# One Step Multi-Drug Screen Test Cup (Urine)
# Package Insert

Package insert for testing of any combination of the following drugs: Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), AB-Pinaca (K3), Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, 6-Monoacetylmorphine, Marijuana and Benzodiazepines.

*A rapid, one step screening test for the simultaneous, qualitative detection of Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), AB-Pinaca (K3), Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, 6-Monoacetylmorphine, Marijuana, Benzodiazepines and the metabolites in human urine.*

*For forensic use only.*

## INTENDED USE

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

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

| Test | Calibrator | Cut-off (ng/mL) |
|---|---|---|
| Methamphetamine (MET, mAMP) | D-Methamphetamine | 500 |
| Cocaine (COC ) | Benzoylecgonine | 150 |
| Marijuana (THC ) | 11-nor-$\Delta^9$-THC-9 COOH | 50 |
| Morphine (MOP 300) | Morphine | 300 |
| Benzodiazepines (BZO) | Oxazepam | 300 |
| MDMA (Ecstasy) | D,L-3,4-Methylenedioxymethamphetamine (MDMA) | 500 |
| Oxycodone (OXY ) | Oxycodone | 100 |
| Barbiturates (BAR) | Secobarbital | 300 |
| Buprenorphine (BUP) | Buprenorphine | 10 |
| Methadone (MTD) | Methadone | 300 |
| Phencyclidine (PCP) | Phencyclidine | 25 |
| Amphetamine (AMP) | D-Amphetamine | 500 |
| K2 Synthetic Cannabinoid | JWH-073/JWH-018 | 50 |
| AB-Pinaca (K3) | AB-Pinaca | 10 |
| Ethyl Glucuronide (ETG) | Ethyl Glucuronide | 500 |
| Tramadol (TRA) | Tramadol | 200 |
| Fentanyl (FEN) | Fentanyl | 300 |
| 6-Monoacetylmorphine (6-MAM) | 6-Monoacetylmorphine | 10 |

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

**This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.**

## SUMMARY

### METHAMPHETAMINE (MET, mAMP)

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

### COCAINE (COC)

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

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

### MORPHINE (MOP)

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

### MARIJUANA (THC)

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

### BENZODIAZEPINES (BZO)

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

### OXYCODONE (OXY)

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

### AMPHETAMINE (AMP)

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

### BARBITURATES (BAR)

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

The approximate detection time limits for Barbiturates are:

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

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

### BUPRENORPHINE (BUP)

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

### METHADONE (MTD)

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

### MDMA (ECSTASY)

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

### PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5] Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

### PROPOXYPHENE (PPX)

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

### SYNTHETIC MARIJUANA (K2)

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness.

Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 72 hours after smoking (depending on usage/dosage).

As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclo

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

**AB-PINACA (K3)**

AB-Pinaca is a compound that was first identified as a component of synthetic cannabis products in Japan in 2012.[4] AB-Pinaca acts as a potent agonist for the $CB_1$ receptor ($K_i$ = 2.87 nM, $EC_{50}$ = 1.2 nM) and $CB_2$ receptor ($K_i$ = 0.88 nM, $EC_{50}$ = 2.5 nM) and fully substitutes for $\Delta^9$-THC in rat discrimination studies, while being 1.5x more potent. There have been a number of reported cases of deaths and hospitalizations in relation to this synthetic cannabinoid.

**ETHYL GLUCURONIDE (ETG)**

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

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

**FENTANYL (FEN)**

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

**TRAMADOL (TRA)**

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

**6-MONOACETYLMORPHINE (6-MAM)**

6-Monoacetylmorphine (6-MAM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-acetylmorphine (3-ACM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. Since 6-ACM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opioid used. This is significant because on a urine immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulphate, and heroin. 6-MAM remains in the urine for no more than 24 hours so a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day.

## ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for Oxidants, Specific Gravity, pH, Creatinine, Nitrite and Glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and pH, and to detect the presence of oxidants, Nitrite, Glutaraldehyde and Creatinine in urine are considered to be the best ways to test for adulteration or dilution.

