



iScreen[®] OFD Cotinine Screen

Performance and Results Interpretation



Cotinine Screening

What's new?

**FDA recently exempted cotinine devices
from 510(k) clearance**



Oral Fluid Cotinine

- Cutoff = 30 ng/mL (neat saliva)
- Time to result is 10 minutes; Result is stable for up to 1 hour
- Window of detection 2 days
- Shelf life is 24 months from date of manufacture
- Correlation to Laboratory:
 - >99% specificity; 98% sensitivity

*Only stocked as Alere branded
Catalog I-DCT-B702 BX/25*





iScreen[®] OFD Cotinine Screen

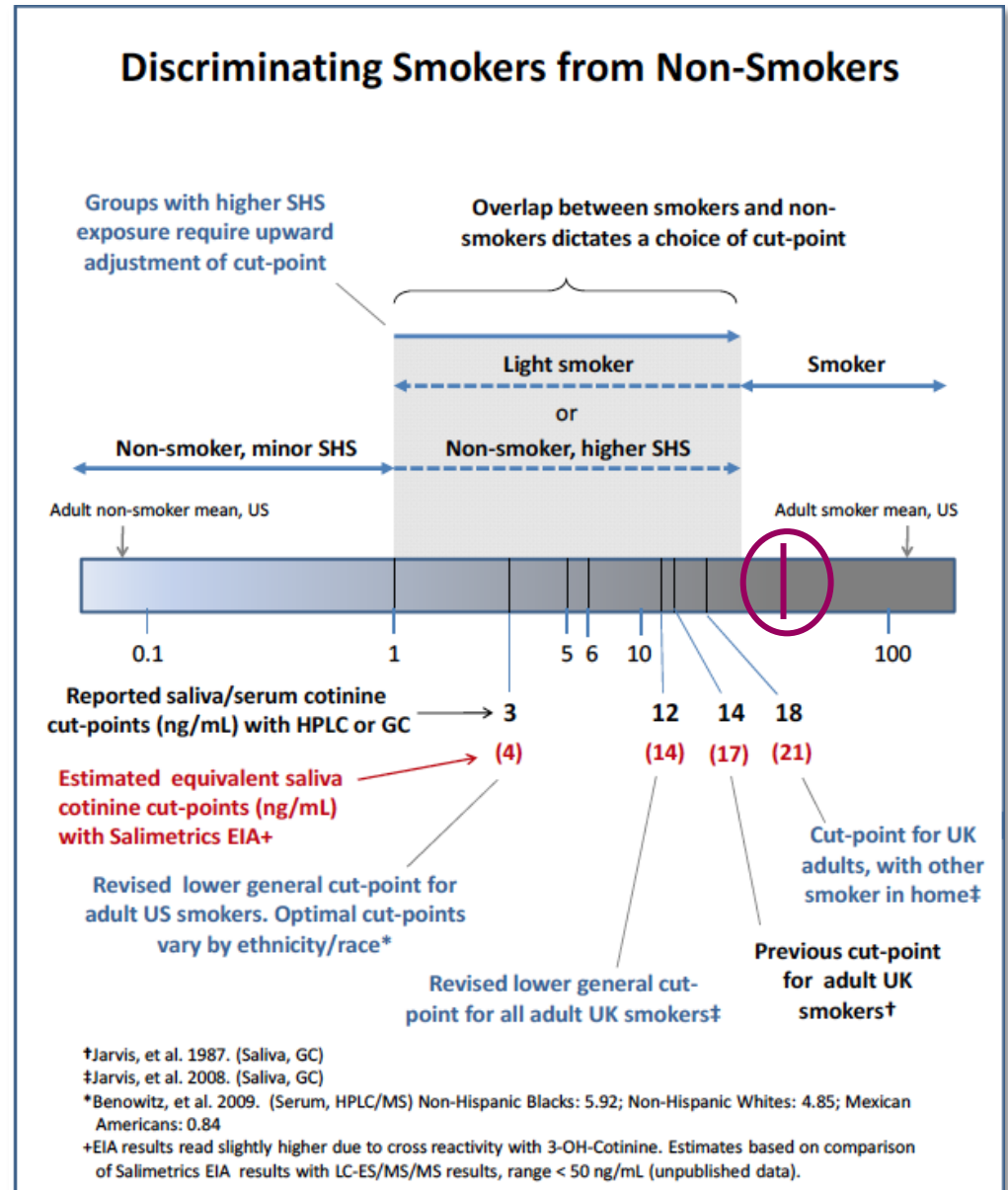
- iScreen OFD Oral Fluid Test Device
 - Rapid on-site screening test device for the detection of cotinine in oral fluid
 - Collect anywhere, anytime
 - Results within minutes
- Gather all necessary testing supplies
 - iScreen OFD device in foil pouch
 - Timer or stop watch



