

Drug Test Cup

Catalogue No. See Box Label

Please read all instructions first and familiarize with the materials before performing the test.

Easy@Home® Drug Test Cup are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine. Secobarbital, Buprenorphine, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Methylenedioxymethamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine with below cutoff concentrations and approximate detection time:

Drug (Identifier)	Calibrator	Cut-off Level	Minimum Detection Time	Maximum Detection Time
Amphetamine (AMP500)	d-Amphetamine	500 ng/mL	2-7 hours	1-2 days
Amphetamine (AMP1000)	d-Amphetamine	1000 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 (COC150)	Benzoylecgonine	150 ng/mL	1-4 hours	2-4 days
Cocaine (COC300)	Benzoylecgonine	300 ng/mL	1-4 hours	2-4 days
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenyl-pyrrolidine	300 ng/mL	3-8 hours	1-3 days
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET500/mAMP500)	D(+)-Methamphetamine	500 ng/mL	2-7 hours	2-4 days
Methamphetamine (MET1000/mAMP1000)	D(+)-Methamphetamine	1000 ng/mL	2-7 hours	2-4 days
Morphine (MOP/OPI300)	Morphine	300 ng/mL	2 hours	2-3 days
Methadone (MTD)	Methadone	300 ng/mL	3-8 hours	1-3 days
Morphine (OPI2000)	Morphine	2000 ng/mL	2 hours	2-3 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-∆9-THC-9-COOH	50 ng/mL	2 hours	Up to 5+ days

Easy@Home® Drug Test Cup offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is intended for over-the-counter use. For

in vitro diagnostic use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Proposyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended confirmatory method.

WARNINGS AND PRECAUTIONS

- 1. The test kit is for external use only.
- 2. Discard after first use. The test kit cannot be used more than once.
- Do not use the test kit beyond expiration date.
- 4. Do not use the test kit if the pouch is punctured or not well sealed.
- 5. Keep out of the reach of children.

CONTENT OF THE KIT

- Test devices, each in one pouch with two desiccants. The desiccants are for storage purposes only and are not used in the test procedure.
- Package Insert
- Adulteration Color Comparison Chart (If equipped).
- Security Seals
- Pieces of Gloves

MATERIAL REQUIRED BUT NOT PROVIDED

Timer or Clock

STORAGE AND STABILITY

- Store at 4°C-30°C (40°F-86°F) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

WHEN TO COLLECT URINE FOR THE TEST?

Collect urine specimen after minimum detection time following suspected drug use. Urine collection time is very important in detecting any drugs of abuse. Each drug is cleared by the body and is detected in the urine at different times and rates. Please refer to the minimum or maximum detection time of each drug in this instruction.

HOW TO COLLECT URINE?

- 1. Remove the test cup from the foil pouch by tearing at the notch. Use it as soon as possible. Instruct the donor to remove the test cup lid and void directly into the test cup until reach the Minimum Urine Level mark (approximately 25 mL). It is acceptable to collect extra volume of urine. If insufficient specimen has been collected, instruct the donor to provide urine specimen again with another new test cup. Wipe off any splashes or spills that may be on the outside of the cup. It is recommended to wear gloves when handling the test cup with urine specimen.
- 2. Observe the temperature strip affixed on the test cup between 2 to 4 minutes after urine is voided into the cup. The temperature between 32°C to 38°C (90°F-100°F) indicates the fresh uncontaminated sample. If the temperature is out of this range, instruct the donor to provide urine specimen again with another new test cup.

HOW TO DO THE TEST?

1. After the urine has been collected properly, tighten the lid and place the test cup on a flat surface. 2. Peel off the label from right to left.

Instructions: Step 1: Collect urine.





READING THE RESULTS

Negative (-)

A colored band is visible in each Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary Positive (+)

A colored band is visible in each Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid

If a colored band is not visible in each of the Control Region (C) or a colored band is only visible in the Test Region (T), the test is invalid. Another test should be run to re-evaluate the specimen. If the new test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number of the test.

Note: There is no meaning attributed to line color intensity or width.

The preliminary positive test result does not always mean that a person took illegal drugs. The 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. Certain drugs of abuse tests are more accurate than others.

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 in 5 minutes. The results can be stable for 30 minutes.

Note: Results after more than 30 minutes may be not accurate and should not be read.



What Is the False Positive Test?

The definition of the false positive test would be the instance where a substance is identified incorrectly by Easy@Home® Drug Test Cup. The most common causes of the false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause the false positive test result.

What Is the False Negative Test?

