



Precision Plus™

Multi Panel Urine Drug Test Cup

Package Insert for OTC/CLIA-waived

For *in vitro* diagnostic use only

The Precision Plus Multi Panel Urine Drug Test Cup offers a variety of solutions for fast and reliable drug testing in the privacy of your own home. This product can detect up to 15 commonly abused drugs in human urine:

Abbreviation	Drug	Cutoff (ng/ml)
AMP	Amphetamine	500
BAR	Barbiturates	300
BUP	Buprenorphine	10
BZO	Benzodiazepines	300
COC	Cocaine	150
EDDP	Methadone Metabolite	300
MET	Methamphetamine	500
MDMA	Ecstasy	500
MTD	Methadone	300
OPI 300	Morphine	300
OPI 2000	Opiates	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
TCA	Tricyclic Antidepressants	1,000
THC	Marijuana	50

This test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry / Tandem Mass Spectrometry (LC/MS/MS) and High-Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in the evaluation of a preliminary positive test result.

This test does not distinguish between drugs of abuse and certain medications. It may yield preliminary positive results when prescription tricyclic antidepressants, barbiturates, benzodiazepines, methadone, buprenorphine or opiates are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

INSTRUCTIONS FOR OTC USE:

BEFORE TESTING

Read the instructions completely.

Check the expiration date on the box. Do not use the test if it is expired. Have a watch, clock or timer ready.

The following items are needed only if you choose to ship samples for confidential confirmation lab testing:

- Pre-addressed shipping box
- Plastic transportation bag
- Identification label

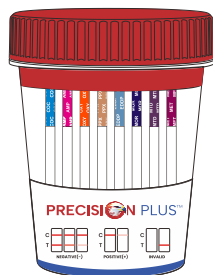
PERFORMING THE TEST

Step 1: Take Out the Test Device

Take the test device from the sealed foil pouch.

Step 2: Apply Urine to the Test Device

1. Remove the cup from the sealed pouch. Write the donor's name or ID in the space provided.
2. **Collect urine** in the cup.



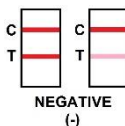
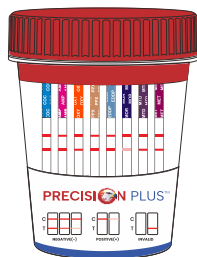
Step 3: Read Result

Read results after 5 minutes. Do not wait longer than 60 minutes.

A red or pink line must appear next to the letter "C" (control) on all of the test strips. The appearance of a red or pink next to the letter "C" on each test strip indicates that the test has worked properly. If you see control lines on all the test strips, you can read your test results.

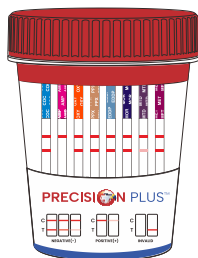
Negative Result:

A red or pink line next to the "T" under the drug name indicates a negative result for that drug. If a test line appears next to the "T" all drugs, the sample is considered negative. Certain lines may appear lighter or thinner than other lines.



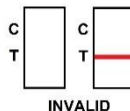
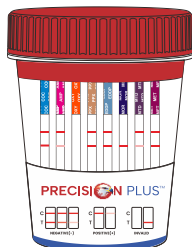
Preliminary Positive Result:

If NO red or pink line appears next to the "T" under the drug name, the sample may contain that drug. Send the sample to a laboratory for confirmation testing.



Invalid Result:

A colored line should always appear next to the letter "C" on every test strip. If no control line appears on any of test strips, the result is invalid.



QUESTIONS AND ANSWERS

The Precision Plus Multi Panel Urine Drug Test Cup is user friendly, if you have question about the test or result, please call our helpline at (866)-526-2873, the Precision Plus team is available to answer your question weekdays from 8 am to 6 pm CST.

What do my test results mean?

Q. The drug line is lighter than control line. Does it mean the drug is present in the urine?

A. No. The drug line may be darker or lighter than the control line. The line intensities of different drugs will vary for many reasons. No matter how faint the drug line appears on the test strip, it is considered a negative result. No further testing is required.

Q. What does a Preliminary Positive Result mean?

A. The sample may contain one or more of the drugs being tested for, and you should take the second step in the process, send the urine to our laboratory for additional confirmatory testing. There is no additional cost to you for laboratory testing. However, it is possible to get a "preliminary positive" when the person did not take the drug.

- Medicinal such as diet pills, inhalers, cough syrup, and pain pills may cause a preliminary positive result.
- The tests may yield preliminary positive results with prescription drugs such as tricyclic antidepressants, barbiturates, benzodiazepine, methadone, buprenorphine (including Subutex, Suboxone, Temgesic, Buprenex, Norspan, and Butrans), and opiates (including morphine, hydrocodone, Oxycodone, and codeine) are ingested, even at therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

Q. What does a Negative Result mean?

A. If you get a negative result, the sample did not contain the drug being tested for. No further testing is required. However, it is possible to get a negative result even if a person has taken drugs. Some reasons why this might happen are:

- The urine sample was collected at the wrong time. It was collected before the drug got into the urine or after it was no longer in the urine.
- The person took a drug other than the one tested for in this test; e.g. they might have taken LSD, when this test is for drugs other than LSD.

