



C-Cup Multi-Drug Urine Test Cup

Catalogue No. See Box Label

The SAFElife® C-Cup Multi-Drug Urine Test Cup contains competitive binding lateral flow immunochromatographic assays for qualitative and simultaneous detection of 6-Monocetyl morphine, Amphetamine, Sebacobarbit, Buprenorphine, Oxycodone, Cocaine, Cotinine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Ethyl Glucuronide, Fentanyl, Gabapentin, Hydroxymorphine, Synthetic Cannabinoids, Ketamine, Kratom, Lysergic acid diethylamide, Methyleneoxyamphetamines, Morphine, Methadone, Methaqualone, Oxycodone, Oxycodone, Phencyclidine, Pregabalin, Propoxyphene, Nortriptyline, Cannabinoids, Tramadol and Alcohol in human urine with below cutoff concentrations and approximate detection time:

Table with columns: Drug (Identifier), Calibrator, Cut-off Level, Minimum Detection Time, Maximum Detection Time. Lists various substances like 6-Monocetyl morphine, Amphetamine, Cocaine, etc. with their respective test parameters.

Configurations of the SAFElife® C-Cup Multi-Drug Urine Test Cup can consist of any combination of the above listed drug analytes.

It is not intended to distinguish between prescription use or abuse of these drugs. Professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method may be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method.

- Warnings and Precautions: 1. The test kit is for external use only. 2. Discard after first use. 3. Do not use the test kit beyond expiration date. 4. Do not use the test kit if the pouch is punctured or not well sealed. 5. Keep out of the reach of children.

CONTENTS OF THE KIT

- 25 SAFElife® C-Cup Multi-Drug Urine Test Cups, each in one pouch with desiccant. The desiccants are for storage purposes only and are not used in the test procedure.
One (1) Package Insert
5 Adulteration/Control Comparison Cards (If equipped)
25 Security Seals
25 Pieces of Gloves

MATERIAL REQUIRED BUT NOT PROVIDED

Timer or Clock

STORAGE AND STABILITY

Store at 39°F-86°F (4°C-30°C) in the sealed pouch up to the expiration date. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE.

SPECIMEN COLLECTION

WHEN TO COLLECT URINE FOR THE TEST?

Collect urine specimen after minimum detection time following suspected drug use. Urine collection time is very important in detecting any drugs of abuse. Each drug is cleared by the body and is detected in the urine at different times and rates. Please refer to the minimum or maximum detection time of each drug in this instruction.

HOW TO COLLECT URINE?

- Remove the test cup from the foil pouch by tearing at the notch. Use it as soon as possible. Instruct the donor to remove the test cup lid and void directly into the test cup until reach the Minimum Urine Volume.
Observe the temperature strip affixed on the top of the cup 2 minutes after the urine is voided into the cup. The temperature between 90°F - 100°F (32°C - 38°C) indicates the fresh uncontaminated specimen. If the temperature is out of this range, instruct the donor to provide urine specimen again with another new test cup.

TEST PROCEDURE

- Test should be performed at room temperature 65°F-86°F (18°C-30°C).
Peel off the label from right to left.
For the adulteration strip(s) if equipped, read results immediately, or at 30 seconds, or at 45 seconds and compare each adulterant pad to verify pad color is within acceptable range according to the Adulteration Color Comparison Card.



READING THE RESULTS

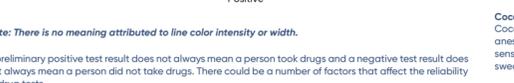
DRUG TEST:

Negative (-): A colored band is visible in each Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary Positive (+)

A colored band is visible in each Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid: If a colored band is not visible in each of the Control Region (C) or a colored band is only visible in the Test Region (T), the test result is invalid. Another test should be performed. If the test result is invalid, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number of the test.



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

A preliminary positive test result does not always mean a person took drugs and a negative test result does not always mean a person did not take drugs. There could be a number of factors that affect the reliability of drug tests.

