

# SmartNotes

## Q&A

### Thermo Scientific Oral Fluid Assays for Drug Testing in the Workplace

Oral fluid is one of the fastest growing matrices used in drug of abuse testing, and part of the Thermo Scientific™ extensive menu for drugs of abuse testing. The following document is designed to provide an overview of oral fluid testing and how it fits into your current laboratory workflows for workplace testing.

#### What are oral fluids?

Oral fluid is the liquid found in the oral (mouth) cavity. It consists of saliva from the salivary glands, cells, and tissue of the gum and cheek, cellular debris, microorganisms, and food residues. Oral fluid primarily consists of water, but also contains electrolytes and enzymes. There is passive diffusion from the blood into the saliva. Therefore, drugs may be detected in oral fluid shortly after oral administration and absorption into the blood. That is why oral fluids **detect recent drug usage**. Oral fluids can also be used as an alternative or compliment to urine drug testing.<sup>1,2</sup>

#### Why use oral fluids for drug testing?

- **Reduce the risk of sample adulteration**  
Oral fluid collection is observed from start to finish, greatly reducing the risk of sample adulteration, and provides easy, on-site collection.
- **Detect recent drug use**  
Oral fluids have the shortest detection window and can differentiate between current vs. past marijuana use.
- **Collect samples anywhere or anytime**  
Oral fluid collection is non-invasive and easy to collect, making it ideal for workplace screening. It provides flexibility and versatility adding convenience to the laboratory workflow.
- **Positivity rates are equivalent or slightly higher than urine**  
Oral fluids primarily detect the parent compound reducing false negatives due to non-reacting metabolites.



### Oral fluid collection reduces the risk of sample adulteration

One of the biggest concerns with urine testing is that the sample can be adulterated, causing the sample to provide a false negative result. Therefore, collection procedures are required to track the “chain of custody” to ensure the sample is not adulterated. For urine, patients must go to a collection station and are supervised throughout the collection process. In some cases this means someone of the same gender may actually watch the full collection process and in others a full protocol is required. Shy bladder (or the inability to urinate) can be an issue. Once collected the sample is sent to the laboratory for analysis. Even with these procedures and additional sample validity testing, drug abusers are still able to cheat the system. All of these procedures add extra time and costs to the test.<sup>1,2</sup>

The collection process is supervised from start to finish. A collection device containing an absorbent pad is placed in the patient’s mouth and some devices, such as the Oral Eze® Collection Device available from Thermo Fisher Scientific, have a colored indicator window to signal when there is enough oral fluid on the pad (usually 1 mL). The pad is then placed in a buffer and sent to the laboratory for analysis. The complete process generally takes less than 10 minutes.<sup>3,4</sup> Since privacy is not an issue, collection can be performed on-site (anywhere, any time) making it easier and more convenient for the patient, providing faster turnaround time for the final result, and saving both time and money.

