

# T-Cup® Compact

## For Forensic Use Only Multi-Drug Urine Test Cup Catalogue No. See Box label

The T-Cup® Compact Multi-Drug Urine Test Cup is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, Cotinine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Ethyl Glucuronide, Fentanyl, Synthetic Cannabinoids, Ketamine, Methylenedioxymethamphetamine, Methamphetamine, Morphine, Methadone, Opiate, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, Cannabinoids, Tramadol, and Alcohol in human urine at specified cutoff levels.

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

The test provides only preliminary test results. A more specific alternative analytical method should be used in order to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods.

It is not intended to distinguish between prescription drug or illicit drug use.

Professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

The multi-drug device may be combined with the adulteration control (Creatinine (CR), Glutaraldehyde (GLU), Nitrite (NI), pH, Specific Gravity (S.G.), and/or Oxidants (OXI)) for the determination of diluted or adulterated urine specimens. The adulteration control is an important pre-screening test for drug-testing. (The adulteration tests are optional, customers can distinguish them from the pouch label).

This package insert applies to multi-drug Cups with or without the adulteration control. Therefore, some information on the performance characteristics of the product may not be relevant to your test. Please refer to the labels on the pouch and the printing on the test to identify which tests are included.

**It is intended for forensic use only.**

### WHAT IS THE T-CUP® COMPACT MULTI-DRUG URINE TEST CUP?

The T-Cup® Compact Multi-Drug Urine Test Cup is an immunochromatographic assay for the qualitative determination of multiple drugs in human urine.

### WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?

Drug(Identifier)	Calibrator	Cut-off level	Minimum detection time	Maximum detection time
Amphetamine (AMP300)	d-Amphetamine	300 ng/mL	2-7 hours	1-2 days
Amphetamine (AMP500)	d-Amphetamine	500 ng/mL	2-7 hours	1-2 days
Amphetamine (AMP1000)	d-Amphetamine	1000 ng/mL	2-7 hours	1-2 days
Secobarbital (BAR200)	Secobarbital	200 ng/mL	2-4 hours	1-4 days
Secobarbital (BAR300)	Secobarbital	300 ng/mL	2-4 hours	1-4 days
Buprenorphine(BUP)	Buprenorphine	10 ng/mL	4 hours	1-3 days
Oxazepam (BZO100)	Oxazepam	100 ng/mL	2-7 hours	1-2 days
Oxazepam (BZO200)	Oxazepam	200 ng/mL	2-7 hours	1-2 days
Oxazepam (BZO300)	Oxazepam	300 ng/mL	2-7 hours	1-2 days
Cocaine (COC100)	Benzoyllecgonine	100 ng/mL	1-4 hours	2-4 days
Cocaine (COC150)	Benzoyllecgonine	150 ng/mL	1-4 hours	2-4 days
Cocaine (COC300)	Benzoyllecgonine	300 ng/mL	1-4 hours	2-4 days
Cotinine (COT)	Cotinine	200 ng/mL	2-8 hours	1-7 days
EDDP100	2-ethylidene-1,5-dimethyl-3,3-diphenyl pyrrolidine	100 ng/mL	3-8 hours	1-3 days
EDDP300	2-ethylidene-1,5-dimethyl-3,3-diphenyl pyrrolidine	300 ng/mL	3-8 hours	1-3 days
Ethyl Glucuronide (EtG)	Ethyl Glucuronide	500 ng/mL	1-2 hours	Up to 3+ days
Fentanyl (FTY)	Norfentanyl	20 ng/mL	1-4 hours	1-3 days
Synthetic Cannabinoid (K2)	JWH-018 Pentanoic Acid JWH-073 Butanoic Acid	50 ng/mL 50 ng/mL	8-12 hours	Up to 5+ days
Ketamine (KET 300)	Ketamine	300 ng/mL	2-4 hours	2-3 days
Ketamine (KET 1000)	Ketamine	1000 ng/mL	2-4 hours	2-3 days
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine	D(+)-Methamphetamine	300 ng/mL	2-7 hours	2-4 days

(MET300/mAMP300)				
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
Morphine (MOP/OPI100)	Morphine	100 ng/mL	2 hours	2-3 days
Morphine (MOP/OPI300)	Morphine	300 ng/mL	2 hours	2-3 days
Methadone (MTD200)	Methadone	200 ng/mL	3-8 hours	1-3 days
Methadone (MTD300)	Methadone	300 ng/mL	3-8 hours	1-3 days
Opiate (OPI)	Morphine	2000 ng/mL	2 hours	2-3 days
Oxycodone (OXY)	Oxycodone	100 ng/mL	4 hours	1-3 days
Phencyclidine (PCP)	Phencyclidine	25 ng/mL	4-6 hours	7-14 days
Propoxyphene (PPX)	Propoxyphene	300 ng/mL	2 hours	2-3 days
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL	8-12 hours	2-7 days
Cannabinoids (THC25)	11-nor- $\Delta^9$ -THC-9-COOH	25 ng/mL	2 hours	Up to 5+ days
Cannabinoids (THC40)	11-nor- $\Delta^9$ -THC-9-COOH	40 ng/mL	2 hours	Up to 5+ days
Cannabinoids (THC50)	11-nor- $\Delta^9$ -THC-9-COOH	50 ng/mL	2 hours	Up to 5+ days
Tramadol (TRA 100)	Tramadol	100 ng/mL	8-12 hours	3-7 days
Tramadol (TRA 200)	Tramadol	200 ng/mL	8-12 hours	3-7 days
Tramadol (TRA 1000)	Tramadol	1000 ng/mL	8-12 hours	3-7 days
Alcohol (ETOH)	Alcohol	0.04 g/dL	-	-

### WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or not sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes.

### CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch contains a test and two desiccants. The desiccants are for storage purposes only, and are not used in the test procedures.
2. Security sealed labels.
3. Leaflet with instructions for use.
4. Adulteration Color Chart. (Provided with Kits including Adulteration Control.)

### MATERIAL REQUIRED BUT NOT PROVIDED

Timer or clock

### STORAGE AND STABILITY

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

### SPECIMEN COLLECTION

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

Collect the urine sample for the test in the minimum detection time after the suspected drug use. Exactly when the urine sample is collected is very important in detecting any drug. This is because each drug is cleared by the body at different rates. Please refer to the section "WHAT IS THE CUT-OFF VALUE AND APPROXIMATE DETECTION TIME?" in this instruction for use for the minimum/maximum detection time for each drug.

