National Laboratory Certification Program
DRUG TESTING MATTERS

2023

# Validating Specimen Collection Devices for Oral Fluid Drug Testing

*This is the fifth part of the **Drug Testing Matters** series on drug testing method validation. This part covers validating oral fluid specimen collection devices. The first part covered validating immunoassay methods; the second part covered validating specimen validity tests (SVT); and the third and fourth parts covered validating mass spectrometry methods.*

## Oral Fluid Overview

Since 2004, improvements to oral fluid drug testing include enhancing measurand sensitivity and specificity, growing the scientific literature base for test methods and interpreting test results, and adopting oral fluid testing in non-regulated workplace and clinical drug testing sectors. In 2011, the federal U.S. Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) Drug Testing Advisory Board decided to support oral fluid as an alternative specimen to urine following a review of the physiological composition of oral fluid, tested drugs and cutoffs, collection devices, and best practices for laboratory methodologies (initial and confirmatory testing). The *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid* (OFMG) (published October 25, 2019) were effective January 1, 2020 (1).

Oral fluid is a complex solution comprising saliva (from submandibular, sublingual, parotid, and minor salivary glands), crevicular fluid (from between the gums and teeth), cellular debris, bacteria, and food residues (2, 3). The oral fluid matrix is water with electrolytes (e.g., potassium, sodium, chloride, bicarbonates, and phosphates) and various organic substances (e.g., enzymes, immunoglobulins, and mucins) (4). The volume of saliva production varies from about 500 to 1,500 mL per day, and the volume of buccal cavity oral fluid that remains after swallowing averages about 1 ml (0.9 mL for male adults; 0.8 mL for female adult) (5). Oral fluid is dynamic and changes with the flow rate of saliva production. Saliva pH is generally more acidic than plasma pH (pH 7.4) and may range from 6.0 to 7.8. Oral fluid pH rises as increased saliva flow increases the amount of bicarbonate (6).

Drug excretion into oral fluid is somewhat different than into urine:

- Direct Deposition – Deposition of parent drug into oral fluid occurs by multiple routes of administration, including oral, insufflated (snorted), transmucosal, inhaled, and smoked. Following direct deposition of parent drug, metabolites generally appear later in oral fluid. For some drugs (e.g., cocaine and heroin), hydrolysis of parent drug to metabolite(s) may occur (7, 8).
- Passive Diffusion – Diffusion of free, non-ionized, non-protein bound drug (and metabolites) from blood into oral fluid is the primary means of entry. Lipophilic drugs diffuse into oral fluid more readily than water-soluble metabolites. Parent (unmetabolized) drug is frequently the primary analyte present in oral fluid.

Drug use detection times are influenced by many factors, including molecular characteristics of the drug (lipophilicity, pKa), dose, route of administration, frequency of drug use, biology of the individual, specimen type, and the sensitivity of the detection system. In general, drug detection times in oral fluid are somewhat shorter than observed for urine—oral fluid detection time is 5 to 48 hours after use; urine detection time is 1.5 to 4 days (or longer with chronic drug use) (9, 10). Drug test positivity rates (non-regulated workplace testing) for oral fluid are the same as or higher than urine positivity rates and demonstrate the equivalency of these specimen types in detecting drug use.

Oral fluid has inherent specimen collection advantages over urine as a drug test specimen. Oral fluid collection occurs using direct observation, which should lessen the risk of donors manipulating the specimen (e.g., substitution and adulteration) and, unlike direct observed urine collections, the specimen collector does need not be the same gender as the donor.

## Oral Fluid Specimen Collection and Device Overview

The following oral fluid specimen collection criteria are based upon the requirements of the OFMG.

Oral fluid specimen collection may be performed using:

- A collection device using a pad placed in diluent after collection, or
- Expectoration into a device. (For oral fluid specimens collected by expectoration, follow the same/similar criteria as applicable.)