- **Oxidants (OX):** Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- **Specific Gravity (S.G.):** Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- **pH:** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values below pH 4.0 or above pH 9.0 may indicate the sample has been altered.
- **Nitrite (NIT):** Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
- **Glutaraldehyde (GLU):** Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
- **Creatinine (CRE):** Creatinine is one way to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

## PRINCIPLE

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

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

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

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

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

## REAGENTS

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

## ADULTERANT TESTS (SPECIMEN VALIDITY TEST) REAGENTS

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

## PRECAUTIONS

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

## STORAGE AND STABILITY

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

## SPECIMEN COLLECTION AND PREPARATION

***WHEN TO COLLECT URINE FOR THE TEST?***

The minimum detection time is 2-7 hours, so you may collect urine samples 2-7 hours after suspected drug use.

***HOW TO COLLECT URINE?***

1. Urinate directly into the provided urine cup.

2. Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap. This Labeled Vial urine sample is for shipping to the laboratory for confirmation testing. Make sure that the number on the Labeled Vial matches your personal Identification Number.

3. The residual urine sample in the urine cup is for your self-testing.

**Specimen Storage**

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

## MATERIALS

**Materials Provided**

- Test cups
- Desiccants
- Procedure Card
- Package Insert
- Color Chart Cards for Adulterant Interpretation
- Disposable gloves

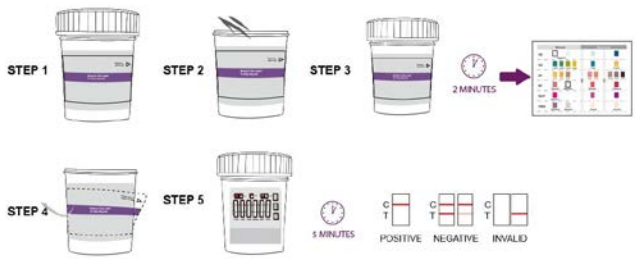
**Materials Required But Not Provided**

- Timer

## DIRECTIONS FOR USE

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

1) Tear the foil bag open, remove test cup and disposable gloves provided for donor. Label the device with donor information. (Fig. 1)
2) Open test cup lid. Urinary directly into the test cup. Be sure to fill up the test cup with the urine specimen between minimum 30 mL to maximum 110 mL (marked on the cup). (Fig. 2)
3) Close the lid securely and place the cup on a flat surface. Start the timer. (Fig. 3)
4) Put on the glove provided. Peel off label to reveal test result.(Fig. 4)
5) Read the adulteration strip at 2 minutes. Compare the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen.
6) Read the drug strip results at 5 minutes. DO NOT INTERPRET RESULT AFTER 10 MINUTES. (Fig. 5)




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

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

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

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

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

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

***What Is A False Positive Test?***

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

***What Is A False Negative Test?***

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

## ADULTERANT INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

## QUALITY CONTROL

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

## LIMITATIONS

1. The One Step Multi-Drug Screen Test Cup (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

## PERFORMANCE CHARACTERISTICS

### Accuracy

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

| Specimen | AMP | BAR | BUP | BZO | COC | ETG | FEN | K2 | K3 |
|---|---|---|---|---|---|---|---|---|---|
| Positive | 95.8% | 93.3% | 93.3% | 95.0% | 97.5% | 95.8% | 92.5% | 93.3% | 92.5% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | 97.9% | 96.7% | 96.7% | 97.5% | 98.8% | 97.9% | 96.3% | 96.7% | 96.3% |

| Specimen | MET | MDMA | MOP | 6-MAM | MTD | OXY | THC | PCP | TRA |
|---|---|---|---|---|---|---|---|---|---|
| Positive | 96.7% | 91.7% | 97.5% | 93.3% | 94.2% | 93.3% | 94.2% | 92.5% | 93.3% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | 98.3% | 95.8% | 98.8% | 96.7% | 97.1% | 96.7% | 97.1% | 96.3% | 96.7% |

### Analytical Sensitivity

Total 150 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), AB-Pinaca (K3), Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, 6-Monoacetylmorphine, Marijuana and Benzodiazepines. The cut-off value for the device is verified.

