



Oral Fluids Q&A

1. Why should I implement oral fluid testing?

- Convenient, Easy and Secure Sample Collection.¹
 - Sample collections are supervised from start to finish so sample adulteration is highly unlikely^{2,3}
 - Samples can be collected on site in just 10 minutes or less without the need for a “supervised” restroom visit^{1,2,3,4}
- Oral fluids detect recent drug use generally within 48 hours and as early as 30 minutes post marijuana use. This is important for drugs like marijuana which can stay in the urine for weeks after use.²
- Oral fluids generally detect parent compounds with concentrations similar to circulating blood levels. This means oral fluids can often distinguish between different classes of drugs, reducing false negatives due to non-cross-reacting metabolites.²

2. Can food, gum, tobacco, etc. affect oral fluid drug results?

- Yes. When using the Oral-Eze® Collection Device available from Thermo Fisher Scientific™, we instruct the donor to empty the mouth of gum, food, tobacco, etc. prior to oral-fluid collection. If the donor’s mouth is not empty immediately prior to collection, have the subject rinse his/her mouth with water (up to 4 oz.) and wait a minimum of 10 minutes before collecting a specimen.^{3,4}

3. Can I use the Oral-Eze Collection System with assays from other manufacturers'?

- No. The test kit, calibrators and device make up a system and have been validated and proven together. Different collection devices use different buffers and buffer volumes which can cause erroneous results.⁴

4. How do I know if I've collected enough sample?

- The Oral-Eze Collection Device has a built-in sample window to ensure adequacy of sample collection. A non-toxic indicator dye travels with the sample as it is absorbed into the portion of the pad contained in the handle, and a blue color appears in the window when the collected volume reaches adequate levels. The dye is wholly contained within the handle and never comes into contact with the donor.⁴
- The Oral-Eze Collection Device uses pure cotton fibers on its pad which reduce the chance for allergic reactions in donors, and does not leave a salty or citric after-taste in the mouth.

5. How are the cut-off levels determined for each assay?

- Thermo Fisher Scientific used the proposed Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines along with partnering with leading experts in the industry to set its cut-offs.¹

6. Why is there a dilution factor with Oral-Eze and the CEDIA® oral fluid assays, and do I need to multiply my result by the dilution factor?

- Each manufacturer's collection device is different. Some use neat or undiluted oral fluid, which can be viscous and difficult to test.³ Other devices, like the Oral-Eze Collection System, collect sample on an absorbent pad and then put the pad in buffer which dilutes the sample. The buffer provides a consistent test medium and is used as a preservative to prevent bacterial growth and stabilize the analytes. This allows the sample to be transported to the laboratory at room temperature and stored for up to 21 days at 2 - 30°C.⁴
- The dilution factor used with the Oral-Eze collection device is 1:3 (one part sample to 2 parts buffer). The assay result is reported as a positive or negative result relative to the cutoff calibrator. For the Thermo Scientific™ CEDIA® THC Assay, the cutoff calibrator is equal to 1 ng/mL. This is the diluted value. The equivalent neat value, is 3 ng/mL (1 ng/mL x dilution factor of 3).⁴

7. When collecting an oral fluid specimen, I noticed a small amount of blood on the collection pad. Is this normal?

- Although this is not common, it may occur in some individuals and should not adversely affect the Oral-Eze specimen.

8. Is oral fluid testing as accurate as urine for drug of abuse testing?

- Yes. Based on workplace positivity rates, oral fluid positivity rates were comparable or slightly higher than urine. Overall drug positivity for oral fluid was 5.06% compared to 4.1% for urine.¹
- Thermo Fisher Scientific compared each of its assays to a confirmatory method, LC-MS/MS. The table below shows 100% agreement with the LC-MS/MS.⁴

