

**Department of Health and Human Services  
Substance Abuse and Mental Health Services Administration  
Center for Substance Abuse Prevention**

# **Collection Site Manual**

**for the  
Collection of Oral Fluid Specimens  
for  
Federal Agency Workplace Drug Testing Programs**

**Effective October 2023**

**Note: This manual applies to Federal agency drug testing programs that come under Executive Order 12564 dated September 15, 1986, section 503 of Public Law 100-71, 5 U.S.C. section 7301 note dated July 11, 1987, and the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (88 FR 70814) dated October 12, 2023 (effective October 10, 2023). This manual does not apply to specimens submitted for testing under U.S. Department of Transportation (DOT) Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR Part 40).**

*Disclaimer*

The Department of Health and Human Services (HHS) recommends that each Federal agency use the information contained in this collection site manual to ensure consistency and to improve the overall quality of the review process. This collection site manual is for informational purposes only and can be modified to reflect the Federal Agency's Drug-Free Workplace Policy.

If there are questions regarding this manual, please contact Division of Workplace Programs staff at 240.276.2600 or see <https://www.samhsa.gov/workplace>.

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## **References**

(available at <https://www.samhsa.gov/workplace>)

1. Federal Custody and Control Form (Federal CCF)
2. HHS Oral Fluid Specimen Collection Handbook for Federal Agency Workplace Drug Testing Programs (HHS Oral Fluid Collection Handbook)
3. *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid* (OFMG). Published October 12, 2023 (88 FR 70814), effective October 10, 2023.

## ***Introduction***

The Substance Abuse and Mental Health Services Administration (SAMHSA) within the U.S. Department of Health and Human Services (HHS) establishes the scientific and technical guidelines to be used by U.S. Federal agencies, drug testing facilities, and collection sites used for Federal workplace drug testing specimens. SAMHSA certifies two types of test facilities: laboratories and instrumented initial test facilities (IITFs). IITFs are allowed only for urine testing, and perform only the initial tests for those specimens.

Oral fluid specimens must be collected in accordance with the *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid* (OFMG) published on October 12, 2023 (effective October 10, 2023) and must be sent to an HHS-certified laboratory for testing.

This Collection Site Manual provides explanatory comments and references for each question included in the *Collection Site Checklist for Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs*. SAMHSA developed the Collection Site Manual for Federal agencies' use in evaluating collection sites that provide specimen collection services to the Federal agencies, to verify and document compliance with Federal requirements.

### **Federal Custody and Control Form (Federal CCF)**

All specimens must be collected using chain of custody procedures. **Chain of custody** is the term used to describe the procedures to account for the integrity of each specimen and aliquot (i.e., portion of a specimen used for testing) by tracking handling and storage from the point of specimen collection to final disposition of the specimen and its aliquots. The collector begins the chain of custody at the collection site using the Office of Management and Budget (OMB)-approved Federal CCF to document custody and control of each Federal agency specimen.

The Federal CCF may be used as a paper (hardcopy) form, an electronic (digital) form, or in a combination electronic and paper format. Before an HHS-certified laboratory may use an electronic CCF (ECCF: digital form or combination electronic/paper form) for federally regulated specimens, the test facility must be approved to use that ECCF system by SAMHSA, through the National Laboratory Certification Program (NLCP).

OMB approved the use of the 2023 Federal CCF as of May 1, 2023, for urine and oral fluid specimens. SAMHSA's Division of Workplace Programs (DWP) has released guidance associated with the 2023 Federal CCF. A proof of the current Federal CCF, guidance for its use, and Instructions for Completing the Federal CCF (i.e., separate instructions for urine specimens and for oral fluid specimens) are on the SAMHSA website: <https://www.samhsa.gov/workplace>.

Notes for Expired CCFs for Oral Fluid Specimens:

- The 2023 Federal CCF is the same as the expired 2020 Federal CCF. Therefore, use of the 2020 Federal CCF is approved for federally regulated specimens.
- Expired (urine only) CCFs (2017 or earlier) are not allowed for oral fluid specimens unless the collector documents the required oral fluid collection

information at the time of collection. The documentation must be sent to the laboratory with the specimen, either documented on the Remarks line of the Federal CCF or in a separate memorandum for the record (MFR) signed by the collector.

If a regulated oral fluid specimen is received at a laboratory accompanied by the 2017 Federal CCF, the specimen may be rejected. See section 6.2 regarding the use of an incorrect CCF for an oral fluid specimen.

### ***Collection Site Manual Instructions***

A Federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G and H of the *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid* (OFMG) published on October 12, 2023 (effective October 10, 2023).

This Collection Site Manual is designed to assist the Drug Program Coordinator or designee and collection site personnel in evaluating collection site performance based on onsite inspections and self-evaluations. A Federal agency is responsible for inspecting 5 percent (up to a maximum of 50) collection sites each year, selected randomly from those sites used to collect Federal agency specimens. A Federal agency must investigate reported collection site deficiencies and take appropriate action, which may include an onsite inspection or collection site self-evaluation using the *Collection Site Checklist for Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs* and the HHS Oral fluid Specimen Collection Handbook.

### **Guidance and Information**

To use this manual, you will need:

- Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) published on October 12, 2023 (effective October 10, 2023)
- HHS Oral Fluid Specimen Collection Handbook for Federal Agency Workplace Drug Testing Programs (HHS Oral Fluid Collection Handbook)
- Guidance provided by the Federal agency's drug-free workplace program or by HHS relating to regulated oral fluid specimen collection

### **Terms and Definitions**

Before you can begin using this manual, you need to familiarize yourself with the checklist questions and comments in each section. This can be done by following these easy steps: (1) read each question and the related comments, (2) read the OFMG section(s) referenced for each question, and (3) understand the Federal agency policy.

### **Checklist**

Each question in the *Collection Site Checklist for Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs* is designed to address the requirements in OFMG subparts D, E, F, G and H. The inspector/collection site reviewer answers each question based on these requirements and their review of the collection site standard operating procedures, practice, and records. The individual completing the checklist will:

1. Circle the appropriate **YES** or **NO** answer for each checklist question.
2. If required for a **NO** answer, check the deficient area(s) for the checklist question.
3. Record comments in the space provided to explain the specific reason for each **NO** answer.

## **Section Evaluation**

Each checklist section contains a section evaluation page. The inspector/collection site reviewer uses the section evaluation to summarize and classify the seriousness of identified deficiencies. The individual completing the checklist will:

1. For each checklist question in the section with a **NO** answer, explain the potential problem or identified non-compliance.
2. Mark the overall section evaluation at the top of the page as appropriate:
  - a. Deficiencies require immediate corrective action by the collection site
  - b. Deficiencies were identified but do not require immediate correction action
  - c. No deficiencies were identified.

## **Collection Site Evaluation Form**

The Collection Site Evaluation Form is completed by inspectors (for onsite inspections) and by collection site personnel (for self-evaluations) and is used by the Federal agency Drug Program Coordinator (DPC) or designee to determine the inspection outcome.

## **Inspector/Collection Site Reviewer**

1. In the Overall Section Summary, assign a numerical “score” for each checklist section, based on the section evaluation:
  - a. Record a “0” on the evaluation form for each section summary where serious deficiencies were identified.
  - b. Record a “1” for each section summary where deficiencies were identified but do not require immediate corrective action.
  - c. Record a “2” for each section summary where no deficiencies were identified.
2. In the appropriate “Inspector/Collection Site Reviewer” columns under “Overall Summary of Serious Deficiencies,” list the sections identified as having serious deficiencies and those with no serious deficiencies.
3. Add the individual section scores to determine the rating and record the total in the “Rating” space for “Inspector/Collection Site Reviewer” under “Inspection Outcome.”
4. Sign and date in the appropriate space at the bottom of the form. Inspectors sign the “Onsite Inspection by” line; Collection Site Reviewers sign the “Self-Evaluation by” line.

## Federal Agency Reviewer

1. Review the checklist completed by the inspector (for onsite inspections) or by collection site personnel (for self-evaluations).
2. Based on your review, in the appropriate “Federal Agency/Designee” columns under “Overall Summary of Serious Deficiencies,” list the sections identified as having serious deficiencies and those with no serious deficiencies.
3. Note (e.g., by circling) any sections with evaluations differing from the inspector/collection site reviewer evaluation. If there are differences, calculate a final rating based on your individual section scores.
4. Record the final rating in the “Rating” space for “Federal Agency/Designee” under “Inspection Outcome.”
5. Determine the Inspection Outcome based on the following criteria in each section:

\_\_\_\_\_ *Serious deficiencies were identified (0 points)*  
\_\_\_\_\_ *Deficiencies were identified (1 point)*  
\_\_\_\_\_ *No deficiencies were identified (2 points)*

- a. **Acceptable** = A rating of 5 or greater and no more than 1 section with a serious deficiency identified.
  - b. **Unacceptable** = A rating less than 5 or more than 1 section with a serious deficiency identified.
6. Additional comments concerning the inspection outcome should be recorded in the space provided.



## ***Definitions***

**Adulterated Specimen:** A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of a normal constituent (e.g., nitrite in urine).

**Blind Sample:** A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

**Chain of Custody Documents:** Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots, and must include the name and signature of each individual who handled the specimen(s) or aliquot(s), and the date and purpose of the handling.

**Chain of Custody Procedures:** Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

**Collection Device:** A that is used to collect an oral fluid specimen and may include a buffer or diluent.

**Collection Site:** The location where specimens are collected.

**Collector:** A person trained to instruct and assist a donor in providing a specimen.

**Federal Drug Testing Custody and Control Form (Federal CCF):** The Office of Management and Budget (OMB) approved form that is used to document the collection and the chain of custody of a specimen from the time the specimen is collected until it is received by the testing facility (i.e., HHS-certified laboratory, or for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic (digital), or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer (MRO).