### Analytical Specificity

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

| Drug | Concentration (ng/ml) |
|---|---|
| **MARIJUANA (THC)** | |
| Delta-9-Tetrahydrocannabinol | 50,000 |
| 11-nor-delta-9-THC-carboxyglucuronide | 75 |
| (-)-11-nor-9-carboxy-delta9-THC | 75 |
| 11-Nor-$\Delta^9$-Tetrahydrocannabinol | 50 |
| 11-Hydroxy-$\Delta^9$-Tetrahydrocannabinol | 5,000 |
| 11-Nor-$\Delta^8$-Tetrahydrocannabinol | 50 |
| $\Delta^8$-THC-COOH | 50,000 |
| | |
| **MORPHINE (MOP)** | |
| Morphine | 300 |
| O6-Acetylmorphine | 400 |
| Codeine | 300 |
| EthylMorphine | 100 |
| Heroin | 600 |
| Hydromorphone | 500 |
| Hydrocodone | 50,000 |
| Levorphanol | 1500 |
| Oxycodone | 30000 |
| Procaine | 15000 |
| Thebaine | 6240 |
| | |
| **BENZODIAZEPINES (BZO)** | |
| Alprazolam | 200 |
| Bromazepam | 1,560 |
| Chlordiazepoxide HCL | 1,560 |
| Clobazam | 100 |
| Clonazepam | 780 |
| Clorazepate Dipotassium | 200 |
| Delorazepam | 1,560 |
| Desalkylflurazepam | 400 |
| Diazepam | 200 |
| Estazolam | 2,500 |
| Flunitrazepam | 400 |
| a-Hydroxyalprazolam | 1260 |
| (±) Lorazepam | 1,560 |
| RS-Lorazepam glucuronide | 160 |
| Midazolam | 12,500 |
| Nitrazepam | 100 |
| Norchlordiazepoxide | 200 |
| Nordiazepam | 400 |
| Oxazepam | 300 |
| Temazepam | 100 |
| Triazolam | 2,500 |
| | |
| **OXYCODONE (OXY)** | |
| Naloxone hydrochloride | 10,000 |
| Naltrexone hydrochloride | 50,000 |
| Oxycodone | 100 |
| Hydrocodone | 5,000 |
| Hydromorphone | 5,000 |
| Oxymorphone-D3 | 5,000 |
| Oxymorphone | 200 |
| N-Benzylisopropylamine | 2,500 |
| | |
| **BARBITURATES (BAR)** | |
| Secobarbital | 300 |
| Amobarbital | 300 |
| Alphenal | 750 |
| Aprobarbital | 250 |
| Butabarbital | 2500 |
| Butethal | 2500 |
| Cyclopentobarbital | 500 |
| Pentobarbital | 2500 |
| Phenobarbital | 25000 |
| | |
| **BUPRENORPHINE (BUP)** | |
| Buprenorphine | 10 |
| Norbuprenorphine | 20 |
| | |
| **METHADONE (MTD)** | |
| Methadone | 300 |
| Doxylamine | 5,000 |
| | |
| **MDMA (ECSTASY)** | |
| D,L-3,4-Methylenedioxymethamphetamine (MDMA) | 500 |
| 3,4-Methylenedioxyamphetamine HCI (MDA) | 3,000 |
| 3,4-Methylenedioxyethyla-amphetamine (MDEA) | 300 |
| d-methamphetamine | 2500 |
| d-amphetamine | >100000 |
| l-amphetamine | >100000 |
| l-methamphetamine | >100000 |
| | |
| **PHENCYCLIDINE (PCP)** | |
| Phencyclidine | 25 |
| 4-Hydroxy Phencyclidine | 90 |
| | |
| **K2 (SYNTHETIC CANNABINOID)** | |
| JWH-018 5-Pentanoic acid metabolite | 16 |
| JWH-018 5-Hydroxypentyl metabolite | 1,000 |
| JWH-018 4-Hydroxypentyl metabolite | 25,000 |
| JWH-018 N-(4-hydroxypentyl) metabolite solution | 500 |
| JWH-019 5-hydroxyhexylmetabolite | 500 |
| JWH-019 6-Hydroxyhexyl | 31 |
| JWH-073 4-butanoic acid metabolite | 16 |
| JWH-073 4-Hydroxybutyl metabolite | 500 |
| JWH-210 5-Hydroxypentyl metabolite solution | 10,000 |
| JWH-122 5-Hydroxypentyl metabolite solution | 1,000 |
| Spice Cannabinoid Mix 3 solution | 10,000 |
| JWH-122 4-Hydroxypentyl metabolite solution | 1,562 |
| JWH-122 4-Hydroxypentyl metabolite-D5 solution | 10,000 |
| JWH-019 5-hydroxyhexylmetabolite | 25,000 |
| JWH-018 N-(4-hydroxypentyl) metabolite solution | 1,000 |
| JWH-073 N-(3-Hydroxybutyl) metabolite solution | 10,000 |
| | |
| **AB-PINACA (K3)** | |
| AB-Pinaca (K3) | 10 |
| AB-FUBINACA metabolite | 49 |
| AB-PINACA 5-Hydroxypentyl metabolite | 3 |
| AB-PINACA 4-Hydroxypentyl metabolite | 3 |
| UR-144 S-Hydropentyl metabolite | 50,000 |
| UR-144 5-Pentanoic Acid metabolite | 1,562 |
| UR-144 4-Hydroxypentyl metabolite | 40,000 |
| AB-PINACA 5-Pentanoic acid metabolite | 2 |
| XLR-11 | 70,000 |
| APINACA (AKB-48) 5-Hydroxypentyl metabolite | 25,000 |
| Melatonin | 500,000 |
| MAB-CHMINACA | 2,250 |
| AB-CHMINACA | 750 |
| **ETHYL GLUCURONIDE (EtG500)** | |
| Ethyl-β-D-glucuronide | 500 |
| Ethyl-β-D-glucuronide-D5 | 500 |
| | |
| **FENTANYL (FEN)** | |
| Norfentanyl | 20 |
| Fentanyl | 300 |
| | |
| **TRAMADOL (TRA )** | |
| Tramadol | 200 |