### TEST PROCEDURE

Test should be at room temperature 18°C-30°C (65°F-86°F)

1. Remove the test cup from the foil pouch by tearing at the notch and use it as soon as possible. Open the cap of the test cup and urinate directly into the test cup filling at least to the minimum urine level (approximately 25mL). Wipe off any splashes or spills that may be on the outside of this cup. Re-cap the test cup and place it on a flat surface.

2. Start the timer. Peel off the label from right to left.

**Note: Adulteration test results should be read between 1-2 minutes. Drug test results should be read after 5 minutes.**

3. You may observe the temperature strip affixed on the test cup between 2 to 4 minutes. An adulterated sample may result in a temperature outside of the acceptable range. The temperature range from 32°C-38°C (90°F-100°F) is acceptable. The temperature of the sample will not determine if water has been added or some other liquid.

**For Drug Test:**

Read the drug test results at 5 minutes. **Do not read results after 5 minutes.**



**For Adulteration Test, Alcohol Test and Drug Test:**

- For the adulteration strip(s), compare each reagent pad to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results. If the results indicate adulteration, do not read the drug test results, obtain a new sample. Note: All reagent pads may be read between 1 - 2 minutes. Changes in color after 2 minutes should not be considered.
- Read the alcohol test result at 2 minutes. **Do not read results after 2 minutes.**
- Read the drug test results at 5 minutes. **Do not read results after 5 minutes.**



**READING THE R**

**ADULTERATION CONTROL:**

Semi-quantitative results are obtained by visually comparing the color of each pad with the corresponding color blocks on the enclosed color chart.

**DRUGS-OF-ABUSE TESTS:**

**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.

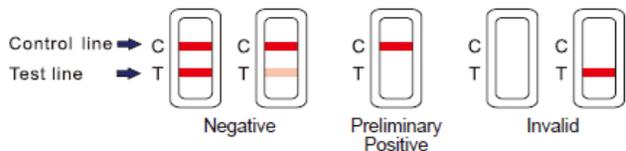
**Preliminary positive (+)**

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

**Invalid**

If a colored band is not visible in each of the control regions or a color band is only visible in each of the test regions, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor, with the lot number.

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.

**ALCOHOL TEST:**

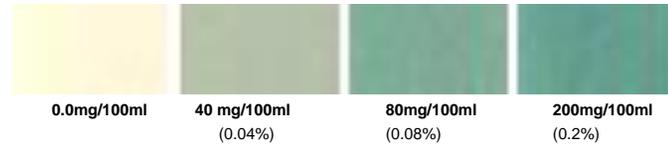
**Negative (-)**

Almost no color change on test pad in comparison with the back-ground of the provided colored chart. The negative result indicates that the concentration of ethyl alcohol in urine is less than 0.04%.

**Preliminary positive (+)**

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

**Approximate Alcohol Concentration**



**Invalid**

The test should be considered invalid if only the edge of the reaction pad turned color that might be ascribed to insufficient sampling. The subject should be re-tested.

**IMPORTANT:** The result you obtained is called preliminary for a reason. The sample should be tested by a 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 the T-Cup® Compact Multi-Drug Urine 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 T-Cup® Compact Multi-Drug Urine Test Cup. If the sample is diluted, or the sample is adulterated that may cause false negative result.

**TEST LIMITATIONS**

- This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test anything but urine.
- Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

**Note:** The test provides only preliminary test results. A more specific alternative chemical method should be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods. Professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

**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.

### **Cotinine (COT)**

Cotinine is an alkaloid found in tobacco and is also a major metabolite of Nicotine, which produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is found in tobacco products such as cigarettes, tobacco chew, and nicotine patches or gums. It is an addictive substance and is poisonous in a large amount. In addition to addiction, some of the other substances within tobacco products, such as carbon monoxide or tar, are dangerous to the body and can lead to medical conditions such as emphysema, lung cancer, and heart disease. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While Cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of Nicotine which is largely urine PH dependent. Cotinine is stable in body fluids and has a relatively long half-life of approximately 17 hours, and is typically detectable for several days (up to one week) after the use of tobacco, therefore the detection of Cotinine is less dependent on the time of sampling than that of Nicotine.

Nicotine and Cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2–3 days after nicotine use.

### **EDDP**

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

### **Ethyl Glucuronide (EtG)**

Ethyl Glucuronide is a direct metabolite of alcohol. Presence in urine may be used to detect recent alcohol intake, even after alcohol is no longer measurable. Traditional laboratory methods detect the actual alcohol in the body, which reflects current intake within the past few hours (depending on how much was consumed). The presence of EtG in urine is a definitive indicator that it can be detected in the urine for 3 to 4 days after drinking alcohol, even alcohol is eliminated from the body. Therefore, EtG is a more accurate indicator of the recent intake of alcohol than measuring for the presence of alcohol itself. The EtG test can aid in the diagnosis of drunk driving and alcoholism, which has important significance in the forensic identification and medical examination.

### **Fentanyl (FTY)**

Fentanyl is a potent, synthetic narcotic analgesic with a rapid onset and short duration of action. It was first synthesized by Janssen Pharmaceutica (Belgium) in the late 1950s, and it is approximately 100 times more potent than morphine. Fentanyl is a strong agonist at the  $\mu$ -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.

### **Ketamine (KET)**

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

### **Synthetic cannabinoids (K2)**

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

### **Methylenedioxymethamphetamine (MDMA)**

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and 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/OPI300)**

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/OPI300) of the T-Cup® Compact Multi-Drug Urine Test Cup yields a positive result when the morphine in 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.

### **Opiate (OPI)**

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

The test for Morphine 2000 (OPI) of the T-Cup® Compact Multi-Drug Urine Test Cup yields a positive result when the morphine in 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 opiate 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 hours 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.

### **Phencyclidine (PCP)**

Phencyclidine is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilizer. Phencyclidine can produce hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It has many street names, such as "angel dust" and "crystal cyclone," etc. phencyclidine can be administered orally, by nasal ingestion, smoking, or by intravenous injection. It is metabolized in the liver and excreted through the kidneys in urine in unchanged form and oxidized metabolites with a half-life of about 12 hours. Suction and urinary acidification in the treatment of overdose typically reduces its half-life from three days to one day.

