Oral Fluid Drug Screen to assess smoking status

- Sensitivity: 30 ng/mL in neat oral fluid
- Sterilized collector
- >99% correlation with clinical specimens
- Calibrated to (-) Cotinine with excellent affinity for trans-3’-hydroxycotinine (OH)
- An in-vitro diagnostic test for the qualitative detection of Cotinine in undiluted oral fluid
COTININE: ALOFT™
Oral Fluid Drug Screen

TEST SPECIFICATIONS

Cutoff:
30 ng/mL (neat)

Calibrator:
(-)-Cotinine

Precision:
>99% with solutions targeted to +/-50% of the assay cutoff

Accuracy:
>99% with specimens freshly collected using the ALOFT™ device and collector

Specificity:
- Trans-3’-Hydroxycotinine (75% relative reactivity)
- (R,S)-Norcotinine (0.6% relative reactivity)
- S-(−)-Nicotine (<0.1% relative reactivity)

Collection:
The ALOFT™ Oral Fluid Collector consists of a sterilized medical foam affixed to a handle that pairs with the test device.

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Cotinine is the initial metabolite of nicotine. Due to its long half-life relative to parent nicotine and its consistent elimination profile even when specimen pH varies, cotinine is considered a markedly better biomarker for tobacco use than nicotine. Clinical research also suggests that the cotinine metabolite (trans-3’-hydroxycotinine) may be the best oral fluid marker for the oral fluid matrix. The ALOFT™ cotinine oral fluid drug screen is sensitive to cotinine and OH-cotinine.

The sensitivity of the ALOFT™ test was purposefully chosen based on the following technical factors:
- Unlike contemporary lab-based assays, ALOFT™ uses undiluted saliva

- The antibody pair used in the ALOFT™ Cotinine Oral Fluid Drug Screen is reactive to both (-)-cotinine and its predominant metabolite trans-3’-hydroxycotinine (OH-cotinine).

- Given the sensitivity to both cotinine and OH-cotinine, Advin suggests a confirmation cutoff for oral fluid cotinine (or OH-cotinine) of 10 ng/mL.

- An oral fluid confirmation cutoff of 10 ng/mL for cotinine or OH-cotinine definitively identified donors who self-reported smoking.1

- The oral fluid confirmation cutoff of 10 ng/mL for cotinine or OH-cotinine definitively excluded false positive results from non-smoking donors.

The ALOFT™ Cotinine Oral Fluid Drug Screen is an in vitro diagnostic test for the qualitative detection of (-)-cotinine in undiluted oral fluid at a cutoff concentration of 30 ng/mL. The test provides a preliminary result only; presumptive positive results should be confirmed using an alternate chemical methodology (such as LC/MS-MS) if donor doesn’t acknowledge nicotine use or if your policies require.