



FREQUENTLY ASKED QUESTIONS Oral Fluid Drug Testing with Oral-Eze

BENEFITS

Q; Why choose lab-based oral fluid drug testing?

A: Oral fluid testing offers confidential lab-based drug test results from a minimally-invasive, observed collection. It is excellent at detecting recent drug use because it can screen for drugs in a donor's system soon after use. By using oral fluid instead of urine, donors can collect and cap their own oral fluid samples on-site and in the presence of a monitor, reducing the likelihood of tampering or a donor challenge later in the drug testing process. Oral fluid drug testing can be used for employment, random, reasonable suspicion, return-to-duty and post-accident drug testing.

Q: What are the benefits of using Oral-Eze for lab-based oral fluid drug testing?

A: Oral-Eze is an innovative lab-based oral fluid collection system, that simplifies the collection process for routine drug testing.

- The Oral-Eze Oral Fluid Collector has a built-in indicator window for determining when a sufficient quantity of oral fluid has been collected. The window turns blue when an adequate volume of sample is collected which helps to reduce the number of drug tests that are reported as "quantity insufficient" (QNS) by the laboratory.
- Typically, an Oral-Eze collection takes 5 minutes or less. Oral-Eze testing is performed the day it arrives at our laboratory, with negative screening results reported the same day. Non-negative results are confirmed, reviewed and typically reported within 72 hours of receipt.
- Because an Oral-Eze collection is observed, there is less risk of adulteration or tampering by the donor.
- Oral-Eze detects a wide range of drugs which include amphetamine, methamphetamines (including MDMA and its metabolite), opiates (codeine, morphine, hydrocodone, hydromorphone, 6-AM), cocaine (metabolite), THC and phencyclidine (PCP).
- Offering an improved donor experience, Oral-Eze does not have a salty or citric taste.

THE COLLECTION EXPERIENCE

Q. How long does it take to collect an oral fluid sample with Oral-Eze?

A. The Oral-Eze collection is complete when the indicator window turns blue. This typically occurs within 5 minutes. In our studies, 83 percent of donors provided an adequate sample in 5 minutes or less. With that said, every donor is different. Collectors should coach their donors regarding how to provide an adequate sample volume. *Before beginning the collection, instruct the donor to pool their saliva and then, once the Oral-Eze collector is in their mouth, to direct saliva towards the pad.* Ask the donor to refrain from swallowing and talking, instead directing that saliva towards the device. Ensure that the donor keeps the device in their mouth for the allotted time or until the indicator window turns blue.

Q. What is the best practice for transferring the pad from the collector to the tube?

A. Once the indicator window turns blue, instruct the donor to simply place their thumb on the ridges of the collector handle and slide forward to detach the pad into the collection tube. If the pad does not immediately detach into the tube, lightly press the pad against the lip of the tube and withdraw the collector handle. If the pad is not sufficiently saturated with oral fluid, as indicated by a blue color in the indicator window, it may be more difficult to detach.

Q: Does coughing or talking affect the result because the donor takes the device out of their mouth?

A: While not recommended, coughing, talking or otherwise departing from the standard collection process should not impact the result of the test. However, these behaviors may slow the collection time, and are thus not recommended.

TRANSPORTATION

Q: What is the turnaround time?

A: Testing is performed the day an Oral-Eze sample arrives at the laboratory and a negative screening result is typically reported the same day. Non-negative (e.g. "positive") results are confirmed, reviewed and typically reported within 72 hours of receipt.

Q: How do I get the specimen to the laboratory?

A: The oral fluid specimen should be sent using the same mode of transportation – Quest Diagnostics or overnight courier – that you currently utilize. If you are new to oral fluid testing, your Account Management representative will assist in determining the optimum mode of transportation.

Q: Which laboratory processes oral fluid drug tests?

A: Our Lenexa, Kansas laboratory performs oral fluid drug tests.

ADULTERATION

Q: Can an oral fluid test be beaten?

A: We have not found any adulterants that can beat the test at this time, nor are we aware of any devices used to cheat an oral fluid test. Of course, donors may attempt to introduce something onto the pad or collection vial. This risk is minimized because every collection is directly observed.

Q: How does the laboratory determine if the specimen is valid?

A: We perform specimen validity testing (an Albumin test) on every oral fluid specimen, giving you the added assurance that the specimen is appropriate for testing. Albumin is an endogenous (i.e. naturally occurring) substance that is expected to be in all donor's oral fluid/saliva. The test helps to ensure that the specimen is oral fluid/saliva and that there is sufficient sample to perform the testing.

REGULATIONS

Q: Is the Oral-Eze test FDA-cleared?