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

**Tramadol (TRA)**

Tramadol [2-(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.

**Alcohol (ETOH)**

Alcohol Test is intended for use to detect the presence of alcohol in urine greater than 0.04%. Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Since the urine alcohol concentration is normally higher than that in saliva and blood, the cutoff concentration for alcohol in urine was set at 0.04%. Normally, it will take at least 30 minutes for the alcohol to be detected in saliva, blood and urine after drinking.

**PRINCIPLE**

The T-Cup® Compact Multi-Drug Urine Test Cup is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is a chromatographic absorbent device in which drugs in a sample competitively combine to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the absorbent end is immersed into urine specimen, the urine is absorbed into the device by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

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

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

**QUALITY CONTROL**

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

Even though there is an internal procedural control line in the test device in the 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 controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot of test received, each new shipment, each new operator and monthly to determine that tests are working properly. This will ensure that the end user has clear understanding of when to perform quality control testing.

**PERFORMANCE CHARACTERISTICS**

**ADULTERATION CONTROL:**

*Expected Results*

**Creatinine:** Daily creatinine excretion, related to muscle mass of the human body, is usually constant. The DOT guideline states that urine specimens with creatinine levels of less than 20 mg/dl are indications of adulteration. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution, sample with creatinine level of lower than 20 mg/dl should be considered adulterated.

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

**Nitrite:** 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.

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

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

**Specific Gravity:** Random urine may vary in specific gravity from 1.005 - 1.025. Adults with average diets and fluid intake will have an average urine specific gravity of 1.016 - 1.022. Elevated urine specific gravity value may be obtained in the presence of moderate quantities of protein. DOT guidelines state that a urine specimen with specific gravity level of less than 1.003 is an indication of adulteration. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is adulterated.

**DRUGS TESTS:**

**Accuracy**

3120 (eighty of each drug) clinical urine specimens were analyzed by GC-MS and by each corresponding drug test. Each test was read by three viewers. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

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 (300)	Viewer A	+ 0	0	2	29	11	100% (91.2% - 100%)
	A	- 10	17	11	0	0	95% (83.5% - 98.6%)
	Viewer B	+ 0	0	1	29	11	100% (91.2% - 100%)
	B	- 10	17	12	0	0	97.5% (87.1% - 99.6%)
	Viewer C	+ 0	0	1	29	11	100% (91.2% - 100%)
	C	- 10	17	12	0	0	97.5% (87.1% - 99.6%)
AMP (500)	Viewer A	+ 0	0	2	30	10	100% (91.2% - 100%)
	A	- 10	17	11	0	0	95% (83.5% - 98.6%)
	Viewer B	+ 0	0	1	30	10	100% (91.2% - 100%)
	B	- 10	17	12	0	0	97.5% (87.1% - 99.6%)
	Viewer C	+ 0	0	2	30	10	100% (91.2% - 100%)
	C	- 10	17	11	0	0	95% (83.5% - 98.6%)
AMP (1000)	Viewer A	+ 0	0	1	11	29	100% (84.5% - 100%)
	A	- 10	18	11	0	0	97.5% (82% - 100%)
	Viewer B	+ 0	0	2	11	29	100% (84.5% - 100%)
	B	- 10	18	10	0	0	95% (79.5% - 100%)
	Viewer C	+ 0	0	2	11	29	100% (84.5% - 100%)
	C	- 10	18	10	0	0	95% (79.5% - 100%)
BAR (200)	Viewer A	+ 0	0	1	18	20	95% (84.5% - 100%)
	A	- 10	10	19	2	0	97.5% (79.5% - 100%)
	Viewer B	+ 0	0	2	20	20	100% (84.5% - 100%)
	B	- 10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	+ 0	0	2	18	20	95% (84.5% - 100%)
	C	- 10	10	18	2	0	95% (79.5% - 100%)
BAR (300)	Viewer A	+ 0	0	2	20	20	100% (84.5% - 100%)
	A	- 10	10	18	0	0	95% (79.5% - 100%)
	Viewer B	+ 0	0	2	20	20	100% (84.5% - 100%)
	B	- 10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	+ 0	0	2	20	20	100% (84.5% - 100%)
	C	- 10	10	18	0	0	95% (79.5% - 100%)
BZO (100)	Viewer A	+ 0	0	2	21	18	97.5% (91.2% - 100%)
	A	- 10	18	10	1	0	95.0% (83.5% - 98.6%)
	Viewer B	+ 0	0	1	20	18	95% (91.2% - 100%)
	B	- 10	18	11	2	0	97.5% (87.1% - 99.6%)
	Viewer C	+ 0	0	1	22	18	100% (91.2% - 100%)
	C	- 10	18	11	0	0	95% (87.1% - 99.6%)
BZO (200)	Viewer A	+ 0	0	2	22	18	100% (91.2% - 100%)
	A	- 10	18	10	0	0	95.0% (83.5% - 98.6%)
	Viewer B	+ 0	0	1	22	18	100% (91.2% - 100%)
	B	- 10	18	11	0	0	97.5% (87.1% - 99.6%)
	Viewer	+ 0	0	1	22	18	100% (91.2% - 100%)
	Viewer	- 10	18	11	0	0	97.5% (87.1% - 99.6%)