ALCOHOL TEST:

Negative (-): Almost no color change on test pad in comparison with the provided colored chart. The negative result indicates that the concentration of ethyl alcohol in urine is less than 0.04 g/dL.

Preliminary Positive (+)

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

Approximate Alcohol Concentration

Table showing approximate alcohol concentration ranges: 0.0 mg/100 mL (0.04%), 40 mg/100 mL (0.08%), 80 mg/100 mL (0.16%), 200 mg/100 mL (0.2%).

Invalid

The test should be considered invalid if only the edge of the reaction pad turned color that might be ascribed to insufficient sampling. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor, with the lot number.

What is the False Positive Test?

The definition of the false positive test would be an instance where a substance is identified incorrectly by the SAFElife® C-Cup Multi-Drug Urine Test Cup. The most common causes of the false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause the false positive test result.

What is the False Negative Test?

The definition of the false negative test is that the initial drug is present but isn't detected by the SAFElife® C-Cup Multi-Drug Urine Test Cup. If the specimen is diluted or adulterated, it may cause false negative result.

What is the False Negative Test?

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TEST LIMITATIONS

- This test kit has been developed for testing urine specimen only. No other fluids have been evaluated.
This test kit is not intended for use on adulterated urine specimens.
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SUMMARY

6-Monocetyl morphine (6-MAM) Heroin is rapidly metabolized in the body. The half-life in blood is only 3-9 minutes. It is degraded by esterase in the body to 6-monocetyl morphine (hereinafter abbreviated as 6-MAM) and the molecular formula is C21H27NO2. 6-MAM is decarboxylated in the body to form morphine, and morphine cannot be acetylated to form 6-MAM in vivo. 6-MAM in the human body is only derived from the metabolism of heroin. Therefore, the U.S. Department of Health and Human Services (DHHS) recommended 6-monocetyl morphine as a specific test for heroin abuse.

Amphetamine (AMP) Amphetamine and the structurally related "designer" drugs are sympathomimetic amines whose biological effects include potent central nervous system (CNS) stimulation, anorectic, hyperthermic, and cardiovascular stimulant effects. Amphetamine is absorbed from the gastrointestinal tract and is then either excreted unchanged in the urine with a half-life of about 12 hours. It can be detected in the urine for 1 to 2 days after use.

Sebacobarbit (BAR) Barbiturates are a class of central nervous system depressants. They have a wide range of half-life of 2 to 40 hours and can be detected in the urine for 1 to 4 days after use. Phenobarbital is a long acting barbiturate derivative that has been used as a daytime sedative and very extensively as an anticonvulsant. Phenobarbital and sebacobarbit are two examples of a short acting barbiturate sedative. Abuse of barbiturates can lead not only to impaired motor coordination and mental disorder, but also to respiratory collapse, coma and even death.

Buprenorphine (BUP) Buprenorphine is a partial analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex®, Buprenex®, Temgesic® and Suboxone®, all of which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. A 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. The plasma half-life of Buprenorphine is 2-4 hours. While complete elimination of a single dose of the drug can take as long as 6-9 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

Oxycodone (OXO) Benzodiazepines are the most widely used anxiolytic drugs. They are used extensively as anti-anxiety agents, hypnotics, muscle relaxants and anti-convulsants. They are taken orally or sometimes by injection and have a wide range of half-life from 2 to 40 hours. They can generally be detected for 1 to 2 days after Benzodiazepines use. Benzodiazepines are metabolized in the liver. Some Benzodiazepines and their metabolites are excreted in the urine. Their use can result in drowsiness and/or confusion. Benzodiazepines potentiate alcohol and other CNS depressants. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period.

Cocaine (COC) Cocaine derived from leaves of coca plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in urine primarily as benzoylecgonine in a short period of time.

