

FREQUENTLY ASKED QUESTIONS: ORAL FLUIDS TESTING

Q. How long after consumption can the individual drugs be detected in saliva?

- A. The time window during which drugs can be detected in oral fluid (or any other bodily fluid) depends on various factors; the sensitivity of the test, the quantity consumed, the frequency of consumption, the time between the drug consumption and the test and a person's individual metabolism. Various studies have shown that amphetamines/ methamphetamines remain in the saliva in sufficient quantities for detection for up to 50 hours, cocaine can be detected for up to 12-36 hours, opiates for up to 24 hours and marijuana for up to 24 hours. (See attached chart comparing blood, urine, oral fluids- Source: Verstraete, Alain G. Therapeutic Drug Monitoring, Volume 26 Number 2.)

Q. Do the test results provide legal proof of drug abuse?

- A. Any on-site drug test can only deliver a general "screening" result. After any non-negative or presumptive positive screening result, a confirmation analysis (e.g. GC/MS or GC/MS/MS) should be conducted. The confirmed positive result should then be verified by a licensed Medical Review Officer (MRO). This process is also highly recommended for any type of urine testing, including lab-based and Point of Care tests.

Q. Does the Federal Government prohibit oral fluid testing?

- A. Yes and No. Because the SAMHSA regulations only apply to lab-based urine testing for five drugs (THC, Cocaine, Opiates, Amphetamine, PCP) and because the U.S. Department of Transportation (DOT) drug and alcohol testing regulations are required by law to use the SAMHSA guidelines, there are no federal workplace programs using oral fluids testing. However, this does not mean that oral fluids testing is prohibited for non-DOT workplace testing. In fact, there are only two states in the U.S. where oral fluids testing is not approved in the state law. Many federal agencies permit and use oral fluid testing like the Federal Bureau of Prisons and U.S. Federal

Probation. For several years now, the Federal Government has been in the process of considering alternative specimens to urine to include hair and oral fluids, and other alternative substances, for DOT testing.

Q. Is it necessary to use a laboratory certified by the federal government's Substance Abuse and Mental Health Services Administration (SAMHSA) for oral fluid confirmation testing?

A. No, in fact, it is not possible. The SAMHSA laboratory certification only applies to urine testing. At the time that the SAMSHA regulations were first developed, and in each subsequent major amendment to the regulations, oral fluids testing was only being used by a very small number of employers. Consequently, the federal government did not consider creating standards for oral fluid testing. However, since that time the number of employers conducting oral fluid testing has increased significantly. Today many laboratories, including SAMHSA-certified labs, conduct oral fluid confirmation testing, though the SAMHSA certification still only applies to urine testing.

Q. Can saliva samples be adulterated?

A. While it is fairly easy to adulterate a urine specimen during an unobserved collection, it is very difficult to adulterate a saliva specimen when the collection is always being directly observed. There are new products being marketed that claim to give a "clean" oral fluids test. However, the likelihood of this happening is reduced dramatically in an observed collection when the OraLab instructions are followed:

1. Drink 4 ounces of water
2. Wait 10 minutes
3. Collect specimen
4. Observe the donor during this entire time

Q. How were the system's key performance data determined?

A. OraLab products undergo rigorous Quality Analysis and Quality Control testing with externally purchased saliva controls to determine that the precision and accuracy of each lot that is produced is within the specifications claimed in the package insert. Using laboratory analysis,

saliva samples are spiked with drugs to determine sensitivity, specificity and accuracy of the oral fluids testing.

Q. Will the OraLab device cross-react with drugs other than illegal drugs.

- A. Yes. Similar to urine, certain over-the-counter drugs and prescription drugs may cause a positive result in a pre-screen test using saliva. Refer to the cross-reactivity list in the package insert to see which drugs could cross-react. However this list is not all-inclusive. Any pre-screened positive should always be confirmed by a GC/MS confirmation at a lab and reviewed by a Medical Review Officer.

Q. Could passive exposure to marijuana smoke be used as an excuse by the donor for a THC positive result when using a saliva test?

- A. THC is detected in oral fluids based on the detection of the parent drug and not the metabolite. For this reason, there is concern that some donors might use the excuse of passive inhalation or contamination of the oral cavity as the reason for the positive result. One of the ways to address this problem in urine was to establish a cutoff level of 50ng/ml or higher before an individual is positive for THC. Similarly, the cutoff level for THC on the OraLab device is 50ng/ml. It is highly unlikely that an individual would ever inhale enough passive marijuana smoke to reach a cutoff level of 50ng/ml or higher.