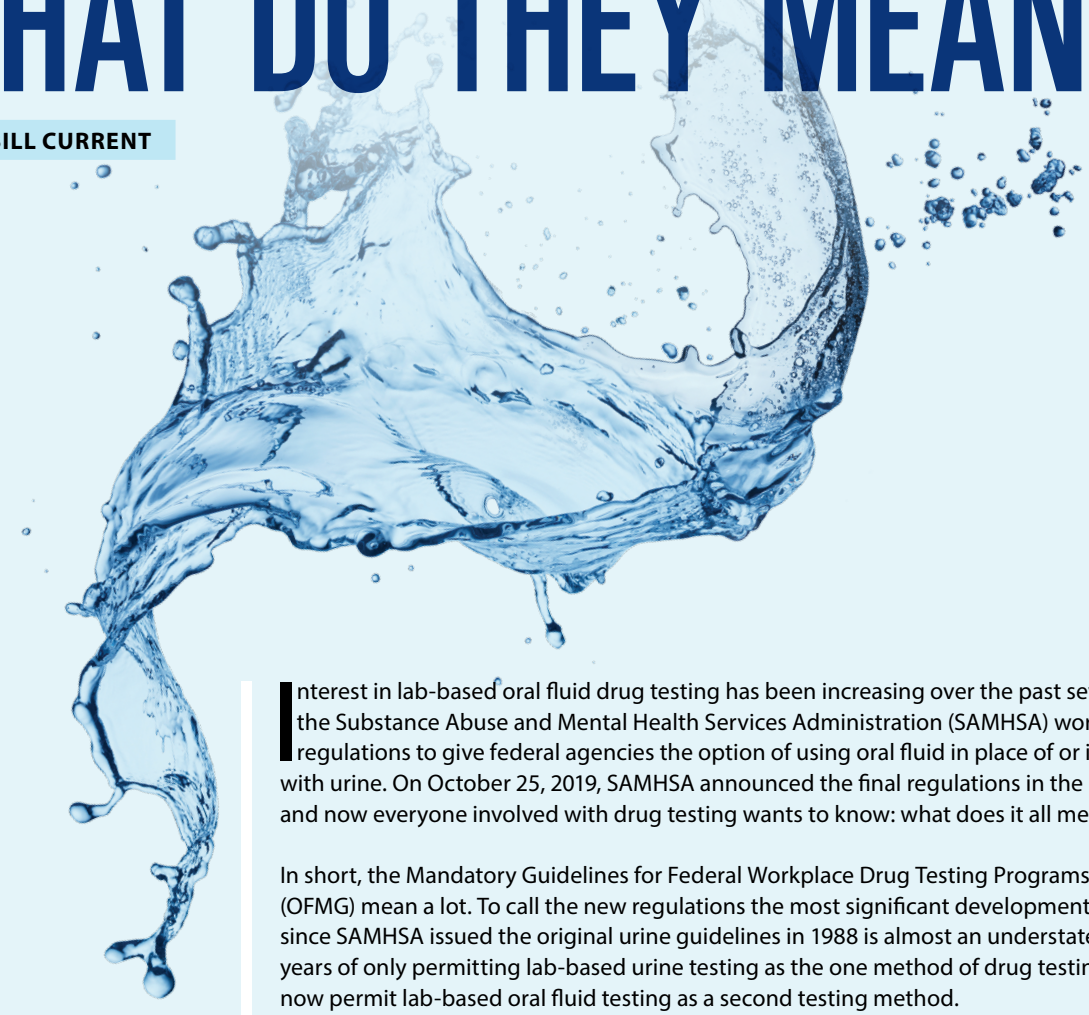
SAMHSA'S NEW ORAL FLUID GUIDELINES:
WHAT DO THEY MEAN?

BY BILL CURRENT



Interest in lab-based oral fluid drug testing has been increasing over the past several years as the Substance Abuse and Mental Health Services Administration (SAMHSA) worked to finalize regulations to give federal agencies the option of using oral fluid in place of or in combination with urine. On October 25, 2019, SAMHSA announced the final regulations in the Federal Register, and now everyone involved with drug testing wants to know: what does it all mean?

In short, the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) mean a lot. To call the new regulations the most significant development in drug testing since SAMHSA issued the original urine guidelines in 1988 is almost an understatement. After 30 years of only permitting lab-based urine testing as the one method of drug testing, the OMFG now permit lab-based oral fluid testing as a second testing method.

Although initially the new guidelines will only apply to federal workplace drug testing programs, they will have a profound impact on every aspect of how drug testing is sold and bought, how testing is conducted, and how results are used to maintain safe and drug-free workplaces.

So, why did SAMHSA develop these new regulations? There are lots of reasons, and they are articulated in the Federal Register announcement. Ultimately, SAMHSA has endorsed lab-based oral fluid testing primarily because of the science. SAMHSA has stated:

> "The scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established and the advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in federal programs with the same level of confidence that has been applied to the use of urine… the OFMG provide the same scientific and forensic supportability of drug test results as the Urine Mandatory Guidelines for Federal Workplace Drug Testing Programs."