### *Collecting an oral fluid specimen*

- The collection device must maintain the integrity of such specimens during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites.
- The collector must collect 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[a] (i.e., using two devices[a] or using one device and subdividing the specimen).
- If the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen), the A and B tubes must have a volume marking clearly noting a level of 1 mL.

### *Oral fluid collection device minimum requirements*

- An oral fluid specimen collection device must provide the following:
  - An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected
  - A sealable, non-leaking container that maintains the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites
  - Components that ensure preanalytical drug and drug metabolite stability
  - Components that do not substantially affect the composition of drugs or drug metabolites in the oral fluid specimen
- Minimum performance requirements:
  - Reliable collection of a minimum of 1 mL of undiluted (neat) oral fluid
  - If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):
    - The volume of oral fluid collected should be at least 1.0 mL ±10%
    - The volume of diluent in the device should be within ±2.5% of the diluent target volume
  - Stability (recoverable concentrations ≥80% of the concentration at the time of collection) of the drugs and/or drug metabolites for 5 days at room temperature (64°F–77°F/18°C–25°C) and under the manufacturer's intended shipping and storage conditions
  - Recover ≥80% (but no more than 120%) of drug or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff

***The remainder of this publication focuses on validating oral fluid specimen collection devices.***

[a] *Department of Transportation (DOT) Part 40 regulations may be different.*

## Oral Fluid Specimen Collection Device Validation[a]

### *Industry Standards*

The method validation requirements described in this article are defined by the HHS and the National Laboratory Certification Program (NLCP) (1, 11) for HHS-certified laboratories that test donor oral fluid specimens in compliance with the OFMG. HHS-certified laboratories conduct forensic drug testing for federal agencies under Executive Order 12564 and Public Law 100-71 and for specific federally regulated industries. The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs affect all federal employees in a testing designated position, which is defined by each agency's Drug-Free Workplace Program.

Additional standards and guidance for forensic drug testing applications are published by the American National Standards Institute and the American Association of Forensic Sciences Standards Board (ANSI/ASB) (12). The ANSI/ASB Standard 036 "Standard Practices for Method Validation in Forensic Toxicology" publication defines forensic toxicology validation practices, such as consensus standards, practice, and protocols, including quality assurance and quality control.

For Clinical Laboratory Improvement Amendments (CLIA) certification of clinical laboratories, the Centers for Medicare & Medicaid Services (CMS) requires laboratories to verify or establish performance specifications for any test system used by the laboratory on or after April 24, 2003 (13).

The goal of validating oral fluid specimen collection devices is to provide objective data that (1) demonstrate that the device performs according to its intended use and (2) establish the device limitations under normal operating conditions. Before implementing new or modified oral fluid collection devices for use with testing donor specimens, laboratories are required to validate their performance.

### *Documentation*

Validation records must include sufficient information to facilitate third-party comprehensive review of studies performed. The study summary and the laboratory's standard operating procedures must describe acceptance criteria for validation study data, agreement of replicate study samples, and defining or excluding true outlier values. Confirmatory test sample analysis must meet the same qualitative criteria (e.g., retention time, mass ratio, internal standard abundance, chromatography criteria) used for specimen analysis.

At a minimum, validation study records must include the following:

- A stated purpose for the validation
- Description of test methods
- Identity of the instrument(s) used for the study
- A listing of the instrument parameters used for the study
- Description of the study samples

[a] *For clarity, this series of articles uses "validation" to cover all aspects of laboratory methods performance assessments, including verification of unmodified FDA-cleared and FDA-approved assays and devices and the validation of laboratory-developed assays.*

- Summary of the statistical data collected to characterize the assay
- A discussion
- A summary with conclusions
- All raw analytical data from the samples analyzed in the study

Laboratories must maintain the validation study records for an indefinite period. Records for validation studies performed within the last 12 months must be available for review during NLCP inspections.

