Serenity Multi-Drug Urine Test Cup Package Insert

For forensic use only.

INTENDED USE

The Serenity Multi-Drug Urine Test Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of any combination of drugs of abuse in human urine specimens at the cut-off concentrations listed below:

Drug	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1,000
Barbiturates (BAR)	Secobarbital	300
Buprenorphine (BUP)	Buprenorphine	10
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	300
Ethyl Glucuronide (EtG)	Ethyl Glucuronide	300
Fentanyl (FYL)	Norfentanyl	20
Gabapentin (GAB)	Gabapentin	1,000
Synthetic cannabinoid（K2）	JWH 018 5-pentanoic acid JWH 073 4-butanoic acid	50
Ketamine (KET)	Ketamine	1,000
Kratom (KRA)	Mitragynine	500
Methylenedioxymethamphetamine (MDMA)	D,L- Methylenedioxy-methamphetamine	500
Methamphetamine (MET)	D-Methamphetamine	1,000
Methadone (MTD)	Methadone	300
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Morphine (OPI)	Morphine	300/2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Psilocybin (PY)	Psilocin	500
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	25/50/200
Tianeptine (TIA/ZAZA)	Tianeptine	500
Tramadol (TRA)	Tramadol	100
Xylazine (XYL)	Xylazine	1,000
Adulteration Strip（Creatinine, Specific Gravity, pH）		/

For forensic use only.

The tests may yield positive results for the prescription drugs Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Ethyl Glucuronide, Fentanyl, Gabapentin, Synthetic Cannabinoid, Ketamine, Kratom, Methylenedioxymethamphetamine, Methamphetamine, Methadone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, Psilocybin, Tricyclic Antidepressants, Marijuana Tianeptine, Tramadol and Xylazine when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The Urine Adulteration Test Strip (Urine) is a semi-quantitative color comparison screen for the detection of Creatinine, Specific Gravity and pH in human urine.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

SUMMARY

AMP (Amphetamine)

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.

BAR (Secobarbital – "Barbiturates")

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 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 detection period for the Barbiturates in the urine is 4-7 days.

BUP (Buprenorphine)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/mL after therapeutic administration, but can range up to 20 ng/mL in abuse situations. The plasma half-life of Buprenorphine is 2-4 hours. 1 While complete elimination of a single-dose of the drug can take as long as 6 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

BZO (Oxazepam– "Benzodiazepines")

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.

COC (Benzoylecgonine - Metabolite of Cocaine)

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, and 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.

EtG (Ethyl Glucuronide)

Ethyl Glucuronide (EtG) is a metabolite of ethyl alcohol which is formed in the body by glucuronidation following exposure to ethanol, such as by drinking alcoholic beverages. It is used as a biomarker to test for ethanol use and to monitor alcohol abstinence in situations where drinking is prohibited, such as in the military, in professional monitoring programs (health professionals, attorneys, airline pilots in recovery from addictions), in schools, in liver transplant clinics, or in recovering alcoholic patients. EtG can be measured in urine by Traditional laboratory methods (GC/MS or LC/MS) up to approximately 80 hours after ethanol is ingested (greatly dependent on the amount of alcoholic and non-alcoholic drinks). EtG is a more accurate indicator of the recent exposure to alcohol than measuring for the presence of ethanol itself.

FYL (Fentanyl)

Fentanyl is a synthetic opioid medicine used to treat moderate to severe pain, it is up to 100 times stronger than other opioids like morphine, heroin or oxycodone. It is a prescription drug that is also made and used illegally. It is also sometimes used to treat patients with chronic pain who are physically tolerant to other opioids. Tolerance occurs when you need a higher and/or more frequent amount of a drug to get the desired effects. Because fentanyl is a powerful prescription opioid it can be misused, abused and cause overdose deaths. Fentanyl is classified as schedule 2 under the controlled substances act (CSA).

GAB (Gabapentin)

Gabapentin is a synthetic neurotransmitter analog medication primarily used to treat neuropathic pain and partial onset seizures. Gabapentin is a prescription drug that must be used under medical supervision, but non-medical misuse has emerged in recent years. For chronic pain patients who have developed tolerance to long-term opioid use, gabapentin is sometimes used as an adjunctive analgesic medication. Because this drug may cause side effects such as sedation and dizziness, high doses can lead to respiratory depression, with risks significantly increasing particularly when used concurrently with opioids.

K2 (SYNTHETIC MARIJUANA)

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 cannabicyclol 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.

KET(Ketamine)

Ketamine is a non-competitive antagonist at the phencyclidine site of the N-methyl-d-aspartate (NMDA) receptor for glutamate. However, its effects are also mediated by interactions with many others receptors. It is a short-acting anesthetic that has been widely used by emergency physicians and can be given intravenously, intramuscularly, orally, and even nasally. Multiple ketamine anesthetics may be safe.

Ketamine was introduced as early as the 1960s, and is not generally used today as a general anesthetic, because of adverse psychological reactions, including delirium, disturbed dreaming, motor adverse reactions, and emergence reactions in about 12% of patients. However, subanesthetic low-dose ketamine has been used for acute pain therapy, day-case surgery, and chronic pain management.

KRA (Kratom)

Mitragyna speciosa is a tropical evergreen tree in thecoffee family native to Southeast Asia. M. speciosaisindigenous to Thailand, Indonesia, Malaysia, Myanmar, and Papua New Guinea, where it has beenusedin traditional medicines since at least theninteenth century. Kratom has opioid properties andsome stimulant-like effects.Mitragynine is classified as a kappa-opioid receptor agonist and is roughly 13 times more potent thanmorphine. Mitragynine is thought to be responsible for the opioid-like effectsKratom, due to its opioid-like action, has been used for treatment of pain and opioid withdrawal. Animalstudies suggest that the primary mitragynine pharmacologic action occurs at the mu and delta-opioidreceptors, as well as serotonergic and noradrenergic pathways in the spinal cord. Stimulation atpost-synaptic alpha-2 adrenergic receptors, and receptor blocking at 5-hydroxytryptamine 2A may alsooccur. The 7-hydroxymitragynine may have a higher affinity for the opioid receptors. Partial agonistactivity may be involved.

