



UScreen Drug Test Cup

Catalogue No. See Box label

For in vitro diagnostic use

The UScreen Drug Test Cup offers qualitative detection of the following drugs of abuse and their principal metabolites in human urine at specified cut-off levels for use in employment and insurance testing: Amphetamine (AMP500), Amphetamine (AMP1000), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC150), Cocaine (COC300), Fentanyl (FTY), Synthetic Cannabinoids (K2), Methylenedioxymethamphetamine (MDMA), Methamphetamine (MET500/mAMP500), Methamphetamine (MET1000/mAMP1000), Opiates 300 (MOP/OPI300), Methadone (MTD), Opiates 2000 (OPI), Oxycodone (OXY), Propoxyphene (PPX), Nortriptyline (TCA), Cannabinoids (THC), Tramadol (TRA).

INTENDED USE

The UScreen Drug Test Cup is a rapid, one-step, lateral flow immunoassay for the visual, qualitative detection of multiple drugs and drug metabolites in human urine, for use in employment and insurance testing.

The various drugs tested and the cutoff levels are listed in the chart below. The UScreen Drug Test Cup has the capacity to test up to 18 drugs, including any combination of drugs listed below. A "Specimen Validity /Adulterant" test strip is also available to test for Oxidants/Bleach, Specific Gravity, Creatinine, PH, Nitrite. The performance data listed in this package insert may or may not be relevant to your particular drug screen cup. Please refer to the box labels and test strip labels on the drug screen cup to determine the drug tests included.

| Drug(Identifier) | Calibrator | Cut-off level | Minimum detection time | Maximum detection time |
|--------------------------------------|---|----------------------|------------------------|------------------------|
| Amphetamine (AMP 500) | d-Amphetamine | 500 ng/mL | 2-7 hours | 1-2 days |
| Amphetamine (AMP 1000) | d-Amphetamine | 1000 ng/mL | 2-7 hours | 1-2 days |
| Secobarbital (BAR) | Secobarbital | 300 ng/mL | 2-4 hours | 1-4 days |
| Buprenorphine (BUP) | Buprenorphine | 10 ng/mL | 4 hours | 1-3 days |
| Oxazepam (BZO) | Oxazepam | 300 ng/mL | 2-7 hours | 1-2 days |
| Cocaine (COC 150) | Benzoylcegonine | 150 ng/mL | 1-4 hours | 2-4 days |
| Cocaine (COC 300) | Benzoylcegonine | 300 ng/mL | 1-4 hours | 2-4 days |
| Fentanyl (FTY) | Norfentanyl | 20 ng/mL | 1-4 hours | 1-3 days |
| Synthetic Cannabinoids (K2) | JWH-018 Pentanoic Acid JWH-073 Butanoic Acid | 50 ng/mL 50 ng/mL | 8-12hours | Up to 5+ days |
| Methylenedioxymethamphetamine (MDMA) | 3,4-Methylenedioxymethamphetamine HCl (MDMA) | 500 ng/mL | 2-7 hours | 2-4 days |
| Methamphetamine (MET500/mAMP500) | D(+)-Methamphetamine | 500 ng/mL | 2-7 hours | 2-4 days |
| Methamphetamine (MET1000/mAMP1000) | D(+)-Methamphetamine | 1000 ng/mL | 2-7 hours | 2-4 days |
| Opiates 300 (MOP/OPI300) | Morphine | 300 ng/mL | 2 hours | 2-3 days |
| Methadone (MTD) | Methadone | 300 ng/mL | 3-8 hours | 1-3 days |
| Opiates 2000 (OPI) | Morphine | 2000 ng/mL | 2 hours | 2-3 days |
| Oxycodone (OXY) | Oxycodone | 100 ng/mL | 4 hours | 1-3 days |
| Propoxyphene (PPX) | Propoxyphene | 300 ng/mL | 8-12hours | 5-10days |
| Nortriptyline (TCA) | Nortriptyline | 1000 ng/mL | 8-12hours | 2-7 days |
| Cannabinoids (THC) | 11-nor- Δ^9 -THC-9-COOH | 50 ng/mL | 2 hours | Up to 5+ days |
| Tramadol (TRA) | Tramadol | 100 ng/mL | 8-12hours | 3-7 days |
| Tramadol (TRA) | Tramadol | 200 ng/mL | 8-12hours | 3-7 days |

This assay provides only a preliminary test result. A more specific analytical method must be used in order to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) and liquid chromatography/tandem mass spectrometry (LC/MS-MS) are preferred confirmatory methods. Professional judgment should be applied to any drug test result, particularly when preliminary results are positive.

PRINCIPLE

The UScreen Drug Test Cup is a competitive immunoassay that is used to screen for the presence of drugs

and/or metabolites in urine. It is a chromatographic absorbent device in which drugs or drug metabolites in a sample compete for a limited number of antibody-dye conjugate binding sites.

