

T-Cup® Multi-Drug Urine Test Cup

Catalogue No. See Box label

CLIA CATEGORIZATION: WAIVED URINE SCREENING TEST RESULTS AT 5 MINUTES

The T-Cup® Multi-Drug Urine Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, Methylenedioxyamphetamine, Methamphetamine, Morphine, Methadone, Opiate, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids and in human urine at specified cutoff levels.

Configuration of the T-Cup® 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. GC/MS or 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 T-Cup® Multi-Drug Urine Test Cup 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 the T-Cup® Multi-Drug Urine Test Cup 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.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

WHAT IS THE T-Cup® Multi-Drug Urine Test Cup?

The T-Cup® Multi-Drug Urine Test Cup is an immunochromatographic assay for the qualitative determination of multiple drugs in human urine. It is intended for over-the-counter and for prescription use.

The test is intended for over-the-counter (OTC) use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drug in a urine sample. Information regarding confirmatory testing the second step in the process, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is not provided.

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

Drug (Identifier)	Calibrator	Cut-off level	Minimum detection time	Maximum detection time
Amphetamine (AMP)	d-Amphetamine	1000 ng/mL	2-7 hours	1-2 days
Secobarbital (BAR)	Secobarbital	300 ng/mL	2-4 hours	1-4 days
Buprenorphine (BUP)	Buprenorphine	10 ng/mL	4 hours	1-3 days
Oxazepam (BZO)	Oxazepam	300 ng/mL	2-7 hours	1-2 days
Cocaine (COC)	Benzoyllecgonine	300 ng/mL	1-4 hours	2-4 days
Methylenedioxyamphet-amine (MDMA)	3,4-Methylenedioxyamphet-amine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET/mAMP)	D(+)-Methamphetamine	1000 ng/mL	2-7 hours	2-4 days
Morphine (MOP/OPI300)	Morphine	300 ng/mL	2 hours	2-3 days
Methadone (MTD)	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	8-12 hours	5-10 days
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL	8-12 hours	2-7 days
Cannabinoids (THC)	11-nor- Δ^9 -THC-9-COOH	50 ng/mL	2 hours	Up to 5+ days

WARNINGS AND PRECAUTIONS

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

CONTENT OF THE KIT

- 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.
- Security sealed labels.
- Leaflet with instructions for use.
- 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.

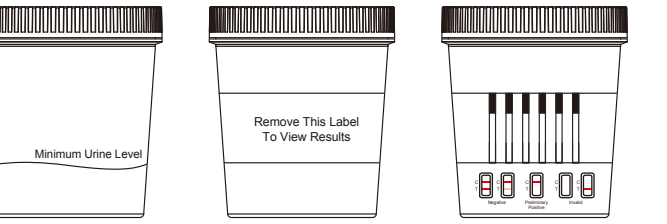
TEST PROCEDURE

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

- 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.
 - 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 at 5 minutes.**
- 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.

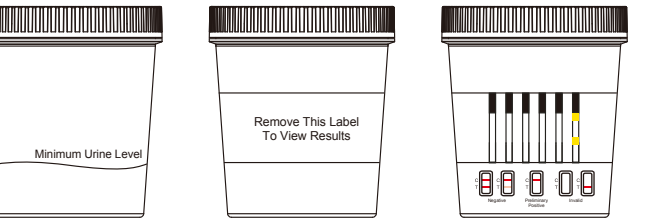
For Drug Test:

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



For Drug and Adulteration 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 drug test results at 5 minutes. Do not read results after 5 minutes.



READING THE RESULTS

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 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.

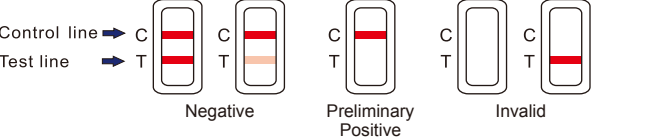
Preliminary positive (+)

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.

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® 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® 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. GC/MS is the preferred confirmatory method. Professional judgment should be exercised with any drug test result, particularly when the preliminary result is positive.

