

# Alere iScreen® OFD–Cotinine Test Device

The Alere iScreen® OFD–Cotinine Test Device is a lateral flow chromatographic immunoassay for the qualitative detection of cotinine in oral fluids at a cutoff concentration of 30 ng/mL. A method comparison study of this device was conducted at a point-of-care site in the Commonwealth of Virginia where at least fifty (50) non-smokers and at least forty (40) smokers were enrolled in this study.

An oral fluid sample was collected from each donor, and was tested on the device by following the directions in the manufacturer’s package insert. After obtaining the rapid test

result, the test device was sent to the laboratory for cotinine analysis of the remaining oral fluid in the device using liquid chromatography-mass spectrometry (LC-MS).

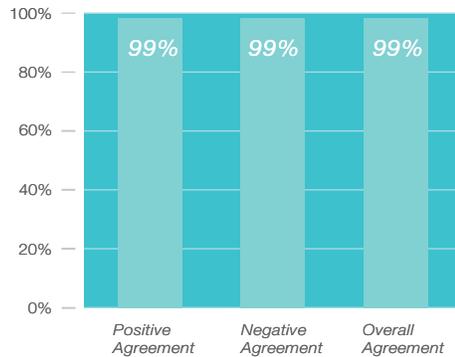
Out of the 97 samples, 42 samples were deemed positive because the cotinine concentrations were above the cutoff of the device (> 30 ng/mL) and 55 samples were deemed negative because the cotinine concentrations were below the cutoff of the device (< 30 ng/mL). Greater than 99% positive, negative, and overall agreements were achieved by this test device as shown in the 2x2 table below.

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Results	LC-MS		Total
	+	-	
+	42	0	42
-	0	55	55
Total	42	55	97

The results were also stratified according to the cotinine concentrations relative to the cutoff of the test device. The study site was able to collect oral fluid samples to fill each bucket, except for the near cutoff negative.

Results	Negative by LC-MS	Near Cutoff Negative by LC-MS (between -50% cutoff and cutoff)	Near Cutoff Positive by LC-MS (between cutoff and +50% cutoff)	High Positive by LC-MS (above +50% of cutoff)	Percent Agreement with LC-MS
Positive	0	0	5	37	>99
Negative	55	0	0	0	>99



**CONCLUSION:** Based on the study results, the acceptance criteria of the study were exceeded. The observed positive and negative agreements between the iScreen OFD–Cotinine Test Device and LC-MS were greater than 95%.