T-Dip® CLIA WAIVED Multi-Drug Urine Test Panel

Catalogue No. See Box label

CLIA CATEGORIZATION: WAIVED
URINE SCREENING TEST RESULTS AT 5 MINUTES

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

Configuration of the T-Dip® Multi-Drug Urine Test Panel can consist of any combination of the above listed drug analytes.

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

The test 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-Dip® Multi-Drug Urine Test Panel may be combined with the adulteration control (Creatinine (CR), Glutaraldehyde (GLU), Nitrite (NI), pH, Specific Gravity (S.G.), and/or Oxidants (OX)) 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-Dip® Multi-Drug Urine Test Panel with or without 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 drugs are included in your test.

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

WHAT IS CLIA WAIVED T-DIP® MULTI-DRUG URINE TEST PANEL?

The T-Dip® Multi-Drug Urine Test Panel 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 specimen. 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)	Benzoylecgonine	300 ng/mL	1-4 hours	2-4 days
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine (MDMA)	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
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL	8-12 hours	2-7 days
Cannabinoids (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL	2 hours	Up to 5+ days

WARNINGS AND PRECAUTIONS

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

CONTENT OF THE KIT

1. 25 Test devices, each in one pouch with two desiccants. The desiccants are for storage purposes only and are not used in the test procedure.
2. One (1) Package Insert
3. One (1) Adulteration Color Comparison Chart (If equipped).

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Timer or Clock

STORAGE AND STABILITY

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

SPECIMEN COLLECTION

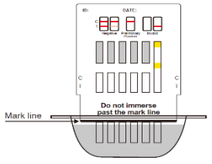
WHEN TO COLLECT URINE FOR THE TEST?

Collect the urine specimen for the test in the minimum detection time after the suspected drug use. Exactly when the urine specimen 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.

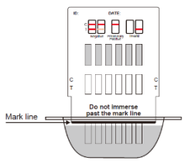
TEST PROCEDURE

Test should be performed at room temperature 18ºC-30ºC (65ºF-86ºF).

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine specimen for approximately 10 seconds. **Make sure that the urine level is not above the marked line printed on the front of the device.**
4. Re-cap the device and lay it flat on a clean, dry, non-absorbent surface.
5. For the adulteration strip(s) if equipped, read results immediately, or at 30 seconds, or at 45 seconds and compare each adulterant pad to verify pad color is within acceptable range according to the Adulteration Color Comparison Chart. If the results indicate adulteration, do not read the drug test results. Instruct the donor to provide urine specimen again with another new test device.
6. For the drug tests, read the results for the drugs at 5 minutes. **Do not read after 5 minutes.**



Drug and adulteration test



Drug test

Note: ***Results after more than 5 minutes may be not accurate and should not be read.***

READING THE RESULTS

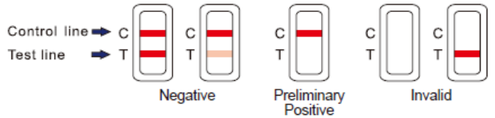
DRUGS TESTS:

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

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

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

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



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

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

What Is the False Positive Test?

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

What Is the False Negative Test?

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

If suspect someone is taking drugs but get the negative test results, please test again at another time, or test for different drugs.

TEST LIMITATIONS

1. This test has been developed for testing urine specimens only. No other fluids have been evaluated. DO NOT use this device to test anything but urine.
2. Adulterated urine specimens may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a specimen is suspected of being adulterated, obtain a new specimen.
3. 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 tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method.

QUESTIONS AND ANSWERS

1. *What does the T-Dip® Multi-Drug Urine Test Panel 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, Benzodiazepines, Buprenorphine, Cocaine, Methylenedioxymethamphetamine, Marijuana, Methamphetamines, Methadone, Morphine, Opiates, Oxycodone, Phencyclidine, and tricyclic antidepressants.

The testing is done in two steps. First, test urine with T-Dip® Multi-Drug Urine Test Panel. Second, if any drug test result is preliminary positive, please send the urine specimen to the drug testing laboratory for confirmatory result.

2. *What is "cut-off level"?*
The cut-off level is the specified concentration of a drug in a urine specimen. If the concentration of a drug in urine is above the cutoff concentration, this drug test result will be preliminary positive. If the concentration of a drug in urine is below the cutoff concentration, this drug test result will be negative.

3. *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.