Q. What does an Invalid Result mean?

A. If any of the strips do not show a control, the result is invalid. We recommend that you re-test or contact your sales representative.

Laboratory Confirmation Testing:

Q. How can a Preliminary Positive Result be confirmed?

A. The urine specimen needs to be sent to our laboratory for confirmation testing. See the shipping instructions in "**Shipping the Urine Sample to the Lab for Confirmation Testing**" section below.

Other Questions:

Q. When is the best time to take the test?

A. The drug test can be used at any time of day. Approximate detection times using each drug are listed in the following table:

Drug	Cutoff	Minimum	Maximum
Amphetamine (AMP)	500 ng/ml	2-7 hours	2-4 days
Cocaine (COC)	150 ng/ml	1-4 hours	2-4 days
Methamphetamine (MET)	500 ng/ml	2-7 hours	2-4 days
Opiates (OPI)	2,000 ng/ml	2 hours	2-3 days
Morphine (OPI 300)	300 ng/ml	2 hours	2-3 days
Marijuana (THC)	50 ng/ml	2 hours	Up to 40 days
Tricyclic Antidepressants (TCA)	1,000 ng/ml	8-12 hours	2-7 days
Phencyclidine (PCP)	25 ng/ml	4-6 hours	7-14 days
Barbiturates (BAR)	300 ng/ml	2-4 hours	1-3 weeks
Benzodiazepines (BZO)	300 ng/ml	2-7 hours	1-4 days
Oxycodone (OXY)	100 ng/ml	1-3 hours	1-2 days
Methadone (MTD)	300 ng/ml	3-8 hours	1-3 days
Ecstasy (MDMA)	500 ng/ml	2-7 hours	2-4 days
EDDP	300 ng/ml	3-8 hours	1-3 days
Buprenorphine (BUP)	10 ng/ml	4-24 hours	3-6 days

The Substance Abuse and Mental Health Services Agency (SAMHSA) has set cutoff levels when testing for marijuana, cocaine, amphetamine, opiates, PCP, Ecstasy and methamphetamine. Screening tests may not detect amounts of drugs in a urine sample that are below the cutoff level. Even if some drug is present in a urine sample, the sample would be considered negative if the drug level is below the cutoff level.

Q. How much urine do I need?

A. The Precision Plus Cup requires just 30 ml of urine. Fill the collection cup of the minimum fill line on the side of the cup. This is enough urine for the initial test and confirmation testing if needed.

Q. Do I have to wait the full 5 minutes before reading the test?

A. Yes, we recommend that you wait the full 5 minutes before reading the result.

Q. Are there any factors that could affect the drug testing result?

- A. Yes, certain factors may affect the drug testing result.
1. Certain over-the-counter medicines and prescription medicines may cause a preliminary positive result.
 2. Urine can be adulterated (i.e. contaminated or tampered) by using bleach, cleaning supplies and other liquids. This may dilute the urine and the test may not be accurate.
 3. Drinking large amount of liquids may dilute the urine so that the drug (if present) cannot be detected.
 4. Failure to use the Precision Plus Cup as directed may result in an inaccurate screening result.

SHIPPING URINE SAMPLES FOR CONFIRMATION TESTING

About confirmation testing:

Negative samples do not need further testing. You should only send preliminary positive samples to a laboratory for confirmation.

Check the provided shipping package:

The following items are provided

- Mailer: Pre-addressed Mailing Box with Transportation Label
- Zip-lock Plastic Transportation Bag
- Identification Label

Package urine samples for shipping:

- Attach the top portion of the identification label to the urine collection cup.
- Attach the lower portion of the identification label to the instruction sheet where labeled "place identification label here." For security reasons, you will need this number to retrieve your lab test results.
- Place the urine collection cup in the zip-lock plastic transportation bag, seal and place into the pre-addressed mailing box and close. On the pre-addressed mailing box label, fill in the sample collection date.
- On the mailing box label, check off the drug(s) that gave a preliminary positive result. IT IS IMPORTANT THAT YOU INDICATE WHICH DRUG WAS POSITIVE SO THAT A LAB CONFIRMATION TEST CAN BE PERFORMED FOR THAT DRUG. WITHOUT THIS LABEL, YOUR SAMPLE CANNOT BE TESTED.
- Mail the preliminary positive urine sample as soon as possible. Urine samples cannot be accurately tested if more than 7 days old.
- The mailing box is not pre-paid. To ensure prompt delivery, be sure to pay the appropriate shipping charges.

TO OBTAIN THE LABORATORY RESULTS

Results will be ready in 2 to 3 days after the sample is received in our laboratory. Results will be accessible via a secure web portal. You will be asked for the identification number that you place on the instruction sheet. You will not get the results without this number.

Call 866-526-2873 to get the results of your test.

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