Morphine (MOP/OP) The opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. The principal metabolites of opiates are morphine, morphine-3-glucuronide normorphine and codeine with a half-life of about 3 hours. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might also be found in the urine of persons who have taken only heroin patches or gums. It is an addictive substance and is poisonous in a large amount. In addition to addiction, some of the other substances within tobacco products, such as carbon monoxide or tar, are dangerous to the body and can lead to medical conditions such as emphysema, lung cancer, and heart disease. In a 24-hour urine, approximately 5% of a nicotine dose is unchanged drug in the urine. The body also excretes about 5% as hydroxycotinine. The concentrations of other metabolites are believed to account for less than 5%. While Cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of Nicotine which is largely urine PH dependent. Cotinine is stable in body fluids and has a relatively long half-life of approximately 17 hours, and is typically detectable for several days after the use of tobacco. The excreted in the urine and metabolized in the liver and excreted in the urine. Cotinine is less dependent on the time of sampling than that of Nicotine. 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.

EDDP

EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine) is the primary metabolite of methadone. Methadone is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. The detection of EDDP is more beneficial than traditional methadone screening since EDDP exists only in urine and is not metabolized to other substances. The tapering and withdrawal of methadone, and methadone with methadone can be ingested. Secondly, renal clearance of EDDP is not affected by urine pH, therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone parent screening.

Ethyl Glucuronide (EtG)

Ethyl Glucuronide is a direct metabolite of alcohol. Presence in urine may be used to detect recent alcohol intake, even after alcohol is no longer measurable. Traditional laboratory methods detect the actual alcohol in the body, which reflects current intake within the past few hours (depending on how much was consumed). The presence of EtG is a definitive indicator that alcohol can be detected in the urine for 2 to 4 days after drinking alcohol, even alcohol is eliminated from the body. Therefore, EtG is a more accurate indicator of the recent intake of alcohol than measuring for the presence of alcohol itself. The EtG test can aid in the diagnosis of drunk driving and alcoholism, which has important significance in the forensic identification and medical examination.

Fentanyl (FTY)

Fentanyl is a potent, synthetic narcotic analgesic with a rapid onset and short duration of action. It was first synthesized by Janssen Pharmaceutics (Belgium) in the late 1950s, and it is approximately 100 times more potent than morphine. Fentanyl is a strong agent at the u-opioid receptor. Historically it has been used to break through pain and is commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with a benzodiazepine. Fentanyl is frequently given intrathecally as part of spinal anesthesia or epidurally for epidural anesthesia and analgesia.

Gabapentin (GAB)

Gabapentin (GAB), sold under the brand name Neurontin, is a medication used to treat epilepsy, neuropathic pain, hot flashes, and restless legs syndrome. In epilepsy, it may be used for those with partial onset of nocturnal seizures. It is also used for the treatment of trigeminal neuralgia, and neuropathic pain in diabetic neuropathy, postherpetic neuralgia, and central neuropathic pain. It is also used to relieve nerve pain following shingles (a painful rash due to herpes zoster infection) in adults. The most common side effects of gabapentin include dizziness, fatigue, drowsiness, ataxia, peripheral edema (swelling of extremities), myalgias, and tremor. Serious side effects may include an increased risk of suicide, aggressive behavior, and drug reaction with eosinophilia and systemic symptoms.

Hydromorphone (HMO)

Hydromorphone, also known as dihydromorphone or dihydromorphone, is a semi-synthetic strong analgesic and opioid-like narcotic analgesic. It is similar to morphine, and its side effects are lighter than morphine. It is mainly used for relieving medium-intensity pain caused by cancer, postoperative and soft tissue trauma.

Synthetic cannabinoids (K2)

Synthetic cannabinoids are psychoactive designer drugs derived of natural herbs sprayed with synthetic chemicals that, when consumed, allegedly mimic the effects of cannabis. It is best known by the brand names K2 and Spice. Synthetic cannabinoids act on the body in a similar way to cannabinoids naturally found in cannabis. However, unlike natural cannabinoids, synthetic cannabinoids do not produce positive results in drug tests for cannabis. It is possible to detect its metabolites in human urine.

Ketamine (KET)

Ketamine is a sort of medical stupefacient. The principal metabolites are non-ketamine. Smoking, marinating, snuffing, and dissolving into drink or alcohol are the primary method of use of ketamine. Ketamine is usually administered in combination with heroin, marijuana, etc. for the relief of moderate to severe pain. Overdose may cause central nervous system effects, do harm to liver and kidney, and even cause death. Ketamine is metabolized in the liver. Over 70% ketamine metabolites and only 5% original drugs are excreted in the urine. They can generally be detected for 2 to 4 hours after ketamine use.

Kratom (KRA)

Kratom (Mitragyna speciosa) is a plant indigenous to Thailand and Southeast Asia. Kratom leaves produce complex stimulant and opioid-like analgesic effects. In Asia, it is often used to relieve pain and to manage pain, diarrhea, cough, and opioid withdrawal. Recently, kratom has become widely available in the United States and Europe by means of smoke shops and the Internet. The clinical manifestations of kratom are not well defined and studies are limited, but its safety profile has become a national and international concern, primarily due to excessive consumption being linked to increases in hospital visits for hepatic injury, seizures, coma, and death. The main active ingredients include Mitragynine and 7-Hydroxymitragynine, which can be detected in urine up to 72 hrs [1-3].

Lysergic acid diethylamide (LSD)

Lysergic acid diethylamide (LSD) is a white powder or colorless liquid that is a strong semi artificial hallucinogen. LSD is manufactured from Lysergic acid which occurs naturally in the ergot fungus that grows on wheat and rye. It is a schedule I controlled substance, available in liquid, Powder, tablet (microdots), and capsule form. LSD is a non-selective 5-HTagonist, may exert its hallucinogenic effect by interacting with 5-HT2A receptors as a partial agonist and modulating the 5HT2A receptors, producing a marked slowing of the firing rate of serotonergic neurons. LSD can cause the user's senses, feelings, memory, and self-awareness to intensify and change for 6 to 12 hours. In addition to causing mental confusion, LSD can also cause physical pain, with symptoms in the nervous system, cardiovascular, and digestive systems. Most LSD users use marijuana, heroin, or other drugs together.

Methylenedioxyamphetamines (MDMA)

Methylenedioxyamphetamines (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 heart rate, increased blood pressure, and increased body temperature. In combination 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 it is a secondary effect of the drug (Nichols and Oberlander, 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.

Methamphetamine (MET/AMP)

Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychomotor activity may appear at half-life of about 15 hours and is increased in intensity with repeated use. The drug is metabolized in the liver and excreted in the urine. Methamphetamine is excreted unchanged and is metabolized by hydroxylation and/or demethylation. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

Morphine (MOP/OP)

Cotinine (COT) Cotinine is an alkaloid found in tobacco and is also a major metabolite of nicotine, which produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is found in tobacco products such as cigarettes, tobacco pipes or gums. It is an addictive substance and is poisonous in a large amount. In addition to addiction, some of the other substances within tobacco products, such as carbon monoxide or tar, are dangerous to the body and can lead to medical conditions such as emphysema, lung cancer, and heart disease. In a 24-hour urine, approximately 5% of a nicotine dose is unchanged drug in the urine. The body also excretes about 5% as hydroxycotinine. The concentrations of other metabolites are believed to account for less than 5%. While Cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of Nicotine which is largely urine PH dependent. Cotinine is stable in body fluids and has a relatively long half-life of approximately 17 hours, and is typically detectable for several days after the use of tobacco. The excreted in the urine and metabolized in the liver and excreted in the urine. Cotinine is less dependent on the time of sampling than that of Nicotine. Nicotine and Cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200

Methadone (MTD)

Methadone is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver and excreted in the urine. Methadone is metabolized in the liver and excreted in the urine. Methadone is less dependent on the time of sampling than that of Nicotine. Nicotine and Cotinine are rapidly eliminated by the kidney; the window of detection for methadone in urine at a cutoff level of 200

Methaqualone (MQL)

Methaqualone is a sedative that falls outside the benzodiazepine and barbiturate classes. It was once a widely prescribed and recreational drug, but its current use is largely relegated to Africa, particularly South Africa. Because it faced few restrictions when it first entered the market, the drug was widely prescribed and perceived as uniquely safe. We now know methaqualone can be used recreationally and can cause physical dependence. A lot of lore exists around the effects. In reality, it's not a massively unique substance and it can be compared to barbiturates, ethanol, cannabis, and meperidine. Methaqualone is a sedative that can be used to increase the activity of the GABA receptors in the brain and nervous system. When GABA activity is increased, blood pressure drops and the breathing and pulse rates slow, leading to a state of deep relaxation. These properties explain why methaqualone was originally mainly prescribed for insomnia. Methaqualone peaks in the bloodstream within several hours, with a half-life of 20-40 hours. Regular users build up a physical tolerance, requiring larger doses for the same effect. Overdose can lead to nervous system shutdown, coma and death.

Opiate (OP)

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 in the urine 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. The test for Morphine 2000 (OP) of the SAFElife® C-Cup Multi-Drug Urine Test Cup yields a positive result when the morphine in urine exceeds 2000 ng/mL.

Oxycodone (OXY)

Oxycodone is known as Oxycotin and Roxicodone. It is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiates derived from opium. Like other opiates, Oxycodone is characterized by its analgesic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analgesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of Oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and cardiac arrest. Oxycodone is metabolized by H- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. 3 to 6% of a single dose of Oxycodone is excreted in a 24-hour urine collection and consists of 13-19% free Oxycodone, 7-29% glucuronide conjugated Oxycodone, 14-46% glucuronide conjugated Oxycodone and an unknown amount of noroxycodone. The detection time window of Oxycodone is 1-3 days following use.

Phencyclidine (PCP)

Phencyclidine (PCP) Phencyclidine was originally used as an anesthetic agent and a veterinary tranquilizer. Phencyclidine can produce hallucinations, lethargy, disorientation, and other side effects. PCP is a dissociative anesthetic that produces effects similar to those of cocaine, but with more intense and longer-lasting effects. PCP is a dissociative anesthetic that produces effects similar to those of cocaine, but with more intense and longer-lasting effects. PCP is a dissociative anesthetic that produces effects similar to those of cocaine, but with more intense and longer-lasting effects.

Pregabalin (PGB)

Pregabalin (PGB) Pregabalin is a synthetic analogue of gamma-aminobutyric acid (GABA), which is similar to gabapentin in structure and action, and has antiepileptic, analgesic and anxiolytic activities. About 98% of pregabalin is recovered in the urine as the active drug after radiation labeling. Therefore, pregabalin abuse can be determined directly by measuring the amount of pregabalin in urine.

Propoxyphene (PPX)

Propoxyphene, a synthetic opiate agonist, is structurally similar to methadone. Propoxyphene is a narcotic analgesic used to relieve mild to moderate pain. The principal metabolites are norendropropoxyphene. The combination usage of propoxyphene, aspirin, acetaminophen or other sedatives can lead cooperative interaction. Abuse of propoxyphene can lead to nausea, vomiting, constipation, dizziness, blurred vision, poisoning, lung dropsy and even death. Propoxyphene is metabolized in the liver and excreted in urine as norendropropoxyphene. Thus the presence of the propoxyphene or its metabolites in the urine indicates propoxyphene use.

Nortriptyline (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 several times a day. TCAs are metabolized in the liver. The main active ingredients include Amitriptyline and 7-Hydroxymitragynine, which can be detected in urine up to 72 hrs [1-3].

Cannabinoids (THC)

Cannabinoids are hallucinogenic agents derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC & Cannabinol can be metabolized and excreted as 11-nor-9-tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. They can be detected for 1 to 5 days after use. Smoking is the primary method of use of Cannabinoids/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

Tramadol (TRA)

Tramadol (2-(dimethylamino)ethyl-1-(3-methoxyphenyl) cyclohexanol) is used similarly to codeine, to treat moderate to moderately severe pain. It is a synthetic analog of the phenanthrene alkaloid codeine and, as such, is an opioid and also a prodrug (codeine is metabolized to morphine, tramadol is converted to O-desmethyl tramadol). Both tramadol and its metabolite, O-desmethyl tramadol (detemol M), respectively. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% of the dose is excreted as metabolites.

Alcohol (ETOH)

Alcohol Test is intended for use to detect the presence of alcohol in urine greater than 0.04%. Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person's metabolites are excreted in the urine varies with the amount of alcohol consumed. A standard established a BAC of 0.02% (0.02 g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Since the urine alcohol concentration is normally higher than that in saliva and blood, the cutoff concentration for alcohol in urine was set at 0.04%. Normally, it will take at least 30 minutes for the alcohol to be detected in saliva, blood and urine after drinking.

PRINCIPLE

The SAFElife® C-Cup Multi-Drug Urine Test Cup are competitive immunoassays that are used to screen for the presence of drugs of abuse in urine. It is characterized by the use of drugs in a sample competitively combine to a limited number of drug monoclonal antibody (mouse) conjugate binding sites. When the absorbent end is immersed into urine specimen, the urine is absorbed into the device by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored band in the Test Region (T) that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the respective drug monoclonal antibody conjugate preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the Test Region (T), indicating a potentially positive result.

To serve as a procedure control, a colored band will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials. Even though there is an internal procedure control in the test device in the Control Region (C), the use of external controls is strongly recommended as a good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot, each new shipment and each new operator to determine that tests are working properly.

PERFORMANCE CHARACTERISTICS

ADULTERATION CONTROL:

Expected Results

Creatinine (CR): Creatinine reacts with a creatinine indicator in an alkaline medium to form a purplish-brown color complex if creatinine in the urine is present at the normal level. The color intensity is directly proportional to the concentration of creatinine. A urine specimen with creatinine concentration of less than 20 mg/dL produces a very light, or no pad color change, which indicates adulteration in the form of spinal dilution.

Glutaraldehyde (GL):

Glutaraldehyde (GL): Glutaraldehyde is not a natural component of human urine and it should not be present in normal urine. The presence of glutaraldehyde in the urine specimen indicates the possibility of adulteration. However, false positive may result when ketone bodies are present in urine. Ketone bodies may appear in urine when a person is in ketoadiposis, starvation or other metabolic abnormalities.

Nitrite (NI):

Nitrite (NI): Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dL may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. In this adulteration control, nitrite level above 15 mg/dL is considered abnormal.

Oxidants/Bleach (OX):

Oxidants/Bleach (OX): The presence of Bleach and other oxidizing reagents in the urine is indicative of adulteration since oxidizing reagents are not normal constituents of urine. Other oxidizing reagents include Hydrogen Peroxide, Ferricyanide, Persulfate, Pyridinium Chlorochromate, etc.

pH (PH):

pH (PH): Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 8.0 are indicative of adulteration.

Specific Gravity (SG):

Specific Gravity (SG): The specific gravity test is based on the pKa change of certain pre-treated polyelectrolytes in relation to the ionic concentration. The pad colors will change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. A urine specific gravity below 1.003 or above 1.025 is considered abnormal.

DRUG TEST:

Accuracy

Each (eight) of each drug urine specimens were analyzed by GC-MS and by each corresponding drug Free. Test results were read by three viewers. 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:

Table with columns: Drug Test, Result, Free, Less than Half the Cutoff, Near Cutoff Negative (50% below the cutoff and the cutoff), Near Cutoff Positive (Between the cutoff

THC (50)	Viewer C	+	0	0	2	20	20	100% (91.2% - 100%)
	Viewer	-	10	13	15	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	17	18	22	100% (84.5% - 100%)
THC (100)	Viewer A	+	0	0	1	18	0	97.5% (82% - 100%)
	Viewer B	-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
THC (200)	Viewer A	+	0	0	2	19	0	97.5% (82% - 100%)
	Viewer B	-	10	20	9	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	19	20	97.5% (84.5% - 100%)
THC (500)	Viewer A	+	0	0	2	19	21	100% (84.5% - 100%)
	Viewer B	-	10	20	8	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	18	20	95% (84.5% - 100%)
THC (1000)	Viewer A	+	0	0	2	19	21	100% (84.5% - 100%)
	Viewer B	-	10	20	9	1	0	97.5% (79.5% - 100%)
	Viewer C	+	0	0	1	18	20	95% (84.5% - 100%)

Precision and Sensitivity
 To investigate the precision and sensitivity each drug sample was analyzed at the following concentrations: cutoff +75%, cutoff -50%, cutoff +25%, cutoff +50%, cutoff +75% and the cutoff +100%. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots of the corresponding drug test. Totally 3 operators participated in the study of the corresponding drug test. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day), for a total of 50 determinations per concentration per lot of the corresponding drug test.

Drug Test	Approximate Concentration of Sample (ng/mL)	Number of Determinations per Lot	Results		
			Negative		Positive
			Lot 1	Lot 2	Lot 3
6-MAM	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	50/0	50/0	50/0
	12.5	50	50/0	50/0	50/0
	15	50	50/0	50/0	50/0
	17.5	50	50/0	50/0	50/0
	20	50	50/0	50/0	50/0
	22.5	50	50/0	50/0	50/0
	25	50	50/0	50/0	50/0
AMP (300)	225	50	50/0	50/0	50/0
	300	50	5/45	5/45	4/46
	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
	675	50	0/50	0/50	0/50
	750	50	0/50	0/50	0/50
	825	50	0/50	0/50	0/50
	900	50	0/50	0/50	0/50
EDDP (100)	100	50	6/44	5/45	5/45
	125	50	6/44	7/43	6/44
	150	50	0/50	0/50	0/50
	175	50	0/50	0/50	0/50
	200	50	0/50	0/50	0/50
	225	50	0/50	0/50	0/50
	250	50	0/50	0/50	0/50
	275	50	0/50	0/50	0/50
	300	50	0/50	0/50	0/50
	325	50	0/50	0/50	0/50
AMP (1000)	1000	50	0/50	0/50	0/50
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
	2250	50	0/50	0/50	0/50
	2500	50	0/50	0/50	0/50
	2750	50	0/50	0/50	0/50
	3000	50	0/50	0/50	0/50
	3250	50	0/50	0/50	0/50
EDDP (500)	500	50	5/45	5/45	4/46
	750	50	0/50	0/50	0/50
	1000	50	0/50	0/50	0/50
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
	2250	50	0/50	0/50	0/50
	2500	50	0/50	0/50	0/50
	2750	50	0/50	0/50	0/50
EDDP (1000)	1000	50	0/50	0/50	0/50
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
	2250	50	0/50	0/50	0/50
	2500	50	0/50	0/50	0/50
	2750	50	0/50	0/50	0/50
	3000	50	0/50	0/50	0/50
	3250	50	0/50	0/50	0/50

