





This oral fluid drug screen device for Cotinine is a rapid oral fluid screening test able to be performed without instrumentation with the assay providing a preliminary analytical test result only. Results should be confirmed through gas chromatography mass spectrometry (GC/MS)

FLEXIBILITY

- Tests for one individual drug
- Cotinine 30ng/ml cut-off

CONVENIENCE

- No test tampering
- No shy bladder issues
- No restrooms required
- Donor remains in your presence at all times
- Simple procedure, collect sample and read test in 10 minutes, no timing required

PERFORMANCE

- Each test has procedural control built in Colloidal gold technology
- Tested for non cross-reactivity against 100 drugs with concentrations up to 100ug/mL

CUT-OFF LEVEL

COT 30ng/mL

СОТ

Cotinine (in saliva) m 30ng/ml

- For determination of smoking status only
- Do not use after expiration date
- Device should remain in sealed pouch until ready to use
- Saliva is not classified as as a biological hazard unless derived from a dental procedure.
- Device is for a single use only

Once converted from nicotine, Cotinine has an in vivo half life in the human body of approx. 20 hours and is typically detectable for several days and up to one week after the use of tobacco/products.

Cotinine levels <10 ng/mL are considered to be consistent with no active smoking. Values of 10ng/mL to 100 ng/mL are associated with light smoking or moderate passive exposure and levels above 300ng/mL are seen in heavy smokers (20 cigarettes or more per day)

The cotinine assay contained within the Oral Fluid Drug Screen Device yields a positive result when the concentration of Cotinine in oral fluid exceeds 30ng/mL

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The Cotinine [™] Oral Fluids single panel screen is a immunoassay rapid screening device for the detection of continine (nicotine) in saliva.

Easy to use, these single panel screens will detect nicotine to 30ng/mL in minutes, with accuracy and cost effectiveness.

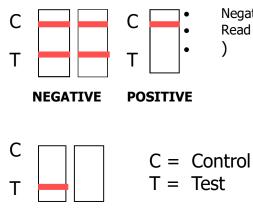
Instructions

- Nil by mouth for a minimum of 10 minutes prior to collection of saliva (no food, drink, gum, cigarettes, water etc)
- 1. Remove device from sealed pouch, unscrew collector cap and remove the collection sponge from the collection chamber **(Step 1)**
- 2. Insert sponge into mouth of donor and saturate sponge with saliva collecting from cheeks, under tongue for a minimum of 3 minutes—sponge must be fully saturated (min 2.tsp or 10 ml saliva required) Collection swab should be free from hard spots when fully saturated.(**Step 2**)
- 3. Once saturated place the collection swab back into the dispenser and insert into the specimen well of the test device (Step 3)
- 4. Remove dispenser cap from other end of device and lie cassette test on flat surface (**Step 4**)
- 5. Using the thumb and index finger squeeze the collection chamber and dispense 3 drops of the collected oral fluid into the specimen well and start the timer **(Step 5)**



Read Results

- 1. Read results at 10 minutes, do NOT read after 1 hr
- 2. **Interpret results,** 2 lines = negative 1 line = positive



INVALID

- Negative results can be read as soon as they appear Read positive (non negative) results at 10 minutes
 - **Negative** = Pass— No drugs detected at cutoff levels
 - **Positive** = Fail—drugs detected at or above cut-off levels -

Line Intensity (colour) in **NOT** important. A feint 2nd line if visible must be read as a NEGATIVE result (pass)

 All positive results are presumptive and should be confirmed through GC/MS