Analyte Tested	Oral-Eze Cutoff-Diluted/Neat(ng/mL)	Tested Concentration (ng/mL)	Neat Oral Fluid by LC-MS/MS (ng/mL)	Diluted Oral Fluid by LC-MS/MS (ng/mL)	# Neg/# Pos Agreement	Percent Agreement
Amphetamines	50 Diluted/150 Neat	75	88.18	26.84	0 Neg/50 Pos	100%
Barbiturates	20 Diluted/60 Neat	30	29.4	9.7	80 Neg/0 Pos	100%
Benzodiazepines	1 Diluted/3 Neat	1.5	1.56	0.48	80 Neg/0 Pos	100%
Buprenorphine	1 Diluted/3 Neat	1.5	1.53	0.54	80 Neg/0 Pos	100%
Cocaine	5 Diluted/15 Neat	7.5	7.46	2.34	50 Neg/0 Pos	100%
Methadone	5 Diluted/15 Neat	7.5	7.35	2.49	80 Neg/0 Pos	100%
Methamphetamines	40 Diluted/120 Neat	60	60.47	17.34	50 Neg/0 Pos	100%
Opiates	10 Diluted/30 Neat	15	17.99	5.07	50 Neg/0 Pos	100%
Oxycodone	10 Diluted/30 Neat	15	14.7	5.06	80 Neg/0 Pos	100%
PCP	1 Diluted/3 Neat	1.5	1.62	0.46	50 Neg/0 Pos	100%
THC	1 Diluted/3 Neat	1.5	1.28	0.39	50 Neg/0 Pos	100%

Please see each assay package insert for full listing of concentrations tested.

9. Do the Thermo Scientific™ CEDIA assays have FDA clearance?

- Both the Oral-Eze Collection System and 6 major screening assays, Amphetamines, Cocaine, Methamphetamines, Opiates, PCP and Cannabinoids (THC) have FDA 510(k) market clearance.

10. Where would I use oral fluid drug testing?

- Though urine is still the predominate matrix used for drug screening, oral fluids is the fastest growing matrix, primarily due to its rapid, easy and non-invasive sample collection. Oral fluid testing is ideal for workplace screening (pre-employment, random, reasonable suspicion, periodic, post-accident, return to duty and return of duty follow-up) and is especially well suited for unscheduled testing such random testing or testing for cause).⁶ It can also be used for testing within the criminal justice system and forensic laboratory testing.

References

1. United States, Congress, Substance Abuse and Mental Health Services, and Secretary of Health and Human Services. "Mandatory Guidelines for Federal Workplace Drug Testing Programs." Mandatory Guidelines for Federal Workplace Drug Testing Programs, vol. 80, No. 94, Federal Register, 2015, pp. 28054–28101. www.gpo.gov/fdsys/pkg/FR-2015-05-15/pdf/2015-11523.pdf
2. Allen, Keith R. "Screening for Drugs of Abuse: Which Matrix, Oral Fluid or Urine?" *Ann Clin Biochem*, vol. 48, no. 6, 1 September 2011, pp. 531–541., doi:10.1258/acb.2011.011116
3. Drummer, O. "Drug Testing in Oral Fluid." *Clin Biochem Rev* Vol 27 August 2006
4. Thermo Scientific, Package Inserts:
Collection of Oral-Fluid Samples with the Oral-Eze Oral-Fluid Collection System
CEDIA Amphetamine OFT Assay
CEDIA Cocaine OFT Assay
CEDIA Methamphetamine OFT Assay
CEDIA Opiate OFT Assay
CEDIA PCP OFT Assay
CEDIA Cannabinoids OFT Assay
CEDIA Barbiturates OFT Assay
CEDIA Benzodiazepines OFT Assay
CEDIA Buprenorphine OFT Assay
CEDIA Methadone OFT Assay
CEDIA Oxycodone OFT Assay
5. United States, Congress, "Medical Devices; Exemptions From Premarket Notification: Class II Devices." *Medical Devices; Exemptions From Premarket Notification: Class II Devices*, Federal Register, 11 July 2017. www.federalregister.gov/documents/2017/07/11/2017-14453/medical-devices-exemptions-from-premarket-notification-class-ii-devices
6. Quest Diagnostics. *A Comprehensive Guide to Establishing a Workplace Drug Testing Program*, 2016, www.employer-solutions-resources.com/whitepaper/drug-testing-guide. 39962-FIN-Drug_Testing_Toolkit_Webinar-Digital.pdf

Clinical Diagnostics

USA

46500 Kato Road
Fremont, CA 94538 USA
Tel. 800-232-3342 / + 1 510-979-5000
sales.diagnostics.fmt@thermofisher.com

Canada

Tel. 905-286-4290
CDD.Canada@thermofisher.com

Find out more at thermofisher.com/OralFluidTesting