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are at or above the target cutoff, the drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein pre-coated in the test region (T). This prevents the development of a distinct colored line in the test region indicating a potentially positive result.

When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein pre-coated in the test region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result.

To serve as a procedure control, a colored line will appear on the control region (C), if the test has been performed properly.

WARNINGS AND PRECAUTIONS

- Not to be used for clinical diagnosis.
- This kit is for external use only. Do not swallow.
- Discard after first use. The test cannot be used more than once.
- Do not use test kit beyond expiration date.
- Do not use the kit if the pouch is punctured or not sealed.
- Keep out of the reach of children.
- Do not read after 5 minutes.

STORAGE AND STABILITY

- Store between 4-30°C (40-86°F) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

MATERIAL

Materials Provided

- 25 Test devices (One test cup per pouch. Each pouch contains a test cup and desiccant. Remove desiccant from pouch. The desiccant is for storage purposes only.)
- One (1) package insert
- One (1) adulteration color comparison chart for interpretation of adulteration test results (if equipped)
- 25 Security seals (if provided)

Material Required But Not Provided

- Timer

SPECIMEN COLLECTION AND PREPARATION

- Wash your hands with soap and warm water. Open the sealed pouch and remove the UScreen Drug Test Cup.
- Give the cup with cap in place to the donor. Have the donor provide a urine sample by removing the cap, and voiding urine directly into the cup. Have the donor replace and tighten the cap, and return the cup with urine sample to the collector.
- The sample volume should be at or above the minimum urine level mark on the cup to provide adequate sample volume for laboratory confirmation, if required.

TEST PROCEDURE

- After the urine has been collected, re-cap the cup and place the UScreen Drug Test Cup on a flat surface.
- Read the temperature immediately to verify that the urine temperature is within the acceptable range 32-38°C (90-100°F).
- Peel the label from right to left.
- If the cup has the adulterant strip option, compare the adulterant test pads to the colors on the adulteration strip color chart at the times specified. Proper read time is critical to ensure correct test results. If adulterant pads indicate abnormal results, a second specimen should be collected and tested. For detailed operation instructions, please refer to the Procedure Card (and Color Chart if included).
- Do not determine a positive result before 5 minutes. Do not interpret any result after 10 minutes.



INTERPRETATION OF RESULTS

Negative (-)

A colored band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

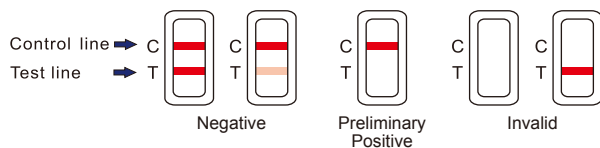
Preliminary Positive (+)

A colored band is visible in each control region. No colored band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

Invalid

If a colored line is not visible in each of the control regions, or a color line is only visible in each of the test regions, the test is invalid. Another test should be run to reevaluate the specimen. Please contact the distributor with the lot number for technical assistance.

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 are a number of factors that influence the reliability of drug tests.

What is a false positive test?

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

What is a false negative test?

The definition of a false negative test is that the initial drug is present but isn't detected by the UScreen Drug Test Cup. If the sample is diluted, or the sample is adulterated that may cause a false negative result.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials.

Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be followed.

LIMITATIONS

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
4. 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.
5. The test result does not distinguish between illicit drugs and prescribed medicines.
6. A positive result may be obtained from certain foods or food supplements.
7. 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.
8. The adulteration assays are for screening purposes only; all abnormal results should be confirmed by an alternative methodology.

SUMMARY

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 properties. They are usually taken orally, intravenously, or by smoking. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or 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. Amphetamine is metabolized to deaminated (hippuric and benzoic acids) and hydroxylated metabolites. Methamphetamine is partially metabolized to amphetamine and its major active metabolite. Amphetamines increase the heart rate and blood pressure, and suppress the appetite. Some studies indicate that heavy abuse may result in permanent damage to certain essential nerve structural in the brain.

Secobarbital (BAR)

Barbiturates are a class of central nervous system depressions. 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. Pentobarbital and secobarbital 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. Barbiturates are taken orally, rectally, or by intravenous and intramuscular injections. Short-acting barbiturates will generally be excreted in urine as metabolites, while the long-acting barbiturates will primarily appear unchanged.

Buprenorphine (BUP)

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™; 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 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

Oxazepam (BZO)

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.

Fentanyl (FTY)

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

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, they are 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, such as THC. Although synthetic cannabinoids do not produce positive results in drug tests for cannabis, it is possible to detect the metabolites in human urine.