A: Yes, both the Oral-Eze Oral Fluid Collection System and the drug tests using the Oral-Eze collection system are FDA-cleared.

Q: What does 'FDA Clearance' mean?

A: FDA Clearance means that the U.S. Food and Drug Administration (FDA) has evaluated both performance data and labeling. An FDA cleared assay meets current standards for accuracy and reliability, including the importance of confirmatory testing when the results of the screening test are positive. Manufacturers of tests with FDA approval or clearance have provided the FDA with data to assure that their tests generate reliable results for the specimens being tested.

Q: Can the Oral-Eze test be used for Department of Transportation (DOT) testing?

A: While the DOT is considering oral fluid for their testing, at this time the DOT has not approved any oral fluid drug testing system.

Q: Is oral fluid testing legal in all 50-states? If no, where is it prohibited?

A: As of 2014, oral fluid testing for drugs of abuse is legal in all U.S. states with the exception of Maine, Vermont, Hawaii and Puerto Rico. States may also have requirements or limitations that vary according to the state's specific laws, the industry involved, or the purpose(s) for which the drug test was conducted. You should obtain additional information as appropriate from an attorney licensed to practice law in the relevant state.

DETECTION/CUTOFFS

Q: What is the detection window for drugs in oral fluid?

A: While every drug and donor is different, oral fluid is widely regarded as the most reliable specimen type for detecting recent use. Oral fluid is able to detect most drugs starting soon after ingestion and extending out for 24-48 hours after use.

Q: How does the detection window for Oral-Eze compare with other methods such as urine?

A: Just like traditional urine testing, the window of detection in oral fluid is different for each drug. Like urine drug testing, oral fluid testing detects recent drug use and may also identify very recent usage that may be missed by urine testing. For most drugs, the maximum window of detection in oral fluid is about 1 to 2 days. By contrast, urine testing detects drugs or their metabolites excreted in one of the body's waste systems and may detect some drugs for a slightly longer period of time (1 to 3 days). Moreover, oral fluid testing may detect drug use 1 to 2 hours after ingestion/use while urine testing usually requires 2-6 hours to detect use after ingestion/use. Even with slightly different detection windows, the positive prevalence ("positivity") rates for urine and oral fluid are quite similar.

Q: What drugs are tested with Oral-Eze?

A: Oral-Eze tests for the following drugs: amphetamine, methamphetamines (including MDMA and its metabolite), opiates (codeine, morphine, hydrocodone, hydromorphone, 6-AM), cocaine (metabolite) THC, and phencyclidine (PCP).

Q: Can the Oral-Eze test detect Ecstasy?

A: Yes, Ecstasy (MDMA) is reported under the methamphetamines group.

Q: Can the Oral-Eze test detect semi-synthetic opiates?

A: Yes, in addition to codeine, morphine and 6-AM, the Oral-Eze opiates panel detects hydrocodone and hydromorphone. All five of these opiates are routinely reported if detected in the oral fluid specimen.

Q: How long are positive (non-negative) specimens retained by the laboratory?

A: Non-negative specimens are retained for a minimum of 12 months (the same as a non-negative urine specimen).

Q: Why are the initial and confirmatory levels different than what I am used to seeing on my reports?

A: The FDA has asked manufacturers of oral fluid drug testing systems to represent cutoffs in terms of the concentration of original ("neat") oral fluid rather than in terms of the concentration in the collection tube after dilution with a buffer preservative. Consequently, all second generation testing systems submitted to the FDA for clearance utilize this cutoff representation. The Oral-Eze Oral Fluid Collection System has a three-fold dilution of neat oral fluid with the buffer preservative solution in the collection tube, consequently the cutoffs for testing systems that utilize the Oral-Eze system are three times higher than some other systems (e.g. opiates with the Intercept[®] collection system have a 10 ng/mL cutoff and opiates with the Oral-Eze collection system have a 30 ng/mL cutoff). The manner in which the cut-off is expressed (neat versus diluted) should not impact detection or positivity rates.

Q: When a test is non-negative and tested positive, what steps are taken to verify for prescription use or misuse?

A: Non-negative results are typically reported by our laboratory to the client's Medical Review Officer (MRO). The MRO will review the results of the oral fluid drug test and may contact the donor to inquire about prescription medications.