| Drug | Concentration (ng/ml) |
|---|---|
| N-desmethyl-tramadol | 500 |
| O-desmethyl-tramadol | 20,000 |
| | |
| **AMPHETAMINE (AMP500)** | |
| D-Amphetamine | 500 |
| D,L-Amphetamine | 750 |
| L-Amphetamine | 16000 |
| Phentermine | 650 |
| (+/-)-Methylenedioxyamphetamine (MDA) | 800 |
| d-Methamphetamine | >100,000 |
| 1-Methamphetamine | >100,000 |
| ephedrine | >100,000 |
| 3,4-Methylenedioxyethylamphetamine (MDE) | >100,000 |
| 3,4-methylenedioxy-methamphetamine (MDMA) | >100,000 |
| | |
| **COCAINE (COC150)** | |
| Benzoylecogonine | 150 |
| Cocaethylene | 2500 |
| Cocaine | 500 |
| Ecgonine | 12,500 |
| Ecgonine methylester | 50,000 |
| | |
| **METHAMPHETAMINE (MET500)** | |
| p-Hydroxymethamphetamine | 15,000 |
| l-Methamphetamine | 4,000 |
| Mephentermine | 25,000 |
| d,l-Amphetamine | 75,000 |
| (1R,2S)-(-)-Ephedrine | 50,000 |
| β-Phenylethylamine | 75,000 |
| d-Methamphetamine | 500 |
| 3,4-Methylenedioxymethamphetamine (MDMA) | 1,000 |
| d-Amphetamine | 50,000 |
| Chloroquine | 12,500 |
| (+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA) | 20,000 |
| Procaine (Novocaine) | 50,000 |
| Trimethobenzamide | 20,000 |
| Ranitidine (Zantac) | 50,000 |
| Fenfluramine | 50,000 |
| | |
| **6-MONOACETYLMORPHINE (6-MAM)** | |
| 6-Moonacetylmorphine | 10 |
| Morphine | >500,000 |
| Codeine | >600,000 |
| Dextromethorphan | >100,000 |
| Dihydrocodeine | >100,000 |
| Heroin HCl | 250 |
| Hydrocodone | >100,000 |
| Hydromorphone | >100,000 |
| Imipramine | >100,000 |
| Levorphanol | >10,000 |
| NorMeperidine | >10,000 |
| Normorphine | >100,000 |
| Nalorphine | >100,000 |
| Naloxone | >100,000 |
| Naltrexone | >100,000 |
| Norcodeine | >100,000 |
| Oxycodone | >100,000 |

