One Step Multi-Drug Screen Test Cup (Urine)

Instructions For Use

Instructions For Use for testing any combination of the following drugs: Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, EDDP (Methadone Metabolites), Ethyl Glucuronide, Fentanyl, Hydrocodone, Hydromorphone, Ketamine, Kratom, K2 (Synthetic Cannabinoid), Lysergic acid diethylamide, Marijuana, Methadone, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tramadol, Tricyclic Antidepressants and 6-Monoacetylmorphine.

A rapid, one step screening test for the simultaneous, qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, EDDP (Methadone Metabolites), Ethyl Glucuronide, Fentanyl, Hydrocodone, Hydromorphone, Ketamine, Kratom, K2 (Synthetic Cannabinoid), Lysergic acid diethylamide, Marijuana, Methadone, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tramadol, Tricyclic Antidepressants, 6-Monoacetylmorphine and the metabolites in human urine.

For Forensic Use Only.

INTENDED USE

The Healgen® **One Step Multi-Drug Screen Test Cup (Urine)** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs, drug metabolites and alcohol at the following cut-off concentrations in urine:[1]

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1,000
Amphetamine (AMP)	D-Amphetamine	500
Amphetamine (AMP)	D-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Barbiturates (BAR)	Secobarbital	200
Benzodiazepines (BZO)	Oxazepam	300
Benzodiazepines (BZO)	Oxazepam	200
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylecgonine	300
Cocaine (COC)	Benzoylecgonine	150
Cotinine (COT)	Cotinine	200
Ecstasy (MDMA)	D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	500
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	300
Fentanyl (FEN)	Fentanyl	300
Fentanyl (FEN)	Fentanyl	200
Fentanyl (FEN)	Fentanyl	100
Fentanyl (FEN)	Norfentanyl	20
Fentanyl (FEN)	Norfentanyl	10
Hydrocodone (HCD)	Hydrocodone	10
Hydromorphone (HMO)	Hydromorphone	300
Ketamine (KET)	Ketamine	1,000
Ketamine (KET)	Ketamine	100
Kratom (KRA)	Mitragynine	250
K2 Synthetic Cannabinoid	JWH-073/JWH-018	50
K2 Synthetic Cannabinoid	JWH-073/JWH-018	25
Lysergic acid diethylamide (LSD)	D-lysergic acid diethylamide	20
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	25
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	20
Methadone (MTD)	Methadone	300
Methadone (MTD)	Methadone	50
Methadone Metabolites (EDDP)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300
Methadone Metabolites (EDDP)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	100
Methamphetamine (MET, mAMP)	D-Methamphetamine	1,000
Methamphetamine (MET, mAMP)	D-Methamphetamine	500
Methamphetamine (MET, mAMP)	D-Methamphetamine	300
Methaqualone (MQL)	Methaqualone	300
Methylenedioxypyrovalerone (MDPV)	3,4-Methylenedioxypyrovalerone	1,000
Opiates (MOP300)	Morphine	300
Opiates (OPI 2000)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tramadol (TRA)	Tramadol	200
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Alcohol (ALC).	Ethanol	>0.04%B.A.C

This test will detect other related compounds, please refer to the Analytical Specificity table in these Instructions For Use.

These tests provide only a preliminary result. A more specific alternative chemical method should be used to obtain a confirmed presumptive positive result if the donor doesn't admit use or anytime required by testing procedures. Gas Chromatography/Mass Spectrometry (GC-MS), Liquid Chromatography/Mass Spectrometry (LC/MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drug screen test result, particularly when evaluating preliminary positive results.

SUMMARY

Urine based drug tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse.

AMPHETAMINE (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days.

Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception. Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

BUPRENORPHINE (BUP)

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

COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity, and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection, and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine.[1,2] Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.[2]

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, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%.[1] While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration.[2] 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.

ECSTASY (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

ETHYL GLUCURONIDE (ETG)

Ethyl Glucuronide (EtG) is a direct metabolite of ethanol alcohol. The presence of EtG in the urine can be used to detect recent alcohol consumption, even after the ethanol alcohol is no longer measurable. Consequently, the presence of EtG in the urine is a definitive indicator that alcohol has been ingested. Traditional laboratory practices typically measure the amount of alcohol present in the body. Depending on the amount of alcohol that has been consumed, this method usually reveals alcohol ingestion within the past few hours.

The presence of EtG in the urine, on the other hand, demonstrates that ethanol alcohol was ingested within the past three or four days, or roughly 80 hours after the ethanol alcohol has been metabolized by the body. As a result, it can be determined that a urine alcohol test employing EtG is a more accurate indicator of the recent consumption of alcohol as opposed to simply measuring for the existence of ethanol alcohol.

