fig. 2).
- 3) After urine specimen has been collected, close the lid securely (turn the lid until it clicks), and return cup to collection official (Fig. 3).
- 4) The collection official will use newly obtained gloves to peel off the label to reveal test results. Read results of alcohol test at 2 minutes, adulterant test at 3 minutes, and drug tests at 5 minutes. **DO NOT INTERPRET ALCOHOL, ADULTERANT AND DRUG TESTS RESULTS AFTER 5 MINUTES** (Fig. 4).



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

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

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

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

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural

techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your supplier.

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, this 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 a 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.
5. 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 diluted 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

1. The **MEGACup® Drug of Abuse Test Cup** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.^{3,4,7}
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen and a new test device.
4. A positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when a 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.
8. 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 procedural error during the alcohol test as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to the "Analytical Specificity" section for alcohol test list of substances that will interfere the test results.

10.An 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 *MEGACup® Drug of Abuse Test Cup* was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for each of the drug types listed 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	Benzoylcgonine
GAB	Gabapentin
HYD	Hydrocodone
THC	11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid
MTD	Methodone
mAMP	Methamphetamine
MDMA	D,L-Methylenedioxymethamphetamine, Methylenedioxyamphetamine
ML	Methaqualone
OPI, MOR	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PGB	Pregabalin
PPX	Propoxyphene
TCA	Nortriptyline
EDDP	2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine
6.ACM	6-Acetylmorphine
COT	Cotinine
K2	JWH-018 Butanoic 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	Methylenedioxypropavalerone

The following results were tabulated from these clinical studies:

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

	mAMP1000	mAMP500	mAMP300	OPI	MOR	COC300	COC150	GAB1000	GAB2000	HYD	PCP	AMP1000	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%
Overall Agreement	98%	>99%	98%	98%	98%	98%	>99%	100%	100%	>98%	95%	98%	98%	99%	98.8%

	TRA50	TRA100	TRA200	MDMA	BZO300	BZO200	MTD	OXY	EDDP300	EDDP100	THC50	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%	>99%	98.8%	96%	98.8%	

	FEN	BUP10	BUP5	6.ACM	COT	K2 50	K2 20	K3	K4	KET	KRA	ETG500	ETG300	MDPV	ML	TCA
Positive Agreement	97.5%	93%	100%	98%	98%	>97%	>97%	97.5%	100%	>99%	97.5%	>99%	>99%	97.5%	98%	
Negative Agreement	100%	95%	95%	>99%	98%	>99%	>99%	97.5%	97.5%	>99%	97.5%	>99%	>99%	95%	97.5%	>99%
Overall Agreement	99%	94%	97.5%	99%	98%	98%	97.5%	98.8%	>99%	97.5%	>99%	>99%	>99%	99%	97.5%	99%

Analyte	BARB	GAB 1000	GAB 2000	HYD	MDMA	BZO 300	BZO 200	MTD	OXY	TCA	THC 50	THC 20	THC 15													
Negative Samples	0	20	0	5	0	5	0	5	0	4	0	4	0	4	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	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	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%	98%	96%	99%	96%	99%	94%	98%	95%	98%	99%	96%	99%	94%	99%	98%	97.5%	100%

Analyte	FEN	PCP	AMP1000	AMP500	AMP 300	mAMP1000	mAMP500	mAMP300	MOR	OPI	PPX	PGB	COT	COC 300														
Negative Samples	0	20	0	1	0	1	0	20	0	20	0	42	0	4	0	4	0	3	0	17	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%	96%	99%	99%	96%	99%	99%	97%	95%	98%	100%	97.5%	98%	98%	96%	99%

Analyte	COC150	EDDP300	EDDP100	BUP 10	BUP 5	6.ACM	ETG 500	ETG 300	TRA 50	TRA 100	TRA 200	MDPV	K3	K4	KRA	ML														
Negative Samples	0	40	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	70	0	70	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	1	19	1	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	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20	
Agreement with GC/MS	99%	99%	98%	95%	95%	95%	97.5%	93%	95%	100%	95%	98%	99%	99%	99%	99%	96%	99%	99%	97.5%	97.5%	97.5%	99%	95%	97.5%	97.5%	97.5%	97.5%	97.5%	

Analyte	KET		K2 20		K2 50	
	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%

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)

Benzoylcgonine 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)

Benzoylcgonine 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)

Hydrocodone conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	30	30 negative	>99%
150	30	30 negative	>99%
225	30	27 negative	90%
300	30	30 positive	>99%
375	30	30 positive	>99%
450	30	30 positive	>99%

MARIJUANA (THC 50)

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

MARIJUANA (THC 20)

11-nor- Δ^9 -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- Δ^9 -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%

METHYLENEDIIOXYMETHAMPHETAMINE (MDMA)

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

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%

METHAQUALONE (MQL)

Methaqualone 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%

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-DIPHENYLPYRROLIDINE (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-DIPHENYLPYRROLIDINE (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)

Methylenedioxypropylvalerone 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 Cut-off Range	n	AMP 1000		BZO 300		BZO 200		COC 300		HYD		THC 50		mAMP 300		K2 50	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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

Drug concentration Cut-off Range	n	K2 20		MTD		mAMP1000		MDMA		MOR		OPI		OXY		PCP		TCA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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 Cut-off Range	n	AMP 300		COC 150		THC 20		mAMP 500	
		-	+	-	+	-	+	-	+
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