**Instrumented Initial Test Facility (IITF):** A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a Responsible Technician.

**Laboratory:** A permanent location where initial and confirmatory testing, reporting of results, and recordkeeping are performed under the supervision of a Responsible Person.

**Medical Review Officer (MRO):** A licensed physician who reviews, verifies, and reports a specimen test result to the Federal agency.

**Oral Fluid Specimen:** An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

**Rejected for Testing:** The result reported by an HHS-certified laboratory or (for urine) HHS-certified IITF when no tests are performed for a specimen because of a fatal flaw or unrecovered correctable error.

**Specimen:** Fluid or material collected from a donor at the collection site for the purpose of a drug test.

**Split Specimen Collection (for Oral Fluid):** A collection in which two specimens [primary (A) and split (B)] are collected, concurrently or serially, and independently sealed in the presence of the donor; or a collection in which a single specimen is collected using a single collection device and is subdivided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

**Substituted Specimen:** A specimen that has been submitted in place of the donor's specimen, as evidenced by the absence of a biomarker or a biomarker concentration inconsistent with that established for a human specimen, as indicated in the biomarker testing panel, or (for urine) creatinine and specific gravity values that are outside the physiologically producible ranges of human urine, in accordance with the criteria to report a urine specimen as substituted in the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG), Section 3.7.

## Section A. Collection Site

### Collection Site

**Question A-1.** *Does the collection site have provisions to ensure donor privacy during the specimen collection procedure? (YES/NO)*

**Comment:** The collection site must have provisions to ensure donor privacy during specimen collections. Only authorized personnel and the donor may be present in the restricted access area where the collection takes place. Note: the collector is not required to be the same gender as the donor.

Reference: OFMG (subpart E – section 5.2.a; subpart H – section 8.1)

**Question A-2.** *Does the collection site have the following? (YES/NO)*

*If NO, check the deficient area(s):*

- a. *A means for washing hands*
- b. *A suitable clean surface, inaccessible to the donor, for the collector to use as a work area*
- c. *A secure temporary storage area for maintaining specimens until they are transferred to an HHS-certified laboratory*

**Comment:** The collection site must have a means for the donor to wash their hands under the collector's direct observation. If there is not a restroom or a sink within the collection area, the collector must provide another means (e.g., hand sanitizer, moist towelette, alcohol-free wipe). The work area is used by the collector to handle the specimens and to complete required paperwork (e.g., Federal CCF). The work area must be clean and not accessible to the donor. The collection site must have an appropriate secure temporary storage area for maintaining specimens until they are transferred to an HHS-certified laboratory. The specimen storage area should not be exposed to high temperatures for an extended period of time, as this may affect the test results of an oral fluid specimen.

Reference: OFMG (subpart E – section 5.2.b - c and subpart H - section 8.4) and HHS Oral Fluid Collection Handbook

**Question A-3.** *Does the collection site have procedures or restrictions to prevent the following? (YES/NO)*

*If NO, check the deficient area(s):*

- a. *Unauthorized access to the site during the collection*
- b. *Unauthorized access to the collection materials/supplies*
- c. *Unauthorized access to collection site records*
- d. *Donor access to items that could be used to adulterate or substitute the specimen, or otherwise adversely affect the oral fluid collection*

**Comment:** To ensure specimen integrity, the collection site must have procedures or restrictions in place to prevent unauthorized access as described in this question.

Reference: OFMG (subpart E - section 5.2.d-f) and HHS Oral Fluid Collection Handbook

**Question A-4.** *Does the collection site have the required supplies for Federal agency oral fluid specimen collections? (YES/NO)*

**Comment:** The collection site must have all the supplies needed to complete an oral fluid split specimen collection such as collection kits (i.e., with single-use collection device), Federal CCFs, tamper-evident tape/seals, leak-resistant container (e.g., plastic bag) with separate sealable compartments for specimen tubes and CCF, absorbent material, shipping containers, and disposable gloves. Collection kits must include an FDA-approved, single-use collection device capable of collecting a minimum of 1 mL of undiluted (neat) oral fluid. (See Section C, page 21, for types of split oral fluid collections that may be used.) If the collection device contains a diluent (or other component that modifies the volume), the volume of oral fluid collected by the device should be at least 1.0 mL  $\pm$  10 percent. Collection devices must not substantially affect the composition of drugs and/or metabolites in the specimen collected.

The collection site must maintain a supply of paper Federal CCFs, to be used in the event of a software/hardware problem preventing collections using an ECCF. In addition, collection sites must have the ability to print the Federal ECCF on demand. This capability allows the collector to print the Federal CCF in the event of a problem preventing completion of a collection using an ECCF (e.g., allowing for handwritten collector and donor signatures in the event of a problem with the electronic signature system or when a donor refuses to sign electronically but agrees to sign using a wet-ink signature).

Reference: OFMG (subpart G – section 7.1 through 7.3) and HHS Oral Fluid Collection Handbook

**Question A-5.** Is access to collection supplies restricted to authorized personnel? (YES/NO)

**Comment:** It is the collector's responsibility to prevent unauthorized access to collection supplies. To minimize the chances of tampering, donors must not have access to collection site supplies.

Reference: OFMG (subpart E - section 5.5.a.3)

**Question A-6.** *Does the collection site have the name and telephone number of the designated representative for each Federal agency for which specimens are collected? (YES/NO)*

*If YES,*

1. Is this information readily available to each collector, in the event that a problem or issue arises during a collection? (YES/NO)

**Comment:** The collection site must have the name and telephone number of the designated representative for each Federal agency readily available, so collectors can contact the agency as needed about problems or issues that arise during the specimen collection procedure.

Reference: OFMG (subpart D - section 4.5.c)

**Question A-7.** *Does the collection site have procedures to prohibit the following individuals from serving as a specimen collector? (YES/NO)*

*If **NO**, identify the deficient area(s):*

- a. *Hiring official or donor's immediate supervisor unless there is no feasible alternative and the individual is a trained collector*
- b. *Co-worker in the same testing pool or who works with the donor on a daily basis*
- c. *The applicant or employee (i.e., the specimen donor)*
- d. *Employee of an HHS-certified laboratory who can link the donor with the specimen drug test results*
- e. *Relatives or personal friends of the donor*

**Comment:** To avoid a conflict of interest, the collection site must prohibit individuals as described in this question from collecting a specimen.

Reference: OFMG (subpart D - section 4.1.b-c, subpart D - section 4.2.a – d)

## Section Evaluation

**Question A-8. For the Collection Site Section:**

- Serious deficiencies were identified (0 points)*
- Deficiencies were identified (1 point)*
- No deficiencies were identified (2 points)*

Note: *This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.*

Describe basis for the above selection:

## **Section B. Personnel**

### **Collectors**

**Question B-1.** *During interview by the inspection team, did each collector demonstrate a working knowledge of the collection procedures described in the OFMG, the manufacturer instructions for each oral fluid collection device that will be used by the collector for the Federal agency specimens, and any other guidance provided by the Federal agency related to specimen collection procedures? (YES/NO)*

*If NO, identify the individual(s) and deficient area(s) of knowledge.*

**Comment:** Prior to performing specimen collections for a Federal agency, each collector must demonstrate a working knowledge of the collection procedures described in the OFMG, the HHS Oral Fluid Collection Handbook, *the manufacturer instructions for each oral fluid collection device that will be used by the collector for the Federal agency specimens*, and any other guidance provided by the Federal agency related to specimen collection procedures. The extent of knowledge is routinely assessed by observing the individual perform a real or mock collection and asking questions concerning practices and procedures. To avoid distracting the collector during a real collection, inspectors should hold questions until after the collection is completed and the donor has left the site.

Reference: OFMG (subpart D - section 4.3.a.1-2)

**Question B-2.** *Was documentation of training for each collector provided for review during the inspection? (YES/NO)*

*If NO, note the collector(s) with missing training documentation.*

**Comment:** The collection site must provide each collector's training records to the inspectors for review. Inspectors should note any collectors with missing training documentation.

Reference: OFMG (subpart D - section 4.3.c)

**Answer questions B-3 through B-8 for the records provided.**

**Question B-3.** *Does each collector maintain their training documentation? (YES/NO)*

**Comment:** Each collector is required to maintain documentation of current training and refresher training and present it to a Federal agency upon request. The collection site may maintain the originals or maintain copies of the training documents. If the collection site provides copies for review, the inspectors may request one or more collectors to provide their original training records during the inspection.

Reference: OFMG (subpart D - section 4.3.c and section 4.5.b)

**Question B-4.** *Did each collector complete initial training for each collection device used before they began collecting specimens for a Federal agency? (YES/NO)*

**Comment:** An individual may not perform specimen collections until their training as a collector on that device has been completed and documented.

Reference: OFMG (subpart D - section 4.3.d)

**Question B-5.** *Has each collector (as applicable) completed refresher training at least every five years from the date of initial training? (NA/YES/NO)*

**Comment:** Each collector must complete refresher training every five years.

Reference: OFMG (subpart D - section 4.3.b)

**Note:** The collector training outlined in Questions B-6 and B-7 below must be conducted using a paper Federal CCF. To use an electronic Federal CCF for Federal agency oral fluid collections, a trained collector must complete separate additional training from the ECCF system provider. That training should address use of the ECCF system for uneventful collections as well as problems that may arise during an ECCF collection including, but not limited to, a donor's refusal to test, a printer problem, insufficient specimen, and a donor's refusal to sign the CCF.