	C	-	10	18	11	0	0	95% (87.1% - 99.6%)
<b>BZO (300)</b>	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%)
<b>COC (100)</b>	Viewer	+	0	0	2	27	13	100% (91.2% - 100%)
	A	-	10	15	13	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	2	27	13	100% (91.2% - 100%)
	B	-	10	15	13	0	0	95% (83.5% - 98.6%)
<b>COC (150)</b>	Viewer	+	0	0	1	27	13	100% (91.2% - 100%)
	A	-	10	15	14	0	0	97.5% (87.1% - 99.6%)
	Viewer	+	0	0	2	30	10	100% (91.2% - 100%)
	B	-	10	18	10	0	0	95% (83.5% - 98.6%)
<b>COC (300)</b>	Viewer	+	0	0	1	30	10	100% (91.2% - 100%)
	A	-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	2	11	29	100% (84.5% - 100%)
	B	-	10	10	19	0	0	97.5% (82% - 100%)
<b>COT</b>	Viewer	+	0	0	2	11	29	100% (84.5% - 100%)
	A	-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	1	28	10	95% (84.5% - 100%)
	B	-	10	10	19	2	0	97.5% (82% - 100%)
<b>EDDP (100)</b>	Viewer	+	0	0	2	29	10	97.5% (84.5% - 100%)
	A	-	10	10	18	1	0	95% (79.5% - 100%)
	Viewer	+	0	0	1	29	10	97.5% (91.2% - 100%)
	B	-	10	18	11	1	0	97.5% (87.1% - 99.6%)
<b>EDDP (300)</b>	Viewer	+	0	0	2	30	10	100% (91.2% - 100%)
	A	-	10	18	10	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	1	29	10	97.5% (91.2% - 100%)
	B	-	10	18	11	1	0	97.5% (87.1% - 99.6%)
<b>EtG</b>	Viewer	+	0	0	2	30	10	100% (91.2% - 100%)
	A	-	10	18	10	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	1	21	9	97.5% (82% - 100%)
	B	-	10	12	18	1	0	100% (84.5% - 100%)
<b>FTY</b>	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
	A	-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
	B	-	10	12	17	0	0	97.5% (82% - 100%)
<b>KET (300)</b>	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
	A	-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	18	21	97.5% (82% - 100%)
	B	-	10	12	17	1	0	97.5% (84.5% - 100%)
<b>KET (1000)</b>	Viewer	+	0	0	0	18	21	97.5% (82% - 100%)
	A	-	10	12	16	2	0	95% (79.5% - 100%)
	Viewer	+	0	0	0	18	21	97.5% (82% - 100%)
	B	-	10	12	18	1	0	100% (84.5% - 100%)
<b>MET</b>	Viewer	+	0	0	2	21	19	100% (91.2% - 100%)

<b>(mAMP) (300)</b>	A	-	10	11	17	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	2	21	19	100% (91.2% - 100%)
	B	-	10	11	17	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	2	21	19	100% (91.2% - 100%)
<b>MET (mAMP) (500)</b>	C	-	10	11	17	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	2	20	20	100% (91.2% - 100%)
	A	-	10	15	13	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	2	20	20	100% (91.2% - 100%)
<b>MET (mAMP) (1000)</b>	B	-	10	15	13	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	2	20	20	100% (91.2% - 100%)
	A	-	10	16	13	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	2	20	20	100% (84.5% - 100%)
<b>MDMA</b>	B	-	10	16	12	0	0	95% (79.5% - 100%)
	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>BUP</b>	B	-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	2	20	20	100% (84.5% - 100%)
	A	-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	1	16	24	100% (84.5% - 100%)
<b>MOP/OP100</b>	A	-	10	18	11	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	16	24	100% (84.5% - 100%)
	B	-	10	18	11	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	2	16	24	100% (84.5% - 100%)
<b>MOP/OP1300</b>	C	-	10	18	10	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	2	28	12	100% (91.2% - 100%)
	A	-	10	16	12	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	3	28	12	100% (91.2% - 100%)
<b>MTD (200)</b>	B	-	10	16	11	0	0	92.5% (80.1% - 97.4%)
	Viewer	+	0	0	2	28	12	100% (91.2% - 100%)
	A	-	10	16	12	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	2	20	20	100% (84.5% - 100%)
<b>MTD (300)</b>	B	-	10	19	9	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	2	20	20	100% (84.5% - 100%)
	A	-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	20	20	100% (84.5% - 100%)
<b>OPI</b>	C	-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	2	15	25	100% (91.2% - 100%)
	A	-	10	13	15	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	2	15	25	100% (91.2% - 100%)
<b>PCP</b>	B	-	10	13	15	0	0	95% (83.5% - 98.6%)
	Viewer	+	0	0	1	15	25	100% (91.2% - 100%)
	A	-	10	13	16	0	0	97.5% (87.1% - 99.6%)
	Viewer	+	0	0	1	19	21	100% (84.5% - 100%)
<b>TCA</b>	C	-	10	12	18	1	0	100% (84.5% - 100%)
	Viewer	+	0	0	1	17	0	97.5% (82% - 100%)
	A	-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	2	19	21	100% (84.5% - 100%)
<b>OPI</b>	B	-	10	12	16	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	1	19	21	100% (84.5% - 100%)
	A	-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
<b>PCP</b>	B	-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
	A	-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
<b>TCA</b>	C	-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
	A	-	10	13	16	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	2	18	22	100% (84.5% - 100%)
<b>OPI</b>	B	-	10	13	15	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
	A	-	10	13	16	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
<b>PCP</b>	C	-	10	13	16	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
	A	-	10	13	16	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	2	18	22	100% (84.5% - 100%)
<b>TCA</b>	B	-	10	13	15	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	1	18	22	100% (84.5% - 100%)
	A	-	10	13	16	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	1	10	30	100% (84.5% - 100%)
<b>OPI</b>	C	-	10	13	16	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	2	10	30	100% (84.5% - 100%)
	A	-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer	+	0	0	2	10	30	100% (84.5% - 100%)

	B	-	10	19	9	0	0	95% (79.5% - 100%)
	Viewer	+	0	0	1	10	30	100% (84.5% - 100%)
	C	-	10	19	10	0	0	97.5% (82% - 100%)
THC (25)	Viewer A	+	0	0	1	17	22	97.5% (84.5% - 100%)
		-	10	12	17	1	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
THC (40)	Viewer A	+	0	0	2	20	20	100% (91.2% - 100%)
		-	10	13	15	0	0	95% (83.5% - 98.6%)
	Viewer B	+	0	0	1	20	20	100% (91.2% - 100%)
		-	10	13	16	0	0	97.5% (87.1% - 99.6%)
	Viewer C	+	0	0	2	20	20	100% (91.2% - 100%)
		-	10	13	15	0	0	95% (83.5% - 98.6%)
THC (50)	Viewer A	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
OXY	Viewer A	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
PPX	Viewer A	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
K2	Viewer A	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	0	17	22	97.5% (82% - 100%)
		-	10	12	18	1	0	100% (84.5% - 100%)
	Viewer C	+	0	0	0	15	22	92.5% (77% - 100%)
		-	10	12	18	3	0	100% (84.5% - 100%)
TRA (100)	Viewer A	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	20	8	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	1	19	20	97.5% (84.5% - 100%)
		-	10	20	9	1	0	97.5% (79.5% - 100%)
	Viewer C	+	0	0	1	18	20	95% (84.5% - 100%)
		-	10	20	9	2	0	97.5% (82% - 100%)
TRA (200)	Viewer A	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	20	8	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	20	8	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
TRA (1000)	Viewer A	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	20	8	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	1	19	20	97.5% (84.5% - 100%)
		-	10	20	9	1	0	97.5% (79.5% - 100%)
	Viewer C	+	0	0	1	18	20	95% (84.5% - 100%)
		-	10	20	9	2	0	97.5% (82% - 100%)