MDMA (3,4-Methylenedioxy-Metamphetamine - "Ecstasy")

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 have taken a reasonable dose of the drug, is to produce a clenching of the jaws.

MET (Methamphetamine)

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 primarily as Amphetamine, and oxidized and deaminated 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.

MTD (Methadone)

Methadone is a narcotic pain reliever for medium to severe pain. It is also used in the treatment of Heroin (Opiate dependence: Vicodin, Percolate, Morphine, etc.) addiction. Oral Methadone is very different than the IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like Heroin.
Methadone is a long-acting pain reliever producing effects that last between 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.

6-MAM (6-Monoacetylmorphine)

6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine (6-AM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. 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. 6-MAM is naturally found in the brain, but in such small quantities that detection of this compound in urine virtually guarantees that heroin has recently been consumed.

OPI (Morphine - “Opiate”)

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 and 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.

OXY (Oxycodone)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5 mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%).1 The window of detection for Oxycodone in urine is expected to be similar to that of other opioids such as morphine.

PCP (Phencyclidine)

Phencyclidine, also known as PCP, 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. PCP is most 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 PCP.
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. PCP is excreted in the urine as unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

PPX (D-Propoxyphene)

Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. It is prescribed in the United States for the relief of moderate pain. DarvocetTM, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Physiological effects of propoxyphene include respiratory depression. Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than that of propoxyphene (6 to 12 hours). Norpropoxyphene demonstrates substantially less central-nervous system depression than propoxyphene, but shows a greater local anesthetic effect.

PY (Psilocybin)

Psilocybin is the major psychoactive alkaloid of some species of mushrooms distributed worldwide. Psilocybin-containing mushrooms are one of the major hallucinogenic drugs of abuse today. In a medium dosage (12–20 mg p.o.), psilocybin was found to produce a well-controllable altered state of consciousness. This state is marked by stimulation of affect, enhanced ability for introspection and altered psychological functioning in the direction of Freudian primary processes, known otherwise as hypnagogic experience and dreams. Especially noteworthy are perceptual changes such as illusions, synaestesias, affective activation, and alterations of thought and time sense. The effects last from 3 to 6 hours1.Both psilocin (at 90-97%) and psilocybin (3-10%), are detectable in human urine, unmodified (only 3-10%) and in particular conjugated with glucuronic acid. The majority is excreted within 3 hours after oral administration and is completely eliminated from the body within 24 hours.

TCA (Tricyclic Antidepressants)

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 and 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.

THC (11-nor-Δ^9-THC-9-COOH- “Marijuana”)

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).

TIA(Tianeptine)

Tianeptine is an antidepressant drug with structural similarities to the tricyclic antidepressant agents and a selective promoter of 5-HT uptake in the body and in vivo. Itis often used to treat depression and various anxiety and depression-based neuroses, can also be used for menopausal psychosis, and is also effective for depressive neurosis, chronic alcoholism and depression after alcohol withdrawal. However, excessive use of Tianeptine can cause side effects. The most common adverse effects are nausea, constipation, abdominal pain, headache, dizziness and changes in dreaming, long-term use can cause dependence and withdrawal.1The elimination half-life of Tianeptine is about 2.5h, only a very small amount of Tianeptine is excreted through the kidneys (8%), and its metabolites are excreted mainly through the kidneys. The main metabolite (MC5; pentanoic acid) has some minor antidepressant activity.

TRA(Tramadol)

Tramadol, a synthetic codeine analogue, has a weak affinity with opioid receptors. Analgesic effect is produced by inhibiting the re-uptake of norepinephrine by neuronal synapses, increasing the concentration of 5-hydroxytryptamine outside neurons, and affecting the transmission of pain. Its action intensity is 1/10~1/8 of morphine. No respiratory inhibition, little dependence, significant analgesic effect. It has antitussive effect, with the intensity of 50% of codeine. It does not affect the release of histamine and does not cause spasm of smooth muscle. Both oral and injection absorption are good, and the analgesic effect is the same. After oral administration, it takes effect 10 to 20 minutes and lasts for 4 to 8 hours. It is metabolized in the liver, and 80% of it is excreted from the urine in its original form and metabolites within 24 hours.

XYL(Xylazine)

Xylazine is not a controlled substance; it is marketed as a veterinary drug and used as a sedative, analgesic and muscle relaxant. In humans, it could cause central nervous system depression, respiratory depression, bradycardia, hypotension, and even death. Most of the non-fatal cases required medical intervention. Over recent years xylazine has emerged as an adulterant in recreational drugs, such as heroin or speedball (a cocaine and heroin mixture). Its chronic use is reported to be associated with physical deterioration and skin ulceration. Literature shows some similar pharmacologic effects between xylazine and heroin in humans. These similar pharmacologic effects may create synergistic toxic effects in humans. Therefore, fatalities among drug users may increase due to the use of xylazine as an adulterant. Xylazine alone has proven harmful to humans and even more when it is combined with drugs of abuse.

Adulteration Test

CRE (Creatinine)

Tests for specimen dilution. Creatinine is a waste product of Creatine, and is an amino-acid contained in muscle tissue and found in urine. A person may attempt to foil a drug test by drinking excessive amounts of water or diuretics such as herbal teas to flush the system. Creatinine and Specific Gravity are two ways to check for dilution and flushing, which are the most common mechanisms used to circumvent drug testing. Low Creatinine and Specific Gravity levels may indicate diluted urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with human urine.

SG (Specific Gravity)

Tests for specimen dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

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 outside of this range may indicate that the specimen has been altered.

PRINCIPLE

The Serenity Multi-Drug Urine 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 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.
The Adulteration test contains chemically treated reagent pads. 3-5 minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of specific gravity, pH and creatinine in human urine which can help assess the integrity of the urine sample.