**Question B-6.** *Do the initial and refresher training records for each collector document training on the following subjects? (YES/NO)*

*If NO, identify the individual and records and check the deficient area(s):*

- a. *The steps to correctly perform a collection using each type of collection device to be used for Federal agency specimens*
- b. *The proper completion and distribution of the Federal CCF*
- c. *Problem collections*
- d. *Fatal flaws and correctable flaws and how to correct problems in collections*
- e. *Collector responsibilities to maintain the integrity of the collection process, to protect the privacy of donors, to ensure the security and integrity of specimens, and to maintain proper conduct*

**Comment:** A qualified trainer for collectors must perform training on these topics during initial collector training and during refresher training at least every five years. Training documentation should clearly indicate these training topics on the certificate or in the training manual. Before using an additional or revised collection device for a Federal agency program, a trained oral fluid collector must complete training by a qualified trainer on the topics above and demonstrate proficiency using that device as described under Question B-7.

Reference: OFMG (subpart D - section 4.3.a.3) and HHS Oral Fluid Collection Handbook

**Question B-7.** *Do the initial and refresher training records for each collector document their proficiency in collections by successful completion of five (5) consecutive error-free mock collections? (YES/NO)*

*If NO, identify the individual and records and check the deficient area(s):*



- a. Two uneventful scenarios
- b. One insufficient specimen quantity scenario
- c. One scenario in which the donor refuses to sign the Federal CCF
- d. One scenario in which the donor refuses to initial the tamper-evident tube label/seal

**Comment:** Initial and refresher training must include the successful completion of five (5) consecutive error-free mock collections (i.e., two uneventful scenarios, one insufficient specimen quantity scenario, one in which the donor refuses to sign the Federal CCF, and one in which the donor refuses to initial the tamper-evident tube label/seal). When training for multiple collection devices, the proficiency demonstration must include two uneventful collection scenarios for each device. The trainer may require the use of only one device type for the other three scenarios (i.e., items b-d above).

Before using an additional or revised collection device for a Federal agency specimen, a trained oral fluid collector must demonstrate proficiency by successfully completing at least two consecutive error-free mock collections using that device. (The trainer may choose to require three consecutive error-free mock collections.)

Reference: OFMG (subpart D - section 4.3.a.4.i) and HHS Oral Fluid Collection Handbook

**Question B-8.** *Do the initial and refresher training records for each collector include the following? (YES/NO)*

*If NO, identify the individual and records and check the deficient area(s):*

- a. Documentation that the training was conducted in person or by means allowing real-time observation and interaction between trainer and trainee.
- b. Written attestation by the trainer that the mock collections were error-free.
- c. Documentation of the trainer's qualifications at the time of the training.

**Comment:** A qualified trainer for collectors must monitor and evaluate the trainee and must attest in writing that all of the required consecutive mock collections were error-free. Training records must document that training was either conducted in person by a qualified trainer or by a means allowing real-time observation and interaction between trainer and trainee. The records should document the trainer's qualifications at the time of the training on the certificate or in the training manual.

Reference: OFMG (subpart D - section 4.3.a.4.ii, and subpart D - section 4.4.c) and HHS Oral Fluid Collection Handbook

## **Collector Trainers**

**Answer the remaining Section B questions if collection site employees serve as collector trainers.**

**Question B-9.** *During interview by the inspection team, did each collector trainer demonstrate a working knowledge of the collection procedures described in the OFMG, the HHS Oral Fluid Collection Handbook, the manufacturer instructions for the specific collection device(s), and any other guidance provided by the Federal agency related to the collection procedures? (YES/NO)*

**Comment:** Each collector trainer must demonstrate a working knowledge of the collection procedures described in the OFMG, the HHS Oral Fluid Collection Handbook, and any other guidance provided by the Federal agency related to specimen collection procedures prior to performing specimen collections. Because collectors must be trained to use one or more specific collection devices for Federal agency specimens, the trainer must demonstrate a working knowledge of the manufacturer instructions for the specific device(s).

Reference: OFMG (subpart D – section 4.3.a.1-2) and HHS Oral Fluid Collection Handbook

**Question B-10.** *Was documentation of training for each trainer provided for review during the inspection? (YES/NO)*

*If NO, note the trainer(s) with missing training documentation.*

**Comment:** For each staff member performing collector training, the collection site must provide training records to the inspectors for review. Inspectors should note any trainers with missing training documentation.

Reference: OFMG (subpart D - section 4.4.c)

**Complete the remaining Section B questions for the records provided.**

**Question B-11.** *Does each trainer maintain their training documentation? (YES/NO)*

**Comment:** Each trainer is required to maintain documentation of initial and refresher training and present it to a Federal agency upon request. The collection site may maintain the originals or maintain copies of the training documents. If the collection site provides copies for review, the inspectors may request one or more trainers to provide their original training records during the inspection.

Reference: OFMG (subpart D - section 4.4.c)

**Question B-12.** *Do the training records for each collector trainer document at least one of the following qualifications? (YES/NO)*

- The trainer is qualified as a collector and has regularly conducted drug test collections for a period of at least one year using the specific collection device(s),
- The trainer successfully completed a “train the trainer” course given by an organization (e.g., manufacturer, private entity, contractor, or Federal agency), including training on the specific collection device(s)

**Comment:** To be qualified as a collector trainer, the individual must be qualified as a collector and have regularly conducted drug test collections using the specific device(s) for at least one year OR must have completed a “train the trainer” course provided by an organization (e.g., manufacturer, private entity, contractor, or Federal agency). The individual must complete device-specific training to be qualified to train collectors on that device.

Reference: OFMG (subpart D - section 4.4.a.1-2) and HHS Oral Fluid Collection Handbook

**Question B-13.** *Has each trainer (as applicable) completed refresher training at least every five years from the date of initial training? (NA/YES/NO)*

**Comment:** Each collector trainer must undergo refresher training at least every five years.

Reference: OFMG (subpart D - section 4.4.b)

## Section Evaluation

### Question B-14. *For the Personnel Section:*

- Serious deficiencies were identified (0 points)*
- Deficiencies were identified (1 point)*
- No deficiencies were identified (2 points)*

Note: *This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.*

Describe basis for the above selection:

## **Section C. Specimen Collection Procedures**

All specimen collections under the OFMG are to be split specimen collections. The OFMG require collection of at least 1 mL of undiluted (neat) oral fluid each for the primary (A) specimen and split (B), either simultaneously or serially as follows:

- Two specimens collected simultaneously with two separate collection devices;
- Two specimens collected serially with two separate collection devices (i.e., collection of the second specimen must begin within two minutes after completion of the first collection);
- Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or
- A single specimen collected using a single collection device, that is subsequently divided into two specimens.

**Question C-1.** *Does the collector prepare the collection site to deter the adulteration or substitution of a specimen? (YES/NO)*

**Comment:** Collectors must prepare the collection site prior to specimen collection, taking all reasonable steps to prevent adulteration or substitution of the specimen.

Reference: HHS Oral Fluid Mandatory Guidelines (subpart H – section 8.2)

**Question C-2.** *Does the collector begin the collection without delay once the donor arrives at the collection site? (YES/NO)*

**Comment:** The collector must begin the collection procedure once the donor arrives at the collection site. The collection process must not be delayed because an authorized employer or employer representative is late arriving.

Reference: OFMG (subpart H – section 8.3.b)

**Question C-3.** *When a donor does not arrive at the collection site at the assigned time for the drug test, does the collector contact the Federal agency representative to obtain guidance on the appropriate action to be taken? (YES/NO)*

**Comment:** If the donor is required by the agency to arrive within a window of time and is outside of that window, the collector must contact the Federal agency representative to obtain guidance on the appropriate action to be taken.

Reference: OFMG (subpart H – section 8.3.a)

**Question C-4.** *Does the collector perform only one specimen collection at a time? (YES/NO)*

**Comment:** To ensure specimen integrity, the collector must perform only one donor collection at a time.

**Note:** As time permits, the collector may start the collection process for other donors during the 10-minute wait period (see question C-10.e below); however, the collector must reverify the donor's ID vs. that recorded on the Federal CCF prior to resuming the collection process, and must perform each collection one at a time, directly observing the donor throughout the collection.

Reference: OFMG (subpart E - section 5.5.a.2)

**Question C-5.** *Does the collector properly verify donor identity? (YES/NO)*

*Proper forms of identification include:*

- Driver's license
- Employee badge issued by the employer
- Photo identification issued by a Federal, state, or local government agency

**Comment:** The collector must verify the identity of the donor by requesting photo identification (i.e., driver's license, employee badge issued by the employer, or other photo identification issued by Federal, state, or local government) from the donor prior to specimen collection. If the donor does not have proper photo identification, the collector must contact the supervisor of the donor or the Federal agency representative who can positively identify the donor. If the identity of the donor cannot be established, the collector must stop the collection procedure.

Reference: OFMG (subpart H – section 8.3.c)

**Question C-6.** *Does the collector provide identification to the donor when requested? (YES/NO)*

**Comment:** The collector must provide identification (e.g., employee badge, employee list) to the donor if requested.

Reference: OFMG (subpart H – section 8.3.d)

**Question C-7.** *Does the collector describe the basic collection procedures to the donor and instruct the donor that they may read the instructions for completing the Federal CCF? (YES/NO)*

**Comment:** The collector must describe the basic collection procedures to the donor and instruct the donor that they may read the Instructions for Completing the Federal CCF for an Oral Fluid Collection. These instructions and the collection device-specific instructions must be provided to the donor at the time of the collection (i.e., as a hardcopy, onscreen, or posted at the collection site). The collector must also inform the donor that these instructions are available upon request.