Each end-user laboratory must validate the oral fluid collection devices. Off-site validations performed by other entities (e.g., manufacturer, other laboratory) may be used only to provide additional documentation.

### *Validation of Oral Fluid Collection Devices*

Oral fluid devices must be validated by the laboratory before implementation in regulated testing. The following studies are required:

- Volume of collected oral fluid*
- Volume of diluent*
- Analyte recovery
- Analyte stability

** Validation of the volume of collected oral fluid and diluent is only required for devices using a diluent.*

*Note: The laboratory should assess devices from three different lots by dividing the number of replicates evenly between the lots. If three lots are not available, the laboratory can conduct the validation with the available lots but must conduct additional studies before using new device lots until data from three lots are available. See Exhibit 1 for examples.*

*Exhibit 1. Required Devices When Three Lots Are Not Available*

| Total devices required | Available lots | | | Lots available later | |
|---|---|---|---|---|---|
| | Lot 1 | Lot 2 | Lot 3 | Lot 2 | Lot 3 |
| **Three lots available** | | | | | |
| 15 total devices | 5 devices | 5 devices | 5 devices | N/A | N/A |
| 6 total devices | 2 devices | 2 devices | 2 devices | N/A | N/A |
| **Two lots available** | | | | | |
| 15 total devices | 8 devices | 7 devices | | 5 devices | |
| 6 total devices | 3 devices | 3 devices | | 3 devices | |
| **One lot available** | | | | | |
| 15 total devices | 15 devices | | | 5 devices | 5 devices |
| 6 total devices | 6 devices | | | 3 devices | 3 devices |

### *Volume of Collected Oral Fluid*

*Only required for devices using a diluent.* Collect specimens from 15 volunteers and determine (volumetrically or gravimetrically) the volume collected. It is acceptable to use the difference between the weight of the complete device, or the pad, before and after collection. The collected oral fluid volume should be within 90% and 110% (±10%) of the manufacturer specified volume, which should be understood as a 95% prediction interval (95% of all devices should meet requirement). Laboratories may calculate the interval as the mean plus or minus two standard deviations.

In addition, laboratories should investigate the robustness of the collection (e.g., by asking donors to suck on the pad at the end of the collection or prolonging the collection after the indicator has changed color).

*Exhibit 2. Example of Study to Validate Collected Oral Fluid Volume*

| OF Collection Device: <Name>, Lot <##>, Exp Date <##> | | | | | |
|---|---|---|---|---|---|
| OF Devices Volunteer # | Collected (mL) | Acceptance Within ±10% Yes/No | OF Collection Device Limits Target, −10%, +10% (mL) | | |
| | | | Device Target (mL) | 90% of Target (mL) | 110% of Target (mL) |
| 1 | 1.03 | Yes | 1.00 | 0.90 | 1.10 |
| 2 | 0.99 | Yes | 1.00 | 0.90 | 1.10 |
| 3 | 0.98 | Yes | 1.00 | 0.90 | 1.10 |
| 4 | 1.01 | Yes | 1.00 | 0.90 | 1.10 |
| 5 | 0.94 | Yes | 1.00 | 0.90 | 1.10 |
| 6 | 1.08 | Yes | 1.00 | 0.90 | 1.10 |
| 7 | 0.96 | Yes | 1.00 | 0.90 | 1.10 |
| 8 | 1.05 | Yes | 1.00 | 0.90 | 1.10 |
| 9 | 0.96 | Yes | 1.00 | 0.90 | 1.10 |
| 10 | 0.96 | Yes | 1.00 | 0.90 | 1.10 |
| 11 | 0.97 | Yes | 1.00 | 0.90 | 1.10 |
| 12 | 1.01 | Yes | 1.00 | 0.90 | 1.10 |
| 13 | 1.00 | Yes | 1.00 | 0.90 | 1.10 |
| 14 | 0.99 | Yes | 1.00 | 0.90 | 1.10 |
| 15 | 0.94 | Yes | 1.00 | 0.90 | 1.10 |
| | Mean (mL) | Acceptance Yes/No | STDev (mL) | Mean −2 STDev (mL) | Mean +2 STDev (mL) |
| | 0.992 | Yes | 0.040 | 0.91 | 1.07 |

