

(CLIA WAIVED)

DrugCheck® Waive™ Drug Test Card

Test Instruction/ Questions & Answers

(Information for the OTC users and for the health care professional users)

What is DrugCheck® Waive™ Drug Test Card?

DrugCheck® Waive™ Drug Test Card is a drug screening test, and if needed, a confirmation service. It provides preliminary urine screening results for the detection/presence of the following drugs of abuse: Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana (THC), Methamphetamine, Methadone, Ecstasy (MDMA), Opiates, Morphine, Oxycodone, Phencyclidine and Tricyclic Antidepressants. The test detects any or all of these drugs when they are above the detection limit of the test. The test is intended for over-the-counter (OTC) users and for health care professional users.

What is the Cut-off level and approximate detection time?

Drug (Identifier)	Cut-off Level	Minimum detection time	Maximum Detection time
Amphetamine (AMP)	1000 ng/mL	2 – 7 hours	2 – 4 days
Cocaine (COC)	300 ng/mL	1 – 4 hours	2 – 4 days
Methamphetamine (MET)	1000 ng/mL	2 – 7 hours	2 – 4 days
Ecstasy (MDMA)	500 ng/mL	2 – 7 hours	2 – 4 days
Opiates (OPI)	2000 ng/mL	2 hours	2 – 3 days
Opiates 300 (OPI 300)	300 ng/mL	2 hours	2 – 3 days
Phencyclidine (PCP)	25 ng/mL	4 – 6 hours	7 – 14 days
Marijuana (THC)	50 ng/mL	2 hours	Up to 40+ days
Benzodiazepine (BZO)	300 ng/mL	2 – 7 hours	1 – 4 days
Methadone (MTD)	300 ng/mL	3 – 8 hours	1 – 3 days
Barbiturates (BAR)	300 ng/mL	2 – 4 hours	1 – 3 weeks
Tricyclic Antidepressants (TCA)	1000 ng/mL	8 – 12 hours	2 – 7 days
Oxycodone (OXY)	100 ng/mL	1 – 3 hours	1 – 2 days

The DrugCheck® Waive™ Drug Test Card may not detect amount of drugs in a urine sample that are below the cut-off level. Even though some level of drug may be present in a urine sample, the sample would still be considered a Negative Result if the drug level is below the cut-off level.

When is the best time to collect a sample?

The sample should be collected as soon as possible 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 and is detected in the urine at different times and rates.

How much sample do I need?

Fill the Collection Cup to above the 30 mL to 60 mL mark and then fill the sample Vial to two-thirds (2/3) full.

How do I perform a test with the DrugCheck® Waive™ Drug Test Card?

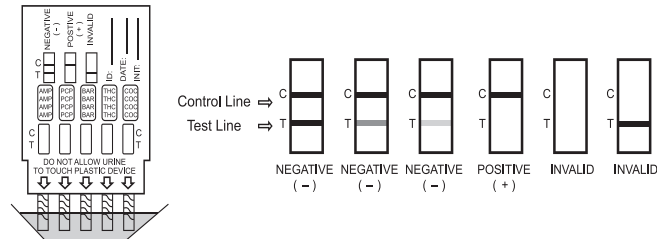
- 1) Begin in a well-lit place. Have a watch or timer ready.
 - 2) Make sure the urine sample and the Drug Screening Test Card are at room temperature before testing
 - 3) Open the foil pouch at the notch and remove the Drug Screening Test Card. Make sure not to touch the test area of the device
 - 4) Remove the cap from the end of the Drug Screening Test Card
 - 5) Immerse the strip(s) of the test card into the urine sample for at least 15 seconds.
- IMPORTANT: Immerse the strip(s) of the test card into the urine sample to at least the level of the wavy lines on the strip(s), but NOT above the arrow(s) on the test card.** (See the illustration in the product insert)
6. Allow the strip(s) of the test card to remain in the urine sample for at least **15 seconds**.
 7. Place the test card on a flat dry surface. Start the timer and wait for the colored line(s) to appear.
 8. Read the test result(s) at 5 minutes.

NEGATIVE RESULTS: A negative result is indicated by two colored lines (of any intensity): one in the control region “C” AND one in the test region “T” This result means that the urine screened negative. **(REMEMBER- EVEN A VERY FAINT LINE IS A NEGATIVE RESULT)**

PRELIMINARY POSITIVE RESULTS: A single colored line which appears in the control region “C” and NO line in the test region “T” means the urine screen is considered to be **PRELIMINARY POSITIVE**. The urine sample must be sent to a laboratory for further testing. More than one test may be “preliminary positive.”

INVALID RESULT: A test should be considered an Invalid Result if no lines appear or if a line appears in the test region “T” without a line in the control region “C.” The presence of a colored line in the control region “C” is necessary to confirm assay performance and must always appear.

(See the illustration in the below)



What does a negative test result mean?