When the A and B specimens are collected serially, the donor is not allowed to rinse their mouth or drink water between A and B specimen collections, and time between the

end of Specimen A collection and beginning of Specimen B collection must not exceed two minutes.

Reference: OFMG (subpart H – sections 8.3.–h.1 and 8.3.a.2) and HHS Oral Fluid Collection Handbook (special instructions for serial split collections)

**Question C-8.** *Does the collector answer any reasonable and appropriate questions that the donor has about the collection process? (YES/NO)*

**Comment:** The collector must answer any reasonable and appropriate questions that the donor has about the collection process.

Reference: OFMG (subpart H – section 8.3.h.3)

**Question C-9.** *Does the collector complete the required information in Step 1 of the Federal CCF? (YES/NO)*

**Comment:** The collector must ensure that Step 1 of the Federal CCF is completed prior to specimen collection. The employer, Medical Review Officer (MRO), collection site, and collector information may be preprinted or handwritten. The collector records the information if it is not present. The collector enters the donor identification information after verifying donor identity and enters a REMARK in Step 2 if the donor refuses to provide their social security number (SSN) or employee identification number. The collector marks the appropriate checkboxes to indicate the testing authority under which the specimen is being collected, the reason for testing, and the drug tests to be performed. The collector also marks the ORAL FLUID checkbox below Step 1.

Reference: Instructions for Completing the Federal CCF for Oral Fluid Specimen Collection and HHS Oral Fluid Collection Handbook

**Question C-10.** *Does the collector take the following steps to deter specimen tampering? (YES/NO)*

*If NO, check the deficient step(s):*

- a. *Ask the donor to remove any unnecessary outer clothing (e.g., coat, jacket)*
- b. *Ask the donor to leave all other personal belongings (e.g., briefcase, purse) with the outer clothing*

*If the collector will not keep the donor under direct observation until the end of the collection:*

- c. *Direct the donor to empty their pockets and display the items for inspection*

- \_\_\_\_\_ d. *Secure any items that could be used to adulterate a specimen that appears to have been inadvertently brought by the donor to the collection site*

*Ask the donor to open their mouth to allow inspection of the oral cavity*

- \_\_\_\_\_ e. *Begin 10-minute wait period after inspection of the donor oral cavity prior to beginning specimen collection*
- \_\_\_\_\_ f. *If the donor removes an item from their mouth as instructed, has abnormally colored saliva, or indicates they have “dry mouth”, provide water to the donor to rinse. Begin 10-minute wait period after donor has rinsed their mouth.*
- \_\_\_\_\_ g. *Direct the donor to wash and dry their hands under the collector’s supervision*

**Comment:** The collector must take the steps listed in this question to deter specimen tampering (see the exception for steps c and d described below).

Steps a and b: The donor is not required to remove any items worn for faith-based reasons. The collector must ensure that all personal belongings (e.g., briefcase, purse) remain with the outer clothing. The donor may retain their wallet.

Steps c and d: The requirement for the collector to inspect the contents of the donor’s pockets applies only when the collector does not keep the donor under direct observation until the end of the collection. If the donor refuses to display the items in their pockets when directed, the collector must proceed with the collection and keep the donor under their direct observation until the end of the collection (including the 10-minute wait period prior to oral fluid collection).

- If the collector sees no items from the donor’s pockets that could be used to adulterate or substitute the specimen, the donor is instructed to place those items back in their pockets and continue with the collection procedure.
- If items are present that could be used to adulterate or substitute a specimen (e.g., common personal care products such as mouthwash, lozenges, capsules), but may have been inadvertently brought by the donor to the collection site, the collector secures the items and proceeds with the collection.
- If an item is present whose purpose is to adulterate or substitute the specimen (e.g., a commercial drug culture product or other substance for which the donor has no reasonable explanation), this is considered a refusal to test. The collector must stop the collection and report the refusal to test as outlined in Question D-9.

Steps e and f: The donor is required to open their mouth and allow the collector to fully inspect the oral cavity.

- If the collector sees no items in the oral cavity that could impede or interfere with the collection, or could be used to adulterate, substitute, or dilute the specimen, the collector starts the 10-minute wait period before collecting the specimen.



- If the collector’s inspection of the donor’s oral cavity reveals any items that could impede or interfere with the collection (e.g., candy, gum, food, tobacco, abnormally colored saliva) or the donor claims to have “dry mouth”, the collector is required to give the donor water (e.g., up to 4 oz) for rinsing. The donor may discard or drink the water after rinsing. Once the donor has completed rinsing the oral cavity, the collector starts the 10-minute wait period before collecting the specimen.
- If the donor claims that they have a medical condition that prevents opening their mouth for inspection, the collector records the reason for not collecting an oral fluid specimen on the Federal CCF, notifies the Federal agency’s designated representative for authorization of an alternate specimen to be collected, and sends the Federal CCF to the Federal agency’s designated representative. See Note below.
- If the donor refuses to remove an item or refuses to rinse as directed, this is considered a refusal to test. The collector must stop the collection and report the refusal to test to the Federal agency as described in Question D-9.

**Step g:** The collector must direct the donor to wash and dry their hands under the collector’s supervision, and to keep their hands within view and avoid touching items or surfaces after handwashing. If the donor refuses to wash their hands when instructed by the collector, this is considered a refusal to test. The collector must stop the collection and report the refusal to test to the Federal as outlined in Question D-9.

**Note:** The Federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency’s designated representative for authorization in each case.

**For serially collected A and B specimens,** the donor is not allowed to rinse their mouth or drink water between A and B specimen collections, and time between the end of Specimen A collection and beginning of Specimen B collection must not exceed two minutes. If either requirement is not met, the collector must discard any collected oral fluid and recollect A and B specimens.

**Reference:** OFMG (subpart H –sections 8.3.e - g, 8.4.a, and 8.6.b.2) and HHS Oral Fluid Collection Handbook (special instructions for serial split collections)

**Question C-11.** *Does the collector note any unusual appearance or behavior of the donor on the Federal CCF? (YES/NO)*

**Comment:** The collector must note any unusual appearance or behavior of the donor on the Federal CCF. If the collector detects conduct that indicates an attempt to tamper with the specimen (e.g., an attempt to bring into the collection site an adulterant or oral fluid substitute), this is considered a refusal to test. The collector must stop the collection and report the refusal to test to the Federal agency as described in Question D-9.

**Reference:** OFMG (subpart H – section 8.4.e)

**Question C-12.** *Does the collector review the procedures for a successful oral fluid specimen collection as detailed in the device-specific manufacturer's instructions? (YES/NO)*

**Comment:** The collector must go over the instructions for the specific oral fluid device with the donor prior to specimen collection.

Reference: HHS Oral Fluid Mandatory Guidelines (subpart H – section 8.4.d) and HHS Oral Fluid Collection Handbook (special instructions for serial split collections)

**Question C-13.** *Are unauthorized personnel prohibited from entering the collection site during the collection procedure? (YES/NO)*

**Comment:** Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

Reference: OFMG (subpart E - section 5.5.a.1-2; subpart H – section 8.1.a)

**Question C-14.** *Are only the collector and the donor allowed to handle the unsealed specimen? (YES/NO)*

**Comment:** The collector must ensure that only the collector and donor handle the unsealed specimen.

Reference: OFMG (subpart E - section 5.5.a.4)

**Question C-15.** *Does the collector remain present and maintain visual contact with the donor during the entire collection process? (YES/NO)*

*If NO, check the deficient area(s):*

- a. *Ensure the donor has positioned the specimen collection device properly for collection*
- b. *Ensure the collection is performed correctly*
- c. *Ensure collection device is working properly*

**Comment:** The collector must be present and maintain visual contact with the donor during the entire procedure for the collection of the oral fluid specimen.

Under the observation of the collector, the donor is responsible for the proper positioning of the specimen collection device for collection. The collector must ensure the collection is performed correctly and that the collection device is working as intended.

For devices containing a diluent, the collector should visually inspect the volume of the diluent in each tube prior to giving it to the donor to ensure the collection device is not defective.

When two specimens are collected serially, collection of the second specimen must begin within two minutes of the completion of the first collection. The collector must take actions specified in special instructions for serial split collections described in the HHS Specimen Oral Fluid Collection Handbook (page 21).

If there is a failure to collect the specimen, the collector must begin the process again, using a new specimen collection device (for both A and B specimens) and notes the failed collection attempt on the Federal CCF. If the donor states they are unable to provide an oral fluid specimen during the collection process or after multiple failures to collect the specimen, the collector follows the procedures outlined in Section 8.6 of the OFMG.

The collector and the donor must complete the collection in accordance with the manufacturer instructions for the collection device.

Reference: OFMG (subpart H – section 8.5.a) and HHS Oral Fluid Collection Handbook (special instructions for serial split collections)

**Question C-16.** *Does the collector ensure the donor has provided a sufficient volume of oral fluid (e.g., 1 mL of undiluted [neat] oral fluid for tube A and 1 mL of undiluted [neat] oral fluid for tube B) for the following types of split specimen collections? (YES/NO)*

If **NO**, check the deficient area(s):

- a. *Two specimens collected simultaneously using two separate collection devices*
- b. *Two specimens collected serially with two separate collection devices*
- c. *Two specimens collected simultaneously using a single collection device that splits the specimen into two separate collection tubes*
- d. *A single specimen collected using a single collection device that is subdivided into two specimen tubes.*

**Comment:** All oral fluid collections are to be collected as a split specimen. Depending on the agency, a variety of methods of collection can be employed to ensure a split specimen is collected.