### *Diluent Volume*

*Only required for devices using a diluent.* Determine (volumetrically or gravimetrically) the amount of diluent in at least 15 devices. It is acceptable to weigh the device with and without diluent. The diluent volume should be within 97.5% and 102.5% (±2.5%) of the manufacturer specified volume, which should be understood as a 95% prediction interval (95% of all devices). Only required for devices using a diluent. Determine (volumetrically or gravimetrically) the amount of diluent in at least 15 devices. It is acceptable to weigh the device with and without diluent. The diluent volume should be within 97.5% and 102.5% (±2.5%) of the manufacturer specified volume, which should be understood as a 95% prediction interval (95% of all devices should meet requirement). Laboratories may calculate the interval as the mean plus or minus two standard deviations.

*Exhibit 3. Example of Study to Validate Diluent Volume*

| OF Collection Device: <Name>, Lot <##>, Exp Date <##> | | | | | |
|---|---|---|---|---|---|
| | | | OF Collection Device Limits Target, −2.5%%, +2.5%% (mL) | | |
| OF Devices # | Diluent (mL) | Acceptance Within ±2.5% Yes/No | Device Target (mL) | 97.5% of Target (mL) | 102.5% of Target (mL) |
| 1 | 1.96 | Yes | 2.00 | 1.95 | 2.05 |
| 2 | 1.97 | Yes | 2.00 | 1.95 | 2.05 |
| 3 | 1.98 | Yes | 2.00 | 1.95 | 2.05 |
| 4 | 1.99 | Yes | 2.00 | 1.95 | 2.05 |
| 5 | 2.01 | Yes | 2.00 | 1.95 | 2.05 |
| 6 | 2.01 | Yes | 2.00 | 1.95 | 2.05 |
| 7 | 2.00 | Yes | 2.00 | 1.95 | 2.05 |
| 8 | 2.00 | Yes | 2.00 | 1.95 | 2.05 |
| 9 | 2.02 | Yes | 2.00 | 1.95 | 2.05 |
| 10 | 2.03 | Yes | 2.00 | 1.95 | 2.05 |
| 11 | 2.01 | Yes | 2.00 | 1.95 | 2.05 |
| 12 | 2.01 | Yes | 2.00 | 1.95 | 2.05 |
| 13 | 1.96 | Yes | 2.00 | 1.95 | 2.05 |
| 14 | 2.00 | Yes | 2.00 | 1.95 | 2.05 |
| 15 | 2.01 | Yes | 2.00 | 1.95 | 2.05 |
| | Mean (mL) | Acceptance Yes/No | STDev (mL) | Mean-2 STDev (mL) | Mean+ 2 STDev (mL) |
| | 1.997 | Yes | 0.021 | 1.96 | 2.04 |

### *Analyte Recovery*

Analyte recovery should be 80%–120% and should be determined using at least six devices for all confirmatory test analytes at or near the initial test cutoff (100%–125%), with all devices meeting the requirement. Recovery can be determined by spiking three sources of certified negative oral fluid or freshly collected oral fluid (synthetic oral fluid is not acceptable). Samples are collected by dipping the device into the oral fluid until the volume indicator indicates a complete collection. The devices are then placed in the kits and allowed to equilibrate before being analyzed. Recovery can be assessed by comparing measured concentrations with either the spiked concentrations or with the same spiked oral fluid sources directly diluted in for example a transfer tube.