### The Oral-Eze Collection System



1. Collect

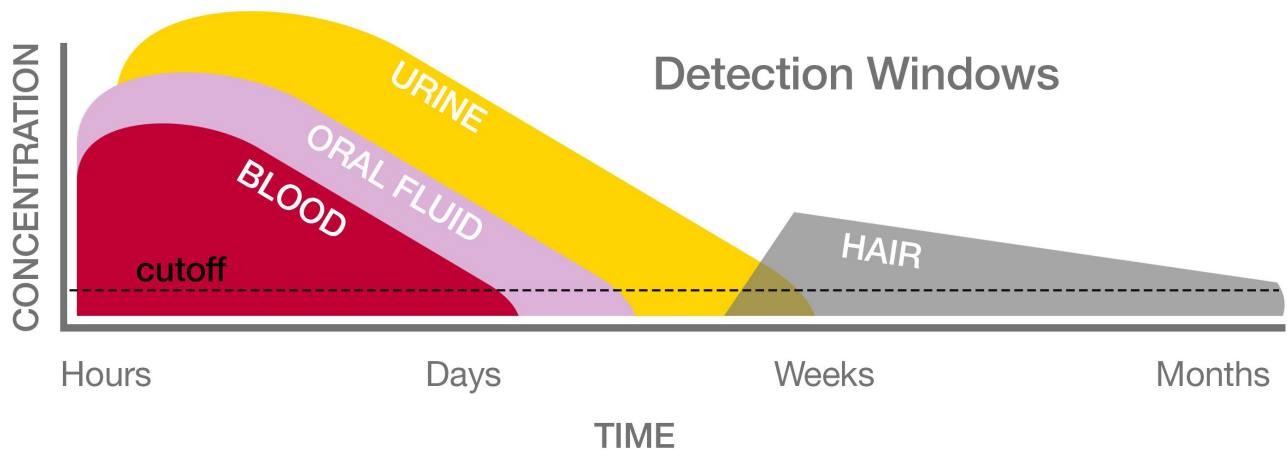
2. Check

3. Detach

4. Cap

### Oral Fluids detect recent drug use

Detection window is when the drug can be detected in the sample. Oral fluid detection windows are generally comparable to blood, and have the shortest detection time. Urine generally takes a bit longer and hair, the longest and is best for determining drug use history. Below is a graph showing detection windows.<sup>5</sup>



The chart below shows the detection window for commonly tested drugs in different matrices. Please note detection times vary based on drug dose, frequency, and cut-off level used for analysis.<sup>6,7,12</sup>

Drugs & Metabolites	Oral Fluid	Urine	Hair
Amphetamine	20-50 hours	Single dose: 24-72 hours Chronic: 9 days	Up to 90 days
Methamphetamine	6-76 hours	Single dose: 31-96 hours	
Cocaine	Single dose: up to 12 hours Chronic: 8-48 hours	Single dose: 14-59 hours Chronic: 123-218 hours	
Cannabinoids (THC)	2-24 hours	Single dose: 9.3-78.4 hours Chronic: up to 67 days	
Opiate	24 hours	36-48 hours	
Phencyclidine (PCP)	1-48 hours	1-3 days	
Barbiturates	50 hours	5-6 days	
Benzodiazepines	5-50 hours	2-7 days	
Methadone	24 hours	24-96 hours	
Oxycodone	1-48 hours	Single dose: 12-36 hours	
Buprenorphine	Up to 5 days	4-8 days	
6-AM	0.5-8 hours	Up to 34.5 hours	

### Oral Fluid positivity rates are equivalent to slightly higher than urine

Once a drug is ingested or smoked, the parent drug is broken down by the body into its metabolites. The parent drug is frequently found in oral fluids, where urine generally measures only the metabolites. This means oral fluids can often distinguish between different classes of drugs, reducing false negatives due to non-crossreacting metabolites.<sup>2</sup>

The detection levels for oral fluids are lower than urine, and detect recent drug use. In some cases, such as marijuana detection, the two matrices (oral fluids and urine) may be complimentary to each other. THC has high lipid solubility and is stored in the fatty cells. This is associated with slow excretion of the drug and its metabolites in urine. A single use of marijuana can result in positive urine results for up to a week, and in long-term or chronic users can produce positive results for over a month. Oral fluids only detect recent marijuana use and only the psychoactive component of marijuana (parent and active metabolites). The use of both matrices, oral fluid and urine, can distinguish between past and current usage.<sup>8</sup>

# Workplace Testing Overview

In 2015, 5% or about a quarter of a billion people globally used drugs. Of these, an estimated 29.5 million people - or 0.6% of the global adult population suffers from drug use disorders, including dependence.<sup>9</sup> Over 60% of the world's illicit drugs are consumed in the US, and the majority of these drug users are employed part-time or full-time.<sup>10,14</sup> According to the National Council on Alcoholism and Drug Dependence (NCADD) drug abuse costs employers \$81 billion annually in absenteeism, loss of company productivity, profitability, not to mention the health, safety and welfare of the staff and public. That is why approximately 4 out of 5 major US companies perform drug testing.<sup>11</sup>

In the workplace screening is done both pre- and post-employment with the goal of creating a drug-free workplace. There are 7 categories of workplace drug screening and together they build and maintain a drug-free workplace program; Pre-Employment Testing, Random Testing, Reasonable Suspicion Testing, Periodic Testing, Post Accident Testing, Return to Duty Testing, and Follow-Up Testing.<sup>10,12,13</sup> Urine and oral fluids can be used in all cases though oral fluid may be a better alternative for unscheduled testing since it can be collected on-site, anytime, anywhere, and detects recent drug use. The table below summarizes each type of testing with recommended matrices.