Drug concentration Cut-off Range	n	BUP 10			PPX			EDDP 300			6-ACM			AMP 500			COT			n	ETG 500			ETG 300		
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+		-	+	-	+		
0% Cut-off	90	90	0	90	0	90	0	90	0	90	0	90	0	90	0	90	0	30	30	0	30	0	30	0		
-50% Cut-off	90	90	0	90	0	90	0	90	0	90	0	90	0	90	0	90	0	30	30	0	30	0	30	0		
-25% Cut-off	90	81	9	81	9	78	12	80	10	81	9	90	0	30	30	0	30	30	0	30	0	30	0	30	0	
Cut-off	90	48	42	44	46	41	49	46	44	45	45	63	27	30	3	27	3	27	3	27	3	27	3	27	3	
+25% Cut-off	90	11	79	12	78	15	75	12	78	10	80	40	50	30	1	29	1	29	1	29	1	29	1	29	1	
+50% Cut-off	90	0	90	0	90	0	90	0	90	0	90	16	74	30	0	30	0	30	0	30	0	30	0	30	0	
2X Cut-off	90	0	90	0	90	0	90	0	90	0	90	0	90	0	90	0	90	30	0	30	0	30	0	30	0	

Drug concentration Cut-off Range	n	EDDP100		FEN		TRA 50		TRA100		TRA 200		MDPV		THC 15		BUP 5		K3		K4		KRA		PGB		BARB		G48100		G48200		MQL			
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+				
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	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	30	0		
-25% Cut-off	30	30	0	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	3	27	2	28	1	29	0	30	0	30	2	28
+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	0	30	0	
+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	0	30	0	

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

Analytical Specificity

The following table listed the concentration of compounds (ng/mL) that were detected positive in urine by the MEGACup® Drug of Abuse Test Cup at a read time of 5 minutes.

AMPHETAMINE (AMP 1000)	Result
(D-Amphetamine, Cutoff = 1,000 ng/mL)	Positive at 1,000 ng/mL
L-Amphetamine	Positive at 100,000 ng/mL
D,L-Amphetamine	Positive at 500 ng/mL
(+/-)-3,4-Methylenedioxyamphetamine (MDA)	Positive at 1,300 ng/mL
Phentermine	Positive at 100,000 ng/mL
Apomorphine	Positive at 50,000 ng/mL
β-Phenylethylamine	Positive at 25,000 ng/mL
Tyramine	Positive at 10,000 ng/mL
Tryptamine	Positive at 25,000 ng/mL
D-Methamphetamine	Negative at ≤ 100,000 ng/mL
L-Methamphetamine	Negative at ≤ 100,000 ng/mL
Ephedrine	Negative at ≤ 100,000 ng/mL
3,4-Methylenedioxyethylamphetamine (MDEA)	Negative at ≤ 100,000 ng/mL

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

AMPHETAMINE (AMP 300)	Result
(D-Amphetamine, Cutoff = 300 ng/mL)	Positive at 300 ng/mL
D,l-amphetamine	Positive at 500 ng/mL
l-amphetamine</	

(+/-)Methylenedioxyamphetamine	Positive at 500ng/mL
BUTALBITAL (BARB)	Result
(Butalbital, Cutoff = 300 ng/mL)	Positive at 300 ng/mL
Secobarbital	Positive at 1,500 ng/mL
Amobarbital	Positive at 3,000 ng/mL
Alphenal	Positive at 250 ng/mL
Aprobarbital	Positive at 200 ng/mL
Allobarbital	Positive at 500 ng/mL
Butabarbital	Positive at 1,000 ng/mL
Butethal	Positive at 500 ng/mL
Cyclopentobarbital	Positive at 300 ng/mL
Pentobarbital	Positive at 1,300 ng/mL
Phenobarbital	Positive at 1,900 ng/mL

BENZODIAZEPINES (BZO 300)	Result
(Oxazepam, Cutoff = 300 ng/mL)	Positive at 300 ng/mL
Alprazolam	Positive at 125 ng/mL
α-Hydroxyalprazolam	Positive at 2,500 ng/mL
Bromazepam	Positive at 1,565 ng/mL
Chlordiazepoxide	Positive at 1,560 ng/mL
Clobazam	Positive at 65 ng/mL
Clonazepam	Positive at 10,000 ng/mL
Clorazepate Dipotassium	Positive at 195 ng/mL
Delorazepam	Positive at 1,560 ng/mL
Desalkylflurazepam	Positive at 1,560 ng/mL
Diazepam	Positive at 115 ng/mL
Estazolam	Positive at 165 ng/mL
Flunitrazepam	Positive at 166 ng/mL
Midazolam	Positive at 6,500 ng/mL
Nitrazepam	Positive at 300 ng/mL
Norchlordiazepoxide	Positive at 250 ng/mL
Nordiazepam	Positive at 400 ng/mL
Temazepam	Positive at 100 ng/mL
Triazolam	Positive at 2,500 ng/mL
DL-Lorazepam	Negative at ≤ 100,000 ng/mL
Methamphetamine	Negative at ≤ 100,000 ng/mL
Morphine	Negative at ≤ 100,000 ng/mL

BENZODIAZEPINES (BZO 200)	Result
(Oxazepam, Cutoff = 200 ng/mL)	Positive at 200 ng/mL
α-Hydroxyalprazolam	Positive at 400 ng/mL
Alprazolam	Positive at 75 ng/mL
Bromazepam	Positive at 5,000 ng/mL
Chlordiazepoxide HCl	Positive at 15 ng/mL
Clobazam	Positive at 30 ng/mL
Clonazepam	Positive at 20,000 ng/mL
Clorazepate Dipotassium	Positive at 2,000 ng/mL
Delorazepam	Positive at 1,000 ng/mL
Desalkylflurazepam	Positive at 260 ng/mL
Diazepam	Positive at 75 ng/mL
Estazolam	Positive at 50 ng/mL
Flunitrazepam	Positive at 200 ng/mL
(±) Lorazepam/ RS-Lorazepam glucuronide	Positive at 1,000 ng/mL
Midazolam	Positive at 10,000 ng/mL
Norchlordiazepoxide	Positive at 750 ng/mL
Nordiazepam	Positive at 150 ng/mL
Temazepam	Positive at 70 ng/mL