COMPOSITION

- Each test kit contains Multi-drug urine test cup, Color chart cards for Adulterant Interpretation and package insert.
- Materials required but not provided: timer.

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 35.6-86°F(2-30°C). Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 59-86°F(15-30°C).
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

Note: *All expiration dates are printed in Year-Month-Day format. 2020-06-18 indicates June 18, 2020.*

WARNINGS, PRECAUTIONS AND LIMITATIONS

- For forensic use only. 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.
- The Serenity Multi-Drug Urine Test Cup provides only a preliminary analytical result. A more specific chemical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test

should be repeated with another urine specimen.

- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- The test does not distinguish between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

The Urine Adulteration Test Strips (Urine) is meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

- **Creatinine:** Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.
- **Specific Gravity:** Elevated levels of protein in urine may cause abnormally high Specific Gravity values.

SPECIMEN COLLECTION AND PREPARATION

1) Urine Assay

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

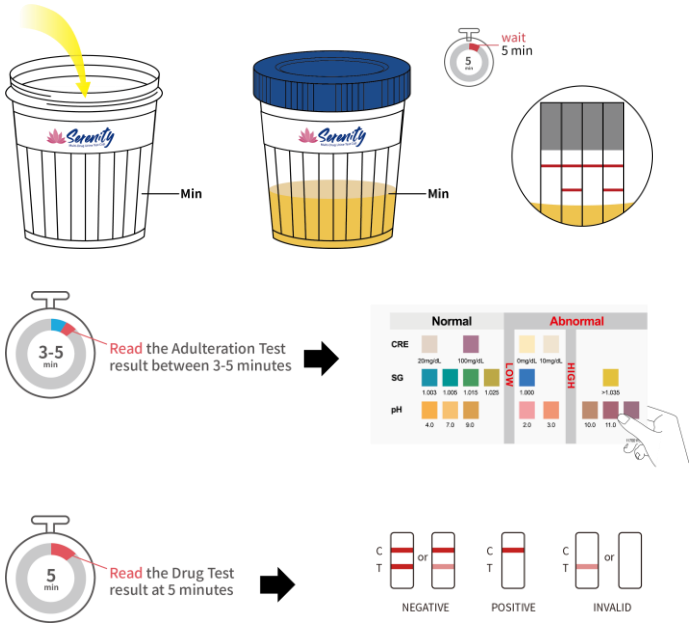
2) Specimen Storage

Urine specimens may be stored at 35.6-46.4°F(2-8°C) for up to 48 hours prior to assay. For prolonged storage, specimens may be frozen and stored below -4°F(-20°C). Frozen specimens should be thawed and mixed before testing.

TEST PROCEDURE

Allow the test, urine specimen, and/or controls to equilibrate to room temperature 59-86°F(15-30°C) prior to testing.

1. Remove the test cup from the sealed pouch and use it within one hour.
2. Open the lid and collect the urine as indicated above, ensuring that the sample is above the minimum fill line.
3. After urine has been collected, close the lid securely and place the urine test cup on a flat surface.
4. Remove the test window cover along the perforated line.
5. Read the adulteration strips between 3-5 minutes according to color chart provided separately. Refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen in case of any positive result for any adulteration test.
6. Read the drug test results at 5 minutes. **DO NOT INTERPRET THE RESULTS AFTER 10 MINUTES.**



INTERPRETATION OF TEST RESULTS

The Result for DOA test:

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

NEGATIVE RESULT



A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug.
NOTE: The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

PRELIMINARY POSITIVE RESULT



A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off for that specific drug.

INVALID RESULTS



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 panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

The Result for Adulteration test:

Results are obtained by visually comparing the reacted color blocks on the test strip to the printed color chart card.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Quality Control testing should follow all applicable state, local and federal regulations.

PERFORMANCE

1. Accuracy

80 clinical urine specimens were analyzed by LC-MS/MS and by the Serenity Multi-Drug Urine Test Cup. 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:

AMP 1000

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	17	21
	Negative	10	15	15	2	0
Operator B	Positive	0	0	1	19	21
	Negative	10	15	14	0	0
Operator C	Positive	0	0	0	18	21
	Negative	10	15	15	1	0
%Agreement among Positives is 97.5%						
%Agreement among Negatives is 99.2%						

BAR 300

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	17	20
	Negative	10	16	14	3	0
Operator B	Positive	0	0	0	18	20
	Negative	10	16	14	2	0
Operator C	Positive	0	0	0	19	20
	Negative	10	16	14	1	0
%Agreement among Positives is 95%						
%Agreement among Negatives is 100%						

BUP 10

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	1	18	20
	Negative	10	15	14	2	0
Operator B	Positive	0	0	2	20	20
	Negative	10	15	13	0	0
Operator C	Positive	0	0	0	18	20
	Negative	10	15	15	2	0
%Agreement among Positives is 96.7%						
%Agreement among Negatives is 97.5%						

BZO 300

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	15	23
	Negative	10	15	15	2	0
Operator B	Positive	0	0	0	16	23
	Negative	10	15	15	1	0
Operator C	Positive	0	0	0	17	23
	Negative	10	15	15	0	0
%Agreement among Positives is 97.5%						
%Agreement among Negatives is 100%						

COC 300

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	2	17	23
	Negative	10	14	14	0	0
Operator B	Positive	0	0	0	15	23
	Negative	10	14	16	2	0
Operator C	Positive	0	0	1	17	23
	Negative	10	14	15	0	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 97.5%						

EtG 300

Serenity Cup	Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)

Operator A	Positive	0	0	0	17	21
	Negative	10	15	15	2	0
Operator B	Positive	0	0	1	19	21
	Negative	10	15	14	0	0
Operator C	Positive	0	0	1	19	21
	Negative	10	15	14	0	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 98.3%						