#### Precision and Sensitivity

To investigate the 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 tests 2 aliquots at each concentration for each lot per day (2 runs/day), for a total of 50 determinations per concentration per lot of the corresponding drug test.

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Results Negative/ Positive		
			Lot 1	Lot 2	Lot 3

AMP (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	5/45	5/45	4/46	
	375	50	0/50	0/50	0/50	
	450	50	0/50	0/50	0/50	
	525	50	0/50	0/50	0/50	
	600	50	0/50	0/50	0/50	
	0	50	50/0	50/0	50/0	
AMP (500)	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	
	0	50	50/0	50/0	50/0	
	250	50	50/0	50/0	50/0	
AMP (1000)	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	
	0	50	50/0	50/0	50/0	
	50	50	50/0	50/0	50/0	
	100	50	50/0	50/0	50/0	
BAR (200)	150	50	48/2	49/1	49/1	
	200	50	4/46	6/44	4/46	
	250	50	3/47	2/48	2/48	
	300	50	0/50	0/50	0/50	
	350	50	0/50	0/50	0/50	
	400	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	
BAR (300)	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	
	0	50	50	50/0	50/0	
	25	50	50	50/0	50/0	
	50	50	50	50/0	50/0	
	75	50	50	46/4	47/3	
	100	50	50	4/46	4/46	
BZO (100)	125	50	50	3/47	2/48	
	150	50	50	0/50	0/50	
	175	50	50	0/50	0/50	
	200	50	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	4/46	4/46	
	250	50	0/50	0/50	0/50	
BZO (200)	300	50	0/50	0/50	0/50	
	350	50	0/50	0/50	0/50	
	400	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	6/44	5/45	6/44	
	BZO (300)	0	50	50/0	50/0	50/0
		75	50	50/0	50/0	50/0
150		50	50/0	50/0	50/0	
225		50	50/0	50/0	50/0	
300		50	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 (100)	0	50	50/0	50/0	50/0
	25	50	50/0	50/0	50/0
	50	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	100	50	4/46	4/46	3/47
	125	50	0/50	0/50	0/50
	150	50	0/50	0/50	0/50
	175	50	0/50	0/50	0/50
	200	50	0/50	0/50	0/50
	COC (150)	0	50	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
	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
	600	50	0/50	0/50	0/50
	COT (200)	0	50	50/0	50/0
50		50	50/0	50/0	50/0
100		50	50/0	50/0	50/0
150		50	48/2	49/1	47/3
200		50	6/44	4/46	5/45
250		50	4/46	3/47	2/48
300		50	0/50	0/50	0/50
350		50	0/50	0/50	0/50
400		50	0/50	0/50	0/50
EDDP (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	46/4	47/3
	100	50	6/44	5/45	5/45
	125	50	2/48	3/47	5/45
	150	50	0/50	0/50	0/50
	175	50	0/50	0/50	0/50
	200	50	0/50	0/50	0/50
	EDDP (300)	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	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
EtG		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	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
	FTY	0	50	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
	40	50	0/50	0/50	0/50
KET (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	48/2	47/3	47/3
	300	50	5/45	5/45	5/45
	375	50	2/48	1/49	3/47
	450	50	0/50	0/50	0/50
	525	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
	KET (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	47/3	48/2	47/3
1000		50	5/45	4/46	5/45
1250		50	2/48	2/48	3/47
1500		50	0/50	0/50	0/50
1750		50	0/50	0/50	0/50
2000		50	0/50	0/50	0/50
MET (mAMP) (300)		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	3/47	5/45	4/46
	375	50	0/50	0/50	0/50
	450	50	0/50	0/50	0/50
	525	50	0/50	0/50	0/50
	600	50	0/50	0/50	0/50
	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
	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
BUP		0	50	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
MOP/OPI100	0	50	50/0	50/0	50/0
	25	50	50/0	50/0	50/0
	50	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	100	50	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
	200	50	0/50	0/50	0/50
	MOP/OPI300	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
525		50	0/50	0/50	0/50
MTD (200)	0	50	50/0	50/0	50/0
	50	50	50/0	50/0	50/0
	100	50	50/0	50/0	50/0
	150	50	50/0	50/0	50/0
	200	50	5/45	6/44	4/46
	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
	MTD (300)	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	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
	PCP	0	50	50/0	50/0
6.25		50	50/0	50/0	50/0
12.5		50	50/0	50/0	50/0
18.75		50	50/0	50/0	50/0
25		50	6/44	4/46	5/45
31.25		50	0/50	0/50	0/50
37.5		50	0/50	0/50	0/50
43.75		50	0/50	0/50	0/50
50		50	0/50	0/50	0/50
TCA		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	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
THC (25)	0	50	50/0	50/0	50/0
	6.25	50	50/0	50/0	50/0

	12.5	50	50/0	50/0	50/0
	18.75	50	50/0	48/2	47/3
	25	50	5/45	5/45	3/47
	31.25	50	2/48	3/47	1/49
	37.5	50	0/50	0/50	0/50
	43.75	50	0/50	0/50	0/50
	50	50	0/50	0/50	0/50
THC (40)	0	50	50/0	50/0	50/0
	10	50	50/0	50/0	50/0
	20	50	50/0	50/0	50/0
	30	50	50/0	50/0	50/0
	40	50	5/45	5/45	3/47
	50	50	0/50	0/50	0/50
	60	50	0/50	0/50	0/50
	70	50	0/50	0/50	0/50
	80	50	0/50	0/50	0/50
	THC (50)	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
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
	200	50	0/50	0/50	0/50
	K2 JWH-018 Pentanoic Acid	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	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
	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
	PPX	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	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
600		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
	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
<b>TRA (200)</b>	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
	250	50	0/50	0/50	0/50
	300	50	0/50	0/50	0/50
	350	50	0/50	0/50	0/50
<b>TRA (1000)</b>	400	50	0/50	0/50	0/50
	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	49/1	49/1
	1000	50	4/46	5/45	5/45
	1250	50	2/48	3/47	2/48
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50