This means that if the sample was collected properly, and if the test was performed according to direction, then none of the drugs screened were present in the sample. However, if drug use is still suspected, you may wish to re-screen at a later time.

What does a preliminary positive test result mean?

This means that if the test has reacted with something in the sample and must be sent to the lab for a more accurate test. Please review the Test Limitations following this section. First, and most important: BE PATIENT. The result you obtained is called preliminary for a reason. The sample MUST be tested by the clinical laboratory in order to determine if a drug of abuse is actually present. You will never know for sure without taking the second step.

Remember, drug screening test is the first step in a two step process:

- Step 1: Screen out (eliminate) the negative samples.
- Step 2: Send any sample which does not give a negative result to a laboratory for further testing.

Test Limitations:

1. Failure to use this kit as directed may result in an insufficient sample or an inaccurate screening result.
2. This test can be used on urine samples only. No other fluids have been evaluated. **DO NOT** use this device to test anything but urine.
3. The laboratories must receive an adequate amount of sample to perform confirmation testing.
 - The urine sample is perishable. Old urine samples may not be suitable for testing.
 - Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result.
4. The possibility exists that substances and factors not described in this instruction may interfere with the test, causing false results (e.g. technical or procedural error).
 - Adulterated urine samples may produce erroneous results.
 - Strong oxidizing agents such as bleach can oxidize drug analytes. If a sample is suspected of being tampered with, a new sample must be obtained.
 - This test provides a screening result. It is not designed to determine the actual concentration of a drug or the level of intoxication.
 - Liability is limited to the purchase price of the kit.

Mailing a Urine Sample to a Laboratory for Confidential Confirmation Testing

- If you get a preliminary positive result, you need to send the sample to a certified Laboratory for confirmation test as soon as possible. If you have obtained a Confirmation Kit from your supplier, the kit includes a sample Vial, a Confirmation Test Label, a specimen bag and pre-addressed mailing box, the following steps are for its use:
1. Ensure that the Vial is about two thirds (2/3) full with the sample and the cap is tightly closed.
 2. Fill out the Confirmation Test Label for the lab:
 - a) Identify the drug that tested positive on the label. For example, if the screening test indicated the THC was positive, mark an “X” next to the THC test.
 - b) Fill in the blank in “Sample Collection Date” _____
 3. Keep the top portion of the label that contains the Identification number and 1-800 toll

- free telephone number for your record, you will need it to obtain the results.
4. Place the Confirmation Test Label onto the side of the vial.
5. Place the sample Vial into the specimen bag and seal the specimen bag.
6. Place the sealed specimen bag into the pre-addressed mailing box. Close the mailing box. **(PLEASE NOTE THAT THE MAILING BOX IS NOT PRE-PAID. YOU MUST ATTACH THE PROPER POSTAGE TO HAVE A CARRIER SERVICE DELIVER IT.)**
7. Place the mailing box in any US Postal Service Office. **(IT IS IMPORTANT TO MAIL IT RIGHT AWAY! Old urine samples may not be suitable for testing.)**
8. Normally you can get the test results in 5 to 10 business days. Dial 1-800 toll free telephone number listed in the top portion of the label, and identify yourself with the Identification number to receive the test result.
9. Test results will be kept on file for thirty (30) days. So you must call within thirty (30) day period to receive your test results. Remember to have your identification number handy when you call. Results will not be disclosed without an ID number.

The following is common street names for some commonly abused drugs:

Drug	Identifier	Street Name
Amphetamine	AMP	Speed, amp, bennie, chalk, black beauties
Cocaine	COC	Big C, coke, snow, flake, candy, crack, blow, rock
Methamphetamine	MET	Crystal, meth, ice, glass
Ecstasy	MDMA	Ecstasy, E Adam, XTC, X
Opiates	OPI	Heroin, H, hairy hombre, horse, jones, scag
Opiates 300	MOR	-----
Phencyclidine	PCP	Angel dust, magic dust, sherms, star dust
Marijuana	THC	Pot, weed, herb, bud, MJ, doobie, reefer, grass joint, homegrown, spliff
Benzodiazepine	BZO	Downers, tranks, benzos
Methadone	MTD	Done, fizzies, chocolate chip cookies, joice, wafer
Barbiturates	BAR	Barbs, birds, red devils, yellow jackets, block busters
Tricyclic Antidepressants	TCA	-----
Oxycodone	OXY	Oxy, killers, OC, oxycotton

What do the laboratory results mean?