Triazolam	Positive at 3,000 ng/mL
BUPRENORPHINE (BUP 10)	Result
(Buprenorphine, Cutoff = 10 ng/mL)	Positive at 10 ng/mL
Buprenorphine-3-D-Glucuronide	Positive at 15 ng/mL
Norbuprenorphine	Positive at 40 ng/mL
Norbuprenorphine-3-D-Glucuronide	Positive at 500 ng/mL
Morphine	Negative at ≤ 100,000 ng/mL
Oxymorphone	Negative at ≤ 100,000 ng/mL
Hydromorphone	Negative at ≤ 100,000 ng/mL

BUPRENORPHINE (BUP 5)	Result
(Buprenorphine, Cutoff = 5 ng/mL)	Positive at 5 ng/mL
Buprenorphine-3-D-Glucuronide	Positive at 15 ng/mL
Norbuprenorphine	Positive at 40 ng/mL
Norbuprenorphine-3-D-Glucuronide	Positive at 500 ng/mL
Morphine	Negative at ≤ 100,000 ng/mL
Oxymorphone	Negative at ≤ 100,000 ng/mL
Hydromorphone	Negative at ≤ 100,000 ng/mL

COCAINE (COC 300)	Result
(Benzoylecgonine, Cutoff = 300 ng/mL)	Positive at 300 ng/mL
Cocaine HCL	Positive at 5,000 ng/mL
Cocaehtylene	Negative at ≤ 100,000 ng/mL
Ecgonine	Negative at ≤ 100,000 ng/mL

COCAINE (COC 150)	Result
(Benzoylecgonine, Cutoff = 150 ng/mL)	Positive at 150 ng/mL
Cocaine HCL	Positive at 3,000 ng/mL
Norcocaine	Negative at ≤ 100,000 ng/mL
Cocaehtylene	Negative at ≤ 100,000 ng/mL
Ecgonine	Negative at ≤ 100,000 ng/mL

GABAPENTIN (GAB 1000)	Result
(Gabapentin, Cutoff = 1,000 ng/mL)	Positive at 1,000 ng/mL
Diflunisal	Positive at 80,000 ng/mL

GABAPENTIN (GAB 2000)	Result
(Gabapentin, Cutoff = 2,000 ng/mL)	Positive at 2,000 ng/mL
Diflunisal	Positive at 100,000 ng/mL

HYDROCODONE (HYD)	Result
(Hydrocodone, Cutoff = 300 ng/mL)	Positive at 300ng/mL
Norhydrocodone HCl	Positive at 12,500ng/mL

MARIJUANA (THC 50)	Result
(11-nor-Δ ⁹ -THC-9-COOH, Cutoff = 50 ng/mL)	Positive at 50 ng/mL
11-hydroxy-Δ ⁹ -Tetrahydrocannabinol	Positive at 15,000 ng/mL
Δ ⁹ -Tetrahydrocannabinol	Positive at 8,000 ng/mL
Δ ⁹ -Tetrahydrocannabinol	Positive at 7,000 ng/mL
Cannabinol	Negative at ≤200,000 ng/mL
Cannabidiol	Negative at ≤200,000 ng/mL

MARIJUANA (THC 20)	Result
(11-Nor-Δ ⁹ - Tetrahydrocannabinol-9-COOH, Cutoff = 20 ng/mL)	Positive at 20 ng/mL
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	Positive at 8,000 ng/mL
Δ ⁹ -Tetrahydrocannabinol	Positive at 5,000 ng/mL
Δ ⁹ -Tetrahydrocannabinol	Positive at 3,000 ng/mL

11-Nor-Δ ⁹ - Tetrahydrocannabinol-9-COOH	Positive at 30 ng/mL
11-Nor-Δ ⁹ -THC-carboxy glucuronide	Positive at 5,000 ng/mL
Cannabinol	Negative at ≤ 100,000 ng/mL
Cannabidiol	Negative at ≤ 100,000 ng/mL

MARIJUANA (THC 15)	Result
(11-Nor-Δ ⁹ - Tetrahydrocannabinol-9-COOH, Cutoff = 15 ng/mL)	Positive at 15 ng/mL
11-Hydroxy-Δ ⁹ -Tetrahydrocannabinol	Positive at 8,000 ng/mL
Δ ⁹ -Tetrahydrocannabinol	Positive at 5,000 ng/mL
Δ ⁹ -Tetrahydrocannabinol	Positive at 3,000 ng/mL
11-Nor-Δ ⁹ - Tetrahydrocannabinol-9-COOH	Positive at 30 ng/mL
11-Nor-Δ ⁹ -THC-carboxy glucuronide	Positive at 5,000 ng/mL
Cannabinol	Negative at ≤ 100,000 ng/mL
Cannabidiol	Negative at ≤ 100,000 ng/mL

METHAMPHETAMINE (mAMP 1000)	Result
(D-Methamphetamine, Cutoff = 1,000 ng/mL)	Positive at 1,000 ng/mL
(+/-)-3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 41,600 ng/mL
DL-Methamphetamine	Positive at 1,000 ng/mL
p-Hydroxymethamphetamine	Positive at 27,000 ng/mL
(+/-)-3,4-Methylenedioxy-methamphetamine (MDMA)	Positive at 8,000 ng/mL
L-Methamphetamine	Positive at 10,000 ng/mL
Trimethobenzamide	Negative at ≤ 100,000 ng/mL
Chloroquine	Negative at ≤ 100,000 ng/mL
Ephedrine	Negative at ≤ 100,000 ng/mL
Fenfluramine	Negative at ≤ 100,000 ng/mL
Procaine (Novocaine)	Negative at ≤ 100,000 ng/mL
Ranitidine (Zantac)	Negative at ≤ 100,000 ng/mL
D-Amphetamine	Negative at ≤ 100,000 ng/mL
L-Amphetamine	Negative at ≤ 100,000 ng/mL
Oxazepam	Negative at ≤ 100,000 ng/mL
Morphine	Negative at ≤ 100,000 ng/mL

