

Multi-Drug Screen Test

(Cat.No.: EDOAP-124)

Easy@Home® Multi-Drug Screen Test (Cat.No.: EDOAP-124) offers fast, accurate and easy drug testing. This test kit is used to detect two drug metabolites, 11-nor-Δ9-THC-9-COOH (THC) and Cotinine (COT). After consumption, the main component of marijuana will be metabolized into 11-nor-Δ9-THC-9-COOH in the liver and excreted in the urine. Hence the urine drug test kit is used to detect this metabolite to indicate the use of marijuana (THC). Cotinine is the inactive metabolite produced by the body when nicotine enters its system and is rapidly broken down. Nicotine is the highly addictive chemical compound present in tobacco products such as: cigarettes, cigars, chewing tobacco, hookah tobacco, and many e-cigarettes. Measuring cotinine is preferred to measuring nicotine because the half-life of cotinine is longer than that of nicotine, meaning it stays in the body longer. Thus, a cotinine urine test is often designed to detect the evidence of nicotine use as a more stable marker.

This dual panel test is for in-vitro diagnostic and over-the-counter use only.

INTENDED USE

Easy@Home® Multi-Drug Screen Test (Cat. No.: EDOAP-124) is rapid urine screening test. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human urine at the following cut off concentrations:

Drug(Identifier)	Calibrator	Cut-off level	Minimum detection time	Maximum detection time
Marijuana(THC)	11-nor-Δ9-THC-9-COOH	50ng/ml	2 hours	Up to 5+days
Cotinine(COT)	Cotinine	200ng/ml	1-8 hours	1-7days

This assay provides only a preliminary test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) is the recommended

confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive.

PRINCIPLE

Easy@Home® Multi-Drug Screen Test (Cat. No.: EDOAP-124) is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.

When testing, the urine is absorbed upward by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane.

When sample drug levels are at or above the target cutoff, the drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein pre-coated in the test region (T). This prevents the development of a distinct colored band in the test region (T) indicating a potentially positive result.

When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein pre-coated in the test region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result.

To serve as a procedure control, a colored line will appear on the control region (C), if the test has been performed properly.

WARNINGS AND PRECAUTIONS

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

STORAGE AND STABILITY

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

CONTENT OF THE KIT

- Test devices in one pouch with one desiccant. The desiccants are for storage purposes only and are not used in the test procedure.
- Package Insert.

MATERIAL REQUIRED BUT NOT PROVIDED

• Timer • Urine collection cup

SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in a collection cup(not included). Urine specimens may be refrigerated 36°F-47°F (2°C-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples at -4°F (-20°C) or below.

Bring frozen or refrigerated samples to room temperature before testing. Use only clear aliquots for testing.

TEST PROCEDURE

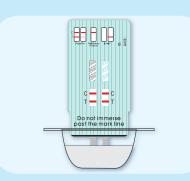
Test must be in room temperature 65°F-86°F (18°C-30°C).

- 1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
- 2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
- 3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure to dip the test in the urine up to without passing the mark line "MAX" line printed on the test device.
- 4. Lay the device flat on a clean, dry, non-absorbent surface.
- 5. Read the result in 5 minutes. Do not read after 5 minutes.

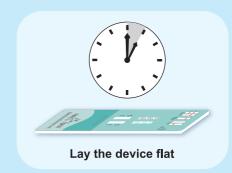
Step 1:

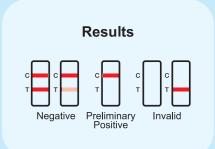
Pull the cap off and immerse the strips into urine for 10 seconds.





Step 2: Read the result in 5 minutes. Do not read after 5 minutes.

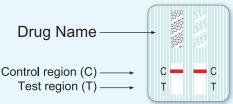




INTERPRETATION OF RESULTS

Preliminary Positive (+)

A colored band is visible in each control $\operatorname{region}(C)$. No colored band appears in the appropriate test $\operatorname{region}(T)$. It indicates a positive result for the corresponding drug of that $\operatorname{specific}$ test $\operatorname{region}(T)$.

