

CLIAwaived™ Inc. Rapid Drug Test Cup

For *in vitro* diagnostic use

CLIA CATEGORIZATION: WAIVED

URINE SCREENING TEST RESULTS IN 5 MINUTES

The CLIAwaived Inc. “RDTC” tests for the possible use of marijuana (THC), cocaine (COC), opiates (OPI), methamphetamines (MET), amphetamines (AMP), phencyclidine (PCP), benzodiazepine (BZO), barbiturates (BAR), methadone (MTD), tricyclic antidepressants (TCA), ecstasy (MDMA) and / or oxycodone (OXY).

The CLIAwaived Inc. RDTC is not for legal or medical diagnostic purposes. For diagnostic and treatment purposes, consult with a healthcare or substance abuse professional. This device is not intended for workplace testing.

BEFORE YOU BEGIN

Read all the information in this pamphlet before performing the test. Make sure you are familiar with the kit contents listed below. Store at room temperature or refrigerated, 36-86°F (2-30°C) in the sealed pouch, away from direct sunlight. Do not use after the expiration date stamped on the package and foil pouch containing the CLIAwaived Inc. RDTC.

MATERIAL PROVIDED

- 25 individually wrapped test devices
- 25 cups for sample collection
- One (1) instruction sheet
- One (1) Adulteration Color Comparison Chart for interpretation of adulteration test result, when applicable. (See page 4)
- 25 security seals (when applicable)

MATERIAL REQUIRED BUT NOT PROVIDED

- Stopwatch or clock

DRUG TEST

Urine Screening Test – RESULTS IN 5 MINUTES.

The CLIAwaived Inc. RDTC tests for the possible use of the drugs listed in the table below. The test you purchased may test for fewer drugs.

Test	Calibrator	Cut-off (ng/ml)
AMP	d-Amphetamine	1000
BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Benzoylcegonine	300
MDMA	3,4-methylenedioxymethamphetamine	500
MET	d-Methamphetamine	1000
MTD	Methadone	300
OPI	Morphine	2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
TCA	Nortriptyline	1000
THC	11-nor- Δ^9 -THC-9-COOH	50

IF YOU GET A NEGATIVE RESULT, this means 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 though the person took 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).

IF YOU GET A “PRELIMINARY POSITIVE” result, this means 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 a laboratory for additional testing. However, it is possible to get a “preliminary positive” when the person did not take the drugs.

- Things such as diet pills, inhalers and cough syrup can cause a preliminary positive result.

COLLECTING THE URINE SAMPLE

Run the test as soon as possible after you collect the sample.

The CLIAwaived Inc. RDTC testing can be performed on a “fresh” warm urine sample. Do not test chilled or refrigerated urine samples unless they have been brought to room temperature first.

CAUTION! Urine samples may be potentially infectious. Wash your hands with soap and warm water before and after collecting the urine sample and performing the CLIAwaived Inc. RDTC.

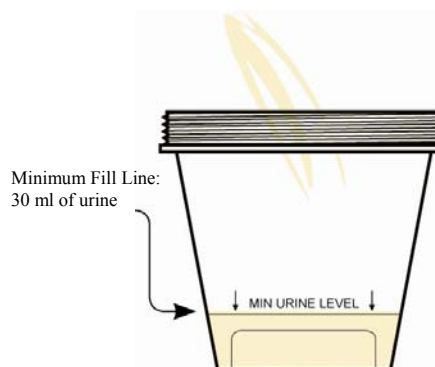
NEVER REUSE THE SAME TEST CUP

Follow these steps to help reduce the possibility of the device altering his or her urine sample.

- Have the donor wash his or her hands with soap and warm water at a sink prior to collecting their urine sample. Make sure the soap has been rinsed off and both hands are dry.
- When possible, turn off the water to the bathroom sinks, toilets, and tubs. Bathroom sinks usually have water shut off handles under the sink.
- Limit access to the bathroom and cabinets. Vinegar, bleach, and detergents may interfere with obtaining an untampered urine sample.

HOW MUCH URINE DO I NEED?

The CLIAwaived Inc. RDTC requires a minimum of 30 ml of urine. Fill the collection cup to the minimum fill line on the side of the cup. This is enough urine for the initial test and confirmation testing if needed.

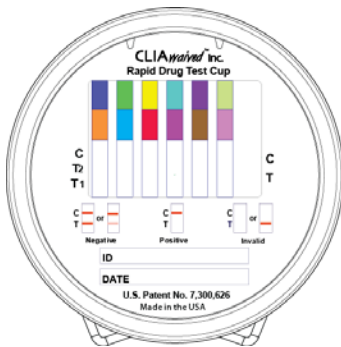


DO NOT REUSE THE TEST KIT. To test a new specimen, use a new CLIAwaived Inc. RDTC. The test kit **CANNOT** be used to retest the same specimen.

PERFORMING THE TEST

1. Fill specimen collection cup to at least the minimum fill level as indicated on collection cup. **IMPORTANT:** If the urine or test cup is cold, bring them to room temperature before you begin.
2. Remove the lid from the sealed pouch.
3. Secure the lid to the cup containing the sample. **IMPORTANT:** Cup lid must be secured tightly by twisting the lid a quarter turn **AFTER** the lid is snug.
4. Place the cup on its side, as shown in the illustration, to activate testing.
5. Wait at least five minutes to read the results. **DO NOT READ RESULTS AFTER 10 MINUTES.**

CAUTION:
Be certain to place on a flat surface to ensure proper migration of the urine sample to the lid containing the test.



CLIAwaived Inc. RDT 12
Drug Test Pictured

READING THE RESULTS

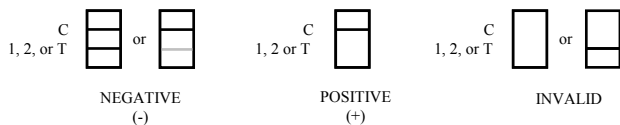
The CLIAwaived Inc. RDT screens for marijuana (THC), cocaine (COC), methamphetamines (MET), opiates (OPI), amphetamines (AMP), ecstasy (MDMA), phencyclidine (PCP), benzodiazepine (BZO), barbiturates (BAR), methadone (MTD), tricyclic antidepressants (TCA) and oxycodone (OXY), depending on the test purchased.

STEP 1:

Check that the test is working properly by looking for a colored line next to the control region (C). You should be able to see this line on all test strips. If you do not see colored line next to the control region (C) on all test strips, your test is not working correctly. If the control line does not form, the test result is invalid and should be repeated.

STEP 2:

Read test only if a colored line appears next to the control region (C) on all test strips.



Negative

If a colored line appears next to the test region (1, 2, or T), the sample is considered negative for that drug. If a colored line appears next to the test region (1, 2, or T) for all drugs, the sample is considered negative and no further testing is required.

IMPORTANT: Certain lines may appear lighter or thinner than other lines. **ANY COLORED LINE NEXT TO THE TEST REGION (1, 2, OR T), NO MATTER HOW DARK OR FAINT, IS CONSIDERED A NEGATIVE RESULT.**

Preliminary Positive

If **NO** colored line appears next to the test region (1, 2, or T) on any test strip, the urine sample may contain that drug.

IMPORTANT: No colored line next to the test region (1, 2, or T) indicates a preliminary positive result for that drug. Clinical consideration and professional judgment should be applied to any drug of abuse result, particularly when preliminary positive results are indicated. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/mass spectrometry (GC/MS) is the recommended confirmatory method for most drugs.

Invalid Test

A colored line should always appear next to the control region (C). If no line appears next to the control region (C), do not read the results for that drug. If you get an invalid result, the test should be repeated.

Understanding the Results

A preliminary positive test result does not always mean a person took illegal drugs. A negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drug of abuse tests are more accurate than others.

What is meant by a Preliminary Positive Result?

The CLIAwaived Inc. RDT is considered a “screening test”. It is the first step in a two-step process. Screening tests are not as accurate as laboratory tests, and it is possible to get a preliminary 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.

Special Note Regarding Prescription Drugs

A positive test result for a prescription drug (BZO, BAR, MTD, TCA, OXY) does not mean that an individual is abusing that drug.

What Does A Negative Screening Result Mean?

This means there is no drug present in the sample, or not enough drug to be considered a preliminary positive test result.

Samples that are negative do not need further testing.

It is possible to get a negative result even though the person took drugs. Some reasons this may happen include:

- The urine sample was collected at the wrong time relative to when the person took the drugs (sample was collected before the drug got in the urine or after the drug was no longer in the urine).
- The person took another drug other than the ones being tested for with the CLIAwaived Inc. RDT.
- The urine sample was adulterated. Bleach and other strong chemicals can degrade drugs in the urine. Also, if other liquids are added to the urine, the urine gets diluted and the concentration of the drug may drop below the level where it can be detected by the test.

Screening tests may not detect amounts of drugs in a urine sample that are below the cut-off level. (see table below). Even though some level of drug may be present in a urine sample, the sample would still be considered **NEGATIVE** if the drug level is below the cut-off level.

TEST LIMITATIONS

1. The CLIAwaived Inc. RDTC is not reusable. Follow the test instructions precisely. Use only human urine samples with this test.
2. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant and oxycodone tests in urine. The Drug Test shows the drug was or was not present at the cutoff level.
3. Certain over-the-counter or prescription drugs may cross-react with the CLIAwaived Inc. RDTC and cause a preliminary positive result for certain drugs. Listed in the chart below are some common medications which may cause a preliminary positive result for the test.
4. For a complete list of substances which may cross-react with this test, please contact Cliawaived, Inc. by our toll-free number (1-888-882-7739).
5. The test will only give accurate results on urine samples. Bleach, cleaning supplies and other liquids may dilute the urine and the test may not be accurate.
6. Once the test starts, read the results after five minutes.
7. Drinking large amounts of liquids may dilute the urine so that the drug (if present) cannot be detected.
8. Failure to use the CLIAwaived Inc. RDTC as directed may result in an inaccurate screening result.
9. If the sample or test is cold, you must bring them to room temperature before you begin.

Examples of common medications that may cross-react with the CLIAwaived Inc. RDTC

Drug or Medication	May Cause Positive For
Lortab [®]	Opiates (OPI)
Lorcet [®]	Opiates (OPI)
Tylenol [®] 3	Opiates (OPI)
Vick's [®] inhaler	Methamphetamines (MET)
Xanax [®]	Benzodiazepines (BZO)

The CLIAwaived Inc. RDTC Cut-off Levels
(Samples at or near the cut-off level provide the greatest margin of error.)

Identifier	Drug Name	Cut-off Level
THC	†Tetrahydrocannabinol	50 ng/ml
COC	†Cocaine	300 ng/ml
MET	†Methamphetamine	1000 ng/ml
AMP	†Amphetamine	1000 ng/ml
MDMA	†Ecstasy	500 ng/ml
OPI	†Morphine, heroin, codeine	2000 ng/ml
PCP	Phencyclidine	25 ng/ml
BZO	Benzodiazepines	300 ng/ml
BAR	Barbiturates	300 ng/ml
MTD	Methadone	300 ng/ml
TCA	Tri-cyclic Antidepressants	1000 ng/ml
OXY	Oxycodone	100 ng/ml

† The Substance Abuse and Mental Health Services Agency (SAMHSA), has set "cut-off" levels when testing for Marijuana, Cocaine, Amphetamine, Opiates, PCP, Ecstasy and Methamphetamine. The CLIAwaived Inc. RDTC is manufactured to conform to those standards. Screening tests may not detect amounts 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 NEGATIVE if the drug level is below the cut-off level.

HOW LONG CAN DRUGS BE DETECTED IN URINE?

Each drug is cleared by the body at different rates. When you can find drugs in the urine depends on the drug taken, how often the person takes the drug, and how the drug was taken. The table below, shows minimum and maximum times you can detect drugs in urine.

Drug	Drug Street Names	Approximate Detection Time	
		Min	Max
Marijuana (THC)	pot, grass, weed, doobie, joint, roach	2 hours	up to 40 days**
Cocaine (COC)	coke, snow, blow, candy, crach	1 - 4 hours	2 - 4 days
Methamphetamines (MET)	crystal meth, speed, glass	2 - 7 hours	2 - 4 days
Amphetamine (AMP)	speed, amp, black beauties	2 - 7 hours	2 - 4 days
Ecstasy (MDMA)	E, XTC, X	2 - 7 hours	2 - 4 days
Opiates (OPI)	heroin, morphine	2 hours	2 - 3 days
Phencyclidine (PCP)	angel dust, rocket fuel	4 - 6 hours	7 - 14 days
Benzodiazepines (BZO)	Downers	2 - 7 hours	1 - 4 days
Barbiturates (BAR)	Downers, barbs, red devils	2 - 4 hours	1 - 3 weeks
Methadone (MTD)	Done	3 - 8 hours	1 - 3 days
Tri-cyclic Antidepressants (TCA)	--	8 - 12 hours	2 - 7 days
Oxycodone (OXY)	--	1 - 3 hours	1 - 2 days

** sometimes longer depending on smoking patterns

ABOUT CONFIRMATION TESTING

Negatives samples do not need further testing. You should send preliminary positive samples to a laboratory for confirmation. Confirmation testing should be performed on all positive test results.