A volume of at least 1 mL of undiluted (neat) oral fluid is to be collected for the specimen designated as “Tube A” and at least 1 mL of undiluted (neat) oral fluid is to be collected for the specimen designated as “Tube B”.

Reference: OFMG (subpart H – section 8.8.a-b) and HHS Oral Fluid Collection Handbook

**Question C-17.** *Does the collector inspect the collected specimen for signs that it may not be a valid oral fluid specimen? (YES/NO)*

**Comment:** The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid oral fluid specimen (e.g., unusual color, presence of foreign objects or material). The collector documents any unusual findings on the Federal CCF, and takes action (e.g., recollection) to obtain an acceptable specimen.

Reference: OFMG (subpart H – section 8.5.a.3)

**Question C-18.** *Does the collector complete the required information in Step 2 of the Federal CCF? (YES/NO)*

**Comment:** The collector must complete entries in Step 2 of the Federal CCF. This includes marking the checkbox for the Collection type: Split, Single, or None provided (with explanatory Remarks) and completing subsequent entries specific to oral fluid specimens.

- Split Type: check the appropriate box to document the split specimen type (serial, concurrent, or subdivided);
- Expiration Date: inspect each device before use to ensure it is within its expiration date. If each device is within date, check the YES box. If a device is out of date, check the NO box and stop the oral fluid collection.
- Volume Indicator(s) Observed: the collector must verify that sufficient oral fluid was collected during the collection as described under Question C-16.
  - For devices with a volume indicator, the collector must observe the volume indicator for each device during oral fluid collection, and mark the box to document this observation after collection of A and B specimens.
  - For devices without a diluent (neat oral fluid specimens), the collector must inspect the markings on the specimen tubes after collection to ensure that at least 1 mL of oral fluid was collected for each of the A and B specimens.

**Note:** Failure to document the Volume Indicator(s) observed box is a fatal flaw, not recoverable after shipment of the specimen to the laboratory.

Reference: OFMG (subpart H – section 8.4.c), Instructions for Completing the Federal CCF for Oral Fluid Specimen Collection, and HHS Oral Fluid Collection Handbook

### *Completion of a Collection*

**Question C-19.** *Does the collector report a refusal if the donor refuses to complete the collection? (YES/NO)*

**Comment:** If the donor fails to remain present through the completion of the collection, fails to follow instructions for the collection device, refuses to begin the collection process after a failure to collect the specimen as outlined in question C-15 above, refuses to provide a split specimen as instructed by the collector, or refuses to provide

an authorized alternate specimen when directed by the collector, the collector stops the collection and reports the refusal to test.

Reference: OFMG (subpart H – section 8.5.b)

**Question C-20.** *In the presence of the donor, does the collector place the appropriate tamper-evident label/seal from the Federal CCF over the lid/cap of each tube to ensure that the lid/cap cannot be removed without destroying the label/seal? (YES/NO)*

**Comment:** The collector must place the tamper-evident label/seal from the Federal CCF over the lid/cap of each tube to ensure that the lid/cap cannot be removed without destroying the label/seal. **This must be performed in the presence of the donor.** The “**A**” label is used for the specimen collected first in a serial collection or the tube designated as A while the “**B**” label is used for the specimen collected second in a serial collection or the tube designated as B.

The label/seal must be positioned such that the expiration date on the tube is not covered by the seal and will allow visual assessment of the contents of the tube.

Reference: OFMG (subpart H – section 8.8.c) and HHS Oral Fluid Collection Handbook

**Question C-21.** *If the tamper-evident label/seal does not adhere to the tube or is damaged, does the collector apply the unacceptable label/seal to the tube, and apply a second, separate tamper-evident seal to seal the specimen tube? (YES/NO)*

**Comment:** In some cases, the tamper-evident label/seal may not adhere to the tube or the label/seal may be accidentally broken or damaged during the collection process. In these instances, the collector must apply the original (unacceptable) labels/seals and apply a second separate tamper-evident seal to each specimen tube. The additional seal should be placed perpendicular to the original label/seal to avoid obscuring information on the label/seal (e.g., specimen ID number associated with the Federal CCF) and avoid obscuring the expiration date on the tubes while allowing visual assessment of the tubes’ contents. The collector must initial and date the second seal, and request that the donor initial the second seal. If the donor refuses to initial the second seal, the collector should note this refusal on the Remarks line in Step 2 and continue with the collection process. This is not considered a refusal to test.

The collector should provide a comment on the Remarks line in Step 2 of the Federal CCF explaining why a second seal was used.

Reference: HHS Oral Fluid Collection Handbook

**Question C-22.** *Does the collector record the date of the collection on the tube seals after placing them on the tubes? (YES/NO)*

**Comment:** The collector must write the date of the collection on the labels/seals after placing them on the specimen tubes (i.e., Tube A and Tube B).

Reference: OFMG (subpart H – section 8.8.c)

**Question C-23.** *Does the collector instruct the donor to initial the specimen tube seals after placing them on the tubes? (YES/NO)*

**Comment:** After placing the labels/seals on the tubes, the collector must direct the donor to initial the labels/seals taking care to avoid damage. If the donor refuses to initial the labels/seals, the collector should note this refusal on the Remarks line in Step 2 and continue with the collection process. This is not considered a refusal to test.

Reference: OFMG (subpart H – section 8.8.d)

**Question C-24.** *Does the collector instruct the donor to read and sign the donor certification statement and to fill out the donor portion in Step 5 on Copy 2 of the Federal CCF? (YES/NO)*

**Comment:** The collector requests that the donor fill out the donor portion in Step 5 on Copy 2 of the Federal CCF by printing their name, and providing their email address, day and evening telephone numbers, and date of birth. If the donor refuses to provide the information, the collector should print the donor's name where indicated.

The collector requests that the donor read, sign, and date the donor statement certifying that the specimen identified was collected from the donor. If the donor refuses to sign the certification statement, the collector should note this refusal on the Remarks line in Step 2 of the Federal CCF and continue with the collection process. This is not considered a refusal to test.

For ECCFs (digital CCFs or combination electronic and paper CCFs): Some of the items (i.e., date of birth, printed name, and telephone numbers) may already have been entered in to the ECCF system prior to the collection. If the donor refuses to sign electronically, but is willing to sign a paper CCF with a wet signature, the collector must print the ECCF, Copies 1-5. The donor must sign in Step 5 of Copies 2-5 using a wet signature and the collector must sign in Step 4 of Copies 1-5 using a wet signature.

Reference: OFMG (subpart H – section 8.8.f) and HHS Oral Fluid Collection Handbook

**Question C-25.** *Does the collector complete the collector chain of custody section and document device expiration dates (as applicable) in Step 4 on Copy 1 of the Federal CCF? (YES/NO)*

**Comment:** The collector must complete Step 4 on Copy 1 of the Federal CCF by signing and printing their name, recording the date and time of the collection, and indicating the delivery service to which the specimen tubes and CCF will be released.

The collector must record the manufacturer's expiration date on each specimen tube in Step 4 (i.e., the A specimen tube expiration date as the Primary/Single Specimen Device Expiration Date, the B specimen tube expiration date as the Split Specimen Device Expiration Date).

For ECCFs: An ECCF system may require the collector to scan or type the expiration date for each device into the ECCF system before use, for the system to check that the collection device is within its expiration date and to mark Step 2 (i.e., when both A and B devices are within date for a split collection). For each oral fluid collection, the collector must visually verify the expiration date on each tube vs. that recorded on the CCF or in the ECCF system.

The laboratory accessioner must be able to verify the expiration dates recorded by the collector vs. those on the tubes.

Reference: OFMG (subpart H – section 8.8.g) and HHS Oral Fluid Collection Handbook

**Question C-26.** *Does the collector place the sealed specimen tubes inside the leak-resistant container, seal the container, and include Copy 1 in the package with the specimen (i.e., in a compartment separate from the specimen tubes)? (YES/NO)*

**Comment:** The collector places both specimen tubes inside the leak-resistant container and seals the container.

For paper CCFs and combination electronic and paper CCFs: the collector places Copy 1 in the specimen package (i.e., in a compartment separate from the specimen bottles).

**Note:** For combination electronic and paper CCFs, Copy 1 sent with the specimen must be either the single authoritative copy or a reprint of Copy 1 that has been signed by the collector using a wet signature.

For digital Federal CCFs: the collector must either include a printed copy of Copy 1 with the specimen OR must apply a label to the outside of the specimen package with the specimen identification number, test facility name and contact information, and the collection site name and contact information.

Reference: OFMG (subpart H – section 8.8.h) and HHS Oral Fluid Collection Handbook

**Question C-27.** *Does the collector provide Copy 5 of the Federal CCF to the donor? (YES/NO)*

**Comment:** The collector gives Copy 5 of the Federal CCF to the donor. This may be a printed copy or a copy provided electronically after the collection. The collector reminds the donor that they may list any prescription medications on the back of Copy 5 or on a separate sheet of paper. This information may help the donor remember which medications they may have taken near the time of the collection, if contacted later by the MRO. This information must not be recorded on any other copy of the Federal CCF or other record maintained or distributed by the collector.