FENTANYL (FEN)

Fentanyl is a synthetic opioid. It has the brand names of Sublimaze, Actiq, Durogestic, Fentora and others. The Fentanyl drug is approximately 100 times more potent than morphine, with 100 micrograms of fentanyl approximately equivalent to 10 mg. of morphine or 75 mg. of meperidine in analgesic activity. The Fentanyl drug is a potent narcotic analgesic with rapid onset and short duration of action. Historically, the fentanyl drug has been used to treat chronic breakthrough pain and is commonly used pre-procedures. Illicit use of pharmaceutical fentanyl drugs first appeared in the mid-1970s. Because the effects of the fentanyl drug last for only a very short time, it is even more addictive than heroin. Regular users may become addicted very quickly. The Fentanyl drug is much more

potent than heroin, and tends to produce significantly worse respiratory depression, making it somewhat more dangerous than heroin to users. Overdoses of fentanyl have caused deaths. In the United States, the fentanyl drug is classified as a Schedule II controlled substance.

HYDROCODONE (HCD)

Hydrocodone is used to treat moderate to severe pain, although it is often prescribed to treat mild pain as well. In liquid formulations, it is used as an antitussive to treat cough. In one study comparing the potency of hydrocodone to that of oxycodone, it was found that it took 50% more hydrocodone to achieve the same degree of miosis (pupillary contraction). The investigators interpreted this to mean that oxycodone is about 50% more potent than hydrocodone.

However, in a study of emergency department patients with fractures, it was found that an equal amount of either drug provided about the same degree of pain relief, indicating that there is little practical difference between them when used for that purpose. Some references state that the analgesic action of hydrocodone begins in 20–30 minutes and lasts about 4–8 hours. The manufacturer's information says onset of action is about 10–30 minutes and duration is about 4–6 hours. Recommended dosing interval is 4–6 hours.

HYDROMORPHONE (HMO)

Hydromorphone, also known as dihydromorphinone, is a centrally acting pain medication of the opioid class. It is made from morphine. It works by changing the way the brain and nervous system respond to pain. Hydromorphone extended-release tablets are used to relieve severe pain in people who are expected to need pain medication around the clock for a long time and who cannot be treated with other medications. Hydromorphone extended-release tablets should only be used to treat people who are tolerant (used to the effects of the medication) to opioid medications because they have taken this type of medication for at least one week and should not be used to treat mild or moderate pain, short-term pain, pain after an operation or medical or dental procedure, or pain that can be controlled by medication that is taken as needed.

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.

KRATOM (KRA)

Kratom leaves produce narcotic-like effects when smoked, chewed, or drank as a suspension, which have recently attracted significant attention due to increased use in Western cultures as an alternative medicine. It is used in therapy for opiate addiction and chronic pain management. The addiction potential and adverse health consequences are becoming an important issue for health authorities. Extensive use of kratom results in prolonged sleep. The withdrawal symptoms include hostility, aggression, muscle pain and inability to work.

LYSERGIC ACID DIETHYLAMIDE (LSD)

D-lysergi acid diethylamide (LSD) is the most potent hallucinogenic substance known to man. Dosages of LSD are measured in micrograms, or millionths of a gram. By comparison, dosages of cocaine and heroin are measured in milligrams, or thousandths of a gram. Compared to other hallucinogenic substances, LSD is 100 times more potent than psilocybin and psilocin and 4,000 times more potent than mescaline. The dosage level that will produce a hallucinogenic effect in humans generally is considered to be 25 micrograms. Over the past several years, the potency of LSD obtained during drug law enforcement operations has ranged between 20 and 80 micrograms per dosage unit. The Drug Enforcement Administration (DEA) recognizes 50 micrograms as the standard dosage unit equivalency.

MARIJUANA (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it 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 smoking marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of Morphine dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. Methadone is a long-acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

METHAMPHETAMINE (MET, mAMP)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in urine indicates Methamphetamine use.

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 European 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.

METHYLENEDIOXYPYROVALERONE (MDPV)

Bath salts’, a form of designer drugs, also promoted as ‘plant food’ or ‘research chemicals’, is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised a ‘legal’ highs. The technical term for ‘bath salts’ is substituted cathinone. Substituted cathinone is synthetic, concentrated version 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 cathinone, 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 Methedrone, MDPV started appearing around 2004 when it was popularized as a club drug, often used in combination with alcohol, GHB, cannabis and other abused drugs, for its desired effects such as euphoria, alertness, talkativeness, and sexual arousal. There are currently no prescribed used for the synthetic stimulants.

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

OPIATES (MOP or OPI)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[4]

OXYCODONE (OXY)

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

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 often administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

PROPOXYPHENE (PPX)

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

SYNTHETIC MARIJUANA (K2)

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 72 hours after smoking (depending on usage/dosage).