QUESTIONS AND ANSWERS

- What does the T-Cup® Multi-Drug Urine Test Cup do?**
These tests indicate if one or more prescription or illegal drugs are present in urine. These tests detect the presence of drugs such as amphetamines, barbiturates, oxazepam, buprenorphine, cocaine, methylenedioxyamphetamine, marijuana, methamphetamines, methadone, morphine, opiates, oxycodone, phencyclidine, tricyclic antidepressants and propoxyphene.
- What is "cut-off level"?**
The cut-off level is the specified concentration of a drug in a urine sample. Above that concentration the test is called positive, and below that concentration it is called negative.
- What are drugs of abuse?**
Drugs of abuse are illegal or prescription medicines (for example, Oxycodone or Valium) that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed it for or for a purpose other than what the doctor prescribed it for.
- What are the Common Street Names for the Drugs to be detected?**

Drug	Common Street Names
Amphetamine (AMP)	Speed, Jelly Beans or Super Jellies, Hearts, Uppers, Pick me ups or Wake me ups, Wake ups, Get ups, Boot ups, Sparkies
Secobarbital (BAR)	Amytal, Downers, Nembutal, Phenobarbital, Reds, RedBirds, Red Devils, Seconal, Tuninal, Yellowjackets
Buprenorphine (BUP)	Bupe, Subbies, Temmies
Oxazepam (BZO)	Benzos, Downers, Nerve Pills, Tranks
Cocaine (COC)	Blow, C, Candy, Coke, Do Aline, Freeze, Girl, Happy Dust, Mama Coca, Mojo, Monster, Nose, Pimp, Shot, Smoking Gun,

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.

Methylenedioxyamphetamine (MDMA)	Snow, Sugar, Sweet Stuff, and White Powder. Ecstasy, E, X, XTC, Adam, Clarity, Lover's Speed
Methamphetamine (MET/mAMP)	Speed, Ice, Chalk, Meth, Crystal, Crank, Fire, Glass
Morphine (MOP)	Aunt Hazel, Big H, Black Pearl, Brown Sugar, Capital H, Charley, China White, Dope, Good Horse, H, Hard stuff, hero, Heroin, Little Boy, Mud, Perfect High, Smack, Stuff and Tar.
Methadone (MTD)	Mixture, Meth, Linctus, Green
Morphine (OPI)	Angel Dust, Belladonna, Black Whack, C, J, Cliffhanger, Crystal Joint, Detroit Pink, Elephant Tranquilizer, Hog, Magic, Peter Pan, Sheets, Soma, TAC, Tanik, White Horizon and Zoom.
Propoxyphene (PPX)	Darvon, Darvocet, Dolene, Propacet 100, Wygesic, SK-65, SK-65 APAP, Tyolet, Genagesic, E-Lor, Balacet, Pain Killer, Pinks, Footballs, PP-Cap
Nortriptyline (TCA)	Blue angels, Blue birds, Vivactil, Anafranil, Janimine, Tofranil
Cannabinoids (THC)	420, Aunt Mary, Baby, Bobby, Boom, Chira, Chronic, Ditch, Ganja, Grass, Greens, Hash, Herb, Mary Jane, Nigra, Pot, Reefer, Rip, Root, Skunk, Stack, Torch, Weed and Zambi.

- How accurate is the test?**
The tests are sensitive to drugs and are accurate. These tests, however, are not as accurate as lab tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug-testing kits.
- If the test results are negative, can the conclusion be that the person is free of drugs?**
This means that if the sample was collected properly and if the test was performed according to direction, then probably none of the drug screened were present in the sample.
- Does a preliminary positive screen test mean that drugs of abuse have been found?**
This means that the test has reacted with something in the sample and the sample should be sent to the lab for a more accurate test.
- What should I do, if the lab test confirms a positive result?**
If you have received a confirmed positive result, please consult with our staff on a proper course of action. We will help you identify counselors who can help you. It is important that you remain calm and do not react in a negative way to the situation. If you do not believe the test result, please consult with your physician. They will have your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

The test is also intended for prescription use. The below sections are for the reference of prescription users. The above sections of WARNINGS AND PRECAUTIONS, CONTENT OF THE KIT, STORAGE AND STABILITY, TEST PROCEDURE, READING THE RESULTS, and TEST LIMITATIONS also apply to the prescription users

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 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 benzoyllecgonine in a short period of time.

Methylenedioxyamphetamine (MDMA)

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

Methamphetamine (MET/mAMP)

Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at half-life of about 15 hours and is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

Morphine (MOP/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® 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, EMDP 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® Multi-Drug Urine Test Cup yields a positive result when the morphine in urine exceeds 2000 ng/ml.