BZO (200)	175	50	0/50	0/50	0/50
	200	50	0/50	0/50	0/50
	225	50	0/50	0/50	0/50
	250	50	0/50	0/50	0/50
	275	50	0/50	0/50	0/50
	300	50	0/50	0/50	0/50
	325	50	0/50	0/50	0/50
	350	50	0/50	0/50	0/50
	375	50	0/50	0/50	0/50
	400	50	0/50	0/50	0/50
BZO (300)	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
	675	50	0/50	0/50	0/50
	750	50	0/50	0/50	0/50
	825	50	0/50	0/50	0/50
	900	50	0/50	0/50	0/50
	975	50	0/50	0/50	0/50
	1050	50	0/50	0/50	0/50
COC (100)	100	50	4/46	4/46	3/47
	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
	225	50	0/50	0/50	0/50
	250	50	0/50	0/50	0/50
	275	50	0/50	0/50	0/50
	300	50	0/50	0/50	0/50
	325	50	0/50	0/50	0/50
COC (150)	150	50	7/43	6/44	7/43
	187.5	50	0/50	0/50	0/50
	225	50	0/50	0/50	0/50
	262.5	50	0/50	0/50	0/50
	300	50	0/50	0/50	0/50
	337.5	50	0/50	0/50	0/50
	375	50	0/50	0/50	0/50
	412.5	50	0/50	0/50	0/50
	450	50	0/50	0/50	0/50
	487.5	50	0/50	0/50	0/50
COC (300)	300	50	0/50	0/50	0/50
	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
	675	50	0/50	0/50	0/50
	750	50	0/50	0/50	0/50
	825	50	0/50	0/50	0/50
	900	50	0/50	0/50	0/50
	975	50	0/50	0/50	0/50
COT (200)	200	50	6/44	4/46	5/45
	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
	450	50	0/50	0/50	0/50
	500	50	0/50	0/50	0/50
	550	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
	650	50	0/50	0/50	0/50
EDDP (500)	500	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
	700	50	0/50	0/50	0/50
	800	50	0/50	0/50	0/50
	900	50	0/50	0/50	0/50
	1000	50	0/50	0/50	0/50
	1100	50	0/50	0/50	0/50
	1200	50	0/50	0/50	0/50
	1300	50	0/50	0/50	0/50
	1400	50	0/50	0/50	0/50
EG (500)	500	50	5/45	4/46	5/45
	600	50	0/50	0/50	0/50
	700	50	0/50	0/50	0/50
	800	50	0/50	0/50	0/50
	900	50	0/50	0/50	0/50
	1000	50	0/50	0/50	0/50
	1100	50	0/50	0/50	0/50
	1200	50	0/50	0/50	0/50
	1300	50	0/50	0/50	0/50
	1400	50	0/50	0/50	0/50
FTY	15	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	50/0	50/0	50/0
	250	50	50/0	50/0	50/0
	300	50	50/0	50/0	50/0
	350	50	50/0	50/0	50/0
	400	50	50/0	50/0	50/0
	450	50	50/0	50/0	50/0
GAB	75	50	46/4	46/4	47/3
	100	50	4/46	4/46	4/46
	125	50	3/47	3/47	2/48
	150	50	0/50	0/50	0/50

HMO	4000	50	0/50	0/50	0/50
	0	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	125	50	50/0	50/0	50/0
	175	50	50/0	50/0	50/0
	225	50	50/0	50/0	50/0
	275	50	50/0	50/0	50/0
	325	50	50/0	50/0	50/0
	375	50	50/0	50/0	50/0
	425	50	50/0	50/0	50/0
K2 JWH-018 Pentanoic Acid	25.0	50	50/0	50/0	50/0
	37.5	50	50/0	50/0	50/0
	50.0	50	50/0	50/0	50/0
	62.5	50	0/50	0/50	0/50
	75.0	50	0/50	0/50	0/50
	87.5	50	0/50	0/50	0/50
	100.0	50	0/50	0/50	0/50
	112.5	50	0/50	0/50	0/50
	125.0	50	0/50	0/50	0/50
	137.5	50	0/50	0/50	0/50
K2 JWH-073 Butanoic Acid	50.0	50	5/45	6/44	5/45
	75.0	50	0/50	0/50	0/50
	100.0	50	0/50	0/50	0/50
	125.0	50	0/50	0/50	0/50
	150.0	50	0/50	0/50	0/50
	175.0	50	0/50	0/50	0/50
	200.0	50	0/50	0/50	0/50
	225.0	50	0/50	0/50	0/50
	250.0	50	0/50	0/50	0/50
	275.0	50	0/50	0/50	0/50
KET (300)	300	50	5/45	5/45	5/45
	375	50	2/48	1/49	3/47
	450	50	0/50	0/50	0/50
	525	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
	675	50	0/50	0/50	0/5