As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclo hexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety. JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. JWH-073 has been identified in numerous herbal products, such as “Spice”, “K2”, K3” and others. These products may be smoked for their psychoactive effects.

TRAMADOL (TRA)

Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine but has a low binding affinity to the mu-opioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.[2] Large doses of Tramadol could develop tolerances and physiological dependency and lead to its abuse. Both Δ (d) and L forms of the isomers are controlled substances. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucuronidation or sulfation in the liver.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity, and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

2-Ethylidine-1.5-dimethyl-3.3-diphenylpyrrolidine (EDDP)

EDDP is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate-dependent patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The tampering of specimens by spiking the urine with methadone can be prevented. Also, renal clearance of EDDP is not affected by urinary pH; therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone test. Methadone is an unusual drug in a sense that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure. Thus, theyarevery difficult to detect with immunoassays targeted to the native compound. Exacerbating this problem, there is a subsection of the population classified as “extensive metabolizers” of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance.

6-MONOACETYLMORPHINE (6-MAM)

6-Monoacetylmorphine (6-MAM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-acetylmorphine (3-ACM). 6-MAM 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-MAM 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-MAM guarantees that heroin was in fact used as recently as within the last day.

ALCOHOL (ALC)

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. Screening of individuals for alcohol consumption is an important method for the identification of individuals who might be at risk due to alcohol use or intoxication. Screening is also an important deterrent against inappropriate alcohol consumption. The blood alcohol concentration at which a person becomes impaired is variable dependent on the individual. Parameters specific to the individual such as physical size, weight, activity level, eating habits and alcohol tolerance all affect the level of impairment. Determination of ethyl alcohol in urine, blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. Alcohol Test is designed to detect ethyl alcohol in urine specimens.

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 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, specimen dilution, or substitution with a non-urine liquid.
- **pH:** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.
- **Nitrite (NIT):** Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- **Glutaraldehyde (GLU):** Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- **Creatinine (CRE):** Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine or a substituted specimen.

PRINCIPLE

(1) The Healgen® **One Step Multi-Drug Screen Test Cup (Urine)** 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 coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

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 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.

(2)Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in urine. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3CHO + H_2O_2$$

$$H_2O_2 + DH_2 \xrightarrow{\text{Peroxidase}} \underset{\text{Blue}}{D} + 2H_2O$$

REAGENTS

Each test line in the test cup contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line. The alcohol test strip contains alcohol oxidase and peroxidase.

ADULTERANT TESTS (SPECIMEN VALIDITY TEST) SUMMARY

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

PRECAUTIONS

- For Forensic Use Only.
- Not to be used for clinical diagnosis.
- Do not use after the expiration date.
- The Test Cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used Test Cup should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated [2-30°C (36-86°F)]. The Test Cup is stable through the expiration date printed on the sealed pouch. The Test Cup must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. Testing of the specimen is recommended immediately, however, if collected in a cup the specimen can be stored for future use.
2. 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 (-4°F)]. If frozen or refrigerated, specimens must be equilibrated to room temperature before testing.

MATERIALS

Materials Provided

- Test cups
- Procedure card
- Disposable gloves
- Color chart cards for alcohol (when applicable)
- Desiccants
- Instructions For Use
- Color chart cards for adulterant interpretation (when applicable)

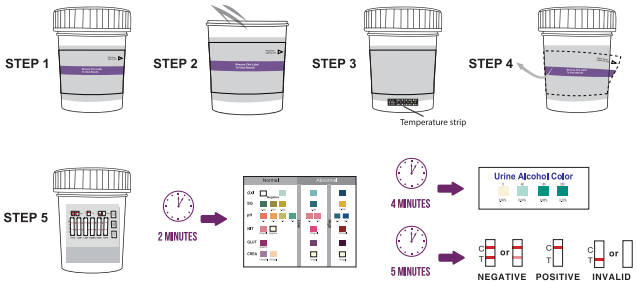
Materials Required but Not Provided

- Timer, clock or watch

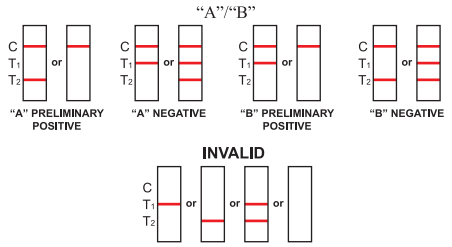
DIRECTIONS FOR USE

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

1) Tear the foil bag open and remove the test cup. Label the device with donor information. (Step 1)
2) Collect a minimum of 30 mL to maximum of 110 mL (marked on cup) of urine specimen. Once the urine specimen has been collected, screw the cap on firmly. Start the timer. (Step 2)
3) Verify the urine temperature is within an acceptable range [32-38°C (90-100°F)] by reading the green mark on the temperature indicator strip. (Step 3)
4) Using gloves, the collector should peel off the label to reveal the test result. (Step 4)
5) If the cup contains adulteration strips, read the adulteration strip pads using the color card at 2 minutes. If the cup contains alcohol strip, read the strip pads using the color card at 4 minutes. (Step 5)
6) Interpret the drug strip results at 5 minutes. (Step 5)
   DO NOT INTERPRET RESULT AFTER 10 MINUTES.
7) If there is a preliminary positive test result, the operator should attach the security seal label over the cap. The security seal should include donors' name, initials, and test date. Do not cover test result window with the security seal.