METHAMPHETAMINE (mAMP 500)	Result
(D-Methamphetamine, Cutoff = 500 ng/mL)	Positive at 500 ng/mL
(±)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 20,000 ng/mL
(±)-Methamphetamine	Positive at 1,000 ng/mL
P-Hydroxymethamphetamine	Positive at 16,000 ng/mL
(±)3,4-MDMA	Positive at 2,000 ng/mL
L-Methamphetamine	Positive at 5,000 ng/mL
Fenfluramine	Positive at 40,000 ng/mL
L-Amphetamine	Positive at 60,000 ng/mL
D-Pseudoephedrine	Negative at ≤ 100,000 ng/mL
Trimethobenzamide	Negative at ≤ 100,000 ng/mL
Chloroquine	Negative at ≤ 100,000 ng/mL
Ephedrine	Negative at ≤ 100,000 ng/mL
Procaine (Novocaine)	Negative at ≤ 100,000 ng/mL
Ranitidine (Zantac)	Negative at ≤ 100,000 ng/mL
D-Amphetamine	Negative at ≤ 100,000 ng/mL
Oxazepam	Negative at ≤ 100,000 ng/mL
Morphine	Negative at ≤ 100,000 ng/mL
(+/-) 3,4-MDA	Negative at ≤ 100,000 ng/mL

METHAMPHETAMINE (mAMP 300)	Result
(D-Methamphetamine, Cutoff = 300 ng/mL)	Positive at 300 ng/mL
(±)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 20,000 ng/mL
(±)-Methamphetamine	Positive at 1,000 ng/mL
P-Hydroxymethamphetamine	Positive at 16000 ng/mL

(±)3,4-MDMA	Positive at 2,000 ng/mL
L-Methamphetamine	Positive at 5,000 ng/mL
Fenfluramine	Positive at 40,000 ng/mL
L-Amphetamine	Positive at 60,000 ng/mL
D-Pseudoephedrine	Negative at ≤ 100,000 ng/mL
Trimethobenzamide	Negative at ≤ 100,000 ng/mL
Chloroquine	Negative at ≤ 100,000 ng/mL
Ephedrine	Negative at ≤ 100,000 ng/mL
Procaine (Novocaine)	Negative at ≤ 100,000 ng/mL
Ranitidine (Zantac)	Negative at ≤ 100,000 ng/mL
D-Amphetamine	Negative at ≤ 100,000 ng/mL
Oxazepam	Negative at ≤ 100,000 ng/mL
Morphine	Negative at ≤ 100,000 ng/mL
(+/-) 3,4-MDA	Negative at ≤ 100,000 ng/mL

OPIATE (OPI 2000)	Result
(Morphine, Cutoff = 2,000 ng/mL)	Positive at 2,000 ng/mL
Codeine	Positive at 1,000 ng/mL
Ethylmorphine	Positive at 560 ng/mL
Hydrocodone	Positive at 5,000 ng/mL
Hydromorphone	Positive at 7,315 ng/mL
Levorphanol	Positive at 16,000 ng/mL
6-Monoacetylmorphine	Positive at 1,000 ng/mL
Morphine 3-β-D-Glucuronide	Positive at 1,300 ng/mL
Thebaine	Negative at ≤ 100,000 ng/mL
Norcodeine	Negative at ≤ 100,000 ng/mL
Normorphine	Negative at ≤ 100,000 ng/mL
Oxycodone	Negative at ≤ 100,000 ng/mL
Oxymorphone	Negative at ≤ 100,000 ng/mL
Procaine	Negative at ≤ 100,000 ng/mL
Oxazepam	Negative at ≤ 100,000 ng/mL
Methamphetamine	Negative at ≤ 100,000 ng/mL

OPIATE (OPI 300)	Result
(Morphine, Cutoff = 300 ng/mL)	Positive at 300 ng/mL
6-Acetylmorphine	Positive at 750 ng/mL
Codeine	Positive at 300 ng/mL
Ethylmorphine	Positive at 200 ng/mL
Heroin	Positive at 700 ng/mL
Hydromorphone	Positive at 4,000 ng/mL
Hydrocodone	Positive at 2,000 ng/mL
Levorphanol	Positive at 12,000 ng/mL
Thebaine	Positive at 90,000 ng/mL
Morphine-3-β-Glucuronide	Positive at 450 ng/mL
Oxycodone	Negative at ≤ 100,000 ng/mL
Procaine	Negative at ≤ 100,000 ng/mL

METHADONE (MTD)	Result
(Methadone, Cutoff = 300 ng/mL)	Positive at 300 ng/mL
Levo-α-Acetylmethadol	Positive at 10,000 ng/mL
Alphamethadol	Negative at ≤ 100,000 ng/mL
Doxylamine	Negative at ≤ 100,000 ng/mL
2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine	Negative at ≤ 100,000 ng/mL
2-Ethyl-5-Methyl-3,3-Diphenylpyrrolone	Negative at ≤ 100,000 ng/mL

OXYCODONE (OXY)	Result
(Oxycodone, Cutoff = 100 ng/mL)	Positive at 100 ng/mL

Dihydrocodeine	Positive at 50,000 ng/mL
Hydrocodone	Positive at 10,000 ng/mL
Heroin	Negative at ≤ 100,000 ng/mL
Morphine 3-β-D-Glucuronide	Negative at ≤ 100,000 ng/mL
Codeine	Negative at ≤ 100,000 ng/mL
Hydromorphone	Negative at ≤ 100,000 ng/mL
Morphine	Negative at ≤ 100,000 ng/mL
Acetylmorphine	Negative at ≤ 100,000 ng/mL
Buprenorphine	Negative at ≤ 100,000 ng/mL
Ethylmorphine	Negative at ≤ 100,000 ng/mL

PHENCYCLIDINE (PCP)	Result
(Phencyclidine, Cutoff = 25 ng/mL)	Positive at 25 ng/mL
Phencyclidine Morpholine	Positive at 625 ng/mL
4-Hydroxyphencyclidine	Positive at 250 ng/mL

PREGABALIN (PGB)	Result
(Pregabalin, Cutoff = 2,000 ng/mL)	Positive at 2,000 ng/mL