Oral Fluid Cutoff

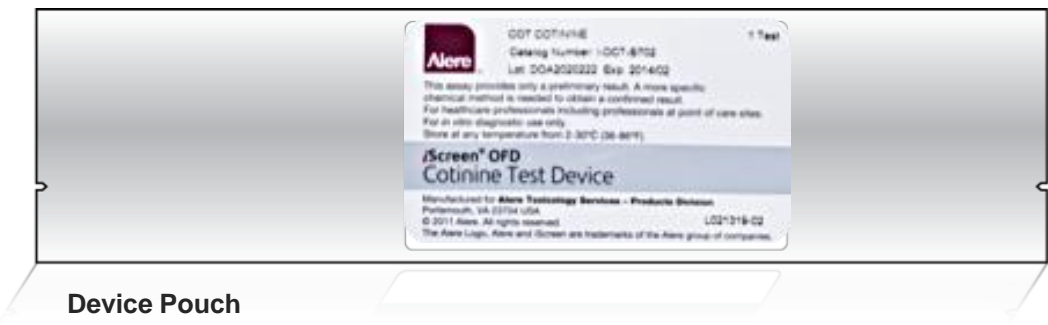
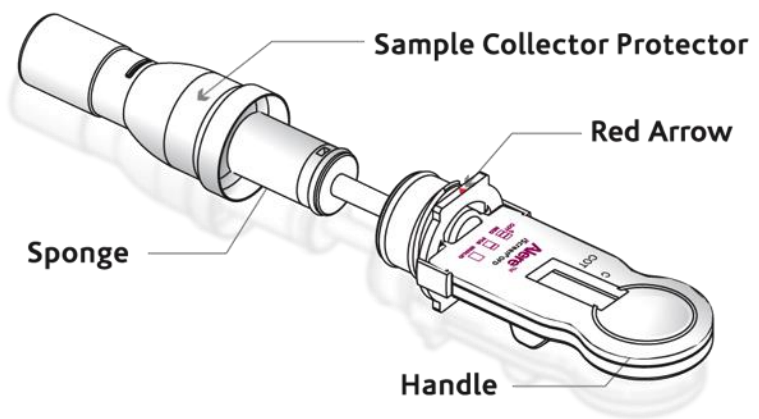
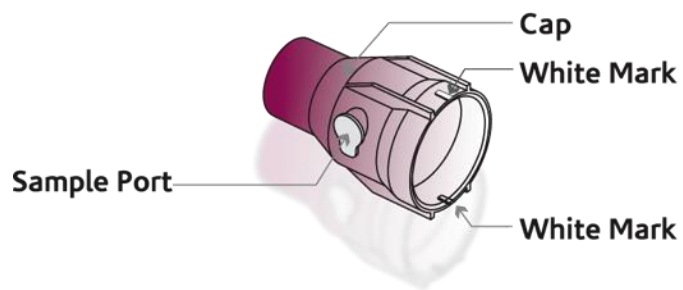
How to address second hand smoke or light-use scenarios?

