

CLIAwaived, Inc Multi-Drug Rapid Cup (Urine) Package Insert

The Rapid Test offers a variety of solutions for fast, accurate and reliable drug testing.

This Rapid Test can detect the possible use of following Drugs of Abuse in urine: AMP/ BAR/ BZO/ COC/ THC/ MOP/ MET/ MTD/ PCP/ TCA/ EDDP/ OXY/ MDMA/ BUP.

The Rapid Test provides only preliminary results and is the first step in a two-step process for identifying drugs in urine.

The second step is confirming the results with GC/MS or LS-MS/MS.

To confirm preliminary positive results obtained by the Single or Multi-Drug Rapid Test, please follow steps outlined in these instructions.

【WARNING】

Read the entire information prior to performing test.

The Rapid Test provide only preliminary results.

Have a watch, clock or timer available.

Do not use the test after expiration date printed on the package.

Do not use the test if its foil pouch is torn or damaged.

The test is for one time use only, do not reuse the test.

Certain foods or medications may cause the test to give false results.

Contaminated or tainted urine sample may give false results.

Keep out of reach of children.

【ITEMS PROVIDED】

• Test Cup

• User Instruction

【ITEMS NOT PROVIDED】

Timer

【STORAGE】

Store the test at 35.6-86°F (2-30°C).

Do not open the pouch until ready for use. **DO NOT FREEZE.**

【TESTING】

Allow the test to reach room temperature before testing.

Step 1: Getting Ready

• Remove the cup from the sealed pouch and use it immediately.

• Open the cap and collect urine in the cup, urine specimen must exceed the minimum urine level line.

• Close the cap tightly.

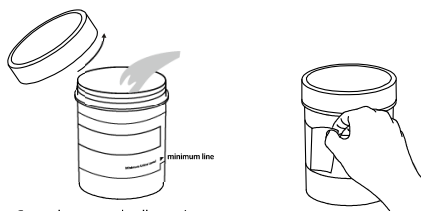
Step 2: Peel off the label

• Peels off the label on the cup body to view the test result window.

Step 3: Read Results

• Read the test results at **5 minutes**, do not read them after 10 minutes.

TEST PROCEDURE Cup



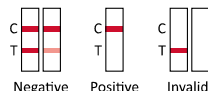
- Open the cap and collect urine.
- Urine volume must exceed the minimum line.
- Close the cap tightly.

- Peel off the label to view results

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2

Reading Result
at 5 minutes.



3

【READ RESULTS】

Each strip only contain 1 drug test, drug name was shown on the top of the strip, the C line(C) region shows validity of a test result and the T line(T) region shows result of the test.

Each test strip and test area should be looked at individually. Do not compare lines between test strips or different areas. Also, do not compare the color or darkness of the lines, or the rate at which the lines appear.

	NEGATIVE: Two colored lines appear on the test strip. One line appears next to the letter 'C' and the other line appears next to the letter 'T', meaning a NEGATIVE RESULT for that drug.
	POSITIVE: Only one colored line appears next to the letter 'C'. No colored line appears next to the letter 'T', meaning a Preliminary Positive Result for that drug.
	INVALID: If after 10 minutes no line appears next to the letter 'C', discard test and repeat with a new test.

Detection Items, Levels and Approximate Detection Times

Drug Name (Abbreviation)	Detectable Level (ng/ml)	Minimum Detection Time *	Maximum Detection Time *
Amphetamine (AMP)	500	3-6 hours	2-4 days
Secobarbital (BAR)	300	4 hours	7 days
Benzodiazepines (BZO)	300	4-6 hours	2-7 days
Buprenorphine (BUP)	10	2-4 hours	3 days
Cocaine (COC)	150	1-4 hours	2-3 days
Marijuana (THC)	50	2 hours	Up to 30 days
Methadone (MTD)	300	12 hours	48 hours
Methamphetamine (MET)	500	2-4 hours	3-5 days
Methylenedioxymethamphetamine (MDMA)	500	1-3 hours	1-4 days
Morphine (MOP)	300	2-4 hours	1-3 days
Morphine (MOP2000)	2000	2-4 hours	1-3 days
Phencyclidine (PCP)	25	4-6 hours	7-14 days
Nortriptyline (TCA)	1,000	2-4 hours	2-3 days
Oxycodone (OXY)	100	2-4 hours	48 hours
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	12 hours	4-5 days

* NOTE: The times are only estimates.

【Q&A】

1. How do I know if the Test worked well?

When the control line(C) appears, it means the test unit is performing well.

2. What does it mean of a Preliminary Result?

The Rapid Test is considered a "screening test". GC/MS and LC-MS/MS are considered the gold standard in laboratory testing for most drugs.

3. How soon can I read my results?

You can read your results after 5 minutes as long as a red line or pink colored line has appeared next to the Control region(C), do not read result after 10 minutes.

4. When is the best time to run the test?

You can run the test at any time of the day.

5. Can the result be wrong? Are there any factors that can affect the test result?

The results will only give accurate results as far as the fresh human urine is

used and followed the instructions carefully. Nevertheless, the result can be incorrect.

Certain food and OTC medications or prescription drugs may cause a preliminary Positive Result.

6. How to read the test if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The test should be considered as negative whatever the color intensity of the test line (T) is.

【CAUTIONS】

1. The Test is for use with human urine only.
2. The Test provides only a preliminary result.
3. It is possible some substances in certain food and drug that may affect test results.
4. A preliminary result does not mean the frequency or time of drug use, nor does it distinguish between drugs and certain foods and/or medications.
5. If you feel that the sample may have been tampered with, a new urine should be collected.

【RESOURCES】

You may contact the following organizations or your health care provider for additional information and counseling regarding substance abuse prevention and treatment:

- Center for Substance Abuse Treatment (CSAT)
1-877-SAMHSA-7 / www.samhsa.gov
- The National Council on Alcoholism and Drug Dependence (NCADD)
1-800-NCA-CALL / www.ncadd.org
- The Treatment Center
1-866-295-6003 / www.thetreatmentcenter.org/

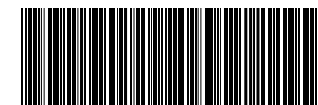
Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

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