### Specificity and Cross Reactivity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

Items	Concentration (ng/mL)	Items	Concentration (ng/mL)
<b>Amphetamine (AMP300)</b>		<b>Cotinine (COT)</b>	
d-Amphetamine	300	Cotinine	200
l-Amphetamine	17,500	<b>EDDP100</b>	
d,l-Amphetamine	850	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
(+/-) 3,4-methylenedioxyamphetamine (MDA)	1,000	Methadone	100,000
Phentermine	1,000	EMDP	100,000
β-Phenylethylamine	100,000	<b>EDDP300</b>	
Tyramine	100,000	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
p-Hydroxynorephedrine	100,000	Methadone	300,000
Phenylpropanolamine	>100,000	EMDP	300,000
(±)Phenylpropanolamine	>100,000	<b>Ethyl Glucuronide (EtG)</b>	
p-Hydroxyamphetamine	100,000	Ethyl Glucuronide	500
Hydroxyamphetamine	6,000	<b>Fentanyl (FTY)</b>	
		Norfentanyl	20
d-Methamphetamine	>100,000	Fentanyl	200
l-Methamphetamine	>100,000	<b>Methadone (MTD200)</b>	
(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	Methadone	200
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	Doxylamine	40,000
Benzphetamine	>100,000	<b>Methadone (MTD300)</b>	
Ephedrine	>100,000	Methadone	300
l-Ephedrine	>100,000	Doxylamine	50,000
l-Epinephrine	>100,000	<b>Methamphetamine (MET300/mAMP300)</b>	
d,l-Epinephrine	>100,000	D(+)-Methamphetamine	300
<b>Amphetamine (AMP500)</b>		D-Amphetamine	10,000
d-Amphetamine	500	Chloroquine	8,000
l-Amphetamine	25,000	(+/-)-Ephedrine	20,000
d,l-Amphetamine	1,500	(-)-Methamphetamine	8,000
(+/-) 3,4-methylenedioxyamphetamine (MDA)	2,500	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	800
Phentermine	1,500	β-Phenylethylamine	10,000
Hydroxyamphetamine	8,000	Trimethobenzamide	3,000
d-Methamphetamine	>100,000	(+/-)3,4-Methylenedioxyethylamphetamine(MDEA)	500
l-Methamphetamine	>100,000	d,l-Methamphetamine	1,000
(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	p-Hydroxymethamphetamine	30,000

(+/-)3,4-Methylenedioxyamphetamine (MDMA)	>100,000	(+/-)3,4-Methylenedioxyamphetamine (MDA)	500
Ephedrine	>100,000	L-Amphetamine	20,000
β-Phenylethylamine	100,000	D,L-Amphetamine	70,000
Tyramine	100,000	Mephentermine	20,000
p-Hydroxynorephedrine	100,000	(1R,2S)-(-)-Ephedrine	>100,000
Phenylpropanolamine	>100,000	L-phenylephrine	>100,000
(±)Phenylpropanolamine	>100,000	<b>Methamphetamine (MET500/mAMP500)</b>	
p-Hydroxyamphetamine	100,000	D(+)-Methamphetamine	500
Benzphetamine	>100,000	D-Amphetamine	25,000
l-Ephedrine	>100,000	L-Amphetamine	37,500
l-Epinephrine	>100,000	Chloroquine	10,000
d,l-Epinephrine	>100,000	(+/-)-Ephedrine	25,000
<b>Amphetamine (AMP1000)</b>		d,l-Methamphetamine	500
d-Amphetamine	1,000	L-Methamphetamine	10,000
d,l-Amphetamine	3,000	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	500
l-Amphetamine	50,000	(+/-)3,4-Methylenedioxyamphetamine (MDA)	500
(+/-) 3,4-methylenedioxyamphetamine (MDA)	5,000	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	1,000
Phentermine	3,000	β-Phenylethylamine	25,000
Hydroxyamphetamine	8,000	Trimethobenzamide	5,000
d-methamphetamine	>100,000	d,l-Amphetamine	75,000
l-methamphetamine	>100,000	p-Hydroxymethamphetamine	15,000
3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	Mephentermine	25,000
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100,000	(1R,2S)-(-)-Ephedrine	50,000
β-Phenylethylamine	100,000	l-Phenylephrine	100,000
Tyramine	100,000	<b>Methamphetamine (MET1000/mAMP1000)</b>	
p-Hydroxynorephedrine	100,000	D(+)-Methamphetamine	1,000
Phenylpropanolamine	>100,000	D-Amphetamine	>100,000
(±)Phenylpropanolamine	>100,000	Chloroquine	50,000
p-Hydroxyamphetamine	100,000	(+/-)-Ephedrine	50,000
Benzphetamine	>100,000	(-)-Methamphetamine	25,000
l-Ephedrine	>100,000	(+/-)3,4-methylenedioxymethamphetamine(MDEA)	4,000
l-Epinephrine	>100,000	β-Phenylethylamine	50,000
d,l-Epinephrine	>100,000	Trimethobenzamide	10,000
Ephedrine	>100,000	(+/-)3,4-Methylenedioxyethylamphetamine(MDEA)	1,000
<b>Barbiturates (BAR200)</b>		d,l-Methamphetamine	1,000
Secobarbital	200	p-Hydroxymethamphetamine	30,000
Amobarbital	9,000	(+/-)3,4-Methylenedioxyamphetamine (MDA)	1,000
Alphenol	100	L-Amphetamine	75,000
Aprobarbital	150	D,L-Amphetamine	100,000
Butabarbital	50	Mephentermine	50,000
Butathal	75	(1R,2S)-(-)-Ephedrine	>100,000
Butalbital	1,700	L-phenylephrine	>100,000
Cyclopentobarbital	400	<b>Methylenedioxymethamphetamine (MDMA)</b>	
Pentobarbital	2,000	3,4-Methylenedioxymethamphetamine (MDMA)	500
Phenobarbital	10,000	3,4-Methylenedioxyamphetamine (MDA)	3,000
<b>Barbiturates (BAR300)</b>		3,4-Methylenedioxyethylamphetamine (MDEA)	300
Secobarbital	300	d-methamphetamine	>100,000
Amobarbital	10,000	d-amphetamine	>100,000
Alphenol	150	<b>Morphine (MOP/OPI100)</b>	
Aprobarbital	200	Morphine	100
Butabarbital	75	Codeine	100
Butathal	100	Ethyl Morphine	75
Butalbital	2,500	Hydrocodone	3,000
Cyclopentobarbital	600	Hydromorphone	800
Pentobarbital	2,500	Levorphanol	5,000
Phenobarbital	10,000	6-Monoacetylmorphine	100
<b>Benzodiazepines (BZO100)</b>		Morphine 3-β-D-glucuronide	200
Oxazepam	100	Norcodeine	5,000
Alprazolam	75	Normorphine	200
a-Hydroxyalprazolam	500	Oxycodone	10,000
Bromazepam	400	Oxymorphone	10,000
Chlordiazepoxide	500	Procaine	100,000
Clobazam	50	Thebaine	2,000

