

# ORAL FLUID DEVICE TRANSITION

## OraSure Intercept to Quantisal by Abbott

### WHAT?

Effective June 3, 2024, CRL is transitioning all oral fluid testing from the Intercept product to Quantisal. CRL will continue to test all Intercept devices that are received at the lab for the foreseeable future.

### WHY? SAMHSA Cut Offs and Split Specimen Availability

CRL is transitioning all non-regulated oral fluid testing to the Quantisal device to ensure that all testing is consistent with the DOT standards, and we are ready for federally regulated oral fluid testing. Abbott is positioned to have the first federally approved split specimen oral fluid device, likely one to two years ahead of other products. Additionally, all assay cutoffs are designed to align to the SAMHSA cutoffs.

Drug Class (Saliva)	ORASURE-Non Dot		Quantisal-1 Non Dot		Quantisal-2 Federal	
	S	C	S	C	S	C
AMPHETAMINE	100 ng/mL	50.0 ng/mL	<b>50 ng/mL</b>	<b>25 ng/mL</b>	<b>50 ng/mL</b>	<b>25 ng/mL</b>
METHAMPHETAMINE	40 ng/mL	50.0 ng/mL	<b>50 ng/mL</b>	<b>25 ng/mL</b>	<b>50 ng/mL</b>	<b>25 ng/mL</b>
MDMA/MDA	n/a	n/a	<b>50 ng/mL</b>	<b>25 ng/mL</b>	<b>50 ng/mL</b>	<b>25 ng/mL</b>
AMP/MAMP	n/a	n/a	n/a	n/a	n/a	n/a
MDA	40 ng/mL	50.0 ng/mL	n/a	n/a	n/a	n/a
MDMA	40 ng/mL	50.0 ng/mL	n/a	n/a	n/a	n/a
COCAINE	5 ng/mL	8.0 ng/mL	<b>15 ng/mL</b>	<b>8.0 ng/mL</b>	<b>15 ng/mL</b>	<b>8 ng/mL</b>
6AM	n/a	4.0 ng/mL	<b>4.0 ng/mL</b>	<b>2.0 ng/mL</b>	<b>4 ng/mL</b>	<b>2 ng/mL</b>
OPIATES	10 ng/mL	40 ng/mL	n/a	n/a	n/a	n/a
OPIATES - COD/MOR	n/a	n/a	<b>30 ng/mL</b>	<b>15 ng/mL</b>	<b>30 ng/mL</b>	<b>15 ng/mL</b>
OPIATES - HYC/HYM	n/a	n/a	<b>30 ng/mL</b>	<b>15 ng/mL</b>	<b>30 ng/mL</b>	<b>15 ng/mL</b>
OPIATES - OXYC/OXYM	n/a	n/a	<b>30 ng/mL</b>	<b>15 ng/mL</b>	<b>30 ng/mL</b>	<b>15 ng/mL</b>
PCP	1 ng/mL	10.0 ng/mL	<b>10.0 ng/mL</b>	<b>10 ng/mL</b>	<b>10 ng/mL</b>	<b>10 ng/mL</b>
THC	1 ng/mL	1.0 ng/mL	<b>4.0 ng/mL</b>	<b>2 ng/mL</b>	<b>4 ng/mL</b>	<b>2 ng/mL</b>
BARBITURATES	20 ng/mL	20.0 ng/mL	60 ng/mL	120 ng/mL	n/a	n/a
BENZODIAZEPINES	1 ng/mL	1.0 ng/mL	20 ng/mL	20.0 ng/mL	n/a	n/a
BUPRENORPHINE	5.0 ng/mL	5.0 ng/mL	5.0 ng/mL	5 ng/mL	n/a	n/a
COTININE	5 ng/mL	5 ng/mL	20 ng/mL	20.0 ng/mL	n/a	n/a
ETG	50 ng/mL	50/200 ng/mL	200 ng/mL	200 / 200 ng/mL	n/a	n/a
ETOH	20.0 mg%	20.0 mg%	40 mg%	40 mg%	n/a	n/a
METHADONE	5 ng/mL	5.0	50 ng/mL	20.0 ng/mL	n/a	n/a
FENTANYL	1.0 ng/mL	1.0 ng/mL	3.00 ng/mL	4.00 ng/mL	n/a	n/a
NORFENTANYL	1.0 ng/mL	1.0 ng/mL	n/a	n/a	n/a	n/a
BATH SALTS	5 ng/mL	5.0 ng/mL	20 ng/mL	20 ng/mL	n/a	n/a
K2	various	various (0.5 / 1.0 ng/mL)	various	various (2.0 / 4.0 ng/mL)	n/a	n/a

\*Bold signifies DOT

### ADDITIONAL ADVANTAGES

- Volume indicator
  - Median collection time just over 3 minutes
- Recovery and stability above 80% for shipped and stored specimens
  - Meets SAMHSA OFMG
- Automated immunoassay screening
  - Faster TAT
  - Improved quality

CRL is confident that this transition positions both us and our clients to meet future industry needs. Quantisal offers a high-quality product that supports effective and efficient testing in the short term and positions us to be one of the first to offer DOT oral fluid testing. We understand, however, that even positive changes are disruptive and can create barriers. We are committed to supporting you and your customers through this transition.



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