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	Result
(Methylenedioxyamphetamine, Cutoff = 500 ng/mL)	Positive at 500 ng/mL
3,4-Methylenedioxyamphetamine HCl (MDA)	Positive at 8,000 ng/mL
3,4-Methylenedioxyethylamphetamine (MDEA)	Positive at 1,000 ng/mL
(-)-ψ-Ephedrine	Positive at 40,000 ng/mL
D-Methamphetamine	Negative at ≤ 100,000 ng/mL
D-Amphetamine	Negative at ≤ 100,000 ng/mL
L-Amphetamine	Negative at ≤ 100,000 ng/mL
L-Methamphetamine	Negative at ≤ 100,000 ng/mL

Methaqualone (MQL)	Result
Methaqualone	Positive at 300 ng/ml
Paracetamol	Positive at >100,000 ng/ml
Procaine HCL	Positive at >100,000 ng/ml

TRICYCLIC ANTIDEPRESSANTS (TCA)	Result
(Nortriptyline, Cutoff = 1,000 ng/mL)	Positive at 1,000 ng/mL
Amitriptyline	Positive at 5,000 ng/mL
Clomipramine	Positive at 15,000 ng/mL
Desipramine	Positive at 1,000 ng/mL
Doxepin	Positive at 2,000 ng/mL
Imipramine	Positive at 600 ng/mL
Nordoxepin	Positive at 1,000 ng/mL
Promazine	Positive at 24,000 ng/mL
Trimipramine	Positive at 4,000 ng/mL
Cyclobenzaprine Hydrochloride	Positive at 1,500 ng/mL
Maprotiline	Negative at ≤ 100,000 ng/mL
Promethazine	Negative at ≤ 100,000 ng/mL
Norclomipramine	Negative at ≤ 100,000 ng/mL

PROPOXYPHENE (PPX)	Result
(Propoxyphene, Cutoff = 300 ng/ml)	Positive at 300 ng/mL
D-Norpropoxyphene	Positive at 1,500 ng/mL

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 300)	Result
(2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine, Cutoff = 300 ng/mL)	Positive at 300 ng/mL
2-Ethyl-5-Methyl-3,3-Diphenylpyrrolone (EMDP)	Negative at ≤ 100,000 ng/mL
Disopyramide	Negative at ≤ 100,000 ng/mL
Methadone	Negative at ≤ 100,000 ng/mL
Levo-α-Acetylmethadol Hydrochloride (LAAM)	Negative at ≤ 100,000 ng/mL
Alphamethadol	Negative at ≤ 100,000 ng/mL
Doxylamine	Negative at ≤ 100,000 ng/mL

2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP 100)	Result
(2-Ethylidene-1 5-Dimethyl-3 3-Diphenylpyrrolidine Cutoff = 100 ng/mL)	Positive at 100 ng/mL
Disopyramide	Negative at ≤ 15,000 ng/mL
Mianserin	Negative at ≤ 25,000 ng/mL
Tramadol	Negative at ≤ 60,000 ng/mL
Venlafaxine hydrochloride	Negative at ≤ 30,000 ng/mL

6-ACETYLMORPHINE (6-ACM)	Result
(6-Acetylmorphine, Cutoff = 10 ng/mL)	Positive at 10 ng/mL
Heroin	Positive at 37.5 ng/mL
Morphine	Positive at 100,000 ng/mL

COTININE (COT)	Result
((-)-Cotinine, Cutoff = 200 ng/mL)	Positive at 200 ng/mL
(-)-Nicotine	Positive at 6,250 ng/mL

SYNTHETIC CANNABINOID (K2 50)	Result
(Synthetic Cannabinoid, Cutoff = 50 ng/mL)	Positive at 50 ng/mL
JWH-018 Pentanoic Acid	Positive at 50 ng/mL
JWH-073 Butanoic Acid	Positive at 50 ng/mL
MAM2201 N-pentanoic acid metabolite	Positive at 200 ng/mL
JWH-398 N-pentanoic acid metabolite	Positive at 400 ng/ml
JWH-210 N-(5-carboxypentyl) metabolite	Positive at 2,500 ng/mL
JWH-073 3-hydroxybutyl metabolite	Positive at 2,500 ng/mL
JWH-018 N-4-hydroxypentyl	Positive at 8,000 ng/mL
JWH-073 4-hydroxybutyl metabolite	Positive at 40,000 ng/mL
JWH-019 5-hydroxyhexyl metabolite	Positive at 40,000 ng/mL
JWH-018 5-hydroxypentyl metabolite	Positive at 45,000 ng/mL
JWH-122 5-hydroxypentyl metabolite	Positive at 50,000 ng/mL
JWH-122 4-hydroxypentyl metabolite	Positive at 50,000 ng/mL
JWH-019 6-hydroxyhexyl metabolite	Positive at 50,000 ng/mL
RCS-4 N-(5-carboxypentyl) metabolite	Positive at 50,000 ng/mL
Trifluoperazine dihydrochloride	Positive at 50,000 ng/mL
Trifluoperazine hydrochloride	Positive at 70,000 ng/mL
2,4,6-Trimethylbenzamide	Positive at 100,000 ng/mL

SYNTHETIC CANNABINOID (K2 20)	Result
(Synthetic Cannabinoid, Cutoff = 20 ng/mL)	Positive at 20 ng/mL
JWH-018 5 pentanoic acid metabolite	Positive at 20 ng/mL
JWH-073 4-butanoic acid metabolite	Positive at 20 ng/mL
MAM2201 N-pentanoic acid metabolite	Positive at 200 ng/mL
JWH-398 N-pentanoic acid metabolite	Positive at 400 ng/mL
JWH-210 N-(5-carboxypentyl) metabolite	Positive at 2,500 ng/mL
JWH-073 3-hydroxybutyl metabolite	Positive at 2,500 ng/mL
JWH-018 N-4-hydroxypentyl	Positive at 8,000 ng/mL
JWH-073 4-hydroxybutyl metabolite	Positive at 40,000 ng/mL
JWH-019 5-hydroxyhexyl metabolite	Positive at 40,000 ng/mL
JWH-018 5-hydroxypentyl metabolite	Positive at 45,000 0ng/mL
JWH-122 5-hydroxypentyl metabolite	Positive at 50,000 ng/mL
JWH-122 4-hydroxypentyl metabolite	Positive at 50,000 ng/mL
JWH-019 6-hydroxyhexyl metabolite	Positive at 50,000 ng/mL
RCS-4 N-(5-carboxypentyl) metabolite	Positive at 50,000 ng/mL
Trifluoperazine dihydrochloride	Positive at 50,000 ng/mL
Trifluoperazine hydrochloride	Positive at 70,000 ng/mL
24,6-Trimethylbenzamide	Positive at 100,000 ng/mL