Workplace Segment	Definition	Scheduled	Suggested Matrix
<b>Pre-Employment Testing</b>	First step of a drug screening program. It is generally performed after a conditional offer of employment has been made. This is the easiest drug screen for employees to pass and is used to screen out applicants with drug abuse issues.	Yes	Urine - testing is relatively inexpensive and detects drug use within approximately 1-7 days after use.
<b>Random Testing</b>	Testing is unannounced and occurs randomly. It is arguably the most effective deterrent of employee drug uses.	No	Oral Fluid - samples can be collected on-site, samples are difficult to adulterate and detects more recent drug use.
<b>Reasonable Suspicion Testing</b>	Testing is performed for suspected cause. Supervisors and managers should be properly trained to recognize signs of drug abuse. An employee under suspicion should not be allowed to drive themselves to a collection center until a negative result is confirmed.	No	Oral Fluid - sample can be collected on-site rather than having two people away from work (employee and driver), sample is difficult to adulterate and it detects more recent drug use.
<b>Periodic Testing</b>	Tests current employees at defined time periods throughout the year.	Yes	Either Oral Fluid or Urine - similar to pre-employment testing. Urine will have a longer detection window but oral fluid samples can be collected on site, so there is no employee downtime.
<b>Post-Accident Testing</b>	Testing is performed to determine if an accident was caused by a positive drug test. It should be conducted within 12 hours of an accident. A positive result could be cause for dismissal.	No	Either Oral Fluid or Urine - urine will have a longer detection window but oral fluid samples can be collected on site, are difficult to adulterate, and will detect more recent drug use.
<b>Return To Duty Testing</b>	Testing is performed on employees who have been previously suspended.	Yes	Urine - similar to pre-employment testing. Urine will have a longer detection window.
<b>Follow-Up Testing</b>	Testing is performed unannounced on previously suspended employees. It is a follow-up to the return to duty testing.	No	Oral Fluid - samples can be collected on-site, samples are difficult to adulterate and detects more recent drug use.

Note: At the time of publication of this SmartNote, SAMHSA does not allow oral fluid use for federal workplace drug testing programs.<sup>19</sup>

## Oral fluid drug testing fits into current laboratory workflows

Using the same laboratory collection sites, the Oral-Eze Oral Fluid Collection System makes sample collection:

**Fast** – approximately 10 minutes

**Easy** – 4 simple steps

**Observed** – reduced chance of sample adulteration

**Assured** – 100% agreement with LC-MS/MS near cut-off calibrator concentrations

Samples can be collected at the customer site or just about anywhere. That's why oral fluids are the perfect matrix for unscheduled testing, such as random workplace screening. The Oral-Eze Oral Fluid Collection System uses the same shipping method already in place at the collection sites as the drugs are stable in the Oral-Eze buffer for up to 21 days at 2-30°C. Once the sample arrives at the laboratory it can be run on any or all of the 11 different drugs of abuse assays, in different configurations to meet the laboratory's drug testing needs.

Applications are available on most commonly used instrumentation and yield approximately 700 tests/kit depending on the analyzer. Each assay uses Thermo Scientific™ CEDIA® Technology which is used by laboratories worldwide, both large and small. Reporting follows the same workflow used for urine; negative screening results are reported out and non-negative results are sent for confirmation and MRO review. Thermo Scientific CEDIA oral fluid assays have excellent agreement with LC-MS/MS. With oral fluids labs will see similar to slightly higher positivity rates compared to urine. For more information, please refer to product package inserts available on our website.

## Workplace Testing Workflow

### Observed Sample Collection



- Use existing collection sites and shipping methods with the Oral-Eze Collection System
- Provides option to collect on-site for unscheduled testing such as Random Workplace Screening
- Greatly reduces sample adulteration because collection is observed from start to finish
- Drugs are stable in the Oral-Eze Collection Device for up to 21 days at 2-30°C

### Automated Screening



- 11 different OFT assays in different size configurations to meet laboratory needs
- Detects recent drug use and compliments urine testing for drugs that stay in the urine longer, i.e. THC and Benzodiazepines
- Assays can be run on commonly used instrumentation providing approximately 700 tests/kit, depending on the analyzer
- Proven CEDIA Technology

### Test Results

Screening Results	
Test	Result
Amphetamine	Negative
Barbiturates	Negative
Benzodiazepines	Negative
Cannabinoids	Negative
Cocaine	Negative
<b>Opiates</b>	<b>Positive</b>
<b>Oxycodone</b>	<b>Positive</b>
Buprenorphine	Negative

### Negative Screening Result

- Report results to employer
- Excellent agreement between Thermo Scientific oral fluid screening assays and LC-MS/MS; 100% agreement near the cut-off calibrators

### Non-Negative Screening Result

- Confirmation testing and MRO review
- Positivity rates in oral fluid are similar or slightly higher than urine



# Automation vs. Point of Care Testing

Workplace drug screening, especially in the US, is one of the most developed and regulated applications. Laboratories receive numerous samples for both urine and oral fluids.<sup>9</sup> Based on the number of samples, automated analysis is much easier and more economical compared to point of care (POC) testing. Today POC oral fluid testing is primarily used in the field to detect driving under the influence. These tests use lateral flow and are read visually. Though they are improving, POC assays are generally considered less accurate and less precise than automated testing.<sup>16,17</sup> Below is a comparison between automation and POC.