Clonazepam	800	Heroin	300
Clorazepate dipotassium	75	<b>Morphine (MOP/OPI300)</b>	
Delorazepam	500	Morphine	300
Desalkylflurazepam	150	Codeine	300
Diazepam	75	Ethyl Morphine	100
Estazolam	800	Heroin	300
Flunitrazepam	1,800	Hydrocodone	5,000
D,L-Lorazepam	>100,000	Hydromorphone	1,000
Midazolam	4,200	Morphine-3-β-d-glucuronide	1,000
Nitrazepam	3,000	6-Monoacetylmorphine	150
Norchlordiazepoxide	75	Normorphine	300
Nordiazepam	300	Oxycodone	10,000
Temazepam	150	Oxymorphone	10,000
Trazolam	800	Thebaine	3,000
Demoxepam	1,500	Levorphanol	10,000
Flurazepam	400	Norcodeine	6,250
<b>Benzodiazepines (BZO200)</b>		Procaine	150,000
Oxazepam	200	<b>Opiate (OPI)</b>	
Alprazolam	150	Morphine	2,000
a-Hydroxyalprazolam	1,000	Codeine	2,000
Bromazepam	500	Ethyl Morphine	1,500
Chlordiazepoxide	1,000	Heroin	2,000
Clobazam	70	Hydrocodone	12,500
Clonazepam	800	Hydromorphone	3,500
Clorazepate dipotassium	150	Levorphanol	75,000
Delorazepam	1,000	6-Monoacetylmorphine	1,500
Desalkylflurazepam	200	Morphine 3-β-D-glucuronide	2,000
Diazepam	150	Norcodeine	12,500
Estazolam	1,000	Normorphine	50,000
Flunitrazepam	2,000	Oxycodone	25,000
D,L-Lorazepam	>100,000	Oxymorphone	25,000
Midazolam	5,000	Procaine	150,000
Nitrazepam	3,000	Thebaine	5,000
Norchlordiazepoxide	100	<b>Oxycodone (OXY)</b>	
Nordiazepam	400	Oxycodone	100
Temazepam	200	Dihydrocodeine	20,000
Triazolam	1,000	Codeine	100,000
Demoxepam	1,800	Hydromorphone	100,000
Flurazepam	450	Morphine	> 100,000
<b>Benzodiazepines (BZO300)</b>		Acetylmorphine	> 100,000
Oxazepam	300	Buprenorphine	> 100,000
Alprazolam	200	Ethylmorphine	> 100,000
a-Hydroxyalprazolam	1,500	Thebaine	> 100,000
Bromazepam	500	Oxymorphone	1,000
Chlordiazepoxide	1,500	<b>Phencyclidine (PCP)</b>	
Clobazam	100	Phencyclidine	25
Clonazepam	800	4-Hydroxyphencyclidine	12,500
Clorazepate dipotassium	200	<b>Propoxyphene (PPX)</b>	
Delorazepam	1,500	d-Propoxyphene	300
Desalkylflurazepam	400	d-Norpropoxyphene	300
Diazepam	200	<b>Synthetic Cannabinoids (K2)</b>	
Estazolam	1,000	JWH-018 Pentanoic Acid	50
Flunitrazepam	2,500	JWH-073 Butanoic Acid	50
D,L-Lorazepam	>100,000	JWH-018 N-4-hydroxypentyl	2,000
Midazolam	12,500	JWH-018 (Spice Cannabinoid)	1,000
Nitrazepam	4,000	JWH-018 4-Hydroxypentyl metabolite-D5 (indole-D5)	1,000
Norchlordiazepoxide	200	JWH-073 (Spice Cannabinoid)	2,000
Nordiazepam	500	JWH-073 3-Hydroxybutyl metabolite	1,000
Temazepam	250	JWH-073 3-Hydroxybutyl metabolite-D5 (indole-D5)	1,000
Triazolam	1,200	JWH-019 6-hydroxypentyl	1,000
Demoxepam	2,000	JWH-122 N-4-hydroxypentyl	2,000
Flurazepam	500	JWH-210 5-Hydroxypentyl metabolite	5,000
<b>Buprenorphine (BUP)</b>		AM2201 4-Hydroxypentyl metabolite	1,000
Buprenorphine	10	<b>Ketamine (KET300)</b>	
Buprenorphine -3-D-Glucuronide	15	Ketamine	300
Norbuprenorphine	20	Methadone	15,000
Norbuprenorphine 3-D-Glucuronide	200	Pethidine	3,750