1. You will be told if the laboratory test result for your urine sample was positive or negative according to confirmation testing.
2. The results you receive will come from the tests performed by laboratory professionals. These tests are run on very accurate and reliable equipment.
3. Positive results are released only when the sample is confirmed to be positive using sophisticated techniques and equipment such as gas chromatography/mass spectrometry.
4. Samples which are screened as negative do not require the second (confirmation) test. *This can mean several things:*
 - a) These drugs were used in the past few days prior to providing the urine sample. Therefore, the person either doesn't do drugs or had not done them just prior to testing.
 - b) The person may only use a small amount of a drug, an amount too small to be detected by the test.
 - c) A person may take a drug that cannot be detected by DrugCheck® Waive™ Drug Test Card. DrugCheck® Waive™ Drug Test Card can only test thirteen (13) drugs and so if any other drugs were in use the test result would be negative.
 - d) The sample may have been tampered with or be unsuitable due to some rare technical interference.
5. Certain foods and medicines may cause a positive test result.
 - a) People can test positive for THC (or marijuana) if they have been continually near to very heavy marijuana smoke for long periods of time even though they did not eat or smoke marijuana themselves.
 - b) Preliminary positive tests may arise from the cross-reactions with other substances.
6. Remember, when a drug is found in the urine, testing
 - a) does not tell us how the drug got there (eaten, inhaled, smoked or injected)
 - b) does not distinguish a prescription medicine from a drug of abuse.
 - c) does not tell if the positive result is from a food that someone ate.
7. In the event a positive result for a drug was confirmed, please consult a proper counselor who can help you. It is important that you remain calm and do not react in a negative way to the situation.
8. If you have received a positive result and you do not believe the test result, please consult with your physician. They will review your background medical history and be able to provide you with detailed information on both the test and the meaning of the result.

What about False Positive Results?

A screening test can give a false positive result. Certain cross reactive substances are known to occur. These can be present due to diet, prescription medicines, over-the-counter medications, etc. This is why it is important to send any sample not giving a negative result to the laboratory for further evaluation.

Analysis by the laboratory, which involves confirmation testing, will determine whether or not a drug is present in the urine. If the laboratory reports a positive result you may be assured that the drug was indeed present. However, it would be incorrect to assume the urine sample came from a drug abuser just because the result is positive. It is necessary to determine how contact with drug occurred.

Can False Negative Results Occur?

If you have observed behavioral changes which you feel could be caused by drug abuse, don't discard the suspicion just because the test result is reported negative. A false negative result can occur for a number of reasons. Certain products are being marketed as a means of defeating drug testing. These interfere with various methods used in either the screening or confirmation tests. Often, the concentration of the drugs in the urine sample is below the cut-off, or sensitivity, of the screening assay. When this occurs, the test is reported negative.

(The Following Technical Information and Additional Information for Health Care Professionals)

Performance Characteristics

The consumer study was conducted among 115 lay users who had no previous experience using drug testing products. The urine samples were prepared to contain strong negative (0% of cutoff), a very weak negative (50% of cutoff), a weak negative (75% of cutoff), a very weak positive (125% of cutoff), a weak positive (150% of cutoff) and high positive (300% of Cutoff). Pure drugs or drug metabolites were spiked into drug free human urine, the final drug concentrations in each urine sample were confirmed by GC/MS but TCA, TCA concentrations in the urine samples was confirmed by HPLC. All incorrect results are obtained at drug concentrations between 50% to 150% cutoff levels. The test results by the lay users are summarized as below:

Drug Names	Cutoff (ng/mL)	#Test	Result Interpretation		Total Agreement with GC/MS
			Correct	Incorrect	
AMP	1000	228	226	2	99.1%
BAR	300	228	223	5	97.8%
BZO	300	228	224	4	98.2%
COC	300	228	223	5	97.8%
MTD	300	228	226	2	99.1%
MET	1000	228	224	4	98.2%
MDMA	500	228	221	7	96.9%
OPI 300	300	228	222	6	97.4%
OXY	100	228	222	6	97.4%
OPI	2000	228	222	6	97.4%
PCP	25	228	225	3	98.7%
TCA	1000	228	224	4	98.2%
THC	50	228	224	4	98.2%

Quality Control

- Built-in Control: the test contains a built-in control feature, the C line. The presence of the C line indicates that the test is performed properly. If a C line does not form, the test is considered invalid. In this case, the testing should be repeated with a new device.
- External Quality Control: Control materials are not supplied with this kit. However, it is recommended that positive and negative controls should be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.
- Test each new lot and shipment by using external quality control materials (positive and negative), with each new untrained operator, monthly for storage, and as otherwise required by your lab internal quality system procedures.

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.

1. National Clearinghouse for Alcohol and Drug Information
Web site: www.health.org Phone#: 1-800-729-6686

2. SAMHSA Health Information Network
Web site: www.health.org Phone# 1-877-SAMHSA-7

3. The national Council on Alcoholism and Drug Dependence
Web Site: www.ncadd.org Phone#: 1-800-NCA-CALL

4. The Parent's Resource Institute for Drug Education, Inc (PRIDE)
Web site: www.pride.org Phone#: 1-402-397-3309

5. American Council for Drug Education (ACDE)
Web site: www.acde.org Phone#: 1-800-488-DRUG

Manufactured for:
Express Diagnostics Int'l. Inc
1550 Industrial Drive
Blue Earth, MN 56013