OralTox® instant oral fluid drug testing
Frequently asked questions

Q: Why drug test?
A: Drug abuse in the workplace puts employers at 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: What is oral fluid drug testing?
A: Oral fluid drug testing offers a minimally invasive, observed collection to detect recent drug use. Using oral fluid, an employer can oversee a collection, reducing the likelihood of tampering or cheating, or a donor challenge later in the drug testing process.

Q: What is OralTox®?
A: OralTox is a lateral flow immunoassay, rapid oral fluid drug test manufactured by Premier Biotech. The OralTox device identifies the absence of illicit drugs within minutes and a result can be read as soon as test and control line appear on any strip (often within two minutes).

Q: What are some of the advantages of OralTox?
A: The advantages of OralTox oral fluid drug testing include:

- Fast test results available within minutes after the collection
- Patented design
- Easy-to-administer procedure with clear results
- FDA 510(k)-listed device
- Saturation indicator on device changes color when a sufficient sample of oral fluid has been collected
- Observed collection reduces the likelihood of donor cheating
- No secured restroom requirements
- Eliminates problems with shy bladder
- Less invasive means of collection that can be done by professionals anywhere and at anytime

Q: What drug testing situations are best suited to an OralTox instant test?
A: Instant oral fluid drug testing can be used for on-site collections at places of employment, hiring events, and job fairs, as well as at collection sites. The flexibility of OralTox provides options that suit most drug testing situations.

Q: How should I incorporate OralTox into my workplace program?
A: OralTox augments existing workplace drug testing programs when an immediate result is needed, an observed collection is desired, or when there is a lack of available secured
restrooms for urine drug test collections. Additionally, recruiting events and on-site testing scenarios present excellent situations for using OralTox.

Q: What is the detection window?
A: OralTox offers near immediate detection of drugs, often as little as two hours after ingestion.

Q: What drugs does OralTox screen for?
A: OralTox screens for amphetamines, cocaine, marijuana, methamphetamine, opiates, oxycodone, and PCP. Test panels can be configured to screen for five, six, or seven drugs. The drug cutoffs are below.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cutoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamines</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Cocaine</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Marijuana</td>
<td>40 ng/mL</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Opiates</td>
<td>40 ng/mL</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>10 ng/mL</td>
</tr>
</tbody>
</table>

Q: Is the OralTox device FDA 510(k) listed?
A: Yes. OralTox is 510(k) listed for amphetamines, cocaine, marijuana, methamphetamine, opiates, oxycodone, and PCP.

Q: Is OralTox effective at detecting marijuana?
A: OralTox is an effective instant oral device for screening THC. However, OralTox is not as sensitive as the Oral-Eze® lab-based oral fluid test when testing for THC.

Q: What is the OralTox saturation indicator?
A: OralTox has a built-in saturation indicator that changes color when a sufficient oral fluid sample has been collected. This mechanism eliminates completion time guesswork from the collection process and helps to reduce recollections stemming from an insufficient oral fluid sample.

Q: How do collectors administer an OralTox oral fluid test with a donor?
A: A collector gives the swab to a donor and instructs him or her to sweep the inside of their mouth (cheek, gums, and tongue) several times. The donor will hold the swab in their closed mouth until a red color on the saturation indicator strip appears in the indicator window of the swab. The donor must not suck or chew on the collection sponge.
Additionally, the donor should not remove the sponge from his or her mouth during the collection. The collection is complete when the saturation indicator changes color appears in the indicator window of the swab. Last, the donor removes collection swab from his or her mouth and hands it to the drug test collector.

Q: How long does an OralTox collection take to complete?
A: When the saturation indicator changes color in the indicator window of the swab, the collection is complete. Most donors will saturate the collection sponge within two to four minutes, however, a collection for individuals who experience dry mouth may exceed four minutes. If after seven minutes the saturation indicator has not changed color, discard the OralTox device and repeat the test.

Q: How does a collector activate an OralTox test for result interpretation?
A: The OralTox test should be placed on a flat surface and remain there for the duration of the test, enabling gravity to wick the oral fluid up the strips. Moving the device, lifting it up, holding it, or tilting it back to read results may interfere with the reading and move the specimen away from the strips. It can also increase the likelihood of an invalid drug test result. Once the handle locks into place, OralTox is airtight and tamper evident. A mechanism inside the OralTox device will now extract the maximum oral fluid sample volume amount for testing. After three minutes, the collector will check the OralTox device to ensure that lines are present for all of the drug test strips. Oral fluid has a tendency to form air bubbles, which can adhere to the bottom of the strip, and prevent result interpretation. If any of the test strips do not have lines beginning to form, gently tap the OralTox drug test device on the table or counter surface. This action will pop any air bubbles that may have formed around the base of the strips and allow capillary action to begin, thereby initiating the test.

