

Multi-Drug Urine Test Cup

INSTRUCTIONS FOR USE

PLEASE READ ALL THE INFORMATION IN THIS INSERT BEFORE PERFORMING THE TEST.

REF See Box Label

This package insert applies to any combination of the multi-drug tests. Therefore, some information may not be relevant to your test. You can identify which drugs and associated cutoffs are included in your test from the box labels and prints on the test device.

INTENDED USE

Multi-Drug Urine Test Cup is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the cutoff concentrations of table below.

Drug (Identifier)	Cut-off level (ng/mL)
Amphetamine (AMP)	1000 or 500
Secobarbital (BAR)	300
Buprenorphine (BUP)	10
Oxazepam (BZO)	300
Cocaine (COC)	300 or 150
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300
Methylenedioxyamphetamine (MDMA)	500
Methamphetamine (MET)	1000 or 500
Morphine (MOP 300/OPI 2000)	2000 or 300
Methadone (MTD)	300
Oxycodone (OXY)	100
Phencyclidine (PCP)	25
Propoxyphene (PPX)	300
Nortriptyline (TCA)	1000
Cannabinoids (THC)	50
6-Monoacetylmorphine (6-MAM)	10

Multi-Drug Urine Test Cup offers any combinations from 1 to 16 drugs 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 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.

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
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 300)	Benzoyllecgonine	300 ng/mL	1-4 hours	2-4 days
Cocaine (COC 150)	Benzoyllecgonine	150 ng/mL	1-4 hours	2-4 days
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL	3-8 hours	1-3 days
Methylenedioxyamphetamine (MDMA)	3,4-Methylenedioxyamphetamine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET 1000)	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
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	7-14 days
Propoxyphene (PPX)	d-Propoxyphene	300 ng/mL	2 hours	2-3 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
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10 ng/mL	2-8 hours	1-3 days

WARNINGS AND PRECAUTIONS

- For external use only. Do not swallow.
- Discard after first use. The test cannot be reused.
- Do not use the test device beyond expiry date.
- Do not use the test device if the pouch is punctured or not well sealed.

- Keep out of the reach of children.
- Read the test result at 5 minutes. Do not read the result after 60 minutes.
- The test is only the first step of the two-step process to provide consumers with information about the presence or absence of the above stated drugs in a urine sample. If you get a 'preliminary positive' test result when you use this product, the second step is to send the cup with urine to the laboratory for confirmation testing.
- By itself, this test will not confirm if someone used a drug of abuse. These types of tests may incorrectly detect the presence of a drug of abuse when the person has consumed certain foods, medicines, diet plan drugs, or nutritional supplements. These are just some examples of the types of things that can cause a false result and there may be others as well. In order to show if someone used a drug of abuse, you will need to send the urine sample to a laboratory to have a second test, called a confirmation test, performed. The cost of the additional testing is not included in the purchase price of this screening test kit.

CONTENTS OF THE TEST KIT

Material provided

- Multi-Drug Urine Test Cup
- Adulteration Color Comparison Chart (If equipped)
- Instructions for use

Materials needed but not provided

- Timer or stopwatch

STORAGE AND STABILITY

1. Store at 35°F - 86°F (2 °C ~ 30 °C) in the sealed pouch up to the expiry date.
2. DO NOT FREEZE.
3. Keep away from direct sunlight, moisture and heat.
4. Use the test within 1 hour of removing from the foil.

SPECIMEN COLLECTION AND STORAGE

WHEN TO COLLECT URINE FOR THE TEST?

Urine collected at any time of the day may be used. You may collect urine samples after the minimum detection time when you suspect you've taken drugs.

HOW TO COLLECT URINE?

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 void directly into the test cup to reach the minimum urine level. Wipe off any splashes or spills that may be on the outside of the cup.

IMPORTANT: The urine sample in the test cup should be enough to reach the Minimum Urine Level on the cup label.

HOW TO DO THE TEST?

Test must be performed at room temperature (59°F - 86°F / 15°C - 30°C).

1. After the urine has been collected, re-cap the test cup and place the test cup on a flat surface.
2. Start the timer. Peel the label from right to left.
3. **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 cup.
4. **For the drug tests:** Read the drug test results at 5 minutes. Do not read the result after 60 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.

DRUG-OF-ABUSE TEST:

Preliminary positive (+)

A color band is visible in each control region (C). If no color band appears in the appropriate drug test region (T), a preliminary positive result is indicated for the corresponding drug of that specific test region.

Negative (-)

If a color band is visible in each control region (C) and the appropriate drug test region (T), it indicates that the concentration of the corresponding drug of that specific test region is absent or below the detection limit of the test.

Invalid

If a color band is not visible in the control region (C), 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. Any visible line is considered to be a line.