Oxycodone (OXY)

Oxycodone is known as Oxycotin and Roxicodone. It is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiates derived from opium. Like other opiates, Oxycodone is characterized by its analgesic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analgesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of Oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and cardiac arrest. Oxycodone is metabolized by N- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% of a single dose of Oxycodone is excreted in a 24 hour urine collection and consists of 13-19% free Oxycodone, 7-29% glucuronide conjugated Oxycodone, 13-14% glucuronic 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 cystone," 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 norexpropoxyphene. The combination usage of propoxyphene, aspirin, acetaminophen or other sedatives can lead cooperative interaction. Abuse of propoxyphene can lead nausea, vomit, astriction, illusion, hallucination, heart poisoning, lung dropsy and even death. Propoxyphene is metabolized in the liver and excreted in urine as norexpropoxyphene. Thus the presence of the propoxyphene or its metabolites in the urine indicates methamphetamine 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 a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC&Cannabinol can be metabolized and excreted as 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. 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.

PRINCIPLE

The T-Cup® Multi-Drug Urine Test Cup is a competitive immunoassay that is used to screen for the presence of drugs 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 test is activate, 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 (duck egg) 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.

SPECIMEN COLLECTION AND PREPARATION

- Collect the urine sample. 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).
- The technician replaces and seals the cap. Check the cap for a tight seal.
- The technician observes temperature strip affixed on the test cup between 2 to 4 minutes to see if the urine is diluted by water or liquid other than urine. The temperature range from 32°C-38°C (90°F-100°F) is acceptable.
- Technician dates and signs the names of the donor and the operator on the cap label.
- Technician dates and initials the security seal and attaches the security seal over the cup cap.

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

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

1200 (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	Viewer A	+ 0	0	2	11	29	100% (84.5% - 100%)
	Viewer B	+ 0	0	2	11	29	100% (84.5% - 100%)
	Viewer C	+ 0	0	1	11	29	100% (84.5% - 100%)
	Viewer A	- 10	18	10	0	0	95% (79.5% - 100%)
	Viewer B	- 10	18	10	0	0	95% (79.5% - 100%)
	Viewer C	- 10	18	11	0	0	97.5% (82% - 100%)
BAR	Viewer A	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer B	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer C	+ 0	0	1	20	20	100% (84.5% - 100%)
	Viewer A	- 10	10	18	0	0	95% (79.5% - 100%)
	Viewer B	- 10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	- 10	10	18	0	0	95% (79.5% - 100%)
BZO	Viewer A	+ 0	0	1	20	20	100% (84.5% - 100%)
	Viewer B	+ 0	0	1	20	20	100% (84.5% - 100%)
	Viewer C	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer A	- 10	10	19	0	0	97.5% (82% - 100%)
	Viewer B	- 10	10	19	0	0	97.5% (82% - 100%)
	Viewer C	- 10	10	18	0	0	95% (79.5% - 100%)
COC	Viewer A	+ 0	0	1	11	29	100% (84.5% - 100%)
	Viewer B	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer C	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer A	- 10	10	18	0	0	95% (79.5% - 100%)
	Viewer B	- 10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	- 10	10	18	0	0	95% (79.5% - 100%)
MET / mAMP	Viewer A	+ 0	0	1	20	20	100% (84.5% - 100%)
	Viewer B	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer C	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer A	- 10	16	13	0	0	97.5% (82% - 100%)
	Viewer B	- 10	16	12	0	0	95% (79.5% - 100%)
	Viewer C	- 10	16	13	0	0	97.5% (82% - 100%)
MDMA	Viewer A	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer B	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer C	+ 0	0	2	20	20	100% (84.5% - 100%)
	Viewer A	- 10	10	18	0	0	95% (79.5% - 100%)
	Viewer B	- 10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	- 10	10	19	0	0	97.5% (82% - 100%)

