



FREQUENTLY ASKED QUESTIONS Oral Fluid Drug Testing with Oral-Eze

BENEFITS AND PRICING

Q: What benefits does Oral-Eze present?

A: The Oral-Eze Oral Fluid Collector has a built-in indicator for determining when a sufficient quantity of oral fluid has been collected. This will reduce the number of tests that are reported as “quantity insufficient” (QNS) by the laboratory. Another benefit is that the oral fluid collector does not have a salty or citric taste.

Q: I’m accustomed to using Intercept[®] and would like to continue ordering that product. Will Quest Diagnostics continue to support other oral fluid testing options?

A: Quest Diagnostics is fully committed to Oral-Eze. On January 1, 2012 we began phasing out the supply of other devices. We realize that specimens collected on the old device will continue to make their way to the laboratory for a period of time, we committed to providing at least 60-day notice prior to this discontinuing our testing of other devices. On September 7, 2012 we provided ~90-day notice that the last day we would test alternative oral fluid devices is November 30, 2012. However, starting on October 1, 2012 we will begin testing alternative oral fluid devices only on Wednesdays and Saturdays. This may impact the turnaround time of some results.

Q: What is the price of this new product?

A: With a sample adequacy indicator, the Oral-Eze system will reduce the number of specimens with an insufficient volume for testing. This reduction will eliminate the need for the redundant purchase of devices, thereby saving our customers money. We are happy to bring you this improved product for the same fee that you currently pay.

Q: Is there also a change in the testing technology that the lab uses?

A: Yes. The testing technology that will now be used by our labs for oral fluid drug tests will enable faster throughput and highly reliable turnaround times.

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 3-5 minutes. In our studies, 83% of donors provided an adequate sample in five minutes or less. With that said, every donor is different. As with all oral fluid collection systems, 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 them to refrain from swallowing and talking, instead directing that saliva towards the device. Ensure that they keep 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 gently slide forward to detach the pad into the collection tube. If the pad does not immediately detach into the tube, gently press the pad against the lip of the tube and gently 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. What makes Oral-Eze taste better than the old device?

A. The Oral-Eze collection pad is simply a cotton fiber filter paper. Unlike some other devices Oral-Eze has not been treated with any salty or citric chemicals.

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 the samples arrive at the laboratory and negative screening results are typically reported the same day. 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 representative will assist in determining the optimum mode of transportation.

Q: Will the laboratory that processes my tests change?

A: No. Our Lenexa, Kansas laboratory will continue to perform 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. Of course, donors may attempt to introduce something onto the pad or collection vial. This risk is minimized because every collection is directly and easily observed. In addition, we are not aware of any devices used to cheat an oral fluid test. The directly observed collection makes Oral-Eze a difficult test to cheat.

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

A: With every specimen, the laboratory performs an Albumin test. This test helps ensure that the specimen is saliva and that there is sufficient saliva to perform the drug testing. The Albumin test is a specimen validity test.

Q: Why are you changing the test for specimen validity?

A: With the change in testing technology for the drug tests, we utilize a different indicator of specimen validity. Albumin is an endogenous (i.e. naturally occurring) substance that is expected to be in all donor's oral fluid/saliva and serves as an excellent test for specimen validity.

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: 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 they have not approved any oral fluid drug testing system.

Q: What does 'FDA Clearance' mean?

A: The 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: Is oral fluid testing legal in all states? If no, where is it prohibited?

A: As of 2012, oral fluid testing for drugs of abuse is legal in all states with the exception of Maine, Vermont, Hawaii and Puerto Rico.

DETECTION/CUTOFFS

Q: What drugs are tested with Oral-Eze?

A: The drugs tested for are the following: Amphetamines, Methamphetamines (including MDMA and its metabolite), Opiates (Codeine, Morphine, Hydrocodone, Hydromorphone, 6-monoacetylmorphine), 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 oxycodone?

A: No, the Oral-Eze test should not be used to detect oxycodone use.

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

A: Yes, in addition to codeine, morphine, and 6-monoacetylmorphine, the Oral-Eze "Opiates" test 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: Will there be any changes in the drugs detected using the Oral-Eze or new testing technology?

A: No. The test menu will remain unchanged. While there will be a reduction in the screening cutoff for amphetamine, the confirmation cutoff levels for amphetamine will remain the same and therefore we expect the positivity rate to be similar.

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

A: The US Food and Drug Administration (FDA) has asked manufacturers of oral fluid 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 will 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 this Oral-Eze system are three times higher (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 cutoff is expressed (neat versus diluted) is not expected to change detection or positivity rates.

Q: Can I still get my reports using the old initial and confirmatory test levels?