FYL 20

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	1	18	22
	Negative	10	16	13	0	0
Operator B	Positive	0	0	1	17	22
	Negative	10	16	13	1	0
Operator C	Positive	0	0	2	17	22
	Negative	10	16	12	1	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 96.7%						

GAB 1000

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	2	17	22
	Negative	10	16	12	1	0
Operator B	Positive	0	0	1	18	22
	Negative	10	16	13	0	0
Operator C	Positive	0	0	1	17	22
	Negative	10	16	13	1	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 96.7%						

K2 50

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	18	20
	Negative	10	16	14	2	0
Operator B	Positive	0	0	2	20	20
	Negative	10	16	12	0	0
Operator C	Positive	0	0	1	20	20
	Negative	10	16	13	0	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 97.5%						

KET 1000

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	1	18	22
	Negative	10	16	13	0	0
Operator B	Positive	0	0	1	18	22
	Negative	10	16	13	0	0
Operator C	Positive	0	0	0	17	22
	Negative	10	16	14	1	0
%Agreement among Positives is 99.2%						
%Agreement among Negatives is 98.3%						

KRA 500

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	2	19	21
	Negative	10	16	12	0	0
Operator B	Positive	0	0	0	16	21
	Negative	10	16	14	3	0
Operator C	Positive	0	0	1	18	21
	Negative	10	16	13	1	0
%Agreement among Positives is 96.7%						
%Agreement among Negatives is 97.5%						

MDMA 500

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	2	20	20
	Negative	10	17	11	0	0
Operator B	Positive	0	0	0	20	20
	Negative	10	17	13	0	0
Operator C	Positive	0	0	1	20	20
	Negative	10	17	12	0	0
%Agreement among Positives is 100%						
%Agreement among Negatives is 97.5%						

MET 1000

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	21	19
	Negative	10	13	17	0	0
Operator B	Positive	0	0	0	19	19
	Negative	10	13	17	2	0
Operator C	Positive	0	0	0	20	19
	Negative	10	13	17	1	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 100%						

MTD 300

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	18	20
	Negative	10	16	14	2	0
Operator B	Positive	0	0	2	20	20
	Negative	10	16	12	0	0
Operator C	Positive	0	0	1	20	20
	Negative	10	16	13	0	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 97.5%						

6-MAM 10

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	18	20
	Negative	10	16	14	2	0
Operator B	Positive	0	0	2	20	20
	Negative	10	16	12	0	0
Operator C	Positive	0	0	1	20	20
	Negative	10	16	13	0	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 97.5%						

OPI 300

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	18	22
	Negative	10	14	16	0	0
Operator B	Positive	0	0	2	18	22
	Negative	10	14	14	0	0
Operator C	Positive	0	0	0	18	22
	Negative	10	14	16	0	0
%Agreement among Positives is 100%						
%Agreement among Negatives is 98.3%						

OPI 2000

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	16	22
	Negative	10	16	14	2	0
Operator B	Positive	0	0	1	18	22
	Negative	10	16	13	0	0
Operator C	Positive	0	0	0	18	22
	Negative	10	16	14	0	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 99.2%						

OXY 100

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	2	19	21
	Negative	10	14	14	0	0
Operator B	Positive	0	0	0	18	21
	Negative	10	14	16	1	0
Operator C	Positive	0	0	0	17	21
	Negative	10	14	16	2	0
%Agreement among Positives is 97.5%						
%Agreement among Negatives is 98.3%						

PCP 25

Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	1	21	18
	Negative	10	18	11	1	0
Operator B	Positive	0	0	1	21	18
	Negative	10	18	11	1	0
Operator C	Positive	0	0	1	22	18
	Negative	10	18	11	0	0
%Agreement among Positives is 98.3%						

%Agreement among Negatives is 97.5%						
PPX 300						
Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	2	19	21
	Negative	10	16	12	0	0
Operator B	Positive	0	0	0	16	21
	Negative	10	16	14	3	0
Operator C	Positive	0	0	1	18	21
	Negative	10	16	13	1	0
%Agreement among Positives is 96.7%						
%Agreement among Negatives is 97.5%						
PY 500						
Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	1	16	22
	Negative	10	16	13	2	0
Operator B	Positive	0	0	1	17	22
	Negative	10	16	13	1	0
Operator C	Positive	0	0	0	16	22
	Negative	10	16	14	2	0
%Agreement among Positives is 95.8%						
%Agreement among Negatives is 98.3%						
TCA 1000						
Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	16	22
	Negative	10	15	15	2	0
Operator B	Positive	0	0	1	18	22
	Negative	10	15	14	0	0
Operator C	Positive	0	0	2	18	22
	Negative	10	15	13	0	0
%Agreement among Positives is 98.3%						
%Agreement among Negatives is 97.5%						
THC 25						
Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	1	16	22
	Negative	10	16	13	2	0
Operator B	Positive	0	0	1	17	22
	Negative	10	16	13	1	0
Operator C	Positive	0	0	0	15	22
	Negative	10	16	14	3	0
%Agreement among Positives is 95%						
%Agreement among Negatives is 98.3%						
THC 50						
Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	1	16	22
	Negative	10	16	13	2	0
Operator B	Positive	0	0	1	17	22
	Negative	10	16	13	1	0
Operator C	Positive	0	0	0	15	22
	Negative	10	16	14	3	0
%Agreement among Positives is 95%						
%Agreement among Negatives is 98.3%						
THC 200						
Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	2	19	21
	Negative	10	14	14	0	0
Operator B	Positive	0	0	0	18	21
	Negative	10	14	16	1	0
Operator C	Positive	0	0	0	17	21
	Negative	10	14	16	2	0
%Agreement among Positives is 97.5%						
%Agreement among Negatives is 98.3%						
TIA 500						
Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	0	18	22
	Negative	10	14	16	0	0
Operator B	Positive	0	0	2	18	22
	Negative	10	14	14	0	0
Operator C	Positive	0	0	0	18	22
	Negative	10	14	16	0	0
%Agreement among Positives is 100%						
%Agreement among Negatives is 98.3%						
TRA 100						
Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	2	19	21
	Negative	10	16	12	0	0
Operator B	Positive	0	0	0	16	21
	Negative	10	16	14	3	0
Operator C	Positive	0	0	1	18	21
	Negative	10	16	13	1	0
%Agreement among Positives is 96.7%						
%Agreement among Negatives is 97.5%						
XYL 1000						
Serenity Cup		Drug-Free	Low Negative (less than -50%)	Near Cutoff Negative (Between -50% and the Cutoff)	Near Cutoff Positive (Between the cutoff and +50%)	High Positive (greater than +50%)
Operator A	Positive	0	0	1	18	22
	Negative	10	16	13	0	0
Operator B	Positive	0	0	1	18	22
	Negative	10	16	13	0	0
Operator C	Positive	0	0	0	17	22
	Negative	10	16	14	1	0
%Agreement among Positives is 99.2%						
%Agreement among Negatives is 98.3%						