| Drug | Concentration (ng/ml) |
|---|---|
| Oxymorphone | >100,000 |

**Precision**

This study is performed 2 runs/day and lasts 25 days for each format with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

| Drug Conc. (Cut-off range) | AMP | | BAR | | BZO | | BUP | | COC | | ETG | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -75% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -50% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -25% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 44 | 6 |
| Cut-off | 32 | 18 | 27 | 23 | 20 | 30 | 26 | 24 | 31 | 19 | 23 | 27 |
| +25% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 8 | 42 |
| +50% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +75% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +100% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off range) | FEN | | K2 | | K3 | | MET | | MDMA | | MOP | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 50 | 0 | 30 | 0 | 30 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -75% Cut-off | 50 | 0 | 30 | 0 | 30 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -50% Cut-off | 50 | 0 | 30 | 0 | 30 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -25% Cut-off | 50 | 0 | 30 | 0 | 26 | 4 | 50 | 0 | 50 | 0 | 50 | 0 |
| Cut-off | 22 | 28 | 14 | 16 | 15 | 15 | 28 | 22 | 30 | 20 | 20 | 30 |
| +25% Cut-off | 0 | 50 | 0 | 30 | 3 | 27 | 0 | 50 | 0 | 50 | 0 | 50 |
| +50% Cut-off | 0 | 50 | 0 | 30 | 0 | 30 | 0 | 50 | 0 | 50 | 0 | 50 |
| +75% Cut-off | 0 | 50 | 0 | 30 | 0 | 30 | 0 | 50 | 0 | 50 | 0 | 50 |
| +100% Cut-off | 0 | 50 | 0 | 30 | 0 | 30 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off range) | 6-MAM | | MTD | | OXY | | PCP | | THC | | TRA | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -75% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -50% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| -25% Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 45 | 5 |
| Cut-off | 23 | 27 | 22 | 28 | 16 | 34 | 16 | 34 | 14 | 36 | 28 | 22 |
| +25% Cut-off | 5 | 45 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 1 | 49 |
| +50% Cut-off | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |
| +75% Cut-off | 0 | 50 | 0 | 30 | 0 | 30 | 0 | 50 | 0 | 50 | 0 | 50 |
| +100% Cut-off | 0 | 50 | 0 | 30 | 0 | 30 | 0 | 50 | 0 | 50 | 0 | 50 |

**Effect of Urinary Specific Gravity**

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The **One Step Multi-Drug Screen Test Cup (Urine)** was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

**Effect of Urinary pH**

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

**Cross-Reactivity**

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), AB-Pinaca (K3), Methadone, Fentanyl, Tramadol, Ethyl Glucuronide, 6-Monoacetylmorphine, Marijuana and Benzodiazepines positive urine. The following compounds show no cross-reactivity when tested with the **One Step Multi-Drug Screen Test Cup (Urine)** at a concentration of 100 µg/mL.

**Non Cross-Reacting Compounds**

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

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4. *Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.*
5. *FDA Guidance Document: Guidance for Premarket Submission for Kits for Screening Drugs of Abuse to be Used by the Consumer, 1997.*


**ADDITIONAL INFORMATION AND RESOURCES**

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

Center for Substance Abuse Treatment www.health.org 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG