



RAPID DRUG 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

RAPID DRUG 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

RAPID DRUG 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)	Benzoylcegonine	300 ng/mL	1-4 hours	2-4 days
Cocaine (COC 150)	Benzoylcegonine	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

- RAPID DRUG TEST CUP
- Adulteration Color Comparison Chart (If equipped)
- Instructions for use
- Performance Characteristics Sheet

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?

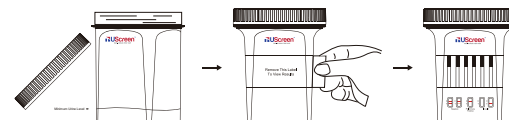
Remove the test cup from the foil pouch by tearing at the notch and use it as soon as possible. Open the cap of the test cup and void directly into the test cup to reach the minimum urine level. Wipe off any splashes or spills that may be on the outside of the cup.

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.

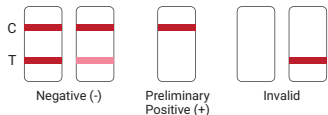
Negative (-)

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.



A preliminary positive test result does not always mean that a person took illegal drugs. A negative test result does not always mean that a person did not take illegal drugs. There could be a number of factors that affect the reliability of drug tests.

IMPORTANT:

The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by RAPID DRUG TEST CUP. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial drug is present but isn't detected by RAPID DRUG TEST CUP. If the sample is diluted or adulterated that may cause false negative result.

If you get a negative test result but you still suspect someone is taking drugs you should test again at another time, or test for different drugs.

ADULTERATION CONTROL

Expected Results

Creatinine (CRE): Daily creatinine excretion, related to muscle mass of the human body, is usually constant. The DOT guideline states that urine specimens with creatinine levels of less than 20 mg/dl are indications of adulteration. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution², sample with creatinine level of lower than 20 mg/dl should be considered adulterated.

Glutaraldehyde (GLU): Glutaraldehyde is not a natural component of human urine and it should not be present in normal urine. The presence of glutaraldehyde in the urine sample indicates the possibility of adulteration. However, false positive may result when ketone bodies are presence in urine. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolic abnormalities.

Nitrite (NIT): Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. In this adulteration control, nitrite level above 7.5 mg/dl is considered abnormal.

pH: Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.

Specific Gravity (S.G.): Random urine may vary in specific gravity from 1.003 - 1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016 - 1.022. Elevated urine specific gravity value may be obtained in the presence of moderate quantities of protein. DOT guidelines state that a urine specimen with specific gravity level of less than 1.003 is an indication of adulteration. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is adulterated.

Oxidants (OXI): The presence of Bleach and other oxidizing reagents in the urine is indicative of adulteration since oxidizing reagents are not normal constituents of urine. Other oxidizing reagents include Hydrogen Peroxide, Ferricyanide, Persulfate, Pyridinium Chlorochromate...etc.

Pyridinium Chlorochromate (PCC): The presence of any chromate in urine is indicative of adulteration as chromate is not a normal constituent of urine.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. **DO NOT** use this device to test specimen other than urine.
2. Technical or procedural errors, as well as interfering substances in the urine specimen may cause incorrect results.
3. Contaminated or adulterated urine samples may produce incorrect results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyte. If a sample is suspected, repeat the test with another urine sample.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
5. A negative result may not indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. You can't retrieve your confirmed results without knowing your PIN (Personal Identification Number).

QUESTIONS AND ANSWERS

1. What does the RAPID DRUG TEST CUP do?

These tests indicate if one or more prescription or illegal drugs are present in urine. These tests detect the presence of drugs such as amphetamine, secobarbital, buprenorphine, oxazepam, benzoylcegonine, EDDP, MDMA, methamphetamine, morphine, methadone, oxycodone, phencyclidine, propoxyphene, nortriptyline, marijuana and 6-Monoacetylmorphine.