2. Analytical Sensitivity and Precision

Total 450 samples equally distributed at concentrations of concentrations of -100% cutoff, -75% cut off, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff, +75% cutoff and +100% cutoff were tested using three different lots of each device by three different operators. This study is performed 2 runs/day and lasts 25 days for each format with three lots. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Benzoylecgonine, Ethyl Glucuronide, Norfentanyl, Gabapentin, Synthetic Cannabinoid, Ketamine, Mitragynine, Methylenedioxymethamphetamine, Methamphetamine, Methadone, 6-Monoacetylmorphine, Morphine, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, Marijuana, Tianeptine, Tramadol and Xylazine. The cut-off value for the device is verified.
“+25% cutoff ” sample where it is observed that the positive concordance rate exceeds 90%, “+50% cutoff, +75% cutoff and +100% cutoff” sample where it is observed that the results were all positive, the results for “Cutoff” sample where it is observed that the positive result was about 50%, “-25% cutoff ” sample where it is observed that the negative concordance rate exceeds 90%,the results for “-100% cutoff, -75% cut off, -50% cutoff” sample where it is observed that the result were all negative. It indicates that the precision of the Serenity Multi-Drug Urine Test Cup is good.

The results are given below:

Drugs	Concentration (ng/mL)	n	Lot1		Lot2		Lot3	
			-	+	-	+	-	+
AMP 1000	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	25	25	27	23	24	26
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
BAR 300	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	23	27	22	28	26	24
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
BUP 10	0	50	50	0	50	0	50	0
	2.5	50	50	0	50	0	50	0
	5	50	50	0	50	0	50	0
	7.5	50	50	0	50	0	50	0
	10	50	23	27	26	24	25	25
	12.5	50	0	50	0	50	0	50
	15	50	0	50	0	50	0	50
	17.5	50	0	50	0	50	0	50
	20	50	0	50	0	50	0	50
BZO 300	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	24	26	25	25	27	23
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
COC 300	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0

	300	50	27	23	26	24	24	26
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
EtG 300	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	25	25	26	24	28	22
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
FYL 20	0	50	50	0	50	0	50	0
	5	50	50	0	50	0	50	0
	10	50	50	0	50	0	50	0
	15	50	50	0	50	0	50	0
	20	50	25	25	26	24	23	27
	25	50	0	50	0	50	0	50
	30	50	0	50	0	50	0	50
	35	50	0	50	0	50	0	50
	40	50	0	50	0	50	0	50
GAB 1000	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	24	26	23	27	25	25
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
K2 50	0	50	50	0	50	0	50	0
	12.5	50	50	0	50	0	50	0
	25	50	50	0	50	0	50	0
	37.5	50	48	2	47	3	50	0
	50	50	23	27	27	23	26	24
	62.5	50	3	47	0	50	2	48
	75	50	0	50	0	50	0	50
	87.5	50	0	50	0	50	0	50
	100	50	0	50	0	50	0	50
KET 1000	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	25	25	27	23	24	26
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
KRA 500	0	50	50	0	50	0	50	0
	125	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	375	50	50	0	50	0	50	0
	500	50	25	25	28	22	26	24
	625	50	0	50	0	50	0	50
	750	50	0	50	0	50	0	50
	875	50	0	50	0	50	0	50
	1,000	50	0	50	0	50	0	50
MDMA 500	0	50	50	0	50	0	50	0
	125	50	50	0	50	0	50	0

	250	50	50	0	50	0	50	0
	375	50	50	0	50	0	50	0
	500	50	24	26	22	28	25	25
	625	50	0	50	0	50	0	50
	750	50	0	50	0	50	0	50
	875	50	0	50	0	50	0	50
	1,000	50	0	50	0	50	0	50
MET 1000	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	26	24	24	26	23	27
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
MTD 300	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	24	26	27	23	22	28
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
6-MAM 10	0	50	50	0	50	0	50	0
	2.5	50	50	0	50	0	50	0
	5	50	50	0	50	0	50	0
	7.5	50	46	4	47	3	47	3
	10	50	23	27	25	25	25	25
	12.5	50	2	48	3	47	2	48
	15	50	0	50	0	50	0	50
	17.5	50	0	50	0	50	0	50
	20	50	0	50	0	50	0	50
OPI 300	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	25	25	26	24	22	28
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
OPI 2000	0	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	1,000	50	50	0	50	0	50	0
	1,500	50	50	0	50	0	50	0
	2,000	50	23	27	24	26	27	23
	2,500	50	0	50	0	50	0	50
	3,000	50	0	50	0	50	0	50
	3,500	50	0	50	0	50	0	50
	4,000	50	0	50	0	50	0	50
OXY 100	0	50	50	0	50	0	50	0
	25	50	50	0	50	0	50	0
	50	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	100	50	27	23	23	27	26	24
	125	50	0	50	0	50	0	50
	150	50	0	50	0	50	0	50
	175	50	0	50	0	50	0	50
	200	50	0	50	0	50	0	50