Reference: HHS Oral Fluid Collection Handbook

**Question C-28.** *Does the collector prepare the sealed tamper-resistant package containing the specimen tubes and Federal CCF for transport to the HHS-certified laboratory? (YES/NO)*

**Comment:** The collector places the sealed specimen package into a shipping container (e.g., box or express carrier mailer). Several specimen packages may be placed in one shipping container. The collector then seals the container. It is not necessary to use a shipping container if the specimen packages are to be hand-delivered to the laboratory.

**Note:** If the tamper-evident label/seal from the Federal CCF is broken on the specimen tube after the donor leaves the collection site, the collection must be cancelled. The collector notifies the Federal agency's designated representative that the label/seal was broken on the specimen tube(s).

Reference: HHS Oral Fluid Collection Handbook

**Question C-29.** *Are the specimen tubes and Federal CCF appropriately safeguarded until they are retrieved for transport to the HHS-certified laboratory? (YES/NO)*

**Comment:** If the specimens are not shipped immediately, the collector is responsible for ensuring specimen security. For specimens not in a shipping container, the collector must take necessary steps to prevent any possible tampering or access by unauthorized personnel. Specimen packages in a sealed shipping container should be protected against theft or damage prior to pick-up by the designated delivery service.

Reference: OFMG (subpart E – section 5.2.c and subpart H - section 8.8.i) and HHS Oral Fluid Collection Handbook

**Question C-30.** *Does the collector send Copy 2 of the Federal CCF to the Medical Review Officer (MRO) and Copy 4 of the Federal CCF to the agency's designated representative after the collection? (YES/NO)*

**Comment:** The collector must send Copy 2 of the Federal CCF to the MRO and Copy 4 to the Federal agency's representative as soon as possible once the collection is complete (e.g., within 24 hours of the collection or during the next business day). Acceptable methods of transmitting a paper Federal CCF include faxing to a secure fax machine, sending a scanned image to a secure computer, or sending by mail or courier.

Reference: HHS Oral Fluid Collection Handbook

**Question C-31.** *Are specimens submitted to an HHS-certified laboratory within 24 hours after the collection or during the next business day? (YES/NO)*

**Comment:** Specimens must be submitted to the laboratory within 24 hours after the collection or during the next business day.

Reference: OFMG (subpart H – section 8.8.h) and HHS Oral Fluid Collection Handbook



## Section Evaluation

### Question C-32. *For the Specimen Collection Procedures Section:*

- Serious deficiencies were identified (0 points)*
- Deficiencies were identified (1 point)*
- No deficiencies were identified (2 points)*

Note: *This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.*

Describe basis for the above selection:

## **Section D. Collection Problems**

**Insufficient Specimen – Questions D-1 through D-4 pertain to collections where the donor states that they are unable to provide an oral fluid specimen.**

**Question D-1.** *Does the collector attempt an oral fluid collection when the donor states they are unable to provide a specimen? (YES/NO)*

*If **NO**, check the deficient step(s):*

- a. *Requests that the donor follow the instructions for the specific collection device and attempt to provide an oral fluid specimen*
- b. *Provides a drink (up to 8 oz.) when the donor indicates they may provide a specimen after drinking fluids*
- c. *Allows a wait period up to 1 hour for the donor to provide a sufficient oral fluid specimen*
- d. *Directs the donor to remain at the collection site (in an area designated by the collector) during the wait period*

**Comment:** The collector must begin the collection regardless of whether the donor states that they cannot provide a specimen. When the donor states they are unable to provide an oral fluid specimen, the collector requests that the donor follow the instructions for the specific collection device and attempt to provide an oral fluid specimen. The donor demonstrates their inability to provide a specimen when after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device (see question D-6 below).

If the donor indicates that they may be able to provide a specimen after drinking fluids, the collector gives the donor a drink (up to 8 ounces). **The donor is not required to drink fluids.** The collector must wait 10 minutes from the time the donor drinks fluids before beginning specimen collection.

The collector must allow up to one hour for the donor to provide a sufficient specimen. The collector should be sensitive to how frequently the donor is asked to provide a specimen. It is recommended that the collector allow sufficient time to only have one additional attempt rather than documenting several unsuccessful attempts.

During the wait period between collection attempts, the donor must remain in an area at the collection site (designated by the collector) to prevent the donor from possibly compromising the collection process. At a minimum, the donor must remain under the direct observation of the collector during the final 10 minutes of the wait period before the collection attempt.

**Note:** If the donor refuses to attempt to provide a specimen or leaves the collection site before the process is completed, this is considered a refusal to test. The collector reports the refusal to test as outlined in Question D-9.

**Special instructions for serial split collections:** When A and B specimens are collected serially, the donor is not allowed to drink or rinse their mouth between the two collections. Collection of the second specimen must begin within two minutes of the completion of the first collection. See special instructions for serial split collections in the HHS Oral Fluid Collection Handbook

Reference: OFMG (subpart H – section 8.6) and HHS Oral Fluid Collection Handbook

**Question D-2.** *Does the collector record each failed collection attempt on the Remarks line of the Federal CCF? (YES/NO)*

**Comment:** The collector must record each collection attempt made by the donor to provide a sufficient volume of specimen (e.g., on the Remarks line of the Federal CCF).

Reference: HHS Oral Fluid Collection Handbook

**Question D-3.** *Does the collector discontinue the collection procedure in the following situations? (YES/NO)*

- *The donor has demonstrated that they are unable to provide a specimen*
- *The donor has not provided sufficient volume of specimen in one hour from the time of the donor's first attempt*

**Comment:** If the donor states they are unable to provide a specimen after attempting to provide a specimen or if the donor has not provided a sufficient specimen after a one hour wait period from the first attempt, the collector is to discontinue the collection.

Reference: OFMG (subpart H –8.6.b.2) and HHS Oral Fluid Collection Handbook

**Question D-4.** *When discontinuing a collection, does the collector take the following steps? (YES/NO)*

*If NO, check the deficient area(s):*

- \_\_\_ a. *Mark the “None Provided” checkbox in Step 2 of the Federal CCF*
- \_\_\_ b. *Record the reason for not collecting the specimen on the Remarks line in Step 2 of the Federal CCF*
- \_\_\_ c. *Notify the agency's designated representative for authorization to collect an alternate specimen or follow the standard protocol from the Federal agency*
- \_\_\_ d. *Discard the oral fluid collected (if any)*
- \_\_\_ e. *Discard Copy 1 of the Federal CCF (no valid specimen was collected) and maintain Copy 3 in the collection records*
- \_\_\_ f. *Distribute the remaining Federal CCF copies within 24 hours or the next business day:*

- Send Copy 2 to the MRO
- Send Copy 4 to the Federal agency's designated representative

**Comment:** When a donor has not provided a sufficient specimen, the collector must follow all steps listed above. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen (i.e., urine). The Federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case.

Reference: OFMG (subpart H –8.6.b) and HHS Oral Fluid Collection Handbook

## **Refusal to Test**

**Question D-5.** *Does the collector report a “refusal to test” in the following situations? (YES/NO)*

*If **NO**, check the deficient area(s):*

- a. *The donor fails to appear for any test within a reasonable time as determined by the Federal agency*
- b. *The donor leaves the collection site before completion of the collection*
- c. *The donor fails to provide a specimen (e.g., oral fluid or another authorized alternate specimen type)*
- d. *The donor fails to cooperate with any part of the testing process (e.g., refuses to empty pockets, disrupts the collection process, fails to rinse mouth when directed by the collector, refuses to provide a split specimen)*
- e. *The donor brings materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen*
- f. *The donor attempts to adulterate, substitute, or dilute the specimen*
- g. *The donor admits to the collector that they have adulterated or substituted their specimen*

**Comment:** A Federal agency will take adverse action against an employee whose drug test specimen is reported as a refusal to test. The collector must report a refusal to test in the situations listed above.

Reference: OFMG (subpart A – section 1.7.a.1-10, subpart H – section 8.5b) and HHS Oral Fluid Collection Handbook

**Question D-6.** *When reporting a “refusal to test,” does the collector take the following steps? (YES/NO)*

*If **NO**, check the deficient step(s):*

- a. *Discard the oral fluid collected (if any)*
- b. *Immediately notify the agency's designated representative of the refusal (e.g., by telephone, secure fax machine, e-mail)*
- c. *Document the refusal to test with appropriate comments, signature, and date in the Remarks line of Step 2 of the Federal CCF*

\_\_\_\_ d. *Send all copies of the Federal CCF to the Federal agency's designated representative*

**Comment:** When reporting a refusal to test, the collector must discard all oral fluid collected (if any). The collector must immediately notify the Federal agency's designated representative by a means (e.g., by telephone, secure fax machine, e-mail) that ensures immediate receipt of the refusal notification. The collector must document the refusal to test with appropriate comments, signature, and date in the Remarks line of Step 2 of the Federal CCF and send all copies of the Federal CCF to the Federal agency's designated representative.

Reference: OFMG (subpart A - Section 1.8.b, subpart H - section 8.9)

### **Collector Errors**

**Question D-7.** *When the collector realizes that an incorrect or expired Federal CCF was used prior to packaging the specimen tubes, does the collector document on the form that the specimen is a Federal agency specimen and provide the reason for the incorrect form? (YES/NO)*

**Comment:** If an incorrect or expired Federal CCF is used, the collector must document on the form that the specimen is a Federal agency specimen and provide the reason for the incorrect form. The collector must include all collection information required on the current Federal CCF for that specimen type (e.g., observation of volume indicators for an oral fluid collection device with diluent). Based on the documentation provided by the collector, the laboratory will handle and test the specimen as a Federal agency specimen.