4. *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, Sparkles
Secobarbital (BAR)	Amytal, Downers, Nembutal, Phenobarbital, Reds, Red Birds, Red devils, Seconal, Tuninal, Yellow jackets
Buprenorphine (BUP)	Bupe, Subbies, Temmies
Oxazepam (BZO)	Benzos, Downers, Nerve Pills, Tranks
Cocaine (COC)	Blow, C, candy, coke, do a line, freeze, girl, happy dust, Mama coca, mojo, monster, nose, pimp, shot, smoking gun, snow, sugar, sweet stuff, and white powder.
Methylenedioxymethamphetamine (MDMA)	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)	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.
Oxycodone (OXY)	OC, Ocycotton, OX, and Kicker
Phencyclidine (PCP)	Angel Dust, Belladonna, Black Whack, CJ, Cliffhanger, Crystal Joint, Detroit Pink, Elephant Tranquilizer, Hog, Magic, Peter Pan, Sheets, Soma, TAC, Tank, White Horizon and Zoom.
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.

5. *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.

6. *If the test results are negative, can the conclusion be that the person is free of drugs?*
This means that if the specimen was collected properly and if the test was performed according to direction, then probably none of the drug screened were present in the specimen.

7. *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 specimen and the specimen should be sent to the lab for a more accurate test.

8. *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.

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.

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.

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.

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 Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

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-Dip® Multi-Drug Urine Test Panel 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-Dip® Multi-Drug Urine Test Panel yields a positive result when the morphine in urine exceeds 2000 ng/mL.
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Oxycodone (OXY)
Oxycodone is known as Oxycontin and Roxicodone. It is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiates derived from opium. Like other opiates, Oxycodone is characterized by its analgesic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analgesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of Oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and cardiac arrest.
Oxycodone is metabolized by N- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% of a single dose of Oxycodone is excreted in a 24 hour urine collection and consists of 13-19% free Oxycodone, 7-29% glucuronide conjugated Oxycodone, 13-14% glucuronide conjugated oxymorphone and an unknown amount of noroxycodone. The detection time window of Oxycodone is 1-3 days following use.

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.

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-Δ9-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-Dip® Multi-Drug Urine Test Panel is a competitive immunoassay that is used to screen for the presence of drugs in urine. It is chromatographic absorbent device in which drugs in a specimen competitively combined 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 specimen 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 specimen drug levels are at or above the target cutoff, the free drug in the specimen binds to the respective drug monoclonal antibody conjugate preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the Test Region (T), indicating a potentially positive result.

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

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

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

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

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

DRUGS TESTS:

Accuracy

1120 (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. Specimens 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 followed:

Drug Test	Result		Drug Free	Less than Half the Cutoff	Near Cutoff Negative (Between 50% below the cutoff and the cutoff)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff)	High Positive (Greater than 50% above the cutoff)	% Agreement with GC/MS or LC/MS (95%CI)
AMP	Viewer A	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	18	10	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	18	10	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	11	29	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
BAR	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	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
BZO	Viewer A	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
BUP	Viewer A	+	0	0	1	16	24	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	16	24	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	16	24	100% (84.5% - 100%)
		-	10	18	11	0	0	97.5% (82% - 100%)
COC	Viewer A	+	0	0	1	11	29	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	2	11	29	100% (84.5% - 100%)
		-	10	10	18	0	0	95% (79.5% - 100%)
MET (mAMP)	Viewer A	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	16	13	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	16	12	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	16	13	0	0	97.5% (82% - 100%)
MDMA	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	1	20	20	100% (84.5% - 100%)
		-	10	10	19	0	0	97.5% (82% - 100%)
MOP/OPI300	Viewer A	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	2	20	20	100% (84.5% - 100%)
		-	10	19	9	0	0	95% (79.5% - 100%)

	Viewer C	+	0	0	1	20	20	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
MTD	Viewer A	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	1	19	21	100% (84.5% - 100%)
		-	10	12	17	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	2	19	21	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 100%)
OPI	Viewer A	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	18	22	100% (84.5% - 100%)
		-	10	20	9	0	0	97.5% (82% - 100%)
OXY	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%)
PCP	Viewer A	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	13	15	0	0	95% (79.5% - 100%)
	Viewer B	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	13	15	0	0	95% (79.5% - 100%)
	Viewer C	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	13	15	0	0	95% (79.5% - 100%)
TCA	Viewer A	+	0	0	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer B	+	0	0	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
	Viewer C	+	0	0	1	10	30	100% (84.5% - 100%)
		-	10	19	10	0	0	97.5% (82% - 100%)
THC	Viewer A	+	0	0	2	18	22	100% (84.5% - 100%)
		-	10	12	16	0	0	95% (79.5% - 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%)