PCP 25	0	50	50	0	50	0	50	0
	6.25	50	50	0	50	0	50	0
	12.5	50	50	0	50	0	50	0
	18.75	50	50	0	50	0	50	0
	25	50	26	24	24	26	22	28
	31.25	50	0	50	0	50	0	50
	37.5	50	0	50	0	50	0	50
	43.75	50	0	50	0	50	0	50
	50	50	0	50	0	50	0	50
PPX 300	0	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	225	50	50	0	50	0	50	0
	300	50	25	25	28	22	26	24
	375	50	0	50	0	50	0	50
	450	50	0	50	0	50	0	50
	525	50	0	50	0	50	0	50
	600	50	0	50	0	50	0	50
PY 500	0	50	50	0	50	0	50	0
	125	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	375	50	50	0	50	0	50	0
	500	50	25	25	24	26	22	28
	625	50	3	47	2	48	3	47
	750	50	0	50	0	50	0	50
	875	50	0	50	0	50	0	50
	1,000	50	0	50	0	50	0	50
TCA 1000	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	27	23	24	26	22	28
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50
THC 25	0	50	50	0	50	0	50	0
	6.25	50	50	0	50	0	50	0
	12.5	50	50	0	50	0	50	0
	18.75	50	30	20	32	18	29	21
	25	50	26	24	24	26	22	28
	31.25	50	10	40	12	38	13	37
	37.5	50	0	50	0	50	0	50
	43.75	50	0	50	0	50	0	50
	50	50	0	50	0	50	0	50
THC 50	0	50	50	0	50	0	50	0
	12.5	50	50	0	50	0	50	0
	25	50	50	0	50	0	50	0
	37.5	50	50	0	50	0	50	0
	50	50	23	27	27	23	26	24
	62.5	50	0	50	0	50	0	50
	75	50	0	50	0	50	0	50
	87.5	50	0	50	0	50	0	50
	100	50	0	50	0	50	0	50
THC 200	0	50	50	0	50	0	50	0
	50	50	50	0	50	0	50	0
	100	50	50	0	50	0	50	0
	150	50	50	0	50	0	50	0
	200	50	24	26	26	24	26	24
	250	50	0	50	0	50	0	50
	300	50	0	50	0	50	0	50

	350	50	0	50	0	50	0	50
	400	50	0	50	0	50	0	50
TIA 500	0	50	50	0	50	0	50	0
	125	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	375	50	50	0	50	0	50	0
	500	50	25	25	23	27	25	25
	625	50	0	50	0	50	0	50
	750	50	0	50	0	50	0	50
	875	50	0	50	0	50	0	50
	1,000	50	0	50	0	50	0	50
TRA 100	0	50	50	0	50	0	50	0
	25	50	50	0	50	0	50	0
	50	50	50	0	50	0	50	0
	75	50	50	0	50	0	50	0
	100	50	24	26	27	23	25	25
	125	50	0	50	0	50	0	50
	150	50	0	50	0	50	0	50
	175	50	0	50	0	50	0	50
	200	50	0	50	0	50	0	50
XYL 1000	0	50	50	0	50	0	50	0
	250	50	50	0	50	0	50	0
	500	50	50	0	50	0	50	0
	750	50	50	0	50	0	50	0
	1,000	50	27	23	24	26	23	27
	1,250	50	0	50	0	50	0	50
	1,500	50	0	50	0	50	0	50
	1,750	50	0	50	0	50	0	50
	2,000	50	0	50	0	50	0	50