Result Illustration for Multi-drug Strips



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

PRELIMINARY POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/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 cup. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

Note: There is no meaning attributed to line color intensity or width.

A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is a False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by Healgen® One Step Multi-Drug Screen Test Cup (Urine). The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is a False Negative Test?

The definition of a false negative test is that the initial substance is present but isn't detected by Healgen® One Step Multi-Drug Screen Test Cup (Urine). If the sample is diluted or adulterated a false negative result may occur.

ALCOHOL/ADULTERANT 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 blocks on the color chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The Healgen® One Step Multi-Drug Screen Test Cup (Urine) 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), Liquid Chromatography/Mass Spectrometry (LC/MS) and their tandem mass-spectrometer versions are the preferred confirmatory method.
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 cup.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result can be obtained when certain foods or food supplements are consumed.

PERFORMANCE CHARACTERISTICS

Accuracy

80 clinical urine specimens were analyzed by GC-MS and by the Healgen® **One Step Multi-Drug Screen Test Cup (Urine)**. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Specimen	AMP1000	AMP500	AMP300	BAR300	BAR200	BZO300	BZO200
Positive	93.3%	95.8%	96.7%	93.3%	94.2%	95.0%	93.3%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	96.7%	97.9%	98.3%	96.7%	97.1%	97.5%	96.7%

Specimen	BUP10	COC300	COC150	COT200	EDDP300	EDDP100	ETG500
Positive	94.2%	92.5%	97.5%	93.3%	95%	93.3%	95.8%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.1%	96.3%	98.8%	96.7%	97.5%	96.7%	97.9%

Specimen	ETG300	FEN300	FEN200	FEN100	FEN20	FEN10	HCD10
Positive	95.8%	92.5%	95.0%	93.3%	92.5%	93.3%	91.7%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.9%	96.3%	97.5%	96.7%	96.3%	96.7%	95.8%

Specimen	HMO300	KET1000	KET100	KRA250	K2 (50)	K2 (25)	LSD20
Positive	95.8%	95.8%	91.7%	94.2%	93.3%	95.8%	93.3%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	97.9%	97.9%	95.8%	97.1%	96.7%	97.9%	96.7%

Specimen	MET1000	MET500	MET300	MDMA500	MDPV1000	MOP300
Positive	96.7%	96.7%	95.8%	91.7%	95.8%	97.5%
Negative	100%	100%	100%	100%	100%	100%
Total	98.3%	98.3%	97.9%	95.8%	97.9%	98.8%

Specimen	MQL300	MTD300	MTD50	OPI2000	OXY100	PCP25	PPX300
Positive	91.7%	94.2%	93.3%	92.5%	93.3%	92.5%	95.0%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	95.8%	97.1%	96.7%	96.3%	96.7%	96.3%	97.5%

Specimen	TCA1000	THC50	THC25	THC20	TRA200	6-MAM10
Positive	92.5%	94.2%	94.2%	91.7%	93.3%	93.3%
Negative	100%	100%	100%	100%	100%	100%
Total	96.3%	97.1%	97.1%	95.8%	96.7%	96.7%

Analytical Sensitivity

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, EDDP (Methadone Metabolites), Ethyl Glucuronide, Fentanyl, Hydrocodone, Hydromorphone, Ketamine, Kratom, K2 (Synthetic Cannabinoid), Lysergic acid diethylamide, Marijuana, Methadone, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tramadol, Tricyclic Antidepressants and 6-Monoacetylmorphine. The cut-off value for the device is verified.

Analytical Specificity

The following table lists compounds that are positively detected in urine by the Healgen® **One Step Multi-Drug Screen Test Cup (Urine)** at 5 minutes.