AB-PINACA (K3)	Result
(AB-Pinaca 5-Pentanoic Acid, Cutoff = 10 ng/mL)	Positive at 10 ng/mL
AB-FUBINACA	Positive at 200 ng/mL
AB-Pinaca	Positive at 100 ng/mL
AB-Pinaca 4-Hydroxypentyl Metabolite	Positive at 15 ng/mL
AB-Pinaca 5-Hydroxypentyl Metabolite	Positive at 15 ng/mL
AB-Pinaca 5-Pentanoic Acid Metabolite	Positive at 10 ng/mL
ADB-Pinaca 5-Pentanoic Acid Metabolite	Positive at 25 ng/mL
UR-144	Negative at 10,000 ng/mL
UR-144 5- Hydroxypentyl Metabolite	Negative at 10,000 ng/mL
UR-144 5- Pentanoic Acid Metabolite	Negative at 10,000 ng/mL
APinaca 5- Hydroxypentyl Metabolite	Negative at 10,000 ng/mL

UR-144 (K4)	Result
(UR-144 5-Pentanoic Acid, Cutoff = 25 ng/mL)	Positive at 25 ng/mL
UR-144 5-Hydroxypentyl Metabolite	Positive at 300 ng/mL
UR-144	Negative at 10,000 ng/mL
AB-Fubinaca	Negative at 10,000 ng/mL
AB-Pinaca	Negative at 10,000 ng/mL
AB-Pinaca 4-Hydroxypentyl Metabolite	Negative at 10,000 ng/mL
AB-Pinaca 5-Hydroxypentyl Metabolite	Negative at 10,000 ng/mL
AB-Pinaca 5-Pentanoic Acid Metabolite	Negative at 10,000 ng/mL
APinaca 5- Hydroxypentyl Metabolite	Negative at 10,000 ng/mL
ADB-Pinaca 5-Pentanoic Acid Metabolite	Negative at 10,000 ng/mL

KETAMINE (KET)	Result
(Ketamine , Cutoff = 1,000 ng/mL)	Positive at 1,000 ng/mL
Methadone	Positive at 100,000 ng/mL
Meperidine	Positive at 30,000 ng/mL
Methamphetamine	Positive at 40,000 ng/mL
Methoxyphenamine	Positive at 20,000 ng/mL
D-methamphetamine	Positive at 40,000 ng/mL
Promethazine	Positive at 50,000 ng/mL
Phencyclidine	Positive at 10,000 ng/mL
Bupivacaine	Positive at 20,000 ng/mL
Disopyramide	Positive at 100,000 ng/mL
Eserine	Positive at 70,000 ng/mL
Glutathione reduced	Positive at 50,000 ng/mL
Mianserin	Positive at 30,000 ng/mL
Naphazoline hydrochloride	Positive at 20,000 ng/mL
Nomifensine	Positive at 100,000 ng/mL
Prilocaine	Positive at 50,000 ng/mL
Promazine	Positive at 100,000 ng/mL
Pyrilamine	Positive at 50,000 ng/mL
Thioridazine hydrochloride	Positive at 100,000 ng/mL
Benzthiazide	Positive at 100,000 ng/mL
Picrotoxin	Positive at 10,000 ng/mL
Phenyltoloxamine	Positive at 100,000 ng/mL
2,4,6-Trimethylbenzamide	Positive at 100,000 ng/mL
Nordiazepam	Positive at 390 ng/mL
Oxazepam	Positive at 300 ng/mL
Temazepam	Positive at 100 ng/mL
Triazolam	Positive at 2,500 ng/mL

KRATOM (KRA)	Result
(Mitragynine, Cutoff = 100 ng/mL)	Positive at 100 ng/mL
7-Hydroxymitragynine	Negative at 10,000 ng/mL

FENTANYL (FEN)	Result
(Fentanyl, Cutoff = 10 ng/mL)	Positive at 10 ng/mL
Valeryl fentanyl HCl	Positive at 5,000 ng/mL
Butyryl fentanyl	Positive at 50 ng/mL
Furanyl fentanyl HCl	Positive at 250 ng/mL
Norfentanyl oxalate	Positive at 25 ng/mL
Ocfentanil	Positive at 5,000 ng/mL
Para-Fluorofentanyl	Positive at 25 ng/mL
(±)-cis-3-Methylfentanyl HCL	Positive at 250 ng/mL
Acetyl fentanyl	Positive at 1,000 ng/mL

TRAMADOL (TRA 50)	Result
(Tramadol, Cutoff = 50 ng/mL)	Positive at 50 ng/mL

TRAMADOL (TRA 100)	Result
(Tramadol, Cutoff = 100 ng/mL)	Positive at 100 ng/mL

TRAMADOL (TRA 200)	Result
(Tramadol, Cutoff = 200 ng/mL)	Positive at 200 ng/mL

ETHYL GLUCURONIDE (ETG 500)	Result
(Ethyl-β-D-glucuronide, Cutoff = 500 ng/mL)	Positive at 500 ng/mL

ETHYL GLUCURONIDE (ETG 300)	Result
(Ethyl-β-D-glucuronide, Cutoff = 300 ng/mL)	Positive at 300 ng/mL

