

Prime Screen® Multi-Drug Urine Test Cup
Catalogue No. See Box label

Please read all instructions first and familiarize with the materials before performing the test.

Prime Screen® Multi-Drug Urine Test Cup is a multi-drug screening test intended for over-the-counter consumer use. It provides qualitative and simultaneous screening results for Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxyamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine at the cutoff concentrations of following table.

Identifier	Drug	Cut-off level
AMP500	Amphetamine	500 ng/mL
AMP1000	Amphetamine	1000 ng/mL
BUP10	Buprenorphine	10 ng/mL
BAR300	Secobarbital	300 ng/mL
BZO300	Oxazepam	300 ng/mL
COC150	Cocaine	150 ng/mL
COC300	Cocaine	300 ng/mL
EDDP300	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL
MET500	Methamphetamine	500 ng/mL
MET1000	Methamphetamine	1000 ng/mL
MDMA500	Methylenedioxyamphetamine	500 ng/mL
MOP300	Morphine	300 ng/mL
OPI2000	Morphine	2000 ng/mL
MTD300	Methadone	300 ng/mL
OXY100	Oxycodone	100 ng/mL
PCP25	Phencyclidine	25 ng/mL
PPX300	Propoxyphene	300 ng/mL
TCA1000	Nortriptyline	1000 ng/mL
THC50	Cannabinoids	50 ng/mL

Prime Screen® Multi-Drug Urine Test Cup offers any combinations from 2 to 15 drugs of abuse test but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

WARNING: This device is not designed to test drugs before they are consumed. When used in this way, this device may not detect certain drugs, including fentanyl, even if present.

WHAT IS Prime Screen® MULTI-DRUG URINE TEST CUP?

Prime Screen® 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 (OTC) use. For in vitro diagnostic use only.

The test is to provide consumers with information concerning the presence or absence of the above stated drug in a urine sample. If you get a "preliminary positive" test result when you use this product, send a portion of the sample to a laboratory for further testing.

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

Drug(Identifier)	Calibrator	Approximately Minimum detection time	Approximately Maximum detection time
Amphetamine (AMP500)	d-Amphetamine	2-7 hours	1-2 days
Amphetamine (AMP1000)	d-Amphetamine	2-7 hours	1-2 days
Secobarbital (BAR300)	Secobarbital	2-4 hours	1-4 days
Buprenorphine (BUP10)	Buprenorphine	4 hours	1-3 days
Oxazepam (BZO300)	Oxazepam	2-7 hours	1-2 days
Cocaine (COC150)	Benzoylcegonine	1-4 hours	2-4 days
Cocaine (COC300)	Benzoylcegonine	1-4 hours	2-4 days
EDDP300	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	3-8 hours	1-3 days
Methylenedioxyamphetamine (MDMA500)	3,4-Methylenedioxy-methamphetamine	2-7 hours	2-4 days

Methamphetamine (MET500)	D(+)-Methamphetamine	2-7 hours	2-4 days
Methamphetamine (MET1000)	D(+)-Methamphetamine	2-7 hours	2-4 days
Morphine (MOP300)	Morphine	2 hours	2-3 days
Methadone (MTD300)	Methadone	3-8 hours	1-3 days
Opiate (OPI2000)	Morphine	2hours	2-3 days
Oxycodone (OXY100)	Oxycodone	4 hours	1-3 days
Phencyclidine (PCP25)	Phencyclidine	4-6 hours	7-14 days
Propoxyphene (PPX300)	Propoxyphene	8-12hours	5-10 days
Nortriptyline (TCA1000)	Nortriptyline	8-12hours	2-7 days
Cannabinoids (THC50)	11-nor-Δ9-THC-9-COOH	2 hours	Up to 5+ days

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 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. Read the drug test result at 5 minutes. The result can be stable for 10 minutes. Do not read the result after 10 minutes.

CONTENT OF THE KIT

1. Test devices, one test in one pouch. One pouch contains a test Prime Screen® and two desiccants. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Security sealed labels.
3. Package Insert.

MATERIAL REQUIRED BUT NOT PROVIDED

Timer or clock

STORAGE AND STABILITY

Store at 4°C-30°C in the pouch unopened until the expiration date.

Keep away from direct sunlight, moisture and heat.

DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

You may collect urine samples in minimum detection time later after suspected drug use. Exactly when the urine sample is collected is very important in detecting any drug of abuse. 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 or maximum detection time of each drug.

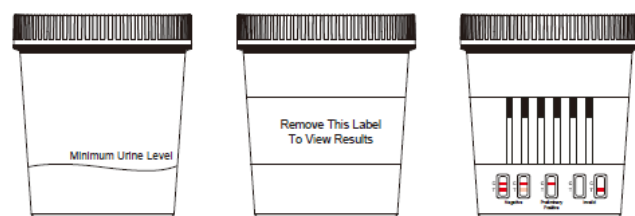
HOW TO COLLECT URINE?

