

Rapid Response™

Saliva Drug Test (COT)

REF COT-2FC141

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 Rapid Response™ Saliva Drug Test (COT) is a lateral flow chromatographic immunoassay for the qualitative detection of COT in oral fluid at the cut-off concentration of 30 ng/mL.

This assay provides only a preliminary result. An alternative laboratory test must be used to confirm the results by this drug test. Gas chromatography/mass spectrometry (GC/MS) is the preferred method confirmation test.

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 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 confirm 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. 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.

Materials

Materials provided

- Test device
- Oral fluid (saliva) collector
- Quick procedure guide
- Security seal labels
- Instructions for use

Materials required but not provided

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

*For Laboratory Confirmatory Test (see Confirmation Testing section)

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.

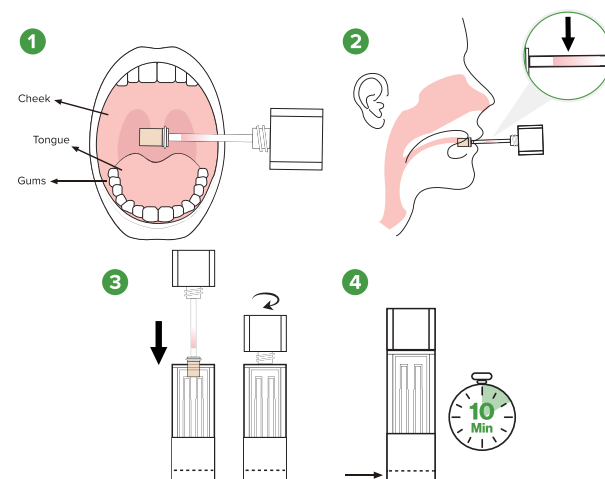
Specimen Collection

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, drinks, 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 (Step 4). Wait for the colored bands to appear in the test results area (See “Interpretation of Results”). 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.

Results Interpretation



PRELIMINARY POSITIVE: 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 positive result. This indicates that the drug concentration in the oral fluid specimen exceeds the designated cut-off for that specific drug.



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.



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

1. **What is a False Positive Test?**
The definition of a false positive test would be an instance where cotinine is identified incorrectly by the Rapid Response™ Saliva Drug Test (COT). 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.
2. **What is a False Negative Test?**
The definition of a false negative test is that the oral fluid specimen contains cotinine but it isn't detected by Rapid Response™ Saliva Drug Test (COT). If the sample is diluted or adulterated, a false negative result may occur.

Questions and Answers

1. **What does the Rapid Response™ Saliva Drug Test (COT) do?**
This test indicates if cotinine 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, 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. **Dose a preliminary positive test mean the drug being tested for 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 that the Labeled cup is tightly closed.

2. Be sure to write your contact info on the mailing box so that the laboratory can send you the message with the confirmed results along with the Personal Identification Number.
3. Place the Labeled device in the plastic bag and seal the plastic bag.
4. Place the sealed plastic bag in the mailing box. Close the mailing box and secure it with packing tape. The mailing address for the laboratory is already on the mailing box.

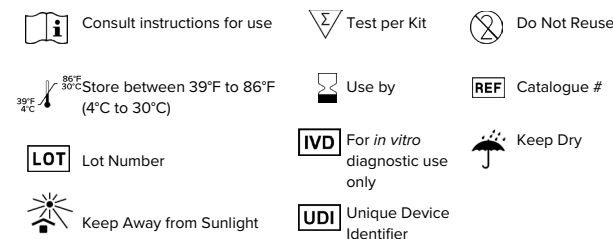
Please note that the mailing box isn't pre-paid. You must attach the proper postage to have a carrier service deliver it. You must also pay for the confirmation testing.

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:

- Center for Substance Abuse Treatment (CSAT) 1-877-SAMHSA-7 www.samhsa.gov
- The National Council on Alcoholism and Drug Dependence (NCADD) www.ncadd.org

Index of Symbols



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Technical Support: 1-888-339-9964
Hours: Monday–Friday, 9:30am–5pm (EST)

