



# Multi-Drug One Step Screen Test Panel (Urine)

## INTENDED USE

The KnowNo™ Multi-Drug One Step Screen Test Panel (Urine) is a rapid qualitative immunoassay. The panel provides preliminary results for the detection of potential abuse of one or more drugs. See list below. This is not a screening panel to monitor prescription medication use. It is for in vitro diagnostic home use. Not for internal use.

Abbreviation	Test
AMP	Amphetamine
COC	Cocaine
MET	Methamphetamine
OPI	Opiates
THC	Marijuana/Hashish

The KnowNo™ One Step Screen Test Panel (Urine) shows the drug was or was not present at the cut-off level.

The Test Panel provides a preliminary test result. Positive results must be confirmed by a more specific analytical method. Follow instructions in the "Sending Sample For Confirmation" section if you get a positive result.

## KIT CONTENTS

**IMPORTANT:** Do not open the pouch until ready to perform the test.

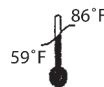
- 1 collection cup
- 1 mailing box
- 1 mailing pouch with absorbant tissue
- 1 Test Instruction Handbook
- 1 Test Panel sealed in foil pouch

## PRECAUTIONS

- Follow the instructions exactly to obtain accurate results.
- Store the test panel in the sealed pouch until use.
- Do not use expired devices.
- Storing the test device above 86°F may shorten its shelf life.
- Dispose of all specimens and used devices according to local, state and federal regulations.
- Do not reuse the test panel.
- Do not use the test if you are color-blind.
- For in vitro diagnostic use only. Not for internal use.

## STORAGE

- Store the kit at room temperature (59-86°F) or longer storage at 35.6-59°F.
- Do not open the sealed pouch until use.
- Do not freeze the test kit. Do not expose the test kit to temperatures over 86°F.



## SAMPLE COLLECTION AND HANDLING

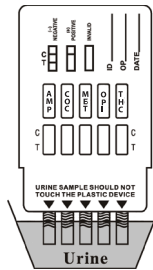
- Collect urine sample in the container provided. Only use the container provided with this kit. Do not combine urine samples. Collect the urine up to the indicated maximum fill line.
- Do not discard the urine sample until the test has been read.
- Test urine sample within eight (8) hours of the urine collection. Send the same sample for lab confirmation (if preliminary positive result is obtained) within 24 hours.

## SCREENING PROCEDURES

**IMPORTANT: Bring Test Panel and urine sample to room temperature before test.**

1. Remove contents from the container (box). Set the box aside. You may use it as shipping box for confirmatory test later.

2. Make sure the pouch is at room temperature before opening.
3. Find a well-lit place to observe the color change on the test panel.
4. Have a watch or timer ready.
5. Remove test panel from the sealed pouch.
6. Label the panel with patient identification and the date. Use the panel as soon as possible.
7. Take off the cap outside of the test end with arrows pointing toward the urine specimen. Immerse the test panel vertically into the urine specimen for at least 10-15 seconds. Immerse the test panel in urine ensuring that it does not touch the plastic casing (as indicated on the test panel). Do not pass the arrows on the test panel when immersing the panel. See illustration below.



Note: Immerse the test panel to at least the level of the wavy lines on the strip(s).

8. Start the timer.
9. Remove the Test Panel from the urine sample after 10-15 seconds.
10. Replace the cap back onto the device. Set the device on a clean and level surface.
11. Read test results on all test strips between 4 and 7 minutes.



**IMPORTANT: Do not read results before 4 minutes or after 7 minutes.**

## INTERPRETATION OF RESULTS

**Each test strip is labeled with abbreviations for a test. For example, "COC" is for cocaine test. A complete list for each test can be found in the Questions & Answers section of this booklet. IMPORTANT:**

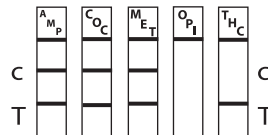
- Read each test independently.
- Do not compare color intensity of one test to another.
- Do not compare color intensity of the T line to the C line.

1. Check that the test is working properly.

The area between the two letters C on each side of the window is called the control region. A color line in the control region is called C line. The area between the two letters T is called the test region. A color line in the test region is called T line.

For the test to work properly, C line must appear within 4 minutes. If C line does not appear within 4 minutes on a test strip, the test is not working correctly. The result is invalid. In this case, repeat the test with a new device. If the test is still invalid using the second device, contact Know Inc. at 1-888-KNOW-NO-8.

In the example below, because there is no color line in either control region or test region on test for OPI and hence it is invalid. On test for THC, a line appears in the test region only and there is no C line, therefore this test is invalid.



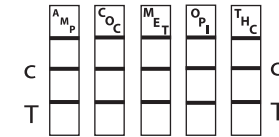
Invalid for opiates and THC (marijuana).