Morphine	>100,000	Methylamphetamine	3,750
Oxymorphone	>100,000	Methoxyphenamine	3,750
Hydromorphone	>100,000	Promethazine	7,500
<b>Cannabinoids (THC25)</b>		Phencyclidine	7,500
11-nor-Δ9-THC-9-COOH	25	<b>Ketamine (KET1000)</b>	
11-nor-Δ8-THC-9-COOH	15	Ketamine	1,000
11-hydroxy-Δ9-Tetrahydrocannabinol	2,500	Methadone	50,000
Δ8- Tetrahydrocannabinol	900	Pethidine	12,500
Δ9- Tetrahydrocannabinol	4,500	Methylamphetamine	12,500
Cannabinol	16,000	Methoxyphenamine	12,500
Cannabidiol	50,000	Promethazine	25,000
<b>Cannabinoids (THC40)</b>		Phencyclidine	25,000
11-nor-Δ9-THC-9-COOH	40	<b>Nortriptyline (TCA)</b>	
11-nor-Δ8-THC-9-COOH	20	Nortriptyline	1,000
11-hydroxy-Δ9-Tetrahydrocannabinol	4,000	Nordoxepin	1,000
Δ8- Tetrahydrocannabinol	1,100	Trimipramine	3,000
Δ9- Tetrahydrocannabinol	4,800	Amitriptyline	1,500
Cannabinol	18,000	Promazine	1,500
Cannabidiol	80,000	Desipramine	200
<b>Cannabinoids (THC50)</b>		Imipramine	400
11-nor-Δ9-THC-9-COOH	50	Clomipramine	12,500
11-nor-Δ8-THC-9-COOH	30	Doxepin	2,000
11-hydroxy-Δ9-Tetrahydrocannabinol	5,000	Maprotiline	2,000
Δ8- Tetrahydrocannabinol	1,300	Promethazine	25,000
Δ9- Tetrahydrocannabinol	5,000	<b>Tramadol (TRA100)</b>	
Cannabinol	20,000	Tramadol	100
Cannabidiol	100,000	<b>Tramadol (TRA200)</b>	
<b>Cocaine (COC100)</b>		Tramadol	200
Benzoylcegonine	100	<b>Tramadol (TRA1000)</b>	
Cocaine	250	Tramadol	1,000
Cocsaethylene	4,000		
Ecgonine	10,000		
Ecgonine methyl Ester	>100,000		
<b>Cocaine (COC150)</b>			
Benzoylcegonine	150		
Cocaine	375		
Cocsaethylene	6,250		
Ecgonine	16,000		
Ecgonine methyl Ester	>100,000		
<b>Cocaine (COC300)</b>			
Benzoylcegonine	300		
Cocaine	750		
Cocsaethylene	12,500		
Ecgonine	32,000		
Ecgonine methyl Ester	>100,000		

#### Effect of Urinary Specific Gravity

12 urine samples with density ranges (1.005-1.025) were collected and spiked with each drug at 25% below and 25% above cutoff level. Each sample was tested by three batches of the corresponding drug test. Three laboratory assistants read the result per batch of the corresponding drug test. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

#### Effect of Urinary PH

The pH of an aliquot of negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with each drug at 25% below and 25% above cutoff levels. Each sample was tested by three batches of the corresponding drug test. Three laboratory assistants read the result per batch of the corresponding drug test. The result demonstrates that varying ranges of pH do not interfere with the performance of the test.

#### Interfering Substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff for the corresponding drug test. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples tested showed any deviation from the expected results.

Acetaminophen	Estrogen	Diphenhydramine
Acetophenetidin	Fenoprofen	D,L-Octopamine
Acetylsalicylic Acid	Furosemide	DL-Propranolol
Aminopyrine	Genticic Acid	DL-Tyrosine

Amoxicillin	Hydrochlorothiazide	D-Pseudoephedrine
Ampicillin	3-Hydroxytyramine	Noscapine
Apomorphine	Hydrocortisone	O-HydroxyhippuricAcid
Aspartame	Isoxsuprine	Omeprazole
Aspirin	Ketoprofen	OxalicAcid
Atropine	Labetalol	Oxolinic Acid
Diphenhydramine	Lamotrigine	Oxymetazoline
BenzilicAcid	Levonorgestrel	Papaverine
Benzoic Acid	Meperidine	Penicillin V Potassium
Bilirubin	Meprobamate	Penicillin-G
Captopril	NalidixicAcid	Perphenazine
Chloralhydrate	Naloxone	PethidineHCl
Chloramphenicol	Naltrexone	Phenelzine
Chlorothiazide	Naproxen	Prednisone
Chlorpromazine	Niacinamide	Propranolol HCl
Chloroquine	Nifedipine	Quinine
Cholesterol	Nitroglycerin	Ranitidine
Clarithromycin	Norethindrone	Ranitidine HCl
Clonidine	5- Hydroxytyramine	Salicylic Acid
Cotinine	SulfamethazineSulindac	Triamterene
Cortisone	Tetrahydrozoline	Uric Acid
Deoxycorticosterone	Thiamine	Venlafaxine HCl
Dextromethorphan	Thioridazine	Verapamil
Diclofenac	Thioridazine	Sertraline
Diflunisal		Zomepirac
Digoxin		

#### **ALCOHOL TEST:**

##### **Sensitivity**

It is designed for detection of alcohol in urine at the detection sensitivity of 40mg/dL (0.04g/dL)

##### **Interference**

The following substances were added to samples which had alcohol levels of 0 and 0.08%. None of the substances at the concentrations tested interfered in the Alcohol Tests.

Acetaminophen	20 mg/dL
Caffeine	20 mg/dL
Glucose	2,000 mg/dL
Hemoglobin	1 mg/dL
Human Serum Protein	2,000 mg/dL

The following substances may interfere with the Alcohol Test:

Strong oxidizers	Ascorbic acid
Tannic acid	Polyphenolic compounds
Mercaptans	Uric acid
Bilirubin	Oxalic acid

These compounds are not normally present in sufficient amounts in urine to interfere with the test.

#### **BIBLIOGRAPHY OF SUGGESTED READING**

Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.  
 Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elsevier Science Publishing Company, Inc., New York, 1988  
 Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.  
 Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992.  
 Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986  
 Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.  
 McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

#### **INDEX OF SYMBOLS**



Keep away from sunlight



Store between 4°C - 30°C (39°F - 86°F)



Keep dry



Do not re-use

Manufactured by Guangzhou Wondfo Biotech Co., LTD  
 No.8 Lizhishan Road, Science City, Luogang District  
 Guangzhou, Guangdong, P.R. China 510663  
 Made in China

Rev. A1  
 Rel.: 2018/08/30