Methylenedioxyamphetamine (MDMA)

Methylenedioxyamphetamine (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 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/mAMP)

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 psychosis which may appear at half-life of about 15 hours and is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

Morphine (MOP/OPI 300)

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 both be found in the urine of a person who has taken only heroin. The body also changes codeine to morphine. Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the urine indicates heroin, morphine and/or codeine use.

The test for Morphine (MOP) of the UScreen Drug Test Cup yields a positive result when morphine in the urine exceeds 300ng/mL.

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 urine as methadone, EDDP, EMDA and methadol. The kidneys are a major route of methadone excretion. Methadone has a biological half-life of 15 to 60 hours.

Opiates (OPI 2000)

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

The test for Morphine 2000 (OPI) of the UScreen Drug Test Cup yields a positive result when morphine in the urine exceeds 2000 ng/mL.

Oxycodone (OXY)

Oxycodone is known as Oxycontin 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 N- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% 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, 13-14% glucuronide conjugated oxymorphone and an unknown amount of noroxycodone. The detection time window of Oxycodone is 1-3 days following use.

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 nordextropropoxyphene. The combination usage of propoxyphene, aspirin, acetaminophen or other sedatives can lead cooperative interaction. Abuse of propoxyphene can lead nausea, vomit, astriction, illusion, hallucination, heart poisoning, lung dropsy and even death. Propoxyphene is metabolized in the liver and excreted in urine as nordextropropoxyphene. 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 or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

Cannabinoids (THC)

Cannabinoids is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC & Cannabinol can be metabolized and excreted as 11-nor- Δ 9-tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. It 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-(dimethylaminomethyl)-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-desmethyltramadol). Tramadol and its metabolites are excreted primarily in the urine with observed plasma half-lives of 6.3 and 7.4 hours for tramadol and O-desmethyltramadol(denoted M1), respectively. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% of the dose is excreted as metabolites.

PERFORMANCE CHARACTERISTICS

Accuracy

1680 (eighty of each drug) clinical urine specimens were analyzed by GC-MS and by each corresponding UScreen Drug Test Cup. Each test was read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

| Drug test | Result | Drug-free | Less than half the cutoff concentration by GC/MS analysis | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) | %Agreement with GC/MS (95%CI) | |
|-------------------|--------|-----------|---|--|--|---|-------------------------------|-----------------------|
| AMP (500) | Viewer | + | 0 | 0 | 2 | 30 | 10 | 100% (91.2% - 100%) |
| | A | - | 10 | 17 | 11 | 0 | 0 | 95% (83.5% - 98.6%) |
| | Viewer | + | 0 | 0 | 1 | 30 | 10 | 100% (91.2% - 100%) |
| | B | - | 10 | 17 | 12 | 0 | 0 | 97.5% (87.1% - 99.6%) |
| | Viewer | + | 0 | 0 | 2 | 30 | 10 | 100% (91.2% - 100%) |
| | C | - | 10 | 17 | 11 | 0 | 0 | 95% (83.5% - 98.6%) |
| AMP (1000) | Viewer | + | 0 | 0 | 1 | 11 | 29 | 100% (84.5% - 100%) |
| | A | - | 10 | 18 | 11 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer | + | 0 | 0 | 2 | 11 | 29 | 100% (84.5% -100%) |
| | B | - | 10 | 18 | 10 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer | + | 0 | 0 | 2 | 11 | 29 | 100% (84.5% -100%) |
| | C | - | 10 | 18 | 10 | 0 | 0 | 95% (79.5% - 100%) |
| BAR | Viewer | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% -100%) |
| | A | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% -100%) |
| | B | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |

| | | | | | | | | |
|-------------------|----------|---|----|----|----|----|----|-----------------------|
| BUP | Viewer C | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer A | + | 0 | 0 | 1 | 16 | 24 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 18 | 11 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 16 | 24 | 100% (84.5% - 100%) |
| BZO | Viewer B | - | 10 | 18 | 11 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 16 | 24 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 18 | 10 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer A | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| COC (150) | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer B | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer A | + | 0 | 0 | 2 | 30 | 10 | 100% (91.2% - 100%) |
| COC (300) | Viewer A | - | 10 | 18 | 10 | 0 | 0 | 95% (83.5% - 98.6%) |
| | Viewer B | + | 0 | 0 | 1 | 30 | 10 | 100% (91.2% - 100%) |
| | Viewer B | - | 10 | 18 | 11 | 0 | 0 | 97.5% (87.1% - 99.6%) |
| | Viewer C | + | 0 | 0 | 2 | 30 | 10 | 100% (91.2% - 100%) |
| | Viewer C | - | 10 | 18 | 10 | 0 | 0 | 95% (83.5% - 98.6%) |
| FTY | Viewer A | + | 0 | 0 | 2 | 11 | 29 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 11 | 29 | 100% (84.5% - 100%) |
| | Viewer B | - | 10 | 10 | 19 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 11 | 29 | 100% (84.5% - 100%) |
| K2 | Viewer C | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer A | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | Viewer B | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| MDMA | Viewer C | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer A | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 12 | 18 | 3 | 0 | 100% (84.5% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| MET (mAMP) (500) | Viewer B | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer A | + | 0 | 0 | 2 | 20 | 20 | 100% (91.2% - 100%) |
| | Viewer A | - | 10 | 15 | 13 | 0 | 0 | 95% (83.5% - 98.6%) |
| MET (mAMP) (1000) | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (91.2% - 100%) |
| | Viewer B | - | 10 | 15 | 13 | 0 | 0 | 95% (83.5% - 98.6%) |
| | Viewer C | + | 0 | 0 | 2 | 20 | 20 | 100% (91.2% - 100%) |
| | Viewer C | - | 10 | 15 | 13 | 0 | 0 | 95% (83.5% - 98.6%) |
| | Viewer A | + | 0 | 0 | 1 | 20 | 20 | 100% (84.5% - 100%) |
| MOP/OPI300 | Viewer A | - | 10 | 16 | 13 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer B | - | 10 | 16 | 12 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 16 | 12 | 0 | 0 | 95% (79.5% - 100%) |
| MOP/OPI300 | Viewer A | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 19 | 9 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer B | - | 10 | 19 | 9 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |

| | | | | | | | | |
|------------|----------|---|----|----|----|----|----|----------------------|
| MTD | Viewer C | + | 0 | 0 | 1 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 19 | 10 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer A | + | 0 | 0 | 1 | 19 | 21 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 19 | 21 | 100% (84.5% - 100%) |
| OPI | Viewer B | - | 10 | 12 | 16 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 19 | 21 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer A | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| OXY | Viewer B | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | Viewer B | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer A | + | 0 | 0 | 1 | 19 | 21 | 100% (84.5% - 100%) |
| PPX | Viewer A | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 19 | 21 | 100% (84.5% - 100%) |
| | Viewer B | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 19 | 21 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| TCA | Viewer A | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | Viewer B | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| THC | Viewer C | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer A | + | 0 | 0 | 1 | 10 | 30 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 19 | 10 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 10 | 30 | 100% (84.5% - 100%) |
| | Viewer B | - | 10 | 19 | 9 | 0 | 0 | 95% (79.5% - 100%) |
| TRA (100) | Viewer C | + | 0 | 0 | 1 | 10 | 30 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 19 | 10 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer A | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| TRA (200) | Viewer B | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer A | + | 0 | 0 | 2 | 19 | 21 | 100% (84.5% - 100%) |
| | Viewer A | - | 10 | 20 | 8 | 0 | 0 | 95% (79.5% - 100%) |
| MOP/OPI300 | Viewer B | + | 0 | 0 | 1 | 19 | 20 | 97.5% (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%) |
| | Viewer C | - | 10 | 20 | 9 | 2 | 0 | 97.5% (82% - 100%) |
| | Viewer A | + | 0 | 0 | 2 | 19 | 21 | 100% (84.5% - 100%) |
| MOP/OPI300 | Viewer A | - | 10 | 20 | 8 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 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 | 19 | 21 | 100% (84.5% - 100%) |
| | Viewer C | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |

Precision and Sensitivity

To investigate precision and sensitivity, each drug sample was analyzed at the following concentrations: cutoff - 100%, cutoff - 75%, cutoff - 50%, cutoff - 25%, cutoff, 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 tested 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 UScreen Drug Test Cup.

| Drug test | Approximate concentration of sample (ng/mL) | Number of determinations per lot | Results Negative/ Positive | | |
|------------|---|----------------------------------|----------------------------|-------|-------|
| | | | Lot 1 | Lot 2 | Lot 3 |
| AMP (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 | 6/44 | 7/43 | 6/44 |
| | 625 | 50 | 0/50 | 0/50 | 0/50 |
| | 750 | 50 | 0/50 | 0/50 | 0/50 |
| | 875 | 50 | 0/50 | 0/50 | 0/50 |
| | 1000 | 50 | 0/50 | 0/50 | 0/50 |
| 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 |
| | 1000 | 50 | 5/45 | 6/44 | 6/44 |
| | 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 |
| BAR | 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 | 5/45 | 5/45 | 6/44 |
| | 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 | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 2.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 5.0 | 50 | 50/0 | 50/0 | 50/0 |
| | 7.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 10.0 | 50 | 5/45 | 5/45 | 6/44 |
| | 12.5 | 50 | 0/50 | 0/50 | 0/50 |
| | 15.0 | 50 | 0/50 | 0/50 | 0/50 |
| | 17.5 | 50 | 0/50 | 0/50 | 0/50 |
| | 20.0 | 50 | 0/50 | 0/50 | 0/50 |
| BZO | 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 | 6/44 | 5/45 | 6/44 |
| | 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 (150) | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 37.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 75 | 50 | 50/0 | 50/0 | 50/0 |
| | 112.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 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 |
| 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 | 6/44 | 5/45 | 5/45 |
| | 450 | 50 | 0/50 | 0/50 | 0/50 |