1. Remove a 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 to reach the minimum urine level. Wipe off any splashes or spills that may be on the outside of this cup.
2. You may observe the temperature strip affixed on the test cup between 2 to 4 minutes after urine is added to the cup. The temperature ranges from 32°C to 38°C indicates a fresh uncontaminated sample.

HOW TO DO THE TEST?

Test should be at room temperature 18°C - 30°C.

1. After the urine has been collected, re-cap the test cup and place it on a flat surface.
2. Peel the label from right to left. Read the result at 5 minutes. The result can be stable for 10 minutes. Do not read the result after 10 minutes.



Note: Results after more than 10 minutes may be not accurate and should not be read.

READING THE RESULTS

DRUGS TESTS:

Negative (-)

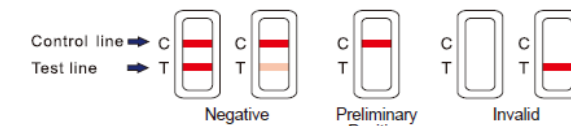
If rose-pink bands are visible in both the control and the test region, it indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary positive (+)

If a rose-pink band is visible in control region but 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 color band is not visible in the control regions, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor or the store, where you bought the product, 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 that a person took illegal drugs. A 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 sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by Prime Screen® 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 Prime Screen® Multi-Drug Urine Test Cup. If the sample is diluted or adulterated that may cause false negative result.

If you get a negative test result but you still suspect someone is taking drugs you should test again at another time, or test for different drugs.

TEST LIMITATIONS

1. 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.
2. 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.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine sample may cause false results.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

QUESTIONS AND ANSWERS

1. What does the Drug of Abuse Urine Test 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 amphetamine, secobarbital, buprenorphine, oxazepam, benzoylcegonine, EDDP, MDMA, methamphetamine, morphine, methadone, oxycodone, phencyclidine, propoxyphene, nortriptyline and marijuana.

The testing is done in two steps. First, you do a quick at-home test. Second, if the test suggests that drugs may be present, you send the sample to a laboratory for confirmation testing.

2. 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 result is called positive, and below that concentration it is called negative.

3. What are drugs of abuse?

Drugs of abuse are illegal or prescription drugs (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, Yellowjackets
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.
Methamphetamine (MET)	Speed, Ice, Chalk, Meth, Crystal, Crank, Fire, Glass
Methylenedioxyamphetamine (MDMA)	Ecstasy, E, X, XTC, Adam, Clarity, Lover's Speed
Buprenorphine(BUP)	Bupe, Subbies, Temmies
Morphine (OPI)	Aunt Hazel, big H, black pearl, brown sugar, capital H, charley, china white, dope, good horse, H, hard stuff, hero, heroina, little boy, mud, perfect high, smack, stuff and tar.
Methadone (MTD)	mixture, meth, linctus, green
Phencyclidine (PCP)	Angel dust, belladonna, black whack, CJ, cliffhanger, crystal joint, Detroit pink, elephant tranquilizer, hog, magic, Peter Pan, sheets, soma, TAC, trunk, white horizon and zoom.
Nortriptyline (TCA)	-----
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.
Oxycodone (OXY)	OC, Ocycton, OX, and Kicker

5. How accurate is the test?

The tests are sensitive to drugs and 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?

Under some conditions, e.g. testing for the wrong drugs, drug metabolism in urine, adulteration, not following storage recommendations, and use of the test cup after the expiration date, false negative results can occur.

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 sample, but not always means that a person took illegal drugs, false positive test results can occur due to some other reasons, e.g. some medications and foods. The sample must be sent to the lab for a more accurate test.

8. What is the principle of Prime Screen® Multi-Drug Urine Test Cup?

Prime Screen® Multi-Drug Urine Test Cup is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine.

When the test is activated, the urine is absorbed into the device by capillary action. Then flowing across the pre-coated membrane, it will be mixed with the respective drug antibody conjugates.

If concentrations of sample drugs are below corresponding detected drugs' cutoff, respective drug antibody conjugates bind to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. This produces a colored line in test region that indicates a negative result.

On the contrary, if concentrations of sample drugs are at or above corresponding detected drugs' cutoff, the free drugs of sample bind to the respective drug antibody conjugates. It prevents the respective drug antibody conjugates from binding to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. Therefore, there is no colored line in the test region that indicates a preliminary positive result. To serve as a procedure control, if the test has been performed properly, a colored line will appear at the Control Region (C).

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-888-444-3657 (9:00 a.m. to 5:00 p.m. CDT M-F).

INDEX OF SYMBOLS



Manufactured by Guangzhou Wondfo Biotech Co., Ltd.
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