2. Read test only if the C line appears within 4 minutes.

Negative:

If both C line and T line appear on a test, the urine sample is negative for that drug.

If both C line and T line appear for all the tests, the urine sample is negative for all the drugs tested. In this case, no further test is required.



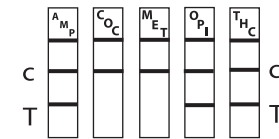
Negative for all drugs tested

Note: Even a very faint T line is negative.

Preliminary Positive:

If C line appears and there is no T line on a test strip, the urine sample may contain that particular drug. In this case, you should take the second step and send the sample to the lab for confirmation. Additional testing by a more accurate laboratory technique such as gas chromatography/mass spectroscopy (GC/MS) or High Performance Liquid Chromatography/mass spectroscopy (HPLC/MS) will be performed. More than one test may be Preliminary Positive.

In the example below, because there is only C line but no T line on test for COC and MET, the test results is preliminary positive for both drugs.



Preliminary Positive for Cocaine and Methamphetamine

Note: If you get a preliminary positive result, you should take the second step and send the sample to the lab for confirmation.

## SENDING SAMPLE FOR CONFIRMATION

If you get a preliminary positive result, send the sample to the lab for confirmation as soon as possible following the steps below.

1. Cap the vial tightly.
2. Fill out the Confirmation Test Label:
  - a. Check the drug tested positive on the Confirmation Test label. For example, if "THC" was tested positive in the screening test, place an "X" next to the "THC".
  - b. Write the date you collected the urine sample in "Sample Collection Date \_\_\_\_\_".
3. Place the confirmation Test Label onto the side of the vial.
4. Keep the top portion of label for your records. You need the Identification Number to get test results from the lab.
5. Place the vial into the specimen bag with an absorbent pad. Seal the bag.
6. Place the sealed plastic bag into the shipping box.
7. Close and seal the box.
8. Send sample by overnight/express delivery to the test lab.
 

Call 1-888-KNOW-NO-8 Monday-Friday 9:00 am to 6:00 pm EST for further assistance.

## GETTING LAB RESULTS

1. Normally you can get test results within 3-10 business days after you ship your sample.
2. Have the Identification Number ready.
3. Call 1-888-KNOW-NO-8 Monday through Friday 9:00 am to 6:00 pm Eastern time.
4. Identify yourself with the Identification Number.

- The lab will give you results for those tests you marked on the label.
- The test lab will keep test results for thirty days. You must call within thirty days after you have sent the sample to get your results. The test results are discarded after 30 days.

### LIMITATIONS

- Not following directions exactly may result in inaccurate screening results.
- This test provides a screening result. A positive result indicates the presence of AMP, COC, MET, OPI, THC, and/or their metabolites in the urine. It does not reflect the degree of intoxication.
- The test provides only a preliminary test result. You must use a more specific method to obtain a confirmed result.
- This product is for testing human urine only. Do not use this device to test anything but urine.
- The urine sample is perishable. If you need a confirmatory test, send sample to the lab as soon as possible. For further details about Lab testing, call 1-888-KNOW-NO-8.
- Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results. When suspected, collect a fresh sample and repeat the test with a new cup.
- Do not use samples suspected of bacterial contamination. The contaminants may interfere with the test and cause false results.
- It is possible that substances and procedural errors not described in this instruction may interfere with the test, causing false results.
- Certain foods and medicines such as cough syrup, diet pills and nutritional supplements may cause a false positive test result with this device.
- This test does not distinguish between drugs of abuse and certain medications.

### QUESTIONS & ANSWERS

#### 1. What does the KnowNo™ Multi-Drug One Step Screen Test Panel (Urine) do?

The Test Panel is a drug screen test. It provides preliminary results for the detection of one or more of the drugs at the cut-off level:

Abbreviation	Test
AMP	Amphetamine
COC	Cocaine
MET	Methamphetamine
OPI	Opiates
THC	Marijuana/Hashish

#### 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 is called positive, and below that concentration it is called negative.

#### 3. What are drugs of abuse?

Examples of drugs of abuse include marijuana, cocaine, opiates, heroin, amphetamines, Ecstasy, and phencyclidine. Prescription drugs, such as morphine, codeine or other painkillers, also may be abused.

#### 4. Common Street Names for Drugs

Drug	Street Name
Amphetamine	Speed, Amp, Chalk
Cocaine	Big C, Coke, Snow, Flake, Candy, Crack, Blow, Rock
Methamphetamine	Crystal-Meth, Ice, Glass, Ecstasy, X, E
Opiates	Heroin, H, Hairy hombre, Horse, Jones, Scag
Marijuana(THC)	Pot, Weed, Herb, Bud, MJ, Doobie, Reefer, Grass, Joint, Homegrown, Spliff

#### 5. How long can the drugs be detected in urine?

The following are guidelines only. The times can vary significantly from these estimates depending on how long the person has been taking the drug, amount of drug they use, or the person's metabolism.

