DOT'S NEW ORAL FLUID DRUG TESTING FINAL RULE:

WHAT DOES IT MEAN?

BY BILL CURRENT

Interest in lab-based oral fluid drug testing has been increasing over the past several years especially since October 25, 2019, when the Substance Abuse and Mental Health Services Administration (SAMHSA) issued final guidelines for lab-based oral fluid testing in federal agencies. Now, less than three years later, the U.S. Department of Transportation (DOT) has released its own final rule that will permit regulated employers to use lab-based oral fluid testing in place of or in combination with lab-based urine testing.

The DOT rule will have a profound impact on every aspect of how drug testing is sold and bought.

What does it all mean for the drug testing industry and employers? A lot!
When SAMHSA issued the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) in 2019 it was considered by many experts to be the most significant development in drug testing since SAMHSA issued the original urine guidelines in 1988. That said, the recent issuance of the new DOT oral fluid rule is something many of those same experts never thought would happen.

Although the SAMHSA guidelines only apply to federal workplace drug testing programs, they are the basis for much of the new DOT rule, though there are some significant differences, which we will cover later in this article. The DOT rule 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, even among non-DOT-covered employers.

So, why did DOT develop these new regulations? DOT highlighted the following benefits of oral fluid testing:

- Combating adulteration/substitution
- All collections are directly observed
- Potential cost savings
- Quick and easy specimen collections
- Fewer collection facility requirements
- Tighter window of detection
- Recent-use detection

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

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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).

What does the DOT rule mean for employers/buyers?

The issuance of the OFMG by SAMHSA in 2019 served as an official endorsement of lab-based oral fluid testing by the federal government, and the guidelines provided a new "gold" standard for how to best utilize the technology. This gave many employers a green light to begin implementing oral fluid testing either in place of, or in combination with, urine drug testing in the most legally defensible way possible. The new DOT rule will only further interest and the switch to oral fluids in the industry.

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, and in some cases the DOT regulations specifically. This means that historically, employers covered by those state laws have only been permitted to utilize urine testing. With the issuance of the DOT final rule, employers in those jurisdictions now have the option of taking advantage of the many benefits of oral fluid testing.

What does DOT final rule mean for collectors?

Just as has been the case with urine collections, the person who collects an oral fluid sample will continue to be a key part of the drug testing process. Oral fluid collector training following the DOT rule will cover two key parts—the regulations and the specific collection device being used.

Under the newly released DOT final rule, collectors may be employers or employees of the employer's company as an alternative to professional technicians. The person being tested cannot conduct their own test nor can a direct supervisor or relative of the person being tested, though some exceptions may be applicable under certain circumstances.

The DOT rule defers to the OFMG regarding many collection device requirements. Collectors may only use an FDA-cleared collection device. Among the requirements, a device must have a built-in volume indicator and be capable of collecting a least 1 mL of "undiluted (neat) oral fluid" OR "an otherwise sufficient amount of oral fluid…to permit an HHS-certified laboratory to analyze the specimen(s)." DOT outlined strict requirements around some device specifications, including the ability for a device to be broken into two/separated into two collection bottles. DOT collections may not occur on two separate devices, even if done concurrently.

Split specimen collections are required by DOT, which 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)..."

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

What does the DOT final rule mean for laboratories?

Laboratories that wish to offer oral fluid analysis must become certified before being able to do so in accordance with the Department of Health and Human Services (DHHS)/SAMHSA. 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 DHHS-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.

It is important to note that the DOT oral fluid rule, which went into effect June 1, 2023, is not truly in effect until there are at least two laboratories certified by SAMSHA to conduct oral fluid testing, one to perform the initial and confirmation tests, and another to analyze split specimens in the event of a challenge to the initial test results. Oral fluid testing will not be available to DOT-regulated employers until such a time as this occurs.

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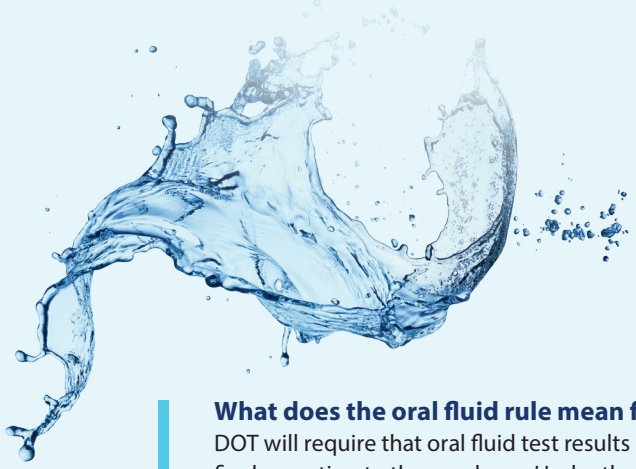

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What does the oral fluid rule mean for MROs?

DOT will require that oral fluid test results be reported to a qualified MRO for interpretation and final reporting to the employer. Under the final rule, MRO requirements and procedures parallel those in place for federal urine drug testing programs.

Transition to oral fluid

At the time, SAMHSA projected that in four years approximately 25-30% of all federal employee drug tests, and eventually 25-30% of all DOT- and Nuclear Regulatory Commission (NRC)-mandated drug tests would be conducted using lab-based oral fluid. DOT did not project how many employers they are anticipating will make the switch, but it is likely that the SAMHSA estimate likely still stands and may in fact be low.

In a 2022 survey of drug testing providers conducted by the Current Consulting Group (CCG), when asked which drug testing method will be most used in the future, about 50% said urine and 44% said oral fluid. That represents a significant paradigm shift among those who sell drug testing.

That said, if the predicted transition rate of 25-30% 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 is on its way to becoming a very commonly utilized drug testing method in the workplace market. It also likely means that many employers who may have been conflicted about continuing their drug testing programs due to budgetary concerns, the legalization of marijuana or a reluctance to rely on urine testing, when given the alternative of oral fluid testing, will choose to keep their drug screening policies in place.

Conclusion

For the professionals who ensure the integrity of each drug test, such as collectors, labs and MROs, the OFMG guidelines and the new DOT final rule will become the "bible" for oral fluid drug testing. For employers, these guidelines will serve as the most legally defensible standard for lab-based oral fluid drug testing. For both groups, service providers and end users of their services, now is the time to consider how 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
2. *"The 2022 Drug Testing Industry Survey." Conducted by the Current Consulting Group.*

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