

Alere iScreen Cotinine Screening

Clinical Procedure



Supplies

- iScreen Oral Fluid Test Device (OFT)
- Gloves
- Placemats
- Timer or Stopwatch

Definition & Purpose

The Alere iScreen Oral Fluid Test Device (OFT) cotinine test is a rapid, oral fluid screening that detects elevated levels of Cotinine in saliva. Cotinine is a metabolite of nicotine. This test is utilized to detect Cotinine which is an indicator of routine, daily, or habitual nicotine (tobacco) use. The window of detection for Cotinine in saliva with a 30ng/mL cutoff is approximately 1-4 days after nicotine use.

Measurement

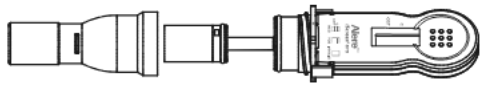
- Ensure the participant has not placed anything in their mouth including food, drink, gum or tobacco products for a least 10 minutes prior to collection.
- Put on gloves, one on each hand.
- Open the test pouch and remove the testing device.
 - Use the device as soon as possible after opening.
- Remove the sample collector protector from the collection sponge.
- Hand the device to the participant and instruct them to insert the sponge into their mouth and actively swab the inside of their mouth and top of their tongue.
- As soon as the sponge softens slightly the participant should gently press the sponge between their tongue and teeth to ensure complete saturation.
 - Instruct the participant that the sponge needs to be saturated with no hard spots left.
- Collect the sample for at least 3 minutes.
- Remove the collector from the participant's mouth.
- Align the red arrow on the device with the white marks on the cap and insert the device vertically into the cap. Press down firmly until the cap reaches the thread.
- Twist the cap clockwise 180 degrees until the red arrow aligns with the other white mark.
- Place the testing device horizontally on a placemat on a clean, level surface facing up.
- Read results in 10 minutes. Do not read results after one hour.

Interpreting Results

- Each test includes a control (C) line to ensure proper device function.
- A line next to C and COT indicate a negative result.
 - The line color intensity may vary. The test results should be interpreted as negative even if the line is faint in color.
- A line next to C and the absence of a line next to COT indicates a positive result.
- If no lines appear, the test result is invalid.
 - Utilize a new device and repeat the test, using a new saliva sample from the participant.
- Document test result on consent form/onsite data collection page and on participant's results handout.

See Page 2 for Visual Aid

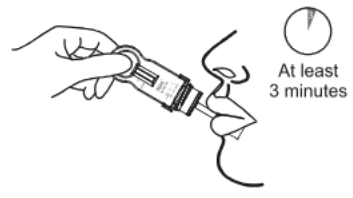
Visual Aid



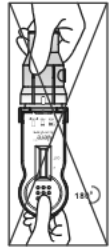
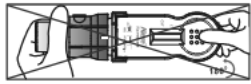
Step 1



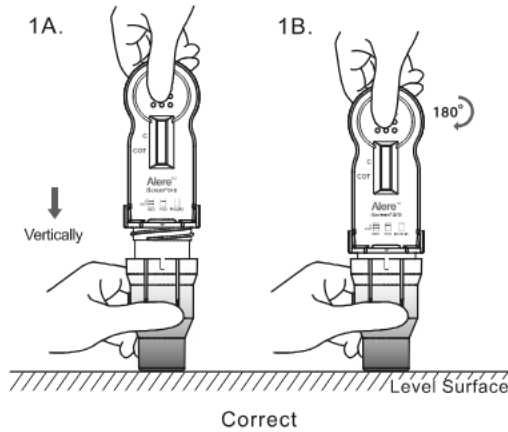
Step 2



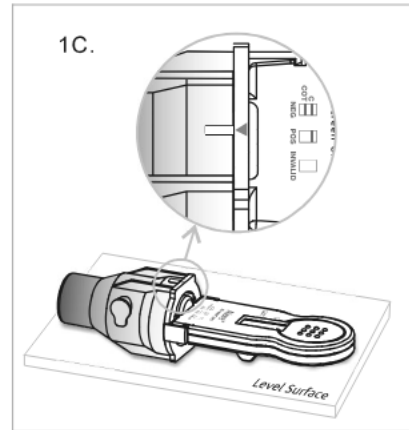
Step 3



Incorrect



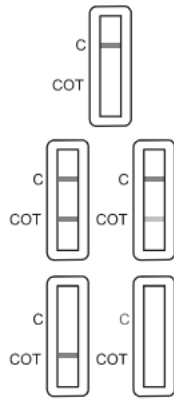
Step 4



Step 5



Read the drug strip results at 10 minutes.
 Test results stable up to 60 minutes.



Positive

Negative

Invalid

Step 6