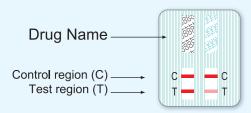




Positive

Negative (-)

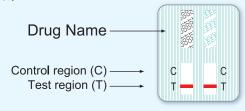
A colored band is visible in each control region(C) and the appropriate test region(T). It indicates that the concentration of the corresponding drug of that specific test region(T) is zero or below the detection limit of the test.

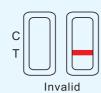




Invalid

If a colored band is not visible in each of the control region(C) or a colored band is only visible in each of the test region(T), the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.





Note:

- 1. There is no meaning attributed to line color intensity or width.
- 2. The abbreviations of drug names in the product images are just for demonstration. Please refer to the labels on the packaging and the prints on the test strip to identify which drugs are included in your test.

LIMITATIONS

- 1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
- Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyses. If a sample is suspected of being adulterated, obtain a new sample.
- 3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentra tion of drugs or the level of intoxication
- 4. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- 6. The test result does not distinguish between drugs of abuse and certain medicines.
- 7. A false positive result might be obtained from certain foods or food supplements.

QUESTIONS AND ANSWERS

1. What does the drug of abuse urine test do?

The drug of abuse urine test indicates if one or more prescription or illegal drugs are present in urine. This Easy@Home drug test kit is designed to detect the presence of Marijuana and Cotinine.

2. What is cotinine and why do we test for it?

Cotinine is the first-stage metabolite of nicotine, and nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation, In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

Nicotine and cotinine are rapidly eliminated by the kidney, the plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration, while cotinine can be detected in urine up to 2-3 days after nicotine use. As a result, cotinine is considered a good biological marker for determining nicotine use.

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

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

Drug	Street Names
Marijuana(THC)	Weed, dank, pot, ganja, zig zag,bud, grass, hydro,
Cotinine(COT)	Tobacco, cigarettes, smokes, cigs, fags, butts, nicotine

5. How accurate is the test?

The tests are sensitive to drugs and accurate. These tests, however, are not as accurate as confirmatory 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. There are known as cross-reactions.

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 the directions, then none of the drug screened were present in the urine. The concentration of drug screened in the urine specimen was zero or below the cutoff level.

7. Does the COT test panel pick up on secondhand tobacco smoke?

It is possible for people who do not or have not used tobacco to test positive for a low level of cotinine if they are exposed to secondhand smoke. If you use nicotine replacement medicine, such as gum or a patch, the cotinine test result most likely will be affected as well.

8. Will I get a positive test result if I had one cigarette in the past 72 hours?

Nicotine and cotinine are rapidly eliminated by the kidney; Cotinine can be detected in urine up to 2-3 days after nicotine use. Maximum detection time is 1-7 days in most cases. If the amount of cotinine metabolite in the body reaches the cutoff of 200 ng/mL, the result will show positive if you test during this detection time frame.

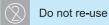
9. What is the principle of Easy@Home® Multi-Drug Screen Test?

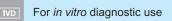
Easy@Home® Multi-Drug Screen Test are competitive immunoassays that is used to screen for the presence of drugs of abuse in urine. When the test is activated, the urine is absorbed into the device by capillary action. Then flowing across the pre-coated membrane, it will be mixed with the respective drug antibody conjugates. If concentrations of sample 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 a colored line in test region that indicates a negative result. On the contrary, if concentrations of sample drugs are at or above corresponding detected drugs' cutoff, the free drugs of sample 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 line in the test region that indicates a preliminary positive result. To serve as a procedure control, if the test has been performed properly, a colored line will appear at the Control Region (C).

MEANING OF SYMBOLS ON PACKAGE



Keep dry





Consult instructions for use

Questions?

Any questions, please call us toll-free at

1-855-822-6999

Monday – Friday 9:00 a.m.-5:00 p.m. Central Time.
To learn more, please visit us at:

www.healthcare-manager.com

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V01: 20220810