| | | | | | |
|---------------------------|-------------------|----|------|------|------|
| FTY | 525 | 50 | 0/50 | 0/50 | 0/50 |
| | 600 | 50 | 0/50 | 0/50 | 0/50 |
| | 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 | 4/46 | 5/45 | 5/45 |
| | 25 | 50 | 0/50 | 0/50 | 0/50 |
| | 30 | 50 | 0/50 | 0/50 | 0/50 |
| | 35 | 50 | 0/50 | 0/50 | 0/50 |
| K2 JWH-018 Pentanoic Acid | 40 | 50 | 0/50 | 0/50 | 0/50 |
| | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 12.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 25.0 | 50 | 50/0 | 50/0 | 50/0 |
| | 37.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 50.0 | 50 | 5/45 | 6/44 | 5/45 |
| | 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 |
| K2 JWH-073 Butanoic Acid | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 12.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 25.0 | 50 | 50/0 | 50/0 | 50/0 |
| | 37.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 50.0 | 50 | 5/45 | 6/44 | 5/45 |
| | 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 |
| | MDMA | 0 | 50 | 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 | 7/43 | 6/44 | 5/45 |
| 625 | | 50 | 0/50 | 0/50 | 0/50 |
| 750 | | 50 | 0/50 | 0/50 | 0/50 |
| 875 | | 50 | 0/50 | 0/50 | 0/50 |
| 1000 | | 50 | 0/50 | 0/50 | 0/50 |
| MET (mAMP) (500) | | 0 | 50 | 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 | 5/45 | 4/46 | 4/46 |
| | 625 | 50 | 0/50 | 0/50 | 0/50 |
| | 750 | 50 | 0/50 | 0/50 | 0/50 |
| | 875 | 50 | 0/50 | 0/50 | 0/50 |
| | 1000 | 50 | 0/50 | 0/50 | 0/50 |
| | MET (mAMP) (1000) | 0 | 50 | 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 |
| 1000 | | 50 | 5/45 | 6/44 | 4/46 |
| 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 |
| MOP/O PI300 | | 0 | 50 | 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 | 7/43 | 5/45 | 6/44 |
| | 375 | 50 | 0/50 | 0/50 | 0/50 |
| | 450 | 50 | 0/50 | 0/50 | 0/50 |

| | | | | | |
|-----------|------|----|------|------|------|
| MTD | 525 | 50 | 0/50 | 0/50 | 0/50 |
| | 600 | 50 | 0/50 | 0/50 | 0/50 |
| | 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 | 5/45 | 7/43 | 5/45 |
| | 375 | 50 | 0/50 | 0/50 | 0/50 |
| | 450 | 50 | 0/50 | 0/50 | 0/50 |
| | 525 | 50 | 0/50 | 0/50 | 0/50 |
| OPI | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 500 | 50 | 50/0 | 50/0 | 50/0 |
| | 1000 | 50 | 50/0 | 50/0 | 50/0 |
| | 1500 | 50 | 50/0 | 50/0 | 50/0 |
| | 2000 | 50 | 5/45 | 5/45 | 6/44 |
| | 2500 | 50 | 0/50 | 0/50 | 0/50 |
| | 3000 | 50 | 0/50 | 0/50 | 0/50 |
| | 3500 | 50 | 0/50 | 0/50 | 0/50 |
| | 4000 | 50 | 0/50 | 0/50 | 0/50 |
| | OXY | 0 | 50 | 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 | 4/46 | 4/46 | 5/45 |
| 125 | | 50 | 0/50 | 0/50 | 0/50 |
| 150 | | 50 | 0/50 | 0/50 | 0/50 |
| 175 | | 50 | 0/50 | 0/50 | 0/50 |
| PPX | 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 | 6/44 | 5/45 | 5/45 |
| | 375 | 50 | 0/50 | 0/50 | 0/50 |
| | 450 | 50 | 0/50 | 0/50 | 0/50 |
| | 525 | 50 | 0/50 | 0/50 | 0/50 |
| TCA | 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 |
| | 1000 | 50 | 6/44 | 5/45 | 4/46 |
| | 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 |
| | THC | 0 | 50 | 50/0 | 50/0 |
| 12.5 | | 50 | 50/0 | 50/0 | 50/0 |
| 25.0 | | 50 | 50/0 | 50/0 | 50/0 |
| 37.5 | | 50 | 50/0 | 50/0 | 50/0 |
| 50.0 | | 50 | 4/46 | 4/46 | 5/45 |
| 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 |
| TRA (100) | | 0 | 50 | 50/0 | 50/0 |
| | 25 | 50 | 50/0 | 50/0 | 50/0 |
| | 50 | 50 | 50/0 | 50/0 | 50/0 |
| | 75 | 50 | 48/2 | 49/1 | 47/3 |

| | | | | | |
|-----------|-----|----|------|------|------|
| TRA (200) | 100 | 50 | 4/46 | 5/45 | 5/45 |
| | 125 | 50 | 1/49 | 4/46 | 3/47 |
| | 150 | 50 | 0/50 | 0/50 | 0/50 |
| | 175 | 50 | 0/50 | 0/50 | 0/50 |
| | 200 | 50 | 0/50 | 0/50 | 0/50 |
| | 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 | 4/46 | 6/44 | 5/45 |
| TRA (200) | 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 |

Analytical Specificity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components that are likely to be present in urine. All the components were added to drug-free normal human urine. These concentrations (ng/mL) below also represent the limits of detection for the specified drugs or metabolites.

| Item | Concentration (ng/mL) | Item | Concentration (ng/mL) |
|---|-----------------------|---|-----------------------|
| Amphetamine (AMP 500) | | Methylenedioxyamphetamine (MDMA) | |
| d-Amphetamine | 500 | 3,4-Methylenedioxyamphetamine HCl (MDMA) | 500 |
| d,l-Amphetamine | 1,500 | 3,4-Methylenedioxyamphetamine HCl (MDA) | 3,000 |
| l-Amphetamine | 25,000 | 3,4-Methylenedioxyethylamphetamine (MDEA) | 300 |
| (+/-) 3,4-methylenedioxyamphetamine (MDA) | 2,500 | Methamphetamine (MET 500/mAMP 500) | |
| Phentermine | 1,500 | D(+)-Methamphetamine | 500 |
| d-methamphetamine | >50,000 | MDMA | 10,000 |
| l-methamphetamine | >50,000 | MDEA | 100,000 |
| 3,4-Methylenedioxyethylamphetamine(MDEA) | 50,000 | Methamphetamine (MET 1000/mAMP 1000) | |
| (+/-)3,4-methylenedioxyamphetamine (MDMA) | 50,000 | D(+)-Methamphetamine | 1,000 |
| Amphetamine (AMP 1000) | | D-Amphetamine | 50,000 |
| d-Amphetamine | 1,000 | Chloroquine | 50,000 |
| d,l-Amphetamine | 3,000 | (+/-)-Ephedrine | 50,000 |
| l-Amphetamine | 50,000 | (-)-Methamphetamine | 25,000 |
| (+/-) 3,4-methylenedioxyamphetamine (MDA) | 5,000 | (+/-)3,4-methylenedioxyamphetamine (MDMA) | 2,000 |
| Phentermine | 3,000 | β -Phenylethylamine | 50,000 |
| d-methamphetamine | >100,000 | Trimethobenzamide | 10,000 |
| l-methamphetamine | >100,000 | Opiates 300 (MOP/OPI 300) | |
| 3,4-Methylenedioxyethylamphetamine(MDEA) | 100,000 | Morphine | 300 |
| (+/-)3,4-methylenedioxyamphetamine (MDMA) | 100,000 | Codeine | 300 |
| Barbiturates (BAR) | | Ethyl Morphine | 300 |
| Secobarbital | 300 | Hydrocodone | 5,000 |
| Amobarbital | 300 | Hydromorphone | 5,000 |
| Alphenol | 150 | Morphine-3- β -d-glucuronide | 1,000 |
| Aprobarbital | 200 | Thebaine | 30,000 |
| Butobarbital | 75 | Methadone (MTD) | |
| Butathal | 100 | Methadone | 300 |
| Butalbital | 2,500 | Doxylamine | 50,000 |
| Cyclopentobarbital | 600 | Opiates 2000 (OPI) | |
| Pentobarbital | 300 | Morphine | 2,000 |
| Phenobarbital | 10,000 | Codeine | 2,000 |
| Buprenorphine (BUP) | | Ethylmorphine | 5,000 |
| Buprenorphine | 10 | Hydrocodone | 12,500 |

| | | | |
|---|--------|------------------------------------|----------|
| Buprenorphine 3-D-Glucuronide | 15 | Hydromorphone | 5,000 |
| Norbuprenorphine | 20 | Levorphanol | 75,000 |
| Norbuprenorphine 3-D-Glucuronide | 200 | o-Monoacetylmorphine | 5,000 |
| Benzodiazepines (BZO) | | Morphine 3-β-D-glucuronide | 2,000 |
| Oxazepam | 300 | Norcodeine | 12,500 |
| Alprazolam | 200 | Normorphone | 50,000 |
| a-Hydroxyalprazolam | 1,500 | Oxycodone | 25,000 |
| Bromazepam | 1,500 | Oxymorphone | 25,000 |
| Chlordiazepoxide | 1,500 | Procaine | 150,000 |
| Clonazepam HCl | 800 | Thebaine | 100,000 |
| Clobazam | 100 | Oxycodone (OXY) | |
| Clonazepam | 800 | Oxycodone | 100 |
| Clorazepatedipotassium | 200 | Dihydrocodeine | 20,000 |
| Delorazepam | 1,500 | Codeine | 100,000 |
| Desalkylflurazepam | 400 | Hydromorphone | 100,000 |
| Diazepam | 200 | Morphine | >100,000 |
| Estazolam | 2,500 | Acetylmorphine | >100,000 |
| Flunitrazepam | 400 | Buprenorphine | >100,000 |
| D,L-Lorazepam | 1,500 | Ethylmorphine | >100,000 |
| Midazolam | 12,500 | Propoxyphene (PPX) | |
| Nitrazepam | 100 | d-Propoxyphene | 300 |
| Norchlordiazepoxide | 200 | d-Norpropoxyphene | 300 |
| Nordiazepam | 400 | Nortriptyline (TCA) | |
| Temazepam | 100 | Nortriptyline | 1,000 |
| Triazolam | 2,500 | Nordoxepin | 1,000 |
| Cocaine (COC 150) | | Trimipramine | 3,000 |
| Benzoylcegonine | 150 | Amitriptyline | 1,500 |
| Cocaine HCl | 375 | Promazine | 1,500 |
| Cocaeethylene | 6,250 | Desipramine | 200 |
| Ecgonine | 16,000 | Imipramine | 400 |
| Cocaine (COC 300) | | Clomipramine | 12,500 |
| Benzoylcegonine | 300 | Doxepin | 2,000 |
| Cocaine HCl | 750 | Maprotiline | 2,000 |
| Cocaeethylene | 12,500 | Promethazine | 25,000 |
| Ecgonine | 32,000 | Marijuana (THC) | |
| Fentanyl (FTY) | | 11-nor-Δ9-THC-9-COOH | 50 |
| Norfentanyl | 20 | 11-nor-Δ8-THC-9-COOH | 30 |
| Fentanyl | 200 | 11-hydroxy-Δ9-Tetrahydrocannabinol | 2,500 |
| Synthetic Cannabinoids (K2) | | Δ8- Tetrahydrocannabinol | 7,500 |
| JWH-018 Pentanoic Acid | 50 | Δ9- Tetrahydrocannabinol | 10,000 |
| JWH-073 Butanoic Acid | 50 | Cannabinol | 100,000 |
| JWH-018 N-4-hydroxypentyl | 2,000 | Tramadol (TRA 100) | |
| JWH-018 (Spice Cannabinoid) | 1,000 | Tramadol | 100 |
| JWH-018 4-Hydroxypentyl metabolite-D5 (indole-D5) | 1,000 | Venlafaxine hydrochloride | 50,000 |
| JWH-073 (Spice Cannabinoid) | 2,000 | Tramadol (TRA 200) | |
| JWH-073 3-Hydroxybutyl metabolite | 1,000 | Tramadol | 200 |
| JWH-073 3-Hydroxybutyl metabolite-D5 (indole-D5) | 1,000 | Venlafaxine hydrochloride | 100,000 |
| JWH-019 6-hydroxypentyl | 1,000 | | |
| JWH-122 N-4-hydroxypentyl | 2,000 | | |
| JWH-210 5-Hydroxypentyl metabolite | 5,000 | | |
| AM2201 4-Hydroxypentyl metabolite | 1,000 | | |

Adulteration/Specimen Validity Test

OX: Bleach or other oxidizing agents react with an oxidant indicator to form a color complex. Observation of a blue-green, medium to dark brown, or orange color indicates adulteration with bleach or other oxidizing agents.

S.G.: The specific gravity test is based on the pKa change of certain pretreated 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 1.005 or above 1.025 is considered abnormal.

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 sample 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 specimen dilution.

pH: Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

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 7.5 mg/dl is considered abnormal.

Cross-Reactivity

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, we simulated the above situations by adding the potentially interfering substances at a certain concentration to the specimen. The following components show no cross-reactivity when tested with UScreen Drug Test Cup at a concentration of 100 µg/ml.