Q: How does a collector read test results an OralTox device?
A: Negative drug test results using OralTox can be read as soon as the test and control line appear on any strip, typically within two minutes after the interpretation process begins. At ten minutes, the collector can interpret the OralTox drug test as negative, presumptive positive, or invalid. Any indication of a line in the test region should be considered a line and therefore a negative result. Results cannot be read after 20 minutes.

Q: What is considered an invalid result for OralTox?
A: An OralTox drug test is considered invalid when the control band fails to appear next to an instant drug screen result. Discard the device and repeat the drug test with a new OralTox test kit.

Q: How do I confirm a non-negative test result from an OralTox test?
A: A non-negative OralTox test can be confirmed by completing a second, laboratory-based drug test. We recommend confirming the result using a lab-based urine drug test collected at one of our network collection sites. The urine specimen will be screened and
confirmed at one of our drug testing laboratories. We also offer lab-based oral fluid testing as an option, depending on your testing needs.

It’s important to note that drug test results may vary between instant and lab-based testing as detection windows, drug cutoff levels, and metabolites vary between specimen types. This may lead to inconsistent results between the initial instant oral fluid test and the laboratory-based confirmation test.

Q: What is the difference between OralTox® and Oral-Eze®?
A: OralTox is a rapid oral fluid instant testing device that delivers results in minutes for recent drug use. OralTox is offered by Premier Biotech. Oral-Eze is a laboratory-based oral fluid collection system. Both feature an observed collection and sample adequacy technology to ensure a sufficient amount of oral fluid, or saliva, is collected for testing.

Q: What factors should be considered when evaluating instant and lab-based oral fluid drug testing?
A: The criteria used for evaluating an instant and laboratory-based oral fluid drug test include speed of a test result, window of drug detection, marijuana sensitivity, confirmation testing of non-negative results, drug cutoff levels, legal considerations, convenience, and cost.

Q: How is an OralTox test result reported?
A: An OralTox drug test result can be reported using two methods. For example, an employer can:
  • Record results in a digital file (PDF) or an organization’s internal system
  • Manually enter a result into the Quest Diagnostics drug testing portal called Employer Solutions Portal (ESP)

Q: Will the OralTox test result be shared with a donor after the collection?
A: The decision to share a drug test result with a donor is determined by the employer’s organization. In most cases, the donor is released from the collection area after the oral fluid specimen is collected and prior to reading the drug test result. This allows the process to continue and reduces unnecessary confrontation with a donor, especially if there is a non-negative result. Alternatively, organizations that prefer to complete the testing process with the donor present can release the donor if the OralTox screen indicates a negative result.

Q: What safeguards are built into the OralTox collection to help deter donor cheating and result tampering?
A: Because the OralTox drug test collections are observed and collected in the presence of the employer’s representative, cheating, tampering, and adulteration is difficult.
Q: Is collection training available for OralTox?
A: Yes. Collectors can take a comprehensive online training program that details device information and OralTox collection procedures. If the collector scores 100% on the quiz, he or she will receive a personalized certificate of training for their records.

Q: Is instant oral fluid drug testing permitted in the U.S.?
A: Workplace drug testing laws vary by state in the United States. Always check with a licensed attorney to ensure that your state permits both oral fluid and instant testing.

Q: How do I order OralTox test devices?
A: A Quest Diagnostics account number is required to order OralTox devices. Contact 1.800.877.7484 to set up your account and order OralTox drug testing kits.

Q: How do I properly store OralTox devices?
A: OralTox test devices should be stored at 36-86°F (2-30°C) in their sealed foil package. If storage temperatures exceed 86°F (30°C), test performance may be affected. If the product is refrigerated, an OralTox test device must be brought to room temperature prior to opening the pouch. Do not use an OralTox device after its expiration date.

Q: How much does an OralTox drug test cost?
A: Contact your Sales or Account Management representative for more information about OralTox pricing.

Q: Who should I contact with questions about OralTox?
A: Contact your Sales or Account Management representative for more information, or call our National Customer Support Center at 1.800.877.7484.