3. Analytical Specificity

Drug	Concentration (ng/mL)	% Cross- Reactivity
AMP 1000		
d-Amphetamine	1,000	100%
l-Amphetamine	100,000	--
dl- Amphetamine	3,000	33.30%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	1,000	100%,
Phentermine	6,000	16.70%
Hydroxyamphetamine	100,000	--
d-Methamphetamine	100,000	--
l-Methamphetamine	100,000	--
(+/-)3,4-Methylenedioxyethylamphetamine(MDE)	100,000	--
(+/-)3,4-Methylenedioxymethamphetamine(MDMA)	100,000	--
β-Phenylethylamine	100,000	--
Tyramine	100,000	--
p-Hydroxynorephedrine	100,000	--
Phenylpropanolamine	100,000	--
(±)Phenylpropanolamine	100,000	--
p-Hydroxyamphetamine	100,000	--
d/l-Norephedrine	100,000	--
Benzphetamine	100,000	--
l-Ephedrine	100,000	--
l-Epinephrine	100,000	--
d/l-Epinephrine	100,000	--
BAR 300		
Secobarbital	300	100%
Amobarbital	300	100%
Alphenol	600	50%
Aprobarbital	200	150%
Butabarbital	100	300%
Butethal	200	150%
Butalbital	2,000	15%
Cyclopentobarbital	400	75%
Pentobarbital	200	150%
Phenobarbital	200	150%
BUP 10		
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	15	67%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	200	5%
Morphine	100,000	--
Oxymorphone	100,000	--
Hydromorphone	100,000	--
BZO 300		
Oxazepam	300	100%
Alprazolam	190	157.90%
a-Hydroxyalprazolam	300	100%
Bromazepam	500	60%
Chlordiazepoxide	1,500	20%
Clobazam	110	272.70%
Clonazepam	100,000	--
Clorazepate dipotassium	300	100%
Delorazepam	100,000	--
Desalkylflurazepam	200	150%
Diazepam	190	157.90%
Estazolam	5,000	6%
Flunitrazepam	400	75%
Midazolam	2,200	13.60%
Nitrazepam	200	150%
Norchlordiazepoxide	800	37.50%
Nordiazepam	150	200%
Temazepam	100	300%
Triazolam	6,000	5%
Demoxepam	2,000	15%
Flurazepam	100,000	--
D,L-Lorazepam	75,000	4%
COC 300		
Benzoylecgonine	300	100%
Cocaine	780	38.50%
Cocaethylene	12,500	2.40%
Ecgonine	32,000	0.90%
Ecgonine methyl ester	100,000	0.30%
Norcocaine	100,000	0.30%
EtG 300		
Ethyl- β -D-Glucuronide	300	100%
FYL 20		
Norfentanyl	20	100%
Fentanyl	200	10%
GAB 1000		
Gabapentin	1,000	100%
Pregabalin	17,000	5.88%
K2 50		
JWH 073 4-butanoic acid	50	100%
JWH 018 5-pentanoic acid	50	100%
JWH-073 4-Hydroxybutyl metabolite	200	25%
JWH-018 N-(4-hydroxypentyl) metaboliteS-025	200	25%
JWH-018 5-Hydroxypentyl metabolite	250	20%
JWH-018 (Spice Cannabinoid)	80,000	--
KET 1000		
Ketamine	1,000	100%
Norketamine	3,000	33.33%
KRA 500		
Mitragynine	500	100%
7-hydroxymitragynine	1,000	50%
MDMA 500		
3,4 -Methylenedioxymethamphetamine (MDMA)	500	100%
3,4 -Methylenedioxyamphetamine HCl (MDA)	4,000	12.50%
3,4 -Methylenedioxyethylamphetamine (MDE)	400	125%
d -methamphetamine	100,000	--
d -amphetamine	100,000	--
l-methamphetamine	100,000	--
l- amphetamine	100,000	--
MET 1000		
D(+)-Methamphetamine	1,000	100%
(+/-)3,4-Methylenedioxy-methylamphetamine (MDE)	25,000	4%
D/L-Methamphetamine	1,000	100%
p-Hydroxymethamphetamine	30,000	3.30%
D-Amphetamine	100,000	--
L-Amphetamine	100,000	--
Chloroquine	50,000	2%
(+/-)-Ephedrine	100,000	--
(-)-Methamphetamine	100,000	--
(+/-)3,4-Methylenedioxyamphetamine (MDA)	100,000	--
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	8,000	12.50%
b-Phenylethylamine	50,000	2%
Trimethobenzamide	20,000	5%
d,l-Amphetamine	100,000	--
Mephentermine	50,000	2%
(1R,2S)-(-)-Ephedrine	100,000	--
l-phenylephrine	100,000	--
L-Methamphetamine	100,000	--
MTD 300		
Methadone	300	100%
Doxylamine	100,000	--
EDDP	100,000	--
EMDP	100,000	--
LAAM	100,000	--
Alpha Methadol	100,000	--
6-MAM 10		
6-Monoacethylmorphine	10	100%
Morphine	75,000	--
Buprenorphine	100,000	--
Codeine	100,000	--
Heroin	40	25%
Dihydrocodeine	100,000	--
Ethylmorphine	100,000	--
Hydromorphone	100,000	--
Hydrocodone	100,000	--
Morphine-3- β -D-glucuronide	100,000	--
Thebaine	100,000	--
OPI 300		
Morphine	300	100%
Normorphine	300	100%
Codeine	300	100%
s-Monoacetylmorphine	300	100%
Ethyl Morphine	200	150%
Heroin	300	100%
Hydrocodone	700	43%
Hydromorphone	200	150%
Morphinie-3- β- d- glucuronide	1,000	30%
Oxycodone	100,000	--

Oxymorphone	100,000	--
Thebaine	20,000	2%
Levorphanol	10,000	3%
6-Monoacetylmorphine (6-MAM)	300	100%
Norcodeine	6,250	5%
Procaine	100,000	--
OPI 2000		
Morphine	2,000	100%
Normorphine	50,000	4%
Codeine	2,000	100%
s-Monoacetylmorphine	2,000	100%
Ethyl Morphine	1,500	133.30%
Heroin	2,000	100%
Hydrocodone	12,500	16%
Hydromorphone	3,500	57.10%
Morphinie-3-β-d-glucuronide	2,000	100%
Oxycodone	25,000	8%
Oxymorphone	25,000	8%
Thebaine	50,000	4%
Levorphanol	75,000	2.70%
6-Monoacetylmorphine (6-MAM)	2,000	100%
Norcodeine	12,500	16%
Procaine	100,000	--
OXY 100		
Oxycodone	100	100%
Dihydrocodeine	20,000	0.50%
Hydrocodone	80	125%
Oxymorphone	1,000	10%
Codeine	100,000	--
Hydromorphone	36,000	0.28%
Morphine	100,000	--
Acetylmorphine	100,000	--
Buprenorphine	100,000	--
Ethylmorphine	100,000	--
Thebaine	100,000	--
PCP 25		
Phencyclidine	25	100%
4 -Hydroxyphencyclidine	12,500	0.20%
PPX 300		
d-Propoxyphene	300	100%
d-Norpropoxyphene	300	100%
PY 500		
Psilocin	500	100%
TCA 1000		
Nortriptyline	1,000	100%
Nordoxepine	1,000	100%
Trimipramine	3,000	33.30%
Amitriptyline	450	222.20%
Promazine	1,500	66.7%
Desipramine	200	500%
Imipramine	80	1250%
Clomipramine	1,200	83.30%
Doxepin	2,000	50%
Maprotiline	2,000	50%
Promethazine	100,000	--
Cyclobenzaprine	800	125%
Norclomipramine	12,500	8%
THC 25		
11-nor-Δ^9-THC-9 COOH	25	100%
(-)-11-nor-9-carboxy-Δ^9 -THC	25	100%
11-nor-Δ^8-THC-9-COOH	25	100%
11-nor-Δ^9-THC-carboxy glucuronide	50	50%
Cannabidiol	50,000	--
Cannabinol	50,000	--
Δ^8- Tetrahydrocannabinol	7,500	0.50%
Δ^9- Tetrahydrocannabinol	7,500	0.50%
11-hydroxy-Δ^9-Tetrahydrocannabinol	2,500	1%
THC 50		
11-nor-Δ^9-THC-9 COOH	50	100%
(-)-11-nor-9-carboxy-Δ^9 -THC	50	100%
11-nor-Δ^8-THC-9-COOH	50	100%
11-nor-Δ^9-THC-carboxy glucuronide	100	50%
Cannabidiol	100,000	--
Cannabinol	100,000	--
Δ^8- Tetrahydrocannabinol	15,000	0.50%
Δ^9- Tetrahydrocannabinol	15,000	0.50%
11-hydroxy-Δ^9-Tetrahydrocannabinol	5,000	1%
THC 200		
11-nor-Δ^9-THC-9 COOH	200	100%
(-)-11-nor-9-carboxy-Δ^9 -THC	200	100%
11-nor-Δ^8-THC-9-COOH	200	100%
11-nor-Δ^9-THC-carboxy glucuronide	400	50%
Cannabidiol	100,000	--
Cannabinol	100,000	--
Δ^8- Tetrahydrocannabinol	60,000	0.50%
Δ^9- Tetrahydrocannabinol	60,000	0.50%
11-hydroxy-Δ^9-Tetrahydrocannabinol	20,000	1%
TIA 500		
Tianeptine	500	100%
Tianeptine Metabolite MC5 Sodium Salt	1,500	33.33%
TRA 100		
Tramadol	100	100%
XYL 1000		
Xylazine	1,000	100%
Lidocaine	100,000	--