Drug	Concentration (ng/ml)
AMPHETAMINE (AMP1,000)	
D-Amphetamine	1,000
D,L - Amphetamine (Amphetamine Sulfate)	1,000
Phentermine	1,250
(+/-)-4-Hydroxyamphetamine HCL	600
L-Amphetamine	20,000
3,4-Methylenedioxyamphetamine HCl (MDA)	1,500
d-Methamphetamine	>100,000 ng/mL
l-Methamphetamine	>100,000 ng/mL
ephedrine	>100,000 ng/mL
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000 ng/mL
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000 ng/mL
AMPHETAMINE (AMP500)	
D-Amphetamine	500
D,L-Amphetamine	750
L-Amphetamine	16,000
Phentermine	650
(+/-)-Methylenedioxyamphetamine (MDA)	800
d-Methamphetamine	>100,000
l-Methamphetamine	>100,000
ephedrine	>100,000
3,4-Methylenedioxyethylamphetamine (MDE)	>100,000
3,4-methylenedioxy-methamphetamine (MDMA)	>100,000
AMPHETAMINE (AMP300)	
D-Amphetamine	300
D,L-Amphetamine	450
L-Amphetamine	9,000
Phentermine	450
(+/-)-Methylenedioxyamphetamine (MDA)	600
BARBITURATES (BAR300)	
Secobarbital	300
Amobarbital	300
Alphenal	750
Aprobarbital	250
Butabarbital	2,500
Butethal	2,500
Cyclopentobarbital	500
Pentobarbital	2,500
Phenobarbital	25,000
BARBITURATES (BAR200)	
Secobarbital	200
Amobarbital	200
Alphenal	500
Aprobarbital	200
Butabarbital	2,000
Butethal	2,000
Butalbital	2,000
Cyclopentobarbital	300
Pentobarbital	2,000

Drug	Concentration (ng/ml)
BENZODIAZEPINES (BZO300)	
Alprazolam	200
Bromazepam	1,560
Chlordiazepoxide HCL	1,560
Clobazam	100
Clonazepam	780
Clorazepate Dipotassium	200
Delorazepam	1,560
Desalkylflurazepam	400
Diazepam	200
Estazolam	2,500
Flunitrazepam	400
a-Hydroxyalprazolam	1260
(±) Lorazepam	1,560
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	100
Norchlordiazepoxide	200
Nordiazepam	400
Oxazepam	300
Temazepam	100
Triazolam	2,500
BENZODIAZEPINES (BZO200)	
Alprazolam	200
Bromazepam	1,000
Chlordiazepoxide HCL	1,000
Clobazam	80
Clonazepam	500
Clorazepate Dipotassium	100
Delorazepam	1,000
Desalkylflurazepam	300
Diazepam	100
Estazolam	2,000
Flunitrazepam	300
a-Hydroxyalprazolam	840
(±) Lorazepam	1,000
RS-Lorazepam glucuronide	100
Midazolam	10,000
Nitrazepam	100
Norchlordiazepoxide	100
Nordiazepam	300
Oxazepam	200
Temazepam	800
Triazolam	2,000
BUPRENORPHINE (BUP10)	
Buprenorphine	10
Norbuprenorphine	20
COCAINE (COC300)	
Benzoylecogonine	300
Cocaethylene	300
CocaineHCl	300
COCAINE (COC150)	
Benzoylecogonine	150
Cocaethylene	2,500

Drug	Concentration (ng/ml)
Cocaine	500
Ecgonine	12,500
Ecgonine methylester	50,000
COTININE (COT200)	
Cotinine	200
Nicotine	6,250
ECSTASY (MDMA500)	
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300
d-methamphetamine	2500
d-amphetamine	>100,000
l-amphetamine	>100,000
l-methamphetamine	>100,000
ETHYL GLUCURONIDE (EtG500)	
Ethyl-β-D-glucuronide	500
Ethyl-β-D-glucuronide-D5	500
ETHYL GLUCURONIDE (EtG300)	
Ethyl-β-D-glucuronide	300
Ethyl-β-D-glucuronide-D5	300
HYDROCODONE (HCD10)	
Dihydrocodeine HCL	312.5
EthylMorphine	10,000
Hydrocodone	10
Hydromorphone	2,500
Levorphanol	10,000
Oxymorphone-D3	10,000
Codeine	2,500
Heroin Hydromorphone	>100,000
Oxymorphone	>100,000
6-acetylmorphine	>100,000
Nalorphine	>100,000
Norcodeine	50,000
Morphine	100,000
HYDROMORPHONE (HMO300)	
Hydromorphone	300
Ranitidine	50,000
Gatifloxacin	6,250
Procaine	25,000
Morphine	12,500
Coteine Phosphate	12,500
Heroin	3,125
Naloxone hydrochloride	80,000
Naltrexone hydrochloride	781
Dihydrocodeine HCL	1,526
Hydrocodone	195
Levorphanol	50,000
Oxymorphone-D3	97.65
Codeine	6,250
Heroin Hydromorphone	6,250
Oxymorphone	24.4
6-acetylmorphine	50,000
LAAM HCl	50,000