Drug test	Viewer	+	-	0	1	16	24	100% (84.5% - 100%)	Results		
									Lot 1	Lot 2	Lot 3
BUP	A	+ 0	- 10	18	11	0	0	97.5% (82% - 100%)			
	B	+ 0	- 10	18	11	0	24	100% (84.5% - 100%)			
	C	+ 0	- 10	18	11	0	0	97.5% (82% - 100%)			
	Viewer A	+ 0	- 10	18	11	0	24	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	18	11	0	0	97.5% (82% - 100%)			
	Viewer C	+ 0	- 10	18	11	0	0	97.5% (82% - 100%)			
MOP/ OPI300	Viewer A	+ 0	- 10	19	10	0	0	97.5% (82% - 100%)			
	Viewer B	+ 0	- 10	19	9	0	0	95% (79.5% - 100%)			
	Viewer C	+ 0	- 10	19	10	0	20	100% (84.5% - 100%)			
	Viewer A	+ 0	- 10	19	10	0	0	97.5% (82% - 100%)			
	Viewer B	+ 0	- 10	19	9	0	0	95% (79.5% - 100%)			
	Viewer C	+ 0	- 10	19	10	0	0	97.5% (82% - 100%)			
MTD	Viewer A	+ 0	- 10	12	16	0	0	95% (79.5% - 100%)			
	Viewer B	+ 0	- 10	12	17	0	0	97.5% (82% - 100%)			
	Viewer C	+ 0	- 10	12	16	0	0	95% (79.5% - 100%)			
	Viewer A	+ 0	- 10	12	16	0	0	95% (79.5% - 100%)			
	Viewer B	+ 0	- 10	12	17	0	0	97.5% (82% - 100%)			
	Viewer C	+ 0	- 10	12	16	0	0	95% (79.5% - 100%)			
OPI	Viewer A	+ 0	- 10	0	1	18	22	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	1	18	22	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	1	18	22	100% (84.5% - 100%)			
	Viewer A	+ 0	- 10	0	1	18	22	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	1	18	22	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	1	18	22	100% (84.5% - 100%)			
PCP	Viewer A	+ 0	- 10	0	2	18	22	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	2	18	22	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	2	18	22	100% (84.5% - 100%)			
	Viewer A	+ 0	- 10	0	2	18	22	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	2	18	22	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	2	18	22	100% (84.5% - 100%)			
PPX	Viewer A	+ 0	- 10	0	2	20	20	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	2	20	20	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	2	20	20	100% (84.5% - 100%)			
	Viewer A	+ 0	- 10	0	1	10	30	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	1	10	30	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	1	10	30	100% (84.5% - 100%)			
TCA	Viewer A	+ 0	- 10	0	1	10	30	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	1	10	30	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	1	10	30	100% (84.5% - 100%)			
	Viewer A	+ 0	- 10	0	1	10	30	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	1	10	30	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	1	10	30	100% (84.5% - 100%)			
THC	Viewer A	+ 0	- 10	12	16	0	0	95% (79.5% - 100%)			
	Viewer B	+ 0	- 10	12	17	0	0	97.5% (82% - 100%)			
	Viewer C	+ 0	- 10	12	17	0	0	97.5% (82% - 100%)			
	Viewer A	+ 0	- 10	12	17	0	0	97.5% (82% - 100%)			
	Viewer B	+ 0	- 10	12	17	0	0	97.5% (82% - 100%)			
	Viewer C	+ 0	- 10	12	17	0	0	97.5% (82% - 100%)			
OXY	Viewer A	+ 0	- 10	0	2	19	21	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	2	19	21	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	2	19	21	100% (84.5% - 100%)			
	Viewer A	+ 0	- 10	0	2	19	21	100% (84.5% - 100%)			
	Viewer B	+ 0	- 10	0	2	19	21	100% (84.5% - 100%)			
	Viewer C	+ 0	- 10	0	2	19	21	100% (84.5% - 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
AMP	0	50	50/0	50/0	50/0
	250	50	50/0	50/0	50/0
	500	50	50/0	50/0	50/0
	750	50	50/0	50/0	50/0
	1000	50	5/45	5/45	4/46
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
	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	7/43	5/45	5/45
	375	50	0/50	0/50	0/50
450	50	100/50	0/50	0/50	
525	50	0/50	0/50	0/50	
600	50	0/50	0/50	0/50	
BZO	0	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	150	50	50/0	50/0	50/0
	225	50	50/0	50/0	50/0
	300	50	7/43	6/44	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
	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	50/0	50/0	50/0
	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	0	50	0/50	0/50	0/50
	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	6/44	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
	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	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	
MET / mAMP	0	50	50/0	50/0	



物料编码： 02.032.000.0092-5 项目名称： 说明书(美国常规毒品尿杯T CUP说明书通用版) CLIA WAIVED

尺寸规格： 880*210mm 颜色：  C:100 M:60 Y:20 设计师： 申芳

材质：80g双铜 修改内容： 设计时间： 2018.08.10