*Note: It is acceptable to pool analytes.*

*Exhibit 4. Example of Analyte Recovery Study*

| OF Collection Device: <Name>, Lot <##>, Exp Date <##> | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Analytes ID | OF Device, Analyte Recovery <insert condition, specimen [A or B]> #, ng/mL | | | | | | Acceptance Recovery ±20% Yes/ No | OF Collection Device Limits Targets | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | | Measurand Target (ng/ mL) | 80% of Target (ng/mL) | 120% of Target (ng/mL) |
| THC | 1.76 | 1.87 | 1.84 | 2.03 | 1.9 | 2.11 | Yes | 2.00 | 1.60 | 2.40 |
| COC | 8.19 | 6.85 | 7.26 | 6.54 | 7.46 | 7.25 | Yes | 8.00 | 6.40 | 9.60 |
| BZE | 7.15 | 8.01 | 7.05 | 6.67 | 7.76 | 8.39 | Yes | 8.00 | 6.40 | 9.60 |
| COD | 13.5 | 16.1 | 13.1 | 13.4 | 12.2 | 13.4 | Yes | 15.0 | 12.0 | 18.0 |
| MOR | 14.9 | 15.2 | 13.7 | 12.8 | 12.5 | 12.4 | Yes | 15.0 | 12.0 | 18.0 |
| HYC | 14.0 | 14.4 | 15.9 | 13.5 | 16.5 | 14.8 | Yes | 15.0 | 12.0 | 18.0 |
| HYM | 14.5 | 16.2 | 14.3 | 13.1 | 15.1 | 16.0 | Yes | 15.0 | 12.0 | 18.0 |
| OXY | 16.1 | 12.3 | 14.9 | 13.4 | 15.4 | 12.5 | Yes | 15.0 | 12.0 | 18.0 |
| OXYM | 15.8 | 13.6 | 12.3 | 13.1 | 15.7 | 12.9 | Yes | 15.0 | 12.0 | 18.0 |
| 6-AM | 1.74 | 1.86 | 1.80 | 1.70 | 1.97 | 1.66 | Yes | 2.00 | 1.60 | 2.40 |
| PCP | 9.94 | 9.85 | 9.25 | 10.83 | 10.31 | 9.54 | Yes | 10.00 | 8.00 | 12.00 |
| AMP | 25.8 | 28.2 | 22.7 | 26.1 | 24.4 | 28.5 | Yes | 25.0 | 20.0 | 30.0 |
| MAMP | 27.0 | 21.5 | 27.1 | 23.9 | 21.7 | 24.4 | Yes | 25.0 | 20.0 | 30.0 |
| MDMA | 24.5 | 23.0 | 25.1 | 25.2 | 21.0 | 20.7 | Yes | 25.0 | 20.0 | 30.0 |
| MDA | 20.2 | 23.3 | 24.9 | 22.3 | 21.4 | 20.4 | Yes | 25.0 | 20.0 | 30.0 |

### *Analyte Stability*

Analyte stability should be ≥80% compared with the concentration at the time of collection. It should be determined using at least six devices per time point/condition, with all devices meeting the requirement. Stability samples can be prepared by spiking certified negative oral fluid or freshly collected oral fluid (synthetic oral fluid is not acceptable) at or around the initial test cutoff. Samples are collected by dipping the device into the oral fluid until the volume indicator indicates a complete collection. The devices are then placed in the kits and allowed to equilibrate.

Conditions should include 5 days at room temperature and under the manufacturer's intended shipping and storage conditions for at least 30 days. If the laboratory routinely stores specimens under different conditions (e.g., A specimens in a transfer tube without pad and B specimens unopened in device with pad), both conditions should be tested.

