

SAMHSA MANDATORY ORAL FLUID GUIDELINES

FAQs

The long-awaited release of the Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines for lab-based oral fluid drug testing (OFMG) has finally arrived. The Federal Register announced the new regulations via the reading room on Thursday, October 24 and published the regulations the following day. Of course, with the release of these new regulations, there are many questions. What follows are some of the most frequently asked questions so far, with an emphasis on “so far.”

Q. When do the new regulations go into effect?

The OFMG effective date is January 1, 2020. A 12-18-month implementation period will follow, giving laboratories, device manufacturers, Medical Review Officers (MROs), and collectors the time necessary to comply with the new regulations.

Q. Do the new regulations apply to employers mandated to drug test by the DOT or the NRC?

Currently, the new regulations only apply to drug testing of federal employees. The Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) must engage in their own rulemaking activities before covered employers can use lab-based oral fluid testing in compliance with those regulations. However, adoption of lab-based oral fluid testing by these agencies is anticipated. When the DOT and/or the NRC officially permit lab-based oral fluid testing, SAMHSA's OFMG will be their guiding document.

Q. Do the new guidelines replace lab-based urine drug testing?

No. Federal agencies may choose between urine and oral fluid drug testing, or utilize both testing methods as part of the same program. Under the regulations, either testing method may be used to detect the same drugs under the same circumstances as before. The drugs that can be tested for are marijuana/THC, cocaine, heroin, amphetamines, PCP, oxycodone, hydrocodone, oxycodone, oxycodone, and hydromorphone. These drugs can be tested for under the following circumstances: pre-employment, reasonable suspicion, post-accident, random, return-to-duty, and follow-up.

Q. Do the guidelines allow for testing with rapid or point of care (POCT) oral fluid tests?

No. The OFMG only permit laboratory-based oral fluid drug testing.

Q. Do the OFMG permit on-site collections?

Yes. Per the OFMG, employers will have the option of using trained employees and/or professional collectors to conduct oral fluid collections. These collections may take place at the workplace, or in other locations that meet the OFMG requirements for a collection site. Acceptable collection sites must permit observed collections, collector control of the device(s) throughout the collection process, record storage, and protect donor privacy.

Q. What is included in SAMHSA's oral fluid guidelines?

The OFMG are the oral fluid version of the Urine Mandatory Guidelines. Quoting from the regulations:

“The OFMG establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and methods, confirmatory oral fluid drug test analytes and methods, processes for review by a Medical Review Officer (MRO), and requirements for federal agency actions.”

Q. Is it really that simple?

Yes and no. Drug testing is a science and science can be complicated. One of the good things about the OFMG is they explain complicated issues in an easy-to-understand way. For example, the OFMG require oral fluid collection devices to be FDA-cleared. Among the requirements for FDA clearance is that a device must have a built-in volume indicator and be capable of collecting a least 1 mL of “undiluted (neat) oral fluid.” That sounds complicated, but, as an employer, if you use an FDA-cleared oral fluid collection device from a reputable company such as OraSure, for example, you'll be in compliance.

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Q. Will split specimens be required?

Yes, and the regulations make this requirement very easy to understand. Collections can be performed either simultaneously or serially, meaning a collector can use two devices, each of which must collect 1 mL of neat oral fluid, or the collector can use one device and subdivide the specimens into two, 1 mL samples. With a trained person conducting the collection, and with the use of an FDA-cleared device, oral fluid split specimens will not be a complicated issue.

Q. How do the OFMG affect state drug testing laws?

It is important to remember three key points relative to state drug testing laws:

1. If you are federally mandated to drug test, federal drug testing regulations always trump state drug testing laws. For example, regardless of what type of drug testing a state law may or may not permit, once the DOT approves lab-based oral fluid testing, covered employers will have the option of using both urine and oral fluid testing to comply with that agency's regulations.
2. Historically, only three states have prohibited lab-based oral fluid collections, although there is some impact based on the release of the OFMG. The other 47 states have historically permitted lab-based oral fluid to some extent, though some states have industry-specific regulations and/or workers' or unemployment compensation laws that specify how to conduct drug testing.
3. To an extent, some states require employers to follow the SAMHSA guidelines. We can assume that lab-based oral fluid testing will be permitted in these states once the 12–18-month implementation period is complete, if not sooner. The best advice is to always check local legal requirements to ensure compliance.

Q. Why did SAMHSA issue mandatory guidelines for lab-based oral fluid testing?

In the *Federal Register*, SAMHSA once again articulated the reasons why the agency decided to add lab-based oral fluid testing to the mandatory guidelines. These reasons include:

- **Enhanced Flexibility**— Oral fluid collections provide flexibility to address workplace drug testing needs by permitting the use of either urine or oral fluid, whichever specimen is best suited to the situation.
- **Enhanced Versatility**— Oral fluid collections can occur in a variety of locations and eliminate many collection issues found with urine.
- **Decreased Invalid Tests**— Oral fluid collections, by nature, are observed, which lessens the risks of substitution or adulteration.
- **Saves Time**— Oral fluid collections likely occur at or near the place of work, reducing the time needed away from work.
- **Versatility in Detection**— Oral fluid testing permits “more interpretive insight into recent drug use” due to drug detection immediately upon absorption into the body.

Q: How many drug tests will transition to lab-based oral fluid testing as a result of the OFMG?

SAMHSA estimates that about 7% of the roughly 150,000 annual drug tests of federal employees will transition to oral fluid in the first year, and about 25% after four years. SAMHSA also estimates the same transition rate for the 6 million DOT-mandated drug tests, or about 1.5 million eventually transitioning to oral fluid. If 25% of the nearly 40 million non-mandated workplace drug tests transition to oral fluid, that would be another 10 million or 16 million-plus when combined with the DOT drug tests.

However, according to drug testing industry experts who participated in a 2019 survey conducted by the Current Consulting Group and co-sponsored by OraSure Technologies, 53% of participants indicated that interest in lab-based oral fluid testing among their clients would increase once SAMHSA issued the OFMG. That was up from 38% in the 2018 survey.

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Federal agencies may choose between urine and oral fluid drug testing, or utilize both testing methods as part of the same program



Q: As an employer, what can I do to implement oral fluid testing?

If you are a non-regulated company that would like to begin conducting lab-based oral fluid testing now, speak with your OraSure representative to help with the following:

- Identify your drug-testing objectives
- Update your policy with specific lab-based oral fluid testing language
- Determine how you will collect oral fluid samples (on-site with trained employees and/or professional technicians or at off-site collection facility)
- Prepare supervisors/managers
- Ensure all vendors are ready to provide their services
- Announce the program to your employees

If you are a regulated company that would like to begin conducting lab-based oral fluid testing after the SAMHSA implementation period, speak with your OraSure representative to help with the following:

- Updating your SAMHSA drug testing policy to reflect the addition of lab-based oral fluid testing
- Training employees to conduct on-site oral fluid collections per the regulations, including securing the collection location, using the federal chain of custody form for oral fluid, collecting split specimens, and properly shipping specimens to a certified laboratory for analysis
- How to identify qualified professional collectors, certified laboratories, and trained medical review officers
- Note: SAMHSA- and DOT-covered employers may immediately begin utilizing lab-based oral fluid drug testing for their non-DOT or SAMHSA covered employees or in non-DOT or SAMHSA testing circumstances (OraSure can provide up-to-date state law information to help you comply with applicable legal requirements)

Have more questions? To learn more, contact us at (610)419-7657 or at chooseintercept@orasure.com

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