



Frequently asked questions

Oral fluid drug testing with Oral-Eze®

Q: Why drug test?

A: Drug abuse in the workplace puts employers at a risk of increased accidents, more absenteeism, lower productivity, and higher insurance costs. Oral fluid testing, like all drug testing methodologies, helps to mitigate these risks by filtering out drug users from an employer's workforce as well as deterring drug use within it.

Q: Why choose laboratory-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 drug testing, employers can oversee their donors as they collect their own oral fluid specimens, reducing the likelihood of tampering or a donor challenge later in the drug testing process.

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 drug testing collection process for routine drug testing.

- The Oral-Eze Oral fluid Collection System has a built-in sample adequacy window for determining when a sufficient quantity of oral fluid has been collected. The window turns blue when an adequate volume of specimen is collected which helps to reduce the number of drug tests that are reported as "quantity insufficient" (QNS) by the lab.
- Because an oral fluid collection is observed, there is a lower risk of adulteration or tampering by the donor.
- Typically, an Oral-Eze collection takes 5 minutes or less and testing is performed the day the oral fluid specimen arrives at the laboratory.

Q: What drug testing situations are best suited to an oral fluid drug test?

A: Oral fluid testing is ideal for a broad range of testing situations ranging from pre-employment, to reasonable suspicion, to post-accident testing where the employer is interested in assessing what's in the donors system at the time of collection.

Q: What drugs are tested with Oral-Eze?

A: Our laboratory tests a variety of drugs in oral fluid including amphetamine, methamphetamines (including MDMA and its metabolite), cocaine (metabolite), marijuana (THC), opiates (codeine, morphine, hydrocodone, hydromorphone, 6-AM, oxycodones (oxycodone, and oxymorphone), and phencyclidine (PCP).

Q: Does Oral-Eze detect marijuana well?

A: Yes. New technology in oral fluid testing has proven effective in detecting recent drug use, especially for marijuana. Data from the Quest Diagnostics Drug Testing Index™ revealed that marijuana positivity has increased nearly 75% in oral fluid drug tests in the general U.S. workforce from 2013 to 2016.

Q: What are the cutoffs and analytes for the oral fluid test using the Oral-Eze?

A: See table below.

DRUG CLASS LEVEL	INITIAL TEST LEVEL	CONFIRMATORY LEVEL	CONFIRMATORY METHOD
Amphetamine	150 ng/mL	120 ng/mL	MS
Methamphetamines	120 ng/mL		
Methamphetamine		120 ng/mL	MS
MDMA		120 ng/mL	MS
MDA		120 ng/mL	MS
Cocaine metabolites	15 ng/mL		
Benzoylecgonine		6 ng/mL	MS
Marijuana	3 ng/mL	1.5 ng/mL	MS
Opiates	30 ng/mL		
Morphine		30 ng/mL	MS
Codeine		30 ng/mL	MS
Hydrocodone		30 ng/ml	MS
Hydromorphone		30 ng/mL	MS
6-AM		30 ng/mL	MS
Oxycodones	30 ng/mL		
Oxycodone		30 ng/mL	MS
Oxymorphone		30 ng/mL	MS
Phencyclidine (PCP)	3 ng/ml	1.5 ng/mL	MS

MS includes GC-MS, GC-MS/MS, or LC/MS-MS which may be used for some analytes

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 urine testing?

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. In 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: Where can I find information on drug usage trends in the U.S.?

A: We publish the Quest Diagnostics Drug Testing Index™ (DTI) as a public service for government, media and industry. It has been regarded as a benchmark for national drug positivity trends since first summarizing data from 1988. The strengths of the Drug Testing Index analysis include its large sample size, the longitudinal nature of the monitoring, a testing population that is generally reflective of the U.S. workforce and the quality of our company's drug testing services to confirm positive test results. The latest report and analysis can be found at QuestDiagnostics.com/DTI.

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

A: Yes. Both the Oral-Eze Oral Fluid Collection System and the immunoassay screening tests using the Oral-Eze collection system are FDA-listed.

Q: Who collects an oral fluid drug test specimen?

A: One of the advantages of an oral fluid collection is that the donor controls his or her specimen 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.

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

A. The Oral-Eze collection is complete when the sample adequacy window turns blue. This typically occurs within 5 minutes. In our studies, 83 percent of donors provided an adequate specimen in 5 minutes or less. With that said, every donor is different. Collectors should coach their donors regarding how to provide an adequate specimen 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. [Download our white paper](#) about average collection times.