METHYLENEDIOXYPYROVALERONE (MDPV)	Result
(Methylenedioxypropyvalerone, Cutoff = 1,000 ng/mL)	Positive at 1,000 ng/mL
Butylone	Positive at 1,000 ng/mL
Ethylone	Positive at 1,000 ng/mL
Methylone	Positive at 10,000 ng/mL
Mephedrone	Positive at 10,000 ng/mL
Methedrone	Positive at 10,000 ng/mL
Pyrovalerone	Positive at 4,000 ng/mL
Naphyrone	Positive at ≥100,000 ng/mL
Flephedrone	Positive at ≥100,000 ng/mL
Brompheniramine	Positive at ≥100,000 ng/mL
Methyprylon	Positive at ≥100,000 ng/mL
Zomepirac	Positive at ≥100,000 ng/mL

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 **MEGACup® Drug of Abuse Test Cup** 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. It was spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **MEGACup® Drug of Abuse Test Cup**. The results demonstrated 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, Marijuana, Methadone, Methamphetamine, Methylenedioxyamphetamine, Methaqualone, Opiate, Oxycodone, Phencyclidine, Pregabalin, Propoxyphene, Tricyclic Antidepressants, 2-Ethylidene-1, 5-dimethyl-3, 3-diphepyrrolidine, 6-Acetylmorphine, Cotinine, Synthetic Cannabinoid, AB-Pinaca, UR-144, Ketamine, Kratom, Fentanyl, Tramadol, Ethyl Glucuronide, Methylenedioxypropyvalerone. The following compounds show no cross-reactivity when tested with the **MEGACup® Drug of Abuse Test Cup** at concentrations of 100 µg/mL.

Amphetamine, Buprenorphine, Barbiturates, Benzodiazepines, Cocaine, 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxyamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressant and Marijuana Non-Cross-Reacting Compounds

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Erythromycin	Oxolinic acid
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	Ibuprofen	Salicylic acid
Benzoic acid	Isoproterenol	Serotonin (5- Hydroxytyramine)
Bilirubin	Isoxsuprine	Sulfamethazine
Chloral hydrate	Ketamine	Sulindac
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
Digoxin	Norethindrone	Verapamil
Diphenhydramine	Noscapine	Zomepirac
Ecgonine methyl ester	(±)-Octopamine	

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

Acebutolol Hydrochloride	EthylMorphine	PCP
Acepromazine-d6 hydrochloride	Fenoprofen	Pentobarbital
Acetaminophen	Furosemide	Pentazocine
N-Acetylprocainamide	Gentisic acid	Perphenazine
Acetophenetidin	D-Glucuronic acid	Penicillin G Sodium salt
Alprazolam	Glutethimide	Phenelzine sulfate salt
Alphenal	Guaifenesin	Phenobarbital
Amoxicillin	Hemoglobin porcine	Phentemine HCL
Ampicillin	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	α-Hydroxyhippuric acid	Procaine HCL
R(-)-Apomorphine Hydrochloride	21-Hydroxy progesterone	Promazine hydrochloride
Aprobarital	ρ-Hydroxymethamphetamine	Promethazine
Aspirin	Hydrocortisone	Propoxyphene,d-
Aspartame	Hydrochlorothiazide	Propranolol Hydrochloride
L-Ascorbic Acid	-4-Hydroxyamphetamine HCL	Pseudoephedrine
Atropine	Ibuprofen	Phendimetrazine
6-Acetylmorphine	Imipramine	Phenytion
Acetylsalicylic acid	Ipazid	Quinine
Benzphetamine	Isoxsuprine hydrochloride	Quinidine
Benzilic acid	Isoproterenol Hydrochloride Injection	Quinacrine
Benzoylcegonine	Ketamine hydrochloride	Ranitidine Hydrochloride Tablets
SS Benzoic Acid	Ketoprofen	Nortriptyline Hydrochloride
Bilirubin,Mixed Isomers	Emetine dihydrochloride hydrate	Salicylic Acid
Brompheniramine maleate	Ephedrine-(+/-) hydrochloride	Secobarbital
Buprenorphine	(-)-Ephedrine HCL	Serotonin
Buspirone hydrochloride	[1R,2S] (-) Ephedrine	Noroxymorphone HCL
Butalbital	Erythromycin	Nylidrin hydrochloride
Butabarbital	Eserine	Norfentanyl
Cannabidiol	Estazolam	(±)-Octopamine HCL
Cannabinal	β-Estradiol	Oxalic Acid
Caffeine	(±)-EDDP	Oxolinic Acid
Cetirizine Hydrochloride	Ethyl-p-aminobenzoate	Oxycodone
Chlordiazepoxide HCL	JWH-018 pantanoic acid	Oxymetazoline
Chlorothiazide	JWH-073 butanoic acid	Papaverine
Chloroquine	Labetalol Hydrochloride	(±)-Octopamine HCL
Chlorpheniramine Maleate	Levorphanol	Sertraline HCl
Chlorpromazine Hydrochloride Tablets	Loperamide Hydrochloride	Sulfamethazine,min 99%
Chloramphenicol	Lorazepam	Sulindac
Chloral-Hydrate	Maprotiline hydrochloride	Temazepam
Cholesterol	(±)-MDEA	Terfenadine
Chlorothiazide	(±)-MDA	Terbutaline
Clomipramine	Meperidine	Tetraethylthiuram disulfide
Clonazepam	Meprobamate	Tetrahydrocannabinol, Delta-8-(+)-delta-8-THC)
Clonidine hydrochloride	Methamphetamine hydrochloride	Tetracycline
Clozapine	(±)Methadone	Tetrahydrocortisone 3-(β-D-glucuronide
(-) Cotinine	S(+)-D-methamphetamine	(-)-delta-9-THC)
Cocaethylene	L-methamphetamine	(+/-)11-Hydroxy-delta-9-THC
Cocaine Hydrochloride	Methylphenidate	(-)-11-nor-9-Carboxy-delta9-THC
Cortisone	(±)-MDMA	Thebaine
Creatinine	(±)-MDPV	Theophylline
Cyclopentobarbital	Methyprylon	Thioridazine
Citalopram hydrobromide	Morphine	Thiamine, (Vitamin B1 Tablets)HCL
Dextromethorphan	Morphine-3β-D-glucuronide	DL-Thyroxine
Desipramine	Morphine sulfate salt solution	Tolbutamide
Diazepam	Nalidixic acid	Tramaddl
Diclofenac Sodium salt	Nalorphine hydrochloride	Triamterene
Dicydomine	Naproxen	Trimipramine
Digoxin	Naloxone	Tryptamine
4-Dimethylaminoantipyrine	Naltrexone hydrochloride	Trifluoperazine dihydrochloride
Dihydrocodeine HCL	Nicotinamide (vitamin B3)	DL-Tryptophan
5,5-Diphenylhydantoin	Nimesulide	Triazolam
Diphenhydramine	Nifedipine	Trans-2-phenylcyclo-propylamine hydrochloride
Dopamine	Norcodeine	D/L-Tyrosine
Doxylamine	Nordoxepin hydrochloride	Tyramine
Ecgonine methylester	Norfloxacin Capsule	Uric Acid
Ecgonine HCL	Norethisterone Tablets	Verapamil Hydrochloride
Efavirenz	d-Norpropoxyphene maleate salt	Valproic acid
Ethylone	Noscapine	Zomepirac