*Note: It is acceptable to pool analytes, but at least two pools are recommended so analytes are not combined with their metabolites (e.g., 6-acetylmorphine with morphine). It is acceptable to pool 6-acetylmorphine with codeine, oxycodone with hydrocodone, and oxymorphone with hydromorphone.*

An acceptable scheme could include

- Short- and long-term stability
  - 6 devices analyzed at baseline*
  - 6 devices analyzed after 5 days at room temperature
  - 12 devices (six stored as A specimens, six stored as B specimens) analyzed after 10 days refrigerated**
  - 12 devices (six stored as A specimens, six stored as B specimens) analyzed after 30 days frozen***

**The same baseline samples can also be used for the shipping and freeze–thaw studies.*

***Samples can either be stored 5 days at room temperature before being placed in long-term storage (frozen or refrigerated) or placed into long-term storage directly.*

****Not required if the manufacturer recommends refrigerated storage. In such case, refrigerated storage stability should be studied after 30 days.*

- Shipping study
  - 6 devices analyzed at baseline
  - 6 devices are analyzed after being shipped (using regular packaging) to a location corresponding to the furthest expected shipments of regulated specimens and then back to the laboratory
- Freeze–thaw study (if applicable)*
  - 6 devices analyzed at baseline
  - 12 devices (6 stored as A specimens, 6 stored as B specimens) analyzed after 3 freeze–thaw cycles (at least 24 h at each temperature)**

**Not required if the manufacturer recommends refrigerated storage.*

***Devices do not need to be analyzed after each freeze–thaw cycle. However, if analytes are found to be unstable after three cycles, the laboratory must determine during how many freeze–thaw cycles the analytes are stable by repeating the experiment with analysis after each cycle.*

*Exhibit 5. Example of Analyte Stability Study*

| OF Collection Device: <Name>, Lot <##>, Exp Date <##> | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Analytes ID | OF Device, Analyte Stability <insert condition, specimen [A or B]> #, ng/mL | | | | | | Acceptance ≥80% Recovery Yes/No | OF Collection Device Limits Targets | |
| | 1 | 2 | 3 | 4 | 5 | 6 | | Baseline Average (ng/mL) | 80% of Baseline (ng/mL) |
| THC | 1.80 | 1.77 | 1.81 | 1.83 | 1.86 | 1.74 | Yes | 2.00 | 1.60 |
| COC | 6.99 | 7.54 | 6.94 | 7.25 | 6.50 | 7.24 | Yes | 8.00 | 6.40 |
| BZE | 7.54 | 7.71 | 7.13 | 7.42 | 7.52 | 7.55 | Yes | 8.00 | 6.40 |
| COD | 12.1 | 13.2 | 13.4 | 14.3 | 13.6 | 13.9 | Yes | 15.0 | 12.0 |
| MOR | 13.0 | 13.6 | 13.4 | 13.2 | 14.3 | 14.2 | Yes | 15.0 | 12.0 |
| HYC | 13.9 | 12.9 | 14.3 | 12.6 | 14.0 | 12.4 | Yes | 15.0 | 12.0 |
| HYM | 13.0 | 13.7 | 14.1 | 13.7 | 14.2 | 13.0 | Yes | 15.0 | 12.0 |
| OXY | 13.3 | 14.0 | 14.7 | 13.4 | 13.8 | 13.6 | Yes | 15.0 | 12.0 |
| OXYM | 13.8 | 13.6 | 13.0 | 13.2 | 12.6 | 13.5 | Yes | 15.0 | 12.0 |
| 6-AM | 1.81 | 1.82 | 1.78 | 1.89 | 1.91 | 1.89 | Yes | 2.00 | 1.60 |
| PCP | 9.26 | 9.31 | 8.81 | 9.33 | 8.77 | 9.69 | Yes | 10.00 | 8.00 |
| AMP | 21.6 | 23.0 | 21.6 | 20.6 | 20.5 | 24.4 | Yes | 25.0 | 20.0 |
| MAMP | 22.6 | 22.9 | 23.2 | 22.1 | 23.8 | 21.2 | Yes | 25.0 | 20.0 |
| MDMA | 23.0 | 21.5 | 21.3 | 23.2 | 22.8 | 22.4 | Yes | 25.0 | 20.0 |
| MDA | 21.9 | 22.2 | 21.4 | 20.7 | 22.7 | 23.8 | Yes | 25.0 | 20.0 |

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