Drug	Concentration (ng/ml)
KETAMINE (KET1,000)	
Ketamine	1,000
Norketamine	3,000
Methoxy-amphetamine	12,500
Promethazine	25,000
4-hydroxyphenyl cyclohexyl piperidine	50,000
KETAMINE (KET100)	
Ketamine	100
Norketamine	100
Methoxy-amphetamine	1,250
Promethazine	2,500
4-hydroxyphenyl cyclohexyl piperidine	5,000
KRATOM (KRA250)	
Mitragynine	250
Mitragynine Metabolite	250
7-Hydroxymitragynine	600
Bilirubin	100,000
11-Hydroxy-Δ^9-Tetrahydrocannabinol	80,000
K2 SYNTHETIC CANNABINOID (K2(50))	
JWH-018 5-Pentanoic acid metabolite	50
JWH-018 5-Hydroxypentyl metabolite	500
JWH-018 4-Hydroxypentyl metabolite	400
JWH-018 N-(4-hydroxypentyl) metabolite solution	5,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-019 6-Hydroxyhexyl	5,000
JWH-073 4-butanoic acid metabolite	50
JWH-073 4-Hydroxybutyl metabolite	500
JWH-210 5-Hydroxypentyl metabolite solution	<10,000
JWH-122 5-Hydroxypentyl metabolite solution	<10,000
Spice Cannabinoid Mix 3 solution	<10,000
JWH-122 4-Hydroxypentyl metabolite solution	<10,000
JWH-122 4-Hydroxypentyl metabolite-D5 solution	<10,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	<10,000
JWH-073 N-(3-Hydroxybutyl) metabolite solution	<10,000
K2 SYNTHETIC CANNABINOID (K2(25))	
JWH-018 5-Pentanoic acid metabolite	25
JWH-018 5-Hydroxypentyl metabolite	250
JWH-018 4-Hydroxypentyl metabolite	200
JWH-018 N-(4-hydroxypentyl) metabolite solution	2,500
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-019 6-Hydroxyhexyl	2,500
JWH-073 4-butanoic acid metabolite	25
JWH-073 4-Hydroxybutyl metabolite	250
JWH-210 5-Hydroxypentyl metabolite solution	<10,000
JWH-122 5-Hydroxypentyl metabolite solution	<10,000
Spice Cannabinoid Mix 3 solution	<10,000
JWH-122 4-Hydroxypentyl metabolite solution	<10,000
JWH-122 4-Hydroxypentyl metabolite-D5 solution	<10,000
JWH-019 5-hydroxyhexylmetabolite	<10,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	<10,000
JWH-073 N-(3-Hydroxybutyl) metabolite solution	<10,000
LYSERGIC ACID DIETHYLAMIDE (LSD20)	

Drug	Concentration (ng/ml)
D-lysergic acid diethylamide	20
Fentanyl	75
Norfentanyl	300
MARIJUANA (THC50)	
Delta-9-Tetrahydrocannabinol	50,000
11-nor-delta-9-THC-carboxyglucuronide	75
(-)-11-nor-9-carboxy-delta9-THC	75
11-Nor-Δ^9-Tetrahydrocannabinol	50
11-Hydroxy-Δ^9-Tetrahydrocannabinol	5,000
11-Nor-Δ^8-Tetrahydrocannabinol	50
Δ^8-THC-COOH	50,000
MARIJUANA (THC25)	
Delta-9-Tetrahydrocannabinol	25,000
11-nor-delta-9-THC-carboxyglucuronide	37.5
(-)-11-nor-9-carboxy-delta9-THC	37.5
11-Nor-Δ^9-Tetrahydrocannabinol	25
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2,500
11-Nor-Δ^8-Tetrahydrocannabinol	25
Δ^8-THC-COOH	25,000
MARIJUANA (THC20)	
Delta-9-Tetrahydrocannabinol	20,000
11-nor-delta-9-THC-carboxyglucuronide	30
(-)-11-nor-9-carboxy-delta9-THC	30
11-Nor-Δ^9-Tetrahydrocannabinol	20
11-Hydroxy-Δ^9-Tetrahydrocannabinol	2,000
11-Nor-Δ^8-Tetrahydrocannabinol	20
Δ^8-THC-COOH	20,000
METHADONE (MTD300)	
Methadone	300
Doxylamine	5,000
METHADONE (MTD50)	
Methadone	50
PCP (Phencyclidine)	35,000
Diphenhydramine HCl	50,000
Doxylamine	10,000
EDDP perchlorate	25,000
Disopyramide	7,500
METHADONE METABOLITES (EDDP300)	
EDDP	300
Disopyramide	50,000
Methadone	>100,000
EMDP	500
METHADONE METABOLITES (EDDP100)	
EDDP	100
Disopyramide	20,000
Methadone	>100,000
EMDP	200
METHAMPHETAMINE (MET, mAMP1,000)	
D-Methamphetamine	1,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	60,000