Drug	Detection Times	
	Minimum	Maximum
Amphetamine (Speed)	4-6 hours	2-3 days
Methamphetamine (Ecstasy, X, E)	4-6 hours	2-3 days
Cocaine (Crack)	2-6 hours	2-3 days
Heroin (Opiates)	2-6 hours	1-3 days
Marijuana (Pot)	1-3 hours	1-7 days

#### 6. How accurate is the test?

The test is fairly sensitive to the presence of drugs in the urine. This means that if drugs are present, you will usually get a preliminary positive result. If you get a preliminary positive result, you should send the urine sample to the laboratory for a second, more accurate test.

It is very important to send the urine sample to the lab, because the drug of abuse urine screening may give positive results when no drugs are actually present. Certain foods, food supplements, beverages, diet pills, or over-the-counter medicines can cause a reaction with the tests. Laboratories use a very reliable test, with very few errors, to determine whether or not your sample contains drugs.

Many things can affect the accuracy of this test, including but not limited to:

- The way you did the test
- The way you stored the test or urine
- What the person ate or drank before taking the test
- Any prescription or over-the-counter drugs the person have taken before the test

118 consumers participated in a field study. The results of the study are summarized below. 19 of the 22 incorrect results are at drug concentrations at 50% ~ 150% of the cutoffs. 2 positive samples were read negative. 2 negative samples were read positive.

Drug	Cutoff Conc. (ng/ml)	# Test	Result Interpretation	
			Correct	Incorrect
AMP	1000	592	585	7
COC	300	592	590	2
MET	1000	592	588	4
OPI	2000	592	587	5
THC	50	592	588	4

#### 7. If the test results are negative, can you be sure that the person did not take drug?

No. There are several factors that can make the test results negative even though the person is using drugs. Because

- You may have tested for the wrong drugs.
- You may not have tested the urine when it contained drugs. It takes time for drugs to appear in the urine after a person takes them, and they do not stay in the urine indefinitely. You may have collected the urine too soon or too late to be detected.
- The person knowingly added something to the urine to prevent it from reacting with the test chemicals.
- The chemicals in the test went bad because they were stored incorrectly or they passed their expiration date.

If you get a negative result, but still suspect drug abuse, you can test again at a later time. You should also consider testing other types of drugs. Talk to your doctor if you need more help deciding what steps to take next.

#### 8. What is false positive result?

A false positive result is a screening test read positive when the drug or drug metabolite is not present or its concentration is less than the cutoff level.

#### 9. What does Preliminary Positive mean?

The Multi-Drug One Step Screen Test Panel is a screening test. It is the first step in a two-step process. Screening tests are not as accurate as laboratory test. It is possible to get a positive result when the person did not take drugs. For example, some medicines and food may cause the screening tests to incorrectly read positive. Things such as diet pills, inhalers and cough syrup can cause a positive result. You consult with your doctor to better understand how medications may interfere with this test.

#### 10. What if the lab test confirms a positive result?

The lab uses very accurate and reliable equipment to run the tests. If the lab reports a positive result, it means the drug was present in the urine sample. But do not assume the urine sample came from a drug abuser.

Consider all amphetamine results carefully, even those from the lab. Some over-the-counter medications contain amphetamines that cannot be distinguished from illegally abused amphetamines.

- If you received a positive result and you do not believe the test, consult your doctor. They have your medical history and they can provide you with detailed information.
- If a positive result was confirmed, consult you doctor to identify counselors who will help you. You can also contact one of the resources listed below for help.

#### 11. Additional Resources

National Institute on Drug Abuse  
Phone: 301-443-1124  
www.drugabuse.gov

Center for Substance Abuse Prevention  
Substance Abuse and Mental Health Services Administration  
Phone: 301-443-9110  
www.prevention.samhsa.gov

Centers for Disease Control and Prevention  
Phone: 404-639-3534  
Phone: 800-311-3435 (toll-free)  
www.cdc.gov

Safe and Drug-Free Schools Program  
U.S. Department of Education  
Phone: 800-872-5327  
www.ed.gov

National Clearinghouse for Alcohol and Drug Information  
Phone: 800-729-6686  
www.ncadi.samhsa.gov

National Council on Alcoholism and Drug Dependence  
Phone: 800-622-2255 (toll-free)  
www.ncadd.org

American Council for Drug Education  
Phone: 301-443-3860  
www.niaaa.nih.gov



**Know Inc.**  
218 East Bearss Avenue Suite 337  
Tampa, Florida U.S.A - 33613

For technical assistance call  
1-888-KNOW-NO-8  
Weekdays from 9:00 am to 6:00 pm (EST)  
www.knownodrugtest.com