Q: What are the cutoffs and analytes for the oral fluid drug test using the Oral-Eze Oral Fluid Collection System:

Oral-Eze® Oral Fluid Collection System Cutoffs and Analytes

A: Drug Class Level	Initial Test Level	Confirmatory Level	Confirmatory Method
Amphetamine	150 ng/mL	120 ng/mL	GC/MS
Methamphetamines	120 ng/mL		
Methamphetamine		120 ng/mL	GC/MS
MDMA		120 ng/mL	GC/MS
MDA		120 ng/mL	GC/MS
Cocaine Metabolites	15 ng/mL		
Benzoylcegonine		6 ng/mL	GC/MS
Marijuana	3 ng/mL	1.5 ng/mL	GC/MS
Opiates	30 ng/mL		
Morphine		30 ng/mL	GC/MS
Codeine		30 ng/mL	GC/MS
Hydromorphone		30 ng/mL	GC/MS
Hydrocodone		30 ng/mL	GC/MS
6-Monoacetylmorphine		3 ng/mL	GC/MS
Phencyclidine	3 ng/mL	1.5 ng/mL	GC/MS

GC/MS includes GC/MS/MS which may be used for some analytes.

Q: Does Oral-Eze detect marijuana well?

A: Yes. Recent Drug Testing Index™ data shows that Oral-Eze is effective in detecting marijuana with positivity rates up in 2012 and 2013. We believe that this increase is due in part to the improved technology – sample adequacy indicator and buffer preservative solution – afforded by Oral-Eze as well as the oral fluid drug testing process which utilizes an observed collection.

Q: How does the positivity rate for oral fluid compare with urine?

A:

Oral Fluid vs. Urine (January 2005 – December 2011)

Drug Category	Oral Fluid (N~5.8MM)	Urine (N~3.8MM)
Overall ¹	4.1%	4.3%
Amphetamine ²	0.19%	0.49%
Methamphetamines ³	0.21%	0.15%
Cocaine (Metabolite)	0.74%	0.50%
Marijuana/Metabolite	2.5%	2.2%
Opiates ⁴	0.67%	0.37%
Phencyclidine (PCP)	0.02%	0.02%

¹ Includes test results for other "non-SAMHSA" drugs such as barbiturates and benzodiazepines

² Urine: As a percentage of all tests for "Amphetamines"

³ Oral Fluid: Includes methamphetamine and MDMA/analogues

Urine: As a percentage of all tests for "Amphetamines"

⁴ Oral Fluid: ~71% of tests include hydrocodone and hydromorphone

Urine: ~9% of tests include hydrocodone and hydromorphone

REPORTING

Q: How are the results reported?

A: As with all laboratory-based testing, Oral-Eze results are recorded in the laboratory information system and reported to the client by confidential fax, direct interface (e.g. web services), web reporting via Quest Integrated Solutions (QIS), Employer Solutions Portal (ESP) and printer or voice response.

COLLECTION/SUPPLIES

Q: Who manufactures the drug testing system that utilizes the Oral-Eze device?

A: ThermoFisher is the manufacturer of both the Oral-Eze Oral Fluid Collection System and the testing reagents used by the laboratory.

Q: Can I use my urine custody and control form?

A: It is not recommended. There is an alternative specimen custody and control form that should be used for laboratory-based testing of oral fluid and hair specimens. We offer a [video tutorial](#) that takes you through the process step-by-step process of completing a Chain of Custody Form (CCF) for oral fluid drug testing collections. ***In an emergency situation***, the urine CCF could be used by centering the tamper-evident seal over the top of the oral fluid collection tube. Starting with the end that does not have the specimen ID number printed on the seal, wrap the seal down the side, around the bottom of the Oral-Eze tube and back up the opposite side. The end of the seal that contains the specimen ID number ***must be*** visible. Otherwise, the specimen may be rejected if the laboratory cannot read the specimen ID number.

Q: What is included in my order of Oral-Eze devices?

A: Each Oral-Eze shipment includes testing/collection devices, Chain of Custody Forms which include tamper-evident seals and transportation envelopes. If the specimens are shipped to the laboratory by overnight courier, air bills for shipping the specimen to your designated laboratory are included with the order.

Q: How do I collect a split specimen?

A: Two oral fluid collectors (two oral fluid collection pads) are used and collected either simultaneously or sequentially. If collected simultaneously, the donor should place one collector on each side of the mouth. After the specimen is collected on the swab, have the donor eject one pad in one plastic vial and the other pad in the other plastic vial. If collected sequentially, the second collector should be placed in the donor's mouth no more than 2 minutes after the end of the collection of the first specimen.

Q: Who collects the sample?

A: One of the advantages of an oral fluid collection is that the donor controls his or her sample under direct visual supervision. The "collector" really is an observer and has a small role in the "chain of custody," the process most often challenged by donors. If the donor wants to challenge the collection, the only person to challenge is him or herself. On average, an oral fluid collection with Oral-Eze takes just 3-5 minutes. You can [download a white paper](#) with greater detail about average collection times.

Q: What is the liquid in the vial?