The science of lab-based oral fluid drug testing is sound, credible, legally defensible, and can practically be applied to a typical workplace drug testing program. However, the issuance of new federal regulations is bound to have a broad impact on a diverse and complicated field such as the drug testing industry. Let's briefly review how the regulations will impact the four key players involved in a drug test: the buyer/employer, the collector, the laboratory and the Medical Review Officer (MRO).

The OMFG now permit lab-based oral fluid testing as a second testing method.

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The science of lab-based oral fluid drug testing is sound, credible, and legally defensible

What do the OFMG mean for employers/buyers?

Initially, the new regulations will only apply to federal workplaces. Eventually, it is anticipated that both the U.S. Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) will adopt lab-based oral fluid testing and, when they do, the OFMG will have a direct impact on covered employers. The stated goal is for the DOT to have their regulations for lab-based oral fluid testing in place by the time SAMHSA completes the 12-18-month implementation period.

The issuance of the OFMG will likely have a more immediate impact on non-government, non-mandated workplace drug testing. The OFMG serve as an official endorsement of lab-based oral fluid testing by the federal government, and the guidelines provide a new "gold" standard for how to best utilize the technology. This will give many employers a green light to begin implementing oral fluid testing either in place of, or in combination with, urine drug testing.

Additionally, while lab-based oral fluid testing has historically been legally permitted in 47 states, there are several states with general laws, industry-specific laws, or workers' and/or unemployment compensation laws that defer to the federal guidelines. This means that historically, employers covered by those state laws have only been permitted to utilize urine testing. Presumably, the OFMG now make lab-based oral fluid testing a viable option in some of those jurisdictions.

What do the OFMG mean for laboratories?

Laboratories that wish to offer oral fluid analysis must become certified before being able to do so in accordance with the OFMG. This is a rigorous process very similar to the one labs must go through in order to become certified to analyze urine specimens. Not all labs will choose to become certified for oral fluid testing. However, in the coming months and years, using a SAMHSA-certified laboratory will become the preferred way to conduct oral fluid testing, in much the same way that using a certified lab has been the preferred way to conduct urine testing for three decades.

What do the OFMG mean for collectors?

Just as is the current case with urine collections, the person who collects an oral fluid sample will be a key part of the drug testing process. The OFMG define a collector as someone "who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device." Hence, an oral fluid collector's training will cover two key parts—the regulations and the specific collection device being used.

The OFMG contain specific collection device requirements. For example, collectors may only use an FDA-cleared collection device. Among the requirements for FDA clearance, a device must have a built-in volume indicator and be capable of collecting a least 1 mL of "undiluted (neat) oral fluid."

Split specimen collections are required. The OFMG offers the following guidelines:

> "The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as 'A' (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as 'B' (split) either simultaneously or serially (i.e., using two devices or using one device and subdividing the specimen)..."

With a trained person conducting the collection and using an FDA-cleared device, oral fluid split specimens will not be a complicated issue.

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25-30% of all federal employee drug tests...will be conducted using lab-based oral fluid in four years

Regarding collection sites, the OFMG dictate that collections sites can be permanent or temporary facilities located either at a work site or a remote location. SAMHSA anticipates that many employers will choose to collect oral fluid samples at the work site in order to save time and boost productivity. Collectors must ensure that work site being used for collections meets all the requirements of an approved collection site.

What do the OFMG mean for MROs?

The OFMG require that oral fluid test results be reported to a qualified MRO for interpretation and final reporting to the federal agency or employer. MRO requirements and procedures parallel those in place for federal urine drug testing programs; however, the federal MRO handbook will be revised and updated in the upcoming months.

Conclusion

SAMHSA projects that approximately 25-30% of all federal employee drug tests, and eventually 25-30% of all DOT- and NRC-mandated drug tests, will be conducted using lab-based oral fluid in four years.1 If the same transition estimate is applied to the nearly 40 million non-mandated workplace drug tests conducted annually, it is easy to see how lab-based oral fluid testing will become a major force in the drug testing industry.

For the professionals who ensure the integrity of each drug test, such as collectors, labs, and MROs, the OFMG will become the "bible" for oral fluid drug testing. For employers, the OFMG will serve as the gold standard for lab-based oral fluid drug testing. For both groups, service providers and end users of their services, now is the time to prepare, so that when the 12-18-month implementation period is complete, all groups will be ready to take advantage of this exciting new development.

1. *https://www.federalregister.gov/documents/2019/10/25/2019-22684/mandatory-guidelines-for-federal-workplace-drug-testing-programs-oralfluid*

UPCOMING EVENTS

Why Multiple Testing Methodologies Are Better Than One Webinar
featuring Nina M. French
Dec. 3, 2019 | 2 p.m. Eastern

What is Oral Fluid Testing? Webinar
Jan. 28, 2020 | 2 p.m. Eastern

OraSure Technologies

220 East First Street, Bethlehem, PA 18015

800-ORASURE • chooseintercept@orasure.com