A: Unfortunately, no. Oral fluid drug tests that utilize second generation testing systems, cleared by the FDA at cutoffs expressed in terms of the original oral fluid, must be reported with their FDA-cleared labeling.

Q: Will the test levels be changing for the OraSure product?

A: It is our understanding that OraSure has partnered with Roche Diagnostics in the development and manufacturing of a second generation laboratory testing system using the Intercept[®] collector. These new FDA-cleared assays manufactured by Roche Diagnostics also express cutoffs in terms of original ("neat") oral fluid.

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 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		
Benzoyllecgonine		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: What other drugs does Oral-Eze detect?

A: At this time Oral-Eze will not detect any drugs beyond those listed in the chart above. This includes alcohol, nicotine/cotinine, synthetic drugs and oxycodone.

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 close to when they are ingested 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 drug 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 one-to-two days. By contrast, urine testing detects drugs or their metabolites excreted in one of the body's waste systems and do detect some drugs for a slightly longer period (1 to 3 days). Moreover, oral fluid testing may detect drug use 1 to 2 hours after ingestion/use. 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: 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~38MM)
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

⁴ 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, results are recorded in the laboratory information system and reported to the client by confidential fax, direct interface, web reporting (QIS), printer, or voice response.

Q: Will there be any change in how I receive my results?

A: No. However, your results report will reflect the different screening cutoff for amphetamine and how cutoffs are represented.

Q: Will there be any change in how I interpret the results?

A: No. It will read the same.

COLLECTION/SUPPLIES

Q: Do I have to pay for the collection devices in advance?

A: The cost structure for the Oral-Eze Oral Fluid Collection System will remain unchanged. You will be responsible for purchasing kits and testing separately.

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: There is an alternative specimen custody and control that should be used. It is intended for laboratory based testing of oral fluid and hair specimens.

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

A: Each Oral-Eze shipment includes testing/collection devices, Chain of Custody Forms (CCF) which includes tamper resistant seals, and padded transportation envelopes.

Q: Can the test be run if I use the regular urine custody and control form by mistake or I have run out of the alternate custody and control form?

A: Yes, but the tamper-evident tape on the urine custody and control form (CCF) is designed for the urine bottle and is too long for the oral fluid vial. Consequently, the urine CCF should only be used in an emergency situation. To use the urine custody and control form properly you should center the tamper-evident seal over the top of the oral fluid collection tube. Next, 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 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: How do I collect a split specimen?

A: Two oral fluid collectors (two oral fluid collection pads) are used – 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 them 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 two (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 three to five (3-5) minutes.

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 ten (10) minutes prior to beginning the 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 custody and control form. However, as a reminder, the donor may list them on the back -side of their copy of the form 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”, OSHA does not consider oral fluid a hazardous fluid.

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

A: Yes, you should order the Oral-Eze Oral fluid Collection System from Quest Diagnostics. You can order these supplies just the same as you would order the routine custody and controls forms and the urine collection kits. Simply send an e-mail to es.orders@questdiagnostics.com, fax 267-200-0329, or call 800-877-7484.

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

A: Up to 24 months. Typically, 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: What do I do with all the old Intercept[®] kits I've already purchased?

A: We encourage you to exhaust your existing supply of Intercept[®]. Quest Diagnostics will continue to process both devices for a period of time. However, when you place an order for new oral fluid collection supplies we will automatically transition you to the Oral-Eze product.

Q: Will I need a new CCF form with Oral-Eze?

A: No, however, the next time you order your CCF forms, you will notice the new Oral-Eze test order codes preprinted on the form.

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 orient my staff to the Oral-Eze collection system?

A: Please visit the Employer Solutions web site at Oral-Eze.com to learn more, watch a collection demonstration video, and take our online training.

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

A: Yes. The Oral-Eze supply order codes are:

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

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

Q: What do I receive when I order Oral-Eze Oral fluid Collection Systems?

A: You will receive an Oral-Eze Oral fluid Collection System and a specimen transportation bag (i.e. chain of custody bag) for each Oral-Eze Collection System ordered. Custody and Control Forms must be ordered separately. If the specimens are shipped to the laboratory by overnight courier, air bills for shipping the specimen to your designated laboratory are included with each order of Oral-Eze Oral fluid Collection Systems.

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 screening process are then confirmed, utilizing 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: One of the assays (amphetamine) has a lower screening cutoff level than Intercept[®], but the confirmation level remains the same. Albumin is used as the specimen validity test instead of IgG. A specific type of enzyme immunoassay (EIA), cloned enzyme donor immunoassay (CEDIA[®]), is used as the initial testing technology.

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.