A: The liquid is a buffer preservative solution that stabilizes the oral fluid sample and helps prevent the sample and drugs/metabolites from deteriorating during shipment to the laboratory or storage.

Q: How long must the donor's mouth be empty prior to taking an Oral-Eze test?

A: The donor's mouth must be empty (no food, gum, liquids, tobacco, etc.) for at least 10 minutes prior to beginning the oral fluid drug test.

Q: Will recent oral surgery (root canals, extraction's, etc.), sutures or dentures impact the test?

A: They will not. However, if sutures are located between the lower cheek and gum, it is better to collect the sample from the opposite side of the mouth.

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

A: Although this is not common, it may occur in some individuals and should not adversely affect the specimen collected.

Q: How long is the specimen stable after it has been collected?

A: As a part of the FDA-clearance process, the manufacturer has demonstrated that the specimen and any drugs in the specimen are stable for 21 days after collection. Non-negative specimens tested by the laboratory are stable for at least 1 year when stored frozen.

Q: What if the donor is taking medications and wants to write the names of the medications on the custody and control form?

A: For privacy reasons, the names of medications that the donor may be taking must *not* be listed on the Chain of Custody Form. However, as a reminder, the donor may list them on the back side of their copy of the CCF in the event the donor is contacted by a Medical Review Officer.

Q: Isn't oral fluid a hazardous fluid?

A: No. Because the testing methodology is not classified as a "dental process," the Occupational Health and Safety Administration (OSHA) does not consider oral fluid a hazardous fluid.

Q: What is the shelf life of the Oral-Eze Oral fluid Collection System?

A: The shelf life of Oral-Eze is up to 24 months. Typically, Oral-Eze collection systems will be shipped with a minimum of 12 months remaining shelf life.

Q: If I run out of the collection devices, can I use a different device?

A: No, the testing system used by a laboratory is matched to the collection device used to collect the oral fluid specimen.

Q: How long are positive (non-negative) specimens retained by the laboratory?

A: Non-negative specimens are retained for a minimum of 12 months (the same as a non-negative urine specimen).

Q: Is the pad safe to put in my mouth?

A: Yes, the pad is a cotton-fiber filter paper that has not been treated with any salts or flavorings.

Q: How should I train my staff to use the Oral-Eze collection system?

A: Please visit the Employer Solutions website at Oral-Eze.com to learn more, watch a collection demonstration video and take our [online oral fluid specimen collection training](#).

Q: Do I order Oral-Eze from Quest Diagnostics?

A: Yes, you can order the Oral-Eze Oral Fluid Collection System directly from Quest Diagnostics just as you would order other supplies. Please send an email to es.orders@questdiagnostics.com, fax 267-200-0329 or call 800-877-7484.

Q: What are the supply order codes for Oral-Eze?

A: The Oral-Eze supply order codes are:

160786 Oral-Eze Kit (collection system and specimen transportation bag)

160785 Oral-Eze Kit with shipping supplies (collection system and specimen transportation bag, FedEx mailer, pre-printed air bill)

TECHNICAL

Q: What methodology is used?

A: A two-tiered testing process is used:

- (1) A portion of the oral fluid sample is first screened using enzyme immunoassay (EIA), a proven reliable methodology for routine drug testing.
- (2) Any samples that are presumptively positive in the drug screening process are then confirmed, using another portion of the oral fluid sample, using either gas chromatography/mass spectrometry (GC/MS) or gas chromatography/mass spectrometry/mass spectrometry (GC/MS/MS)

Q: Is EIA forensically defensible?

A: Yes, the technology is well established and is the same technology that has long been used for screening for drugs of abuse in urine.

Q: What is the difference between GC/MS and GC/MS/MS?

A: GC/MS is the more traditional confirmation method for drugs of abuse testing. Both technologies produce a “molecular fingerprint” of the drug or compound being analyzed and provide definitive identification. GC/MS/MS, a newer technology also known as “tandem MS,” generally provides greater sensitivity which may be necessary for the analysis of alternative specimens.

Q: What is different about the Oral-Eze product from the laboratory perspective?

A: A specific type of enzyme immunoassay (EIA), cloned enzyme donor immunoassay (CEDIA[®]), is used as the initial testing technology and the specimen validity test measures albumin.

Q: What is the difference between EIA and ELISA?

A: EIA is the more traditional enzyme immunoassay. The technology has been widely used for the analysis of drugs of abuse in urine. It is homogenous in nature meaning that the analysis is performed without any physical separation during the analysis, which enables faster throughput and improved turnaround times. ELISA is a heterogeneous process which requires several processing steps prior to reading the results. Newer EIA technologies, such as CEDIA[®], permit the detection of the lower concentrations of drugs found in oral fluid samples.