

accutest®

Accutest® Saliva Cotinine Drug Test

INSTRUCTIONS FOR USE

A rapid, screening test for the qualitative detection of Cotinine (COT) in human oral fluid.

For Over-The-Counter (OTC) use only.

For in vitro diagnostic use only.

CLIA Categorization: Waived.

INTENDED USE

The Accutest Saliva Cotinine Drug Test is a lateral flow chromatographic immunoassay for the qualitative detection of cotinine (COT) in oral fluid at the cut-off concentration of 30 ng/ml.

This test provides only a preliminary result. A more specific alternative chemical method should be used to obtain a confirmed presumptive positive result if the donor doesn't admit use or anytime required by testing procedures.

Gas Chroma-tography/Mass Spectrometry (GC-MS), Liquid Chromatography/Mass Spectrometry (LC-MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drug screen test result, particularly when evaluating preliminary positive results.

PRECAUTIONS

- By itself, this test will not confirm if someone used cotinine or nicotine. 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 positive result and there may be others as well. To show if someone used cotinine or nicotine, a sample would need to be sent 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.
- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test should remain in the sealed pouch before use.

STORAGE AND STABILITY

DO NOT FREEZE

- Store as packaged in the sealed pouch either at room temperature or refrigerated [4-30°C (39-86°F)].
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch before use.
- Keep away from direct sunlight, moisture, and heat.
- Do not use beyond the expiration date.

MATERIALS

Materials Provided

- Test device
- Oral fluid (saliva) collector
- Instructions for use

Materials Required but Not Provided

- Timer, clock, or watch
- Disposable gloves
- Mailing box*
- Identification label*
- Plastic sealed bag*

*For Laboratory Confirmatory Test (See Confirmation Testing section).

SPECIMEN COLLECTION

The oral fluid specimen should be collected using the collector provided with the test, following the detailed instructions provided in the "Directions For Use" section below. No other collection device should be used with this test.

Oral fluid collected at any time of the day may be used.

DIRECTIONS FOR USE

Allow the test device to come to room temperature [15-30°C(59-86°F)] prior to testing. **Do not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to specimen collection.**

Do not bite, suck, or chew on the collection swab.

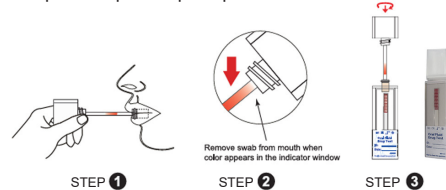
1. Remove the collection swab from the packaging. Relax the mouth and insert the collection swab horizontally into the mouth. Sweep the inside of the mouth (cheeks, gums, and tongue) using a circular motion. (Step 1).
2. Hold the swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab (Step 2). Keep collection swab horizontal to ensure sufficient oral fluid is collected.

Important: After 7 minutes, if the saturation indicator does not turn color, discard the device and repeat the test.

3. Remove the test device from the sealed pouch and place upright on a clean, flat surface. Remove the collection swab from mouth. Keeping the test device upright, gently and slowly insert the collection swab into the test device, swab end first, until the swab reaches the bottom of the test device. Screw downward until the locking flange locks in place (Step 3). The cube must remain upright on a flat surface for test to run.

NOTE: Once the collection swab locks in place, the device is airtight, tamper evident, and ready for disposal or sent to a laboratory for confirmation testing (on presumptive positive result).

4. Set a timer for 10 minutes. Wait for the colored bands to appear in the test results area (See "Interpretation of Results" section below). Results for any single analyte can be read as negative as soon as two lines appear on the analyte strip. Read presumptive positive results at 10 minutes.



INTERPRETATION OF RESULTS

NEGATIVE: *A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicates a negative result.

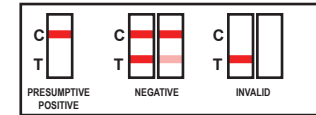
This indicates that the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

PRELIMINARY POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result.

This indicates that the drug concentration in the oral fluid specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact Technical Support.



IMPORTANT: This test provides only a preliminary result.

Refer to "CONFIRMATION TESTING" for a preliminary positive result.

UNDERSTANDING THE TEST RESULTS

What Is a False Positive Test?

The definition of a false positive test would be an instance where cotinine is identified incorrectly by the Accutest Saliva Cotinine Drug Test. 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 oral fluid specimen contains cotinine (COT) but isn't detected by the Accutest Saliva Cotinine Drug Test. If the sample is diluted or adulterated, a false negative result may occur.

QUESTIONS AND ANSWERS

1. What does the Accutest Saliva Cotinine Drug Test do?

This test indicates if cotinine (COT) is present in oral fluid above a certain cut-off level. The testing is done in two steps. First, a quick at-home test is performed. Second, if the test suggests that drugs may be present, 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 an oral fluid sample. Above that concentration, the test is called preliminary positive, and below that concentration, the test is called negative.

3. How accurate is the presence of drugs in oral fluid sample?

In some cases, certain foods and drugs may cause either false positives or false negatives for those who use drug-testing kits.

4. Does a preliminary positive test mean the drug of abuse is present in the sample?

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

CONFIRMATION TESTING

MAILING AN ORAL FLUID SAMPLE TO THE LABORATORY FOR CONFIRMATION TESTING








1. Ensure the test device containing specimen is appropriately labeled.
2. Be sure to include a Phone Number so the laboratory can contact you with the confirmed results.
3. Place the device in an appropriately sealed bag.
4. Ship the sample in a box secured with packing tape to a laboratory for confirmatory testing.

MORE INFORMATION AND RESOURCES

A health care provider, or any of the following organizations listed below can be contacted for additional information and/or counseling regarding substance abuse prevention and treatment:

- American Council for Drug Education (ACDE) 1-800-DRUGHELP www.acde.org
- Center for Substance Abuse Treatment (CSAT) 1-877-SAMHSA-7 www.samhsa.gov
- The National Council on Alcoholism and Drug Dependence (NCADD) 1-800-NCA-CALL / www.ncadd.org

INDEX OF SYMBOLS

	Do not reuse		See Instruction for Use		Expiration Date
	Tests per Kit		Store Between 4-30°C (39-86°F)		Keep Dry
LOT	Batch Number	REF	Catalog#		Keep Away from Sunlight
UDI	Unique Device Identifier	IVD	For <i>in vitro</i> diagnostic use only		

ASSISTANCE:

If you have any questions regarding the use of this product, please call our Technical Support Number 1-800-676-5565 (9:00AM to 5:00PM PST).

MANUFACTURED FOR:

Jant Pharmacal Corporation
 Address: 16530 Ventura Blvd., Suite 512, Encino, CA 91436
 Tel: 1-800-676-5565 Fax: 1-818-986-0235
 Website: www.jantdx.com

Accutest® is a registered trademark of Jant Pharmacal Corporation.