Drug	Concentration (ng/ml)
Trimethobenzamide	20,000
Methamphetamine	1,000
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2,500
Chloroquine	50,000
Ephedrine	100,000
Fenfluramine	50,000
p-Hydroxymethamphetamine	10,000
METHAMPHETAMINE (MET, mAMP500)	
p-Hydroxymethamphetamine	15,000
l-Methamphetamine	4,000
Mephentermine	25,000
d,l-Amphetamine	75,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	75,000
d-Methamphetamine	500
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
d-Amphetamine	50,000
Chloroquine	12,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000
Procaine (Novocaine)	50,000
Trimethobenzamide	20,000
Ranitidine (Zantac)	50,000
Fenfluramine	50,000
METHAMPHETAMINE (MET, mAMP300)	
p-Hydroxymethamphetamine	10,000
l-Methamphetamine	3,000
Mephentermine	15,000
d,l-Amphetamine	50,000
(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	50,000
d-Methamphetamine	300
3,4–Methylenedioxymethamphetamine (MDMA)	1,000
d-Amphetamine	30,000
Chloroquine	7,500
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	12,000
Procaine (Novocaine)	30,000
Trimethobenzamide	12,000
Ranitidine (Zantac)	30,000
Fenfluramine	30,000
METHAQUALONE (MQL300)	
Methaqualone	300
METHYLENEDIOXYPYROVALERONE (MDPV1000)	
3,4-Methylenedioxypyrovalerone	1,000
Ethylone HCl	1,200
Methylone	50,000
Pyrovalerone	50,000
FENTANYL (FEN300)	
Norfentanyl	20
Fentanyl	300
FENTANYL (FEN200)	
Norfentanyl	15
Fentanyl	200

Drug	Concentration (ng/ml)
Sufentanyl	50,000
Fenfluramine	50,000
FENTANYL (FEN100)	
Norfentanyl	10
Fentanyl	100
Buspirone	>100,000
Sufentanyl	25,000
Fenfluramine	25,000
NORFENTANYL (FEN20)	
Norfentanyl	20
Fentanyl	300
NORFENTANYL (FEN10)	
Norfentanyl	10
Fentanyl	150
OPIATE (MOP300)	
Morphine	300
O6-Acetylmorphine	400
Codeine	300
EthylMorphine	100
Heroin	600
Hydromorphone	5,000
Hydrocodone	10,000
Levorphanol	1500
Oxycodone	30,000
Procaine	15,000
Thebaine	6,240
OPIATE (OPI2,000)	
Morphine	2,000
O6-Acetylmorphine	2,500
Codeine	1,000
EthylMorphine	250
Heroin	5,000
Hydromorphone	2,500
Hydrocodone	5,000
Oxycodone	75,000
Thebaine	13,000
OXYCODONE (OXY100)	
Naloxone hydrochloride	10,000
Naltrexone hydrochloride	50,000
Oxycodone	100
Hydrocodone	5,000
Hydromorphone	25,000
Oxymorphone-D3	5,000
Oxymorphone	200
N-Benzylisopropylamine	2,500
PHENCYCLIDINE (PCP25)	
Phencyclidine	25
4-Hydroxy Phencyclidine	90
PROPOXYPHENE (PPX300)	
Norpropoxyphene	300
d-Propoxyphene	300

Drug	Concentration (ng/ml)
TRICYCLIC ANTIDEPRESSANTS (TCA1,000)	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	50,000
Desipramine	5,000
Doxepine	10,000
Imipramine	10,000
Maprotiline	100,000
Nordoxepin	10,000
Promazine	50,000
Promethazine	2,500
Trimipramine	50,000
Cyclobenzaprine Hydrochloride	5,000
Norclomipramine	50,000
TRAMADOL (TRA200)	
Tramadol	200
N-desmethyl-tramadol	500
O-desmethyl-tramadol	20,000
6-MONOACETYLMORPHINE (6-MAM10)	
6-Moonacetylmorphine	10
Morphine	>500,000
Codeine	>600,000
Dextromethorphan	>100,000
Dihydrocodeine	>100,000
Heroin HCl	250
Hydrocodone	>100,000
Hydromorphone	>100,000
Imipramine	>100,000
Levorphanol	>10,000
NorMeperidine	>10,000
Normorphine	>100,000
Nalorphine	>100,000
Naloxone	>100,000
Naltrexone	>100,000
Norcodeine	>100,000
Oxycodone	>100,000
Oxymorphone	>100,000

Precision

This study was performed 2 runs/day and lasts 25 days for each format with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. Data obtained at all testing sites across the intended use populations indicate >99% correlation at +/-50% of each assay cutoff. The results are given below:

Drug Conc. (Cut-off range)	AMP1000		AMP500		AMP300		BAR300		BAR200		BZO300		BZO200	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	18	32	32	18	22	28	27	23	23	27	20	30	24	26
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	BUP10		COC300		COC150		COT200		EDDP300		EDDP100		ETG500	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0

-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	50	0	41	9	44	6
Cut-off	26	24	18	32	31	19	20	30	21	29	30	20	23	27
+25% Cut-off	0	50	0	50	0	50	0	50	0	50	3	47	8	42
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	ETG300		FEN300		FEN200		FEN100		FEN20		FEN10		HCD10	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	42	8	50	0	46	4	43	7	50	0	49	1	50	0
Cut-off	23	27	22	28	22	28	20	30	22	28	25	25	22	28
+25% Cut-off	4	46	0	50	3	47	2	48	0	50	2	48	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	HMO300		KET1000		KET100		KRA250		K2 (50)		K2 (25)		LSD20	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	45	5	44	6	45	5	50	0	50	0	43	7
Cut-off	23	27	18	32	30	20	22	28	18	32	22	28	21	29
+25% Cut-off	5	45	6	44	3	47	4	46	0	50	0	50	3	47
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	MET1000		MET500		MET300		MDMA500		MDPV1000		MOP300	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	47	3	50	0
Cut-off	22	28	28	22	25	25	30	20	23	27	20	30
+25% Cut-off	0	50	0	50	0	50	0	50	4	46	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	MQL300		MTD300		MTD50		OPI2000		OXY100		PCP25		PPX300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	48	2	50	0	45	5	50	0	50	0	50	0	50	0
Cut-off	24	26	22	28	24	26	20	30	16	34	16	34	25	25
+25% Cut-off	6	44	0	50	3	47	0	50	0	50	0	50	0	50
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	TCA1000		THC50		THC25		THC20		TRA200		6-MAM10	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0
-75% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0
-50% Cut-off	50	0	50	0	50	0	50	0	50	0	50	0
-25% Cut-off	50	0	50	0	50	0	50	0	45	5	50	0
Cut-off	22	28	14	36	23	27	25	25	28	22	23	27
+25% Cut-off	0	50	0	50	0	50	0	50	1	49	5	45
+50% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50
+75% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50
+100% Cut-off	0	50	0	50	0	50	0	50	0	50	0	50

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The Healgen® **One Step Multi-Drug Screen Test Cup (Urine)** 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 Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with the Healgen® **One Step Multi-Drug Screen Test Cup (Urine)**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Cotinine, Ecstasy, EDDP (Methadone Metabolites), Ethyl Glucuronide, Fentanyl, Hydrocodone, Hydromorphone, Ketamine, Kratom, K2 (Synthetic Cannabinoid), Lysergic acid diethylamide, Marijuana, Methadone, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tramadol, Tricyclic Antidepressants, 6-Monoacetylmorphine positive urine. The following compounds show no cross-reactivity when tested with the Healgen® **One Step Multi-Drug Screen Test Cup (Urine)** at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Pseudoephedrine	Quinidine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinine
Acetylsalicylic acid	Dexamethasone	Labetalol	Salicylic acid
Amiloride	Dextromethorphan	Loperamide	Serotonin
Amoxicillin	Desipramine	Meprobamate	Sulfamethazine
Ampicillin	Diflunisal	Methoxyphenamine	Sulindac
l-Ascorbic acid	Digoxin	Methylphenidate	Tetracycline
Apomorphine	Droperidol	Nalidixic acid	Tetrahydrocortisone,
Aspartame	Ethyl-p-aminobenzoate	Naproxen	3-Acetate
Atropine	Ethopropazine	Niacinamide	Theobromine
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tolazamide
p-Aminobenzoic Acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
Beclomethasone	Furosemide	Octopamine	Thioridazine Hydrochloride
Caffeine	Gentisic acid	Oxalic acid	D/L-Tyrosine
Cannabidiol	Hemoglobin	Oxyphenbutazone	Tolbutamide
Carbamazepine	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Paclitaxel	Trimethoprim
Chlorpheniramine	α-Hydroxyhippuric acid	Perphenazine	D,L-Tryptophan
Chlorpromazine	Hydroxyprogesterone	Phenelzine	Uric acid
Cholesterol	Isoproterenol-(+/-)	Prednisone	Verapamil
Clonidine	Isoxsuprine	Prilocaine	Zomepirac

BIBLIOGRAPHY

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INDEX OF SYMBOL

	Do not reuse		See Instruction for Use		Expiration Date
	Tests per Kit		Store Between 2-30°C (36-86°F)		Keep Dry
LOT	Batch Number	REF	Catalog#		Keep Away from Sunlight

Manufactured for:
Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
TEL: +1713-733-8088
FAX: + 1713-733-8848
Website: www.healgen.com

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