



Multi-Panel Urine Test

Catalogue No. See Box label

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

INTENDED USE

The Prime Screen® Multi-Drug Urine Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of 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:

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

The Prime Screen® Multi-Drug Urine Test Panel offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is intended for over-the-counter (OTC) use. For *in vitro* diagnostic use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. 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 Panel?

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

The test is only 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. 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	Cut-off level	Minimum detection time	Maximum detection time
Amphetamine (AMP 1000)	d-Amphetamine	1000 ng/mL	2-7 hours	1-2 days
Amphetamine (AMP 500)	d-Amphetamine	500 ng/mL	2-7 hours	1-2 days
Buprenorphine(BUP)	Buprenorphine	10 ng/mL	4 hours	1-3 days
Secobarbital(BAR)	Secobarbital	300 ng/mL	2-4 hours	1-4 days
Oxazepam (BZO)	Oxazepam	300 ng/mL	2-7 hours	1-2 days
Cocaine (COC 300)	Benzoyllecgonine	300 ng/mL	1-4 hours	2-4 days
Cocaine (COC 150)	Benzoyllecgonine	150 ng/mL	1-4 hours	2-4 days
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenyl-pyrrolidine	300 ng/mL	3-8 hours	1~3 days
Methamphetamine (MET1000)	D(+)-Methamphetamine	1000 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET 500)	D(+)-Methamphetamine	500 ng/mL	2-7 hours	2-4 days
Methylenedioxyamphetamine (MDMA)	3,4-Methylenedioxyamphetamine	500 ng/mL	2-7 hours	2-4 days
Morphine (OPI 2000)	Morphine	2000 ng/mL	2 hours	2-3 days
Morphine (MOP 300)	Morphine	300 ng/mL	2 hours	2-3 days
Methadone (MTD)	Methadone	300 ng/mL	3-8 hours	1-3 days
Oxycodone(OXY)	Oxycodone	100 ng/mL	4 hours	1-3 days
Phencyclidine (PCP)	Phencyclidine	25 ng/mL	4-6 hours	7-14days
Propoxyphene (PPX)	d-Propoxyphene	300 ng/mL	2 hours	2-3days
Nortriptyline (TCA)	Nortriptyline	1000 ng/mL	8-12hours	2-7 days
Cannabinoids (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL	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 test kits beyond expiry date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Read the drug test result at 5 minutes. Do not read the result after 30 minutes.

CONTENT OF THE KIT

- Test devices, one test in one pouch. One pouch contains a Test Panel and desiccant. The desiccant is for storage purposes only and are not used in the test procedures.
- Leaflet with instructions for use.

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer or clock
- Urine collection cup

STORAGE AND STABILITY

Store at 39 °F to 86 °F (4 °C ~ 30 °C) in the sealed pouch up to 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.

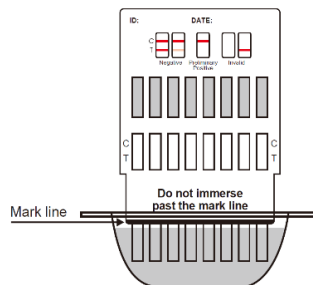
HOW TO COLLECT URINE?

Urinate directly into the urine collection cup. Use only clear aliquots for testing.

HOW TO DO THE TEST?

Test should be at 18 °C ~ 30 °C (65 °F ~ 86 °F).

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the 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 sample for about 10 seconds. **Make sure that the urine level is not above the marker line printed on the front of the device.**
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. The result can be stable for 30 minutes. Do not read the result after 30 minutes.



Note: Results after more than 30 minutes may be not accurate and should not be read.

READING THE RESULTS

Preliminary positive (+)

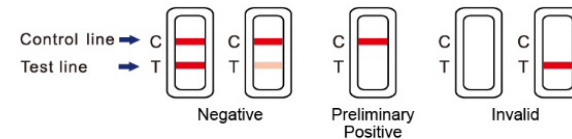
A colored band is visible in each control region. No colored band appears in the appropriate test region. It indicates a preliminary positive result for the corresponding drug of that specific test zone.

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.

Invalid

If a colored band is not visible in each of the control region, 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 Panel. 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 Panel. 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 false 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, benzoylecgonine, 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, Oycotton, 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 device 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 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.

9. *What is the principle of Prime Screen® Multi-Drug Urine Test Panel?*

Prime Screen® Multi-Drug Urine Test Panel 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).

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 <http://ncadi.samhsa.gov/>. 1-800729-6686

Center for Substance Abuse Treatment <https://www.samhsa.gov/about-us/who-we-are/offices-centers/csat> 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence 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 4°C and 30°C



Keep dry



Do not re-use



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