The testing is done in two steps. First, you do a quick at-home test. Second, if the test suggests that drugs may be present, you need to send the sample to a laboratory for confirmation testing.

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 result is positive, and below is negative.

3. What are drugs of abuse?

Drugs of abuse are illegal or prescription drugs (for example, Oxycodone or Valium) that are taken for a non-medical purpose, including taking the medication for longer than your doctor prescribed it for or for a purpose other than what the doctor prescribed it for.

4. What are the Common Street Names for the Drugs to be detected?

Drug	Common Street Names
Amphetamine (AMP)	Speed, Jelly Beans or Super Jellies, Hearts, Uppers, Pick me ups or Wake me ups, Wake ups, Get ups, Boot ups, Sparkles
Secobarbital (BAR)	Amytal, Downers, Nembutal, Phenobarbital, Reds, Red Birds, Red devils, Seconal, Tuninal, Yellowjackets
Oxazepam (BZO)	Benzos, Downers, Nerve Pills, Tranks
Cocaine (COC)	Blow, C, candy, coke, do a line, freeze, girl, happy dust, Mama coca, mojo, monster, nose, pimp, shot, smoking gun, snow, sugar, sweet stuff, and white powder.
Methamphetamine (MET)	Speed, Ice, Chalk, Meth, Crystal, Crank, Fire, Glass
Methylenedioxymethamphetamine (MDMA)	Ecstasy, E, X, XTC, Adam, Clarity, Lover's Speed
Buprenorphine (BUP)	Bupe, Subbies, Temmies
Morphine (OPI)	Aunt Hazel, big H, black pearl, brown sugar, capital H, charley, china white, dope, good horse, H, hard stuff, hero, heroina, little boy, mud, perfect high, smack, stuff and tar.
Methadone (MTD)	mixture, meth, linctus, green
Phencyclidine (PCP)	Angel dust, belladonna, black whack, C.J, cliffhanger, crystal joint, Detroit pink, elephant tranquilizer, hog, magic, Peter Pan, sheets, soma, TAC, trunk, white horizon and zoom.
Nortriptyline (TCA)	----
Cannabinoids (THC)	420, Aunt Mary, baby, bobby, boom, chira, chronic, ditch, ganja, grass, greens, hash, herb, Mary Jane, nigra, Pot, reefer, rip, root, skunk, stack, torch, weed and zambi.
Oxycodone (OXY)	OC, Oycotton, OX, and Kicker

5. How accurate is the test?

The tests are sensitive and accurate. These tests, however, are not as accurate as confirmatory tests. In some cases, certain foods and drugs may cause false positives as well as false negatives for those who use drug-testing kits.

6. If the test results are negative, can the conclusion be that the person is free of drugs?

This means that if the sample was collected properly and if the test was performed

according to direction, none of the drug were present at concentrations above the cutoff.

7. Does a preliminary positive screen test mean that drugs of abuse have been found?

This means that the test has reacted with something in the sample and the sample must be sent to the lab for a more accurate test.

8. What should I do, if the lab test confirms a positive result?

If you have received a confirmed positive result, please consult with counselor for a proper course of action. It is important that you remain calm and do not react in a negative way to the situation. If you do not believe the test result, please consult with your physician. They will have your background medical history and provide you with detailed information on both the test and the meaning of the result.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number **404-840-8900** (Monday – Friday 9:00 am – 5:00 pm, EST) or email to **Sales@transmedco.com**.

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.

National Clearinghouse for Alcohol and Drug Information www.health.org 1-800729-6686

Center for Substance Abuse Treatment www.health.org 1-800-662-HELP

The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL

American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOL



Consult instructions for use



Keep dry



Store at 35°F - 86°F (2°C - 30°C)



Keep away from sunlight



Use-by date



Catalogue number



Batch code



Do not reuse



In vitro diagnostic medical device



Do not use if package is damaged

Distributed by:
TransMed Company, LLC
Alpharetta, GA 30005 USA

MADE IN CHINA

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