If you need assistance call:

Cliawaived, Inc.
1-888-882-7739

COMMONLY ASKED QUESTIONS

Q. The test line is lighter than the line for Control. Does this mean some drug is present?

A. No. The lines need not be the same shade or intensity. The control line may look darker than a test line, or vice versa.

Q. What if I forget to read the result after five minutes?

A. The test must be read after five minutes. If you read the result too early, or after 10 minutes, the test results may be wrong.

Q. I am not sure of my test result. What should I do?

A. The test is working properly as long as the colored line is visible next to the control region (C). The result is negative when there is a line next to the test region (1, 2, or T). The result is a preliminary positive when there is no line next to the test region (1, 2, or T).

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.

ADULTERATION TESTS

Information regarding adulteration tests does not require FDA review.

Adulteration of urine samples may cause erroneous results in drugs of abuse tests by either interfering with the drug screening test and/or destroying the drugs in the urine. Dilution of urine with water is probably the simplest urine adulteration method. Bleach, vinegar, Visine[®], sodium bicarbonate, sodium nitrite, Drano[®], soft drinks and hydrogen peroxide are the examples of adulterants used to adulterate the urine sample. It is important to insure the integrity of urine samples when performing drugs of abuse testing.

Adulteration tests are included in certain versions of the CLIAwaived Inc. RDTC. Each test will generate a color response of chemical indicators. Creatinine and Specific Gravity are used to determine if a sample has been diluted, which can occur either by increased fluid intake or by adding liquid to a urine sample. The Nitrite, Bleach/Oxidant and pH tests will determine if an adulterant has been added to the sample. The results of all adulteration tests are used to determine overall sample integrity.

Cr: Creatinine reacts with a creatinine indicator in an alkaline medium to form a purplish-brown color complex. The color intensity is directly proportional to the concentration of creatinine. A urine sample with a creatinine concentration of less than 20 mg/dL may indicate that the sample has been diluted.

Ni: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. Urine sample containing nitrite at level greater than 15 mg/dl is considered adulterated.

pH: pH determination of urine sample is based on color change of indicator in different acidic or basic medium. The normal urine pH ranges from 4 to 9. Urine pH below 4 or above 9 indicates adulteration with an acidic or basic compound.

Bl: Bleach or other oxidizing agents react with an oxidant indicator to form a color complex. Observation of a blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents.

S.G.: The **Specific Gravity** test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. Urine specific gravity below 1.005 or above 1.025 is considered abnormal.

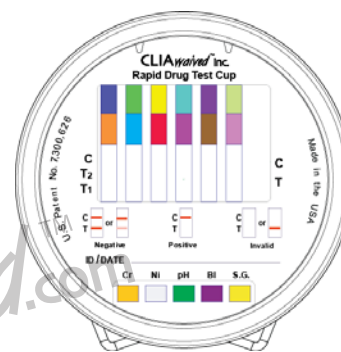
Adulteration test results are obtained by directly comparing the color of each test pad with the color block of Adulteration Color Comparison Chart. Adulterated urine sample will produce abnormal color response. Unadulterated urine sample will produce normal color response within the time identified on the color chart.

PERFORMING THE TEST WITH ADULTERATION

1. Fill specimen collection cup to at least the minimum fill level as indicated on collection cup. **IMPORTANT:** If the urine or test cup is cold, bring them to room temperature before you begin.
2. Remove the lid from the sealed pouch.
3. Secure the lid to the cup containing the sample. **IMPORTANT:** Cup lid must be secured tightly by twisting the lid a quarter turn **AFTER** the lid is snug.
4. Place the cup on its side, as shown in the illustration, to activate testing.
5. Read the results of adulteration test by visually comparing the color of reagent pads to the corresponding blocks on the Adulteration Color Comparison Chart at the time indicated.
6. Wait at least five minutes to read the drug strip results. **DO NOT READ RESULTS AFTER 10 MINUTES.**

CAUTION:

Be certain to place on a flat surface to ensure proper migration of the urine sample to the lid containing the test.



Cup with Adulteration

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