Feature	Automation	POC	Benefits
Runs Multiple Patient Samples in a Single Run	✓	✗	Saves time and money
Tests Multiple Drugs In a Single Run	✓	✓	Saves time
Test 1 to Over 1000 tests/hour*	✓	✗	Saves time
Improved Accuracy at Drug Cutoff Level	✓	✗	Reduces false positive and false negative results, saving time and money
Barcode Providing Positive Sample ID	✓	✗	Reduces errors
Daily Quality Control	✓	✗	Confidence in results - ensures the highest levels of accuracy and precision
Automated Reporting	✓	✗	Streamlines documentation, reduces errors

\* Please refer to the manufacturer's product specification for chemistry analyzer of interest.

## Regulations

Worldwide countries are struggling with drug abuse. Each country incorporates different directives to control drug use. These include disrupting drug traffickers to supporting recovery services which help users break their habit.<sup>18</sup> Drug screening in the workplace is performed to identify users and help promote a drug-free environment. Guidance documents are provided to define standards for oral fluid testing. These documents are regulated by different agencies around the world and do not always include the same cut-off levels. Drug tests need to comply with these guidelines though in some cases these are still in the proposal stage. In these cases manufacturers either develop cut-off levels based off of previously published standards, proposed guidelines and/or input from subject matter experts. Once the guidelines are approved manufacturers will revise their assays to meet the new guidelines.

## Key takeaways regarding the regulatory environment:

- Over 60% of illicit drug use occurs in the US, and US workplace testing is the most developed and regulated.<sup>10</sup>
- Drug testing is needed to provide accurate and precise results that can be used in the workplace or criminal justice system to support the regulations.<sup>15</sup>
- U.S. and Australia/New Zealand guidelines are in the proposal stage with recommended new cut-off levels.
- The US FDA has announced an FDA exemption allowing test kits to be used in reference laboratories for non-federal workplace and insurance screening. Thermo Scientific assays for CEDIA Barbiturates, Benzodiazepines, Buprenorphine, Methadone and Oxycodone will soon be FDA exempt.<sup>19</sup>
- Thermo Scientific has 510(k) approved oral fluid assays for CEDIA Amphetamine, Methamphetamine, Cocaine, Cannabinoids (THC) Opiates, and Phencyclidine (PCP).<sup>4</sup> The majority of oral fluid test kits are for forensic use only.

# Thermo Scientific Oral Fluid Assays

- Complete line of oral fluid test kits including a collection device with a color indicator to ensure there is sufficient fluid to run the test
- 11 Oral fluid assays in different size configurations to meet laboratory needs
- Proven CEDIA technology for maximum accuracy and sensitivity



## Ordering Information

CEDIA OFT	Reagent Kits	Calibrators			Controls			
Description	MCC (1 x 65 mL)	Negative Calibrator Part Number	Cut-off Calibrator Part Number	Calibrator Cut-off (ng/mL)*	Control Part Number	Control-Low (ng/mL)	Control-High (ng/mL)	
<b>Amphetamine</b>	10014947	10014954	10014955	50	10014957	25	75	
<b>Cocaine</b>	10014764			5		2.5	7.5	
<b>Opiate</b>	10014873			10		5	15	
<b>Phencyclidine (PCP)</b>	10014888			1		0.5	1.5	
<b>Barbiturates</b>	10022348		10022355	10022356	20	10	30	
<b>Benzodiazepines</b>	10022349				1	0.5	1.5	
<b>Methadone</b>	10022350				5	2.5	7.5	
<b>Oxycodone</b>	10022351				10	5	15	
<b>Buprenorphine</b>	10022352		10022376	10022377	1	10022377	0.5	1.5
<b>Methamphetamine</b>	10014949		10014950	10014951	40	10014953	20	60
<b>Cannabinoids (THC)</b>	10014910	10014922	10014923	1	10014925	0.5	1.5	

\* Diluted value. For neat value multiply by 3.

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