Q: Is the Oral-Eze pad safe to put in a donor’s mouth?

A: Yes. The pad is a cotton-fiber filter paper that has not been treated with any salts or flavorings, offering an improved donor experience.

Q: How long must the donor’s mouth be empty prior to an Oral-Eze drug 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: Does coughing or talking affect the result because the donor removes the device from their mouth?

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

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

A: No. However, if sutures are located between the lower cheek and gum, it is better to collect the specimen from the opposite side of the mouth.

Q: Is a small amount of blood on the collection pad normal?

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

Q: What if the donor is taking medications and wants to write the names of the medications on the Custody and Control Form (CCF)?

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 MRO.

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

A. Once the Oral-Eze sample adequacy window turns blue indicating that a sufficient sample has been collected, instruct the donors to simply place their thumb on the ridges of the collector handle and slide forward (not push down) 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: 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 collection device 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 collection device should be placed in the donor's mouth no more than 2 minutes after the end of the collection of the first oral fluid specimen.

Q: How do I complete a Custody and Control Form for an oral fluid test?

A: A Custody and Control Form for an alternative drug testing specimen should be used for laboratory-based oral fluid drug test specimens. We offer a [video tutorial](#) that takes you through the step-by-step process to accurately complete a CCF for oral fluid collections.

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

A: 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. Quest published research in the *Journal of Analytical Toxicology* about the drug recovery and stability of Δ -9-tetrahydrocannabinol (THC), using Oral-Eze. The data demonstrates that Oral-Eze provides consistent and reproducible recovery and remarkable THC stability of from the point of collection through laboratory testing, storage, and final disposition.

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

A: Visit our website at Oral-Eze.com to learn more, watch a collection demonstration video and take our complimentary online oral fluid specimen collection training.

Q: What is the standard turnaround time for an Oral-Eze drug test?

A: Testing is performed the day an Oral-Eze drug test specimen 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 does the laboratory determine if the oral fluid specimen is valid?

A: We perform specimen validity testing (a test for albumin) on every oral fluid specimen, giving you the added assurance that the specimen is appropriate for testing. Albumin is an endogenous (naturally occurring) substance that is expected to be in all donors' oral

fluid/saliva. The test helps to ensure that the specimen is oral fluid/saliva and that there is sufficient amount of the specimen to perform the testing.

Q: Can the Oral-Eze test be used for U.S. Department of Transportation (DOT) and other regulated drug testing?

A: While the HHS is considering oral fluid for their testing, at this time neither HHS nor the DOT has approved any oral fluid drug testing system. On May 15, 2015, the Department of Health and Human Services (HHS) published *proposed* mandatory guidelines for using oral fluid in the Federal Register, the first step in the process of enabling the use of oral fluid for the drug testing of federal employees, and as a result, would remove the current requirement of using urine specimens only.

Q: Is oral fluid testing legal in all 50 states? Where is it prohibited?

A: Today, oral fluid testing for drugs can be performed throughout the country 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.

Q: How are the results reported?

A: As with all laboratory-based testing, oral fluid drug test 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.

Q: How are the initial and confirmatory levels reported for oral fluid testing?

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 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 cutoff is expressed (neat versus diluted) should not impact detection or positivity rates.

Q: If an oral fluid test is non-negative and confirmed 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: Can eating poppy seeds produce a positive drug test?

A: In an article published in the *Journal of Analytical Toxicology*, scientists from Quest Diagnostics Employer Solutions compared the impact of the consumption of raw poppy seeds and a poppy containing food product on urine and oral fluid drug tests. The results from this study suggest that there is less of a 'poppy seed defense' from a donor who completes an oral fluid drug test after casual dietary poppy seed consumption rather than a urine test because of the shorter detection window of oral fluid.

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

A: Simply use one of the provided air bills to ship the specimen via overnight courier to a Quest Diagnostics drug testing laboratory. Our Lenexa, Kansas laboratory performs oral fluid drug tests. [Take our online laboratory tour.](#)

Q: How long are non-negative oral fluid specimens retained by the laboratory?

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

Q: What testing methodology is used?

A: A two-tiered testing process is used:

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

Q: Is EIA forensically defensible?

A: Yes. EIA 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 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 specimens.

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: What is the liquid in the vial?

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

Q: Is 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: If I run out of Oral-Eze 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 is included in my supply order of Oral-Eze devices?

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

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

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

Q: Who should I contact with questions about urine drug testing from Quest?

A: Contact your Sales or Account Management representative for more information or call our National Customer Support Center at 1.800.877.7484.