BIBLIOGRAPHY

1. Stewart DJ, Inaba T, Lucassen M, Kalow W. *Clin. Pharmacol. Ther.* April 1979; 25 ed: 464, 264-8.
2. Ambre J. J. *Anal. Toxicol.* 1985; 9:241.
3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.*
4. Tietz NW. *Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.*
5. FDA Guidance Document: *Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.*
6. Robert DeCresce. *Drug Testing in the workplace, 114.*
7. Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA 1982; 487.*
8. OSHA, *The Bloodborne Pathogens Standard 29, Code of Federal Regulations 29 CFR 1910.1030.*
9. CDC, *Centers forDisease Control (CDC) Guidelines, Morbidity and Mortality Weekly Report, Volume 37, Number 24, 1988.*
10. Auwarter V et. al. 'Spice' and other herbal blends: harmless incense or cannabinoid designer drugs? *J. Mass Spectrom.* 44: 832-837 (2009).
11. U.S Drug Enforcement Administration (DEA). *Drugs and Chemicals of Concern: JWH-073. (2009).*
- 12.U.S. Drug Enforcement Administration (DEA). *Drugs and Chemicals of Concern: JWH-018. (2009).*
13. "WCPI Focus on Pain Series: The Three Faces of Fentanyl." *Aspi.wisc.edu.* Retrieved 2010-07-28.
14. "FENTANYL : Incapacitating Agent." *CDC. Retrieved 2014-09-18.*
15. Mutschler, Ernst; Schäfer-Korting, Monika (2001). *Arzneimittelwirkungen (in German) (8 ed.)*. Stuttgart: Wissenschaftliche Verlagsgesellschaft. p. 286. ISBN 3-8047-1763-2.
16. Parry WH, Martorano F, Cotton EK (January 1976). "Management of life-threatening asthma with intravenous isoproterenol infusions." *Am. J. Dis. Child.* 130(1):39–42. doi:10.1001/archpedi.1976.02120020041006. PMID 2007.
17. *Ethyl Glucuronide: An unusual Ethanol Metabolite in Humans. Synthesis, Analytical Data, and Determination in Serum and Urine.* Schmitt G., et al. *Journal of Analytical Toxicology.* 1995, 19:91-94.
18. *Comparison of Urinary Excretion Characteristics of Ethanol and Ethyl Glucuronide.* Dahl H., et al. *Journal of Analytical Toxicology.* 2002, 26:201-204.
19. *Ethyl Glucuronide- the direct ethanol metabolite on the threshold from science to routine use.* Wurst FM et al. *Addiction.* 2003, 98 (S2) 51-61.
20. *Ethyl Glucuronide- A Biological Marker for recent alcohol consumption.* Seidi S. et al. *Addiction Biology.* 2001, 6(3):205-212.
21. *Ethyl Glucuronide: A Biomarker to identify Alcohol use by Health Professionals Recovering from Substance use Disorders.* Skipper G.E et al. *Alcohol and Alcoholism,* 2004, 39(5):445-449.
22. *Ethyl Glucuronide- A marker of Recent Alcohol Consumption with Clinical and Forensic Implications.* Wurst FM et al. *Alcohol.* 2000, 20(2):111-116.
23. *Ethyl Glucuronide (EtG): A new marker to detect Alcohol use in recovering physicians.,* Skipper G.E., et al. *Journal of Medical Licensure and Discipline.* 2004, 90(2): 14-17.
24. *Production of urinary ethanol after sample collection.* Saady, J.J., Poklis, A.and Dalton, H.P. (1993) *Journal of Forensic Sciences* 38, 1467-1471.
25. *Preliminary immunochemical test for the determination of Ethyl Glucuronide in serum and urine: Comparison of screening method results with Gas Chromatography- Mass spectrometry.* Zimmer H., et al. *Journal of Analytical Toxicology.* 2002, 26:11-16.
26. *Confirmatory Analysis of Ethyl Glucuronide in urine by liquid chromatography/Electrosprayionization/Tandem Mass Spectrometry according to forensic guidelines.* Weinmann W. et al. *J. Am. Soc. Mass Spectrom.* 2004, 15(2):188-193.
27. B.W.Corrigan, W.F. Pool,E.L Posvar et al. *Metabolic disposition of pregabalin in healthy volunteers. Clin.Pharmacol.Ther* 69:18,2001.
28. Heltsley, A. DePriest, D.L. Black et al. *Urine drug testing of chronic pain patients. IV. Prevalence of gabapentin and pregabalin.*J.Anal Tox.35:357-359,2011.

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.