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 or LC/MS method. 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	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
BAR	0	50	50/0	50/0	50/0
	75	50	50/0	50/0	50/0
	150	50	50/0	50/0	50/0
	225	50	50/0	50/0	50/0
	300	50	7/43	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
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
BUP	0	50	50/0	50/0	50/0
	2.5	50	50/0	50/0	50/0
	5.0	50	50/0	50/0	50/0
	7.5	50	50/0	50/0	50/0
	10.0	50	6/44	4/46	4/46
	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
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	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	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	4/46	5/45	5/45
	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	50/0
	125	50	50/0	50/0	50/0
	250	50	50/0	50/0	50/0
	375	50	50/0	50/0	50/0
	500	50	6/44	5/45	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
MOP/OPI300	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	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
MTD	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	4/46	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
OPI	0	50	50/0	50/0	50/0
	500	50	50/0	50/0	50/0
	1000	50	50/0	50/0	50/0
	1500	50	50/0	50/0	50/0
	2000	50	5/45	5/45	6/44
	2500	50	0/50	0/50	0/50
	3000	50	0/50	0/50	0/50
	3500	50	0/50	0/50	0/50
	4000	50	0/50	0/50	0/50
OXY	0	50	50/0	50/0	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	6/44	6/44	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
PCP	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	50/0	50/0
	25	50	5/45	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	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	5/45
	1250	50	0/50	0/50	0/50
	1500	50	0/50	0/50	0/50
	1750	50	0/50	0/50	0/50
	2000	50	0/50	0/50	0/50
THC	0	50	50/0	50/0	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

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)
Amphetamine (AMP)		**Methylenedioxymethamphetamine (MDMA)**	
d-Amphetamine	1,000	3,4-Methylenedioxymethamphetaminel (MDMA)	500
d,l-Amphetamine	3,000	3,4-Methylenedioxyamphetamine (MDA)	3,000
l-Amphetamine	50,000	3,4-Methylenedioxyethylamphetamine (MDEA)	300
(+/-) 3,4-methylenedioxyamphetamine (MDA)	5,000	d-methamphetamine	>100,000
Phentermine	3,000	d-amphetamine	>100,000
Phenylpropanolamine	>100,000	**Morphine (MOP/OPI300)**	
d-methamphetamine	>100,000	Morphine	300
l-methamphetamine	>100,000	Codeine	300
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	100,000	Ethyl Morphine	100
(+/-) 3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	Heroin	300
Benzphetamine	>100,000	Hydrocodone	5,000
l-Ephedrine	>100,000	Hydromorphone	1,000
l-Epinephrine	>100,000	Morphine-3-β-d-glucuronide	1,000
d,l-Epinephrine	>100,000	6-Monoacetylmorphine	150
Hydroxyamphetamine	8,000	Normorphine	300
β-Phenylethylamine	100,000	Oxycodone	10,000
Tyramine	100,000	Oxymorphne	10,000
p-Hydroxynorephedrine	100,000	Thebaine	3,000
p-Hydroxyamphetamine	100,000	Levorphanol	10,000
(±)Phenylpropanolamine	>100,000	Norcodeine	6,250
Ephedrine	>100,000	Procaine	150,000
Barbiturates (BAR)		**Methadone (MTD)**	
Secobarbital	300	Methadone	300
Amobarbital	10,000	Doxylamine	50,000
Alphenol	150	**Opiate (OPI)**	
Aprobarbital	200	Morphine	2,000
Butabarbital	75	Codeine	2,000
Butathal	100	Ethyl Morphine	1,500
Butalbital	2,500	Heroin	2,000
Cyclopentobarbital	600	Hydrocodone	12,500
Pentobarbital	2,500	Hydromorphine	3,500
Phenobarbital	10,000	Levorphanol	75,000
Buprenorphine (BUP)		6-Monoacetylmorphine	1,500
Buprenorphine	10	Morphine 3-β-D-glucuronide	2,000
Buprenorphine-3-D-Glucuronide	15	Norcodeine	12,500
Norbuprenorphine	20	Normorphine	50,000
Norbuprenorphine 3-D-Glucuronide	200	Oxycodone	25,000
Morphine	>100,000	Oxymorphone	25,000
Oxymorphone	>100,000	Procaine	150,000
Hydromorphone	>100,000	Thebaine	5,000
Oxazepam (BZO)		**Oxycodone (OXY)**	
Oxazepam	300	Oxycodone	100
Alprazolam	200	Dihydrocodeine	20,000
α-Hydroxyalprazolam	1,500	Codeine	100,000
Bromazepam	500	Hydromorphone	32,000
Chlordiazepoxide	1,500	Morphine	>100,000
Clobazam	100	Acetylmorphine	>100,000
Clonazepam	800	Buprenorphine	>100,000
Clorazepate dipotassium	200	Ethylmorphine	>100,000
Delorazepam	1,500	Thebaine	>100,000
Desalkylflurazepam	400	Oxymorphone	1,000
Diazepam	200	**Phencyclidine (PCP)**	
Estazolam	1,000	Phencyclidine	25
Flunitrazepam	2,500	4-Hydroxyphencyclidine	12,500
D,L-Lorazepam	>100,000	**Propoxyphene (PPX)**	
Midazolam	12,500	d-Propoxyphene	300
Nitrazepam	4,000	d-Norpropoxyphene	300
Norchlordiazepoxide	200	**Nortriptyline (TCA)**	
Nordiazepam	500	Nortriptyline	1,000