- 30 ng/mL cutoff targets routine, daily, and habitual smoker.
- Weeds out light-use smoker, e.g., occasional cigar.





Device Components



The Process: Performing the Screen

- **Give Test Device to Donor**

Note: Test Administrator should not handle the test device once handed to the donor, until the security seal has been applied and Chain of Custody has been established.

- Instruct donor to open device
- Have donor remove plastic sponge protector and discard

- **Set aside cranberry device cap**

- Verify that plastic port seal is on cap
- If not, remove from pouch and insert



The Process: Sample Collection

- Instruct donor on proper procedure for saliva collection
 - Ensure that the donor has not placed anything in mouth for at least **10 minutes** prior to collection. Including food, drink, tobacco products, gum, candy, etc.
 - Actively swab inside of mouth and top of tongue for **3 minutes**
 - Allow saliva to saturate sponge
 - Sponge should soften completely



The Process: Initiating Test



- Donor secures cranberry cap onto the test device
 - The test device should be held vertically and inserted into the cranberry cap, tightening until the red arrow on the test device is aligned with one of the white marks on the cap.
 - Once the cap is in place, the saliva will wick up the test strips – you will see a pink migration indicating proper saliva flow.
 - If either of the test strips fails to wick, have the donor loosen the cranberry cap $\frac{1}{2}$ to $\frac{3}{4}$ of a turn and then re-tighten. This allows the air pressure within the device to equalize and the sample to flow properly.

Failure to wick properly can be caused by insufficient sample volume, extremely viscous saliva, or an air bubble

The Process: Securing the Device

- **Test Completion**
 - Instruct donor to initial and date the silver security seal included in test kit box
 - Donor will place this security seal over device

KEEP THE TEST DEVICE IN VIEW OF BOTH THE DONOR AND ADMINISTRATOR UNTIL DEVICE IS SEALED WITH SECURITY SEAL

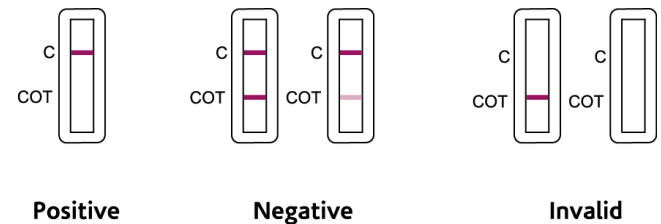
ADMINISTRATOR SHOULD NOT HANDLE DEVICE UNTIL SECURITY SEAL IS IN PLACE



Results: Interpretation and Documentation

- Interpret the test results at 10 minutes
- Results are stable for up to one (1) hour
- The test strip in the device includes an internal procedural Control (C) ensuring proper device function.
- Control lines should form next to the C on the test strip.
- Test interpretation:
 - A line next to the COT or cotinine area a negative test result for that cotinine.
 - The absence of a line next to the COT or cotinine area indicates a presumptive positive result for cotinine.

It is recommended that screen results should not be given to donor.



Results: Interpretation and Documentation

Invalid Test Result

- The test strip within the device includes an internal procedural Control (C) ensuring proper device function.
- Control lines should form on the test strip, indicating the test functioned properly.
- The absence of a Control line on the test strip indicates the test is **INVALID**.
- Discard the test device.
- Perform another test with a new sample and a new device.



Results: Interpretation and Documentation

Negative Test Result

- The appearance of a line next to the COT or cotinine area and the C or control area
- Discard test device
- **Any indication of a line regardless of color intensity is correctly interpreted as a negative test result.**



Results: Interpretation and Documentation

Presumptive Positive Test Result

- The absence of a line next to the COT or cotinine area indicates a presumptive positive test result for Cotinine.
- Example shows: presumptive positive test result for Cotinine



Thank you. Questions?

Technical Services and Questions
800.340.4029



aleretoxicology.com



Smart. Connected. Empowering.