Non Crossing-Reacting Compounds

| | | |
|---------------------------------------|---|--|
| Acetaminophen | Dopamine HCl (except AMP test) | Noscapine |
| Acetophenetidin | Doxepin (except TCA test) | O-Hydroxyhippuric Acid |
| Acetylsalicylic Acid | Doxylamine (except KET, MTD, TRA tests) | Omeprazole |
| Aminopyrine | Egongine Methyl Ester | Oxalic Acid |
| Amoxicillin | β-Estradiol (except BZO test) | Oxazepam (except BZO test) |
| Ampicillin | Ephedrine HCl (except MET/mAMP test) | Oxolinic Acid |
| Apomorphine | Erythromycin (except BZO test) | Oxycodone Acetaminophen (except MOP/OPI300, OPI, OXY tests) |
| Aspartame | Estrogen | Oxymetazoline |
| Aspirin | Fenoprofen | Papaverine |
| Atropine | Fentanyl Citrate (except MDMA test) | Penicillin V Potassium |
| Benadryl | Furosemide | Penicillin-G |
| Benzic Acid | Gentic Acid | Pentobarbital (except BAR, OXY tests) |
| Benzoic Acid | Hydralazine (except BZO test) | Perphenazine |
| Benzoylcegonine (except COC test) | Hydrochlorothiazide | Pethidine HCl |
| Bilirubin | Hydrocodone (except BZO, MOP/OPI300, OPI, OXY tests) | Phenylephrine (except MET/mAMP test) |
| Cannabidiol (except THC, OXY tests) | 3-Hydroxytyramine | Phenelzine |
| Captopril | Hydrocortisone | Phenylephrine (except BAR test) |
| Chloralhydrate | I Caps | Pholcodine (except MOP/OPI300, OPI tests) |
| Chloramphenicol | Ibuprofen (except OXY test) | Prednisone |
| Chlorothiazide | Isoxsuprine | Procaine (except COC test) |
| Chlorpromazine | Ketamine (except OXY test) | Propranolol HCl |
| Chlorquine | Ketoprofen | Quinine |
| Cholesterol | Labeltalol | Ranitidine |
| Clarithromycin | Lamotrigine | Ranitidine HCl |
| Clonidine | Levonorgestrel | Salicylic acid |
| Codine (except MOP/OPI300, OPI tests) | Lofexidine (except OXY test) | Secobarbital (except MET/mAMP, BAR tests) |
| (-) Cofiline | Loperamide (except MTD test) | Serotonin (5-Hydroxytyramine) |
| Cortisone | Maprotiline (except TCA, OXY tests) | Sinus&Allergy (except BZO, MET/mAMP tests) |
| Creatinine | Meperidine | Sulfamethazine |
| Deoxycorticosterone | Meprobamate | Sulindac |
| Dextromethorphan | Methadone (except MTD test) | Tetrahydrocortisone3-(β-Dglucuronide) (except AMP, BAR, OXY tests) |
| Diazepam (except BZO test) | Methamphetamine (except MDMA, MET/mAMP, TCA tests) | Tetrahydrocortisone, 3-acetate (except AMP, BAR, OXY tests) |
| Diclofenac | Methoxyphenamine (except MDMA, MET/mAMP, TCA tests) | Tetrahydrozoline |
| Diflunisal | Morphine-3-b-d-glucuronide (except BZO, MOP, OPI tests) | Thiamine |
| Digoxin | N-Acetylprocainamide (except OXY test) | Thioridazine |
| Diphenhydramine | Nalidixic acid | Triamterene |

| | | |
|---|--|----------------------------------|
| D L-Tryptophan (except AMP, BAR tests) | Naloxone | Trifluoperazine |
| D,L-Isoproterenol (except AMP, BAR tests) | Naltrexone | Trimethoprim |
| D,L-Octopamine | Naproxen | Tyramine (except AMP, BAR tests) |
| DL-Propranolol | Niacinamide | Uric Acid |
| DL-Tyrosine | Nifedipine | Venlafaxine HCl |
| D-Norpropoxyphene | Nitroglycerin | Verapamil |
| D-Propoxyphene (except OXY test) | Norcodein (except MOP/OPI300, OPI, BZO, OXY tests) | Zoloft |
| D-Pseudoephedrine | Norethindrone | Zomepirac |

These results demonstrate that the UScreen Drug Test Cup will not produce positive results with urine samples containing these common substances.

Effect of Urinary Specific Gravity

5 urine samples with specific gravity between 1.000-1.035 were collected and spiked with each drug at 50% below and 50% above the cutoff level. The UScreen Drug Test Cup was tested in duplicate. The results demonstrated that varying ranges of urinary specific gravity do not affect the test result.

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 morphine at 50% below and 50% above cutoff levels. The UScreen Drug Test Cup was tested in duplicate. The results demonstrated that varying ranges of pH do not interfere with the performance of the test.

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MEANING OF SYMBOLS ON PACKAGE



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