Temazepam	250	Nordoxepin	1,000
Triazolam	1,200	Trimipramine	3,000
Demoxepam	2,000	Amitriptyline	1,500
Flurazepam	500	Promazine	1,500
Cocaine (COC)		Desipramine	200
Benzoylecgonine	300	Imipramine	400
Cocaine	750	Clomipramine	12,500
Cocaethylene	12,500	Doxepin	2,000
Ecgonine	32,000	Maprotiline	2,000
Ecgonine methyl Ester	>100,000	Promethazine	25,000
Methamphetamine (MET/mAMP)		**Cannabinoids (THC)**	
D(+)-Methamphetamine	1,000	11-nor-Δ9-THC-9-COOH	50
D-Amphetamine	>100,000	11-nor-Δ8-THC-9-COOH	30
Chloroquine	50,000	11-hydroxy-Δ9-Tetrahydrocannabinol	5,000
(+/-)-Ephedrine	50,000	Δ8-Tetrahydrocannabinol	1,300
(-)-Methamphetamine	25,000	Δ9-Tetrahydrocannabinol	5,000
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	4,000	Cannabinol	20,000
β-Phenylethylamine	50,000	Cannabidiol	100,000
Trimethobenzamide	10,000		
(+/-)3,4-Methylenedioxyethylamphetamine(MDEA)	1,000		
d,l-Methamphetamine	1,000		
p-Hydroxymethamphetamine	30,000		
(+/-)3,4-Methylenedioxyamphetamine (MDA)	1,000		
L-Amphetamine	75,000		
D,L-Amphetamine	100,000		
Mephetermine	50,000		
(1R,2S)-(-)-Ephedrine	>100,000		
L-phenylephrine	>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 range of pH do not interfere with the performance of the test.

Interfering Substances

Clinical urine specimens 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 specimens tested showed any deviation from the expected results.

Acetaminophen
Acetophenetidin
Acetylsalicylic Acid
Aminopyrine
Amoxicillin
Ampicillin
Apomorphine
Aspartame
Aspirin
Diphenhydramine
D,L-Octopamine
DL-Propranolol
DL-Tyrosine
D-Pseudoephedrine
Estrogen
Fenoprofen
Furosemide
Gentisic Acid
Noscapine
O-Hydroxyhippuric Acid
Omeprazole
Oxalic Acid
Oxolinic Acid
Oxymetazoline
Papaverine
Penicillin V Potassium
Penicillin-G
Atropine
Benzilic Acid
Benzoic Acid
Bilirubin
Captopril
Chloralhydrate
Chloramphenicol
Chlorothiazide
Chlorpromazine
Chloroquine
Cholesterol
Clarithromycin
Clonidine
Cotinine
Cortisone
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Hydrochlorothiazide
3-Hydroxytyramine
5- Hydroxytyramine
Hydrocortisone
Isoxsuprine
Ketoprofen
Labetalol
Lamotrigine
Levonorgestrel
Meperidine
Meprobamate
Nalidixic Acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Nitroglycerin
Norethindrone
Perphenazine
Pethidine HCl
Phenelzine
Prednisone
Propranolol HCl
Quinine
Ranitidine
Ranitidine HCl
Sulfamethazine Sulindac
Salicylic Acid
Sertraline
Tetrahydrozoline
Thiamine
Thioridazine
Triamterene
Uric Acid
Venlafaxine HCl
Verapamil
Zomepirac

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ADDITIONAL INFORMATION AND RESOURCES

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

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

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

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

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

INDEX OF SYMBOLS


Keep away from sunlight

Store between 4ºC - 30ºC (39ºF - 86ºF)


Keep dry


Do not re-use

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