4. Effect of Specific Gravity

Eight urine specimens of normal, high, and low specific gravity ranges from 1.000 to 1.035 were spiked with -25% Cutoff and +25% Cutoff of drugs. The Serenity Multi-Drug Urine Test Cup was tested using the eight neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

5. Effect of Urinary pH

The pH of an aliquot negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with -25% Cutoff and +25% Cutoff of drugs. The spiked, pH-adjusted urine was tested with the Serenity Multi-Drug Urine Test Cup. The results demonstrate that varying ranges of pH does 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 positive urine. The following compounds show no cross-reactivity when tested with the Serenity Multi-Drug Urine Test Cup at a concentration of 100 µg/mL, and no interference for albumin at 100mg/dL and no interference for ethanol at 1%.

NON CROSS-REACTIVITY

Acetaminophen
Acetophenetidin
Acetylsalicylic Acid
Acyclovir
Afrin
Aminophylline
Aminopyrine
Amiodarone Hydrochloride
Amlodipine Mesylate
Amoxicillin
Ampicillin
Enalapril Maleate
Erythromycin
Esomeprazole Magnesium
β-Estradiol
Fenofibrate
Fenoprofen
Fluoxetine Hydrochloride
Effexor
Fluvoxamine
Furosemide
Oxymetazoline
Norethindrone
N-Acetylprocain-amide
O-Hydroxyhippuric Acid
Olanzapine
Omeprazole
Oxalic Acid
Oxolinic Acid
Ondansetran
Paliperidone
Pantoprazole
Papaverine
Apomorphine
Aripiprazole
Aspartame
Atomoxetine
Atorvastatin Calcium
Atropine
Benzilic Acid
Benzoic Acid
Bilirubin
Bupropion
Captopril
Carbamazepine
Cefradine
Cephalexin
Chloral Hydrate
Chloramphenicol
Chlorothiazide
Cholesterol
Ciprofloxacin Hydrochloride
Citalopram
Clarithromycin
Clonidine
Clopidogrel Hydrogen Sulphate
Clozapine
Conjugated Estrogens
Cortisone
Creatinine
(-) Cotinine
chlorpheniramine
D,L-Octopamine
D,L-Propranolol
D,L-Tyrosine
Deoxy- corticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Dirithromycin
Domperidone
D-Pseudoephedrine
Duloxetine
Dicyclomine
Gentisic Acid
Glibenclamide
Gliclazide
Glipizide
Glucose
Haloperidol
Hemoglobin
Hydrochlorothiazide
Hydrocortisone
3-Hydroxytyramine
Isosorbide Dinitrate
Isoxsuprine
Ibuprofen
Ketoconazole
Ketoprofen
Labetalol
Lamotrigine
Levofloxacin Hydrochloride
Levonorgestrel
Levothyroxine Sodium
Lidocaine Hydrochloride
Lisinopril
Lithium Carbonate
Liverite
Loperamide
Loratadine
Magnesium
Meperidine
Meprobamate
Metoprolol Tartrate
Mifepristone
Mirtazapine
Montelukast Sodium
Mosapride Citrate
Minocycline
Nalidixic Acid
Naproxen
Niacinamide
Nifedipine
Nikethamide
Nimodipine
Nitroglycerin
Paroxetine Hydrochloride
Penfluridol
PenicillinV Potassium
Penicillin-G
Phenelzine
Pioglitazone Hydrochloride
Piracetam
Pravastatin Sodium
Prednisone
Propylthiouracil
Quetiapine Fumarate
Quinine
Ranitidine
Rifampicin
Risperidone
Salicylic Acid
Serotonin
Sertraline Hydrochloride
Sildenafil Citrate
Simvastatin
Sodium Valproate
Spironolactone
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortsone 3 -acetate
Tetrahydrocortisone 3- (β-D glucuronide)
Tetrahydrocortisone 3- (β-D glucuronide)-
Tetrahydrozoline
Thiamine
Thioridazine
Topiramate
Tramadol Hydrochloride
Trazodone Hydrochloride
Triamterene
Trifluoperazine
Trimethoprim
Uric Acid
Valproate
Verapamil
Vitamin B2
Vitamin C

REFERENCES

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3. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
30°C 86°F 2°C 35.6°F	Storage temperature limitations		Manufacturer		Do not reuse

Manufactured for:
Slash Medical
801 N Congress Ave, Unit 101
Boynton Beach, FL 33426, United States
Customer Service Phone: 1-561-879-7735
Service Hours: Monday through Friday 9:00 AM to 5:00 PM EST

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