The definition of the false negative test is that the initial drug is present but isn't detected by Easy@Home® Drug Test Cup. If the specimen is diluted or adulterated, it may cause the false negative result.

If suspect someone is taking drugs but get the negative test results, please test again at another time, or test for different drugs.

ADULTERATION CONTROL

Expected Results

Creatinine (CR): Creatinine reacts with a creatinine indicator in an alkaline medium to form a purplish-brown color complex if creatinine in the urine is present at the normal level. The color intensity is directly proportional to the concentration of creatinine. A urine sample with creatinine concentration of less than 20 mg/dl produces a very light, or no pad color change, which indicates adulteration in the form of specimen dilution.

Glutaraldehyde (GL): 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 present in urine. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolic abnormalities.

Nitrite (NI): 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 15 mg/dL is considered abnormal.

Oxidants/Bleach (OX): 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, Ferricvanide, Persulfate, Pyridinium Chlorochromate etc.

pH (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.): The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. The pad colors will change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. A urine specific gravity below 1.003 or above 1.025 is considered abnormal.

TEST LIMITATIONS

- 1. This test kit has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use it to test anything other than urine.
- 2. Adulterated urine samples may produce false results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a specimen is suspected of being adulterated, obtain a new specimen.
- 3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause false results.
- 4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication

QUESTIONS AND ANSWERS

- 1. What does the Easy@Home[®] Drug Test Cup do?
- These tests detect if one or more prescription or illegal drugs such as Amphetamine. Secobarbital, Buprenorphine, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Methylenedioxymethamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids are present in urine.

The testing is done in two steps. First, test urine with Easy@Home® Drug Test Cup. Second, if any drug test result is preliminary positive, please send the cup with urine to the drug testing laboratory for confirmatory result.

2. What is "cut-off level"?

The cut-off level is the specified concentration of a drug in a urine sample. If the concentration of a drug in urine is above the cutoff concentration, this drug test result will be preliminary positive. If the concentration of a drug in urine is below the cutoff concentration, this drug test result will be 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 longer than doctor prescribed or for a purpose other than what the doctor prescribed.

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
Buprenorphine (BUP)	Bupe, Subbies, Temmies
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.
Methylenedioxymethamphetamine (MDMA)	Ecstasy, E, X, XTC, Adam, Clarity, Lover's Speed
Methamphetamine (MET/mAMP)	Speed, Ice, Chalk, Meth, Crystal, Crank, Fire, Glass
Methadone (MTD)	mixture, meth, linctus, green
Morphine (MOP/OPI300)	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.
Oxycodone (OXY)	OC, Ocycotton, OX, and Kicker
Phencyclidine (PCP)	Angel dust, belladonna, black whack, CJ, cliffhanger, crystal joint, Detroit pink, elephant tranquilizer, hog, magic, Peter Pan, sheets, soma, TAC, trank, white horizon and zoom.
Propoxyphene (PPX)	Darvon, Darvocet, Dolene, Propacet 100, Wygesic, SK-65, SK-65 APAP, Trycet, Genagesic, E-Lor, Balacet, Pain Killer, Pinks, Footballs, PP-Cap
Nortriptyline (TCA)	Blue angels, Blue birds, Vivactil, Anafranil, Janimine, Tofranil
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.

5. How accurate is the test?

The tests are sensitive to drugs and accurate. These tests, however, are not as accurate as lab 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, then none of the drug screened were present in the urine.
- 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 urine and the urine 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 be able to provide you with detailed information on both the test and the meaning of the result.

9. What is the principle of Easy@Home[®] Drug Test Cup?

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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 1-800-729-6686 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

MEANING OF SYMBO

×	Keep away from sunl
4'C	Store between 4°C-3
Ĵ	Keep dry
(Do not re-use
IVD	For in vitro diagnostic

Easy@Home® Drug Test Cup is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. When the test is activated, the urine is absorbed into the device by capillary action. When flowing across the pre-coated membrane, it will be mixed with the respective drug antibody conjugates. If concentrations of drugs are below corresponding detected drugs' cutoff, respective drug antibody conjugates bind to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. This produces the colored band in Test Region (T) that indicates the negative result. On the contrary, if concentrations of drugs are at or above corresponding detected drugs' cutoff, the free drugs in urine bind to the respective drug antibody conjugates. It prevents the respective drug antibody conjugates from binding to the respective drug-protein conjugates immobilized in the Test Region (T) of the device. Therefore, there is no colored band in the Test Region (T) that indicates the preliminary positive result. To serve as the procedure control, if the test has been performed properly, a colored band will appear at the Control Region (C).

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