**Note:** The collector may document the reason for using the incorrect form on an MFR attached to the form.

Reference: OFMG (subpart E – section 6.2.a-b) and HHS Oral Fluid Collection Handbook

**Question D-8.** *Does the collector provide a memorandum for the record (MFR) when requested by the HHS-certified laboratory or MRO? (YES/NO)*

**Comment:** The collector must take **immediate** steps to provide an MFR to the laboratory, or MRO when notified of an error.

There are three categories of collector errors:

- Fatal flaws that result in a laboratory rejecting a specimen or an MRO cancelling a test,
- Correctable flaws that result in a laboratory rejecting a specimen or an MRO cancelling a test unless the flaw is corrected by an MFR from the collector, or
- Omissions and discrepancies on the Federal CCF that do not require rejection by the laboratory or cancellation by the MRO

**Note:** Federal agencies will investigate reported collection site deficiencies (e.g., specimens rejected for testing due to collector errors).

Reference: OFMG (subpart E – section 6.2.c) and HHS Oral Fluid Collection Handbook

## Section Evaluation

**Question D-9.** *For the Collection Problems Section:*

- Serious deficiencies were identified (0 points)*
- Deficiencies were identified (1 point)*
- No deficiencies were identified (2 points)*

*Note: This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.*

Describe basis for the above selection:

## **Section E. Collection Site Records**

**Question E-1.** Are collection site records including Copy 3 of the Federal Custody and Control Form (Federal CCF) stored for a minimum of two years? (YES/NO)

**Comment:** The collector or collector's employer must maintain collection site records (e.g., Copy 3 of the Federal CCF) for a minimum of two years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Reference: OFMG (subpart E - section 5.4)

**Question E-2.** *Are collection site records stored and disposed of in a manner that ensures donor confidentiality? (YES/NO)*

**Comment:** The collection site must have the ability to store records securely. Records must be stored and disposed of in a manner that ensures donor confidentiality.

Reference: OFMG (subpart E - section 5.3) and HHS Oral Fluid Collection Handbook

**Question E-3.** *Have collectors properly completed the Federal CCF? (YES/NO)*

**Comment:** The collector is responsible for completing Steps 1, 2, and 4 on the Federal CCF.

Reference: HHS Oral Fluid Collection Handbook

**Question E-4.** *Are edits to the Federal CCF properly made, initialed, and dated? (YES/NO)*

**Comment:** The Federal CCF is a forensic document and will be part of the litigation package if a specimen comes under legal challenge. The collector should **never** use correction fluid on the Federal CCF and should never overwrite or obscure information recorded or printed on the Federal CCF. Unclear or improper edits to Federal CCF information (e.g., donor identification numbers, signatures) could compromise the legal defensibility of the document.

If the collector makes an error on a Federal CCF, they should:

1. Make a single line through the erroneous information, leaving the information legible,
2. Write the correct information near (e.g., beside or above) the original annotation, and
3. Initial and date the change.

It is acceptable for the collector to cross out preprinted information on the Federal CCF that is incorrect or inapplicable (e.g., collection site, MRO, laboratory, or employer information). The collector must use the procedures described above for changing the information on the form. This may be necessary in the event of unexpected collections (e.g., accident investigation) or when Federal CCFs at the collection site have outdated information.



Reference: HHS Oral Fluid Collection Handbook

## Section Evaluation

### E-5. For the Collection Site Records Section:

- Serious deficiencies were identified (0 points)
- Deficiencies were identified (1 point)
- No deficiencies were identified (2 points)

*Note: This page is included to facilitate the evaluation of compliance with program requirements. The inspector/reviewer should explain the potential problem or identified non-compliance associated with the checklist questions in this section. Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.*

Describe basis for the above selection:

## Collection Site Evaluation Form

### Overall Section Summary

Checklist Sections		Serious Deficiencies Identified (0)	Deficiencies Identified (1)	No Deficiencies Identified (2)
<b>A. Collection Site</b>				
<b>B. Personnel</b>				
<b>C. Specimen Collection procedures</b>				
<b>D. Collection Problems</b>				
<b>E. Collection Site Records</b>				

### Overall Summary of Serious Deficiencies (List Sections)

<i>Reviewer</i>	<i>Serious Deficiencies were identified</i>	<i>No Serious Deficiencies were identified</i>
Inspector / Collection Site Reviewer		
Federal Agency/ Designee		

### Inspection Outcome

<b>Rating (out of 10)</b>	<i>Acceptable: rating <math>\geq</math> 5 and no more than one section with serious deficiencies</i>	
Inspector / Collection Site Reviewer	___/10	<i>Unacceptable: rating <math>&lt;</math> 5 or more than one section with serious deficiencies</i>
Federal Agency/ Designee	___/10	<b>Outcome:</b>

Additional Comments: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Acceptable Outcome for Inspection: Yes \_\_\_\_\_ No \_\_\_\_\_

Self-Evaluation by: \_\_\_\_\_ Date: \_\_\_\_\_

Onsite Inspection by: \_\_\_\_\_ Date: \_\_\_\_\_

Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

Position/Title: \_\_\_\_\_

## **Attachment 1: OFMG Subparts D-H**

### **Subpart D—Collectors**

- 4.1 Who may collect a specimen?
- 4.2 Who may not collect a specimen?
- 4.3 What are the requirements to be a collector?
- 4.4 What are the requirements to be a trainer for collectors?
- 4.5 What must a Federal agency do before an individual is permitted to collect a specimen?

### **Subpart E—Collection Sites**

- 5.1 Where can a collection for a drug test take place?
- 5.2 What are the requirements for a collection site?
- 5.3 Where must collection site records be stored?
- 5.4 How long must collection site records be stored?
- 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?
- 5.6 What are the privacy requirements when collecting an oral fluid specimen?

### **Subpart F—Federal Drug Testing Custody and Control Form**

- 6.1 What Federal form is used to document custody and control?
- 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

### **Subpart G—Oral Fluid Specimen Collection Devices**

- 7.1 What is used to collect an oral fluid specimen?
- 7.2 What are the requirements for an oral fluid collection device?
- 7.3 What are minimum performance requirements for a collection device?

### **Subpart H—Oral Fluid Specimen Collection Procedure**

- 8.1 What privacy must the donor be given when providing an oral fluid specimen?
- 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?
- 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?
- 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?
- 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?
- 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?
- 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?
- 8.8 How does the collector prepare the oral fluid specimens?
- 8.9 How does the collector report a donor's refusal to test?
- 8.10 What are a Federal agency's responsibilities for a collection site?

## **Subpart D - Collectors**

### Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

(b) The immediate supervisor of a Federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a Federal agency applicant may only collect that Federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

### Section 4.2 Who may not collect a specimen?

(a) A Federal agency employee who is in a testing designated position and subject to the Federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work with that employee on a daily basis.

(b) A Federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (e.g., spouse, ex-spouse, relative) or a personal friend of the employee (e.g., fiancée).

### Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the Federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to the collection procedure described in these Guidelines;

(3) Is trained and qualified to use the specific oral fluid collection device. Training must

include the following:

- (i) All steps necessary to complete an oral fluid collection;
- (ii) Completion and distribution of the Federal CCF;
- (iii) Problem collections;
- (iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and
- (v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include two uneventful collection scenarios, one insufficient specimen quantity scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen tube tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are error-free.

(b) A trained collector must complete refresher training at least every five years that includes the requirements in Section 4.3(a).

(c) The collector must maintain the documentation of their training and provide that documentation to a Federal agency when requested.

(d) An individual may not collect specimens for a Federal agency until the individual's training as a collector has been properly documented.

#### Section 4.4 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors for a specific oral fluid

collection device and may train others to collect oral fluid specimens using that collection device when they have completed the following:

(1) Qualified as a trained collector and regularly conducted oral fluid drug test collections using that collection device for a period of at least one year or

(2) Completed a “train the trainer” course given by an organization (e.g., manufacturer, private entity, contractor, Federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer’s training and provide that documentation to a Federal agency when requested.

Section 4.5 What must a Federal agency do before a collector is permitted to collect a specimen?

A Federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (e.g., third party administrator that provides a collection service, collector training company, Federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the Federal agency representative.

**Subpart E - Collection Sites**

Section 5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (e.g., an accident investigation), another

site may be used for the collection, providing the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

#### Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

- (a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);
- (b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;
- (c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory;
- (d) A restricted access area where only authorized personnel may be present during the collection;
- (e) A restricted access area for the storage of collection supplies; and
- (f) A restricted access area for the secure storage of records.

#### Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

#### Section 5.4 How long must collection site records be stored?

Collection site records (e.g., collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

#### Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

- (a) A collector must do the following to maintain the security and integrity of a specimen:
  - (1) Not allow unauthorized personnel to enter the collection area during the collection procedure;



- (2) Perform only one donor collection at a time;
  - (3) Restrict access to collection supplies before, during, and after collection;
  - (4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;
  - (5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;
  - (6) Ensure that the Federal CCF is completed and distributed as required; and
  - (7) Ensure that specimens transported to an HHS-certified laboratory are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (e.g., specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering;
- (b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory.

Section 5.6 What are the privacy requirements when collecting an oral fluid specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

**Subpart F - Federal Drug Testing Custody and Control Form**

Section 6.1 What Federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-Federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory to automatically reject the specimen for testing or for the MRO to

cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a Federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory must handle and test the specimen as a Federal agency specimen.

(c) If the HHS-certified laboratory or MRO discovers that the collector used an incorrect form, the laboratory or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

## **Subpart G – Oral Fluid Specimen Collection Devices**

### Section 7.1 What is used to collect an oral fluid specimen?

A single-use collection device intended to collect an oral fluid specimen must be used. This 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.

### Section 7.2 What are the requirements for an oral fluid collection device?

An oral fluid specimen collection device must provide:

(a) An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected;

(b) One or two sealable, non-leaking tubes [depending on the device type, as described in Section 8.8(a)] that:

(1) maintain 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,

(2) are sufficiently transparent (e.g., translucent) to enable a visual assessment of the contents (i.e., oral fluid, buffer/diluent, collection pad) for identification of abnormal physical characteristics without opening the tube, and

(3) include the device lot expiration date on each specimen tube (i.e., the expiration date of the buffer/diluent or, for devices without a buffer/diluent, the earliest expiration date of any device component);

(c) Components that ensure pre-analytical drug and drug metabolite stability; and

(d) Components that do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen.

### Section 7.3 What are the minimum performance requirements for a collection device?

An oral fluid collection device must meet the following minimum performance requirements.

(a) Reliable collection of a minimum of 1 mL of undiluted (neat) oral fluid;

(b) If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):

(1) The volume of oral fluid collected should be at least 1.0 mL  $\pm$ 10 percent, and

(2) The volume of diluent in the device should be within  $\pm$ 2.5 percent of the diluent target volume;

(c) Stability (recoverable concentrations  $\geq$ 80 percent of the concentration at the time of collection) of the drugs and/or drug metabolites for five days at room temperature (64-77 °F/18-25 °C) and under the manufacturer's intended shipping and storage conditions; and

(d) Recover  $\geq$ 80 percent (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff listed in the drug testing panel.

## **Subpart H – Oral Fluid Specimen Collection Procedure**

### **Section 8.1 What privacy must the donor be given when providing an oral fluid specimen?**

The following privacy requirements apply when a donor is providing an oral fluid specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor.

### **Section 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?**

The collector must take all reasonable steps to prevent the adulteration or substitution of an oral fluid specimen at the collection site.

### **Section 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?**

The collector must take the following steps before beginning an oral fluid specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the Federal agency policy or contact the Federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (e.g., driver's license; employee badge issued by the employer; an alternative photo identification issued by a Federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the Federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector must provide identification (e.g., employee badge, employee list) if requested by the donor.

(e) The collector asks the donor to remove any unnecessary outer garments (e.g., coat, jacket) that might conceal items or substances that could be used to adulterate or substitute the oral fluid specimen. The collector must ensure that all personal belongings (e.g., purse or briefcase) remain with the outer garments. The donor may retain the donor's wallet. The donor is not required to remove any items worn for faith-based reasons.

(f) If the donor will remain under the collector's direct observation until the end of the collection, including the 10-minute wait period described in Section 8.3(h), the collector proceeds to Section 8.3(g). If the collector will not keep the donor under direct observation from this point until the end of the collection, the collector asks the donor to empty the donor's pockets and display the contents to ensure no items are present that could be used to adulterate or substitute the specimen.

(1) If no items are present that can be used to adulterate or substitute the specimen, the collector instructs the donor to return the items to their pockets and continues the collection procedure.

(2) If an item is present whose purpose is to adulterate or substitute the specimen (e.g., a commercial drug culture product or other substance for which the donor has no reasonable explanation), this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(3) If an item that could be used to adulterate or substitute the specimen (e.g., common personal care products such as mouthwash, lozenges, capsules) appears to have been inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) If the donor refuses to show the collector the items in their pockets, the collector must keep the donor under direct observation until the end of the oral fluid collection.

(g) The collector requests that the donor open the donor's mouth, and the collector inspects the oral cavity to ensure that it is free of any items (e.g., candy, gum, food, tobacco) that could impede or interfere with the collection of an oral fluid specimen or items that could be used to adulterate, substitute, or dilute the specimen.

(1) If an item is present that whose purpose is to adulterate or substitute the specimen (e.g., a commercial drug culture product or other item for which the donor has no reasonable explanation), this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(2) If an item is present that could impede or interfere with the collection of an oral fluid specimen (including abnormally colored saliva), or the donor claims to have "dry mouth," the collector gives the donor water (e.g., up to 4 oz.) to rinse their mouth. The donor may drink the water. If the donor refuses to remove the item or refuses to rinse, this is a refusal to test.

(3) If the donor claims that they have a medical condition that prevents opening their mouth for inspection, the collector follows the procedure in Section 8.6(b)(2).

(h) The collector must initiate a 10-minute wait period prior to collecting the specimen. During these 10 minutes, the collector must:

(1) Explain the basic collection procedure to the donor;

(2) Provide the instructions for completing the Federal CCF for the donor's review, and informs the donor that these instructions and the collection device-specific instructions are available upon request.

(3) Answer any reasonable and appropriate questions the donor may have regarding the collection procedure; and

(4) Inform the donor that they must remain at the collection site (i.e., in the area designated by the collector) during the wait period, and that failure to follow these instructions will be reported as a refusal to test.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

(a) The collector shall instruct the donor to wash and dry the donor's hands under the collector's observation, and to keep their hands within view and avoid touching items or surfaces after handwashing. If the donor refuses to wash their hands when instructed by the collector, this is a refusal to test.

(b) The collector will provide or the donor may select the specimen collection device(s) to be used for the collection. The device(s) must be clean, unused, and wrapped/sealed in original packaging and must be within the manufacturer's expiration date printed on the specimen tube. See Section 8.8(a) for types of specimen collection devices used for oral fluid split specimen collections.

(1) The collector will open the package in view of the donor.

(2) Both the collector and the donor must keep the unwrapped collection devices in view at all times until each collection device containing the donor's oral fluid specimen has been sealed and labeled.

(c) The collector verifies that each device is within the manufacturer's expiration date, and documents this action on the Federal CCF.

(d) The collector reviews with the donor the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(e) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (e.g., an attempt to prevent the device from collecting sufficient oral fluid; an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must report a refusal to test in accordance with Section 8.9.

Section 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the oral fluid specimen:

(a) The collector shall be present and maintain visual contact with the donor during the procedures outlined in this section.

(1) Under the observation of the collector, the donor is responsible for positioning the specimen collection device for collection. The collector must ensure the collection is performed correctly and that the collection device is working properly. If there is a failure to collect the specimen, the collector must begin the process again, beginning with Step 8.4(b), using a new specimen collection device (for both A and B specimens) and notes the failed collection attempt on the Federal CCF. If the donor states that they are unable to provide an oral fluid specimen during the collection process or after multiple failures to collect the specimen, the collector follows the procedure in Section 8.6.

(2) The donor and the collector must complete the collection in accordance with the manufacturer instructions for the collection device.

(3) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid oral fluid specimen (e.g., unusual color, presence of foreign objects or material), documents any unusual findings on the Federal CCF, and takes action (e.g., recollection) to obtain an acceptable specimen.

(b) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection device, refuses to begin the collection process after a failure to collect the specimen as required in Section 8.5(a)(1), refuses to provide a split specimen as instructed by the collector, or refuses to provide an alternate specimen when directed to do so, the collector stops the collection and reports the refusal to test in accordance with Section 8.9.



Section 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

(a) If the donor states that they are unable to provide an oral fluid specimen during the collection process, the collector requests that the donor follow the collector instructions and attempt to provide an oral fluid specimen.

(b) The donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a drink (up to 8 ounces) and waits an additional 10 minutes before beginning the specimen collection (a period of 1 hour must be provided or until the donor has provided a sufficient oral fluid specimen). If the donor simply needs more time before attempting to provide an oral fluid specimen, the donor may choose not to drink any fluids during the 1 hour wait time. The collector must inform the donor that the donor must remain at the collection site (i.e., in an area designated by the collector) during the wait period.

(2) If the donor states that they are unable to provide an oral fluid specimen, the collector records the reason for not collecting an oral fluid specimen on the Federal CCF, notifies the Federal agency's designated representative for authorization to collect an alternate specimen, and sends the appropriate copies of the Federal CCF to the MRO and to the Federal agency's designated representative. The Federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen.

Section 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the Federal agency.

Section 8.8 How does the collector prepare the oral fluid specimens?

(a) All Federal agency collections are to be split specimen collections. An oral fluid split specimen collection may be:

(1) Two specimens collected simultaneously with two separate collection devices;

(2) Two specimens collected serially with two separate collection devices. The donor is not allowed to drink or rinse their mouth between the two collections. Collection of the second specimen must begin within two minutes after the completion of the first collection and recorded on the Federal CCF;

(3) Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or

(4) A single specimen collected using a single collection device, that is subsequently subdivided into two specimens.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Tube A” and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as “Tube B”.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over the cap of each specimen tube. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen tube. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all required information is included on the Federal

CCF.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Tube A and Tube B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory that will be testing the Tube A oral fluid specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

#### Section 8.9 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any oral fluid specimen collected and reports the refusal to test by:

(a) Notifying the Federal agency by means (e.g., telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test including the reason on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the Federal agency's designated representative.

#### Section 8.10 What are a Federal agency's responsibilities for a collection site?

(a) A Federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H of these Guidelines.

(b) A Federal agency (or only one Federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year,

selected randomly from those sites used to collect agency specimens (e.g., virtual, onsite, or self-evaluation).

(c) A Federal agency must investigate reported collection site deficiencies (e.g., specimens reported “rejected for testing” by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (i.e., using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

## **Subpart J - Blind Samples Submitted by an Agency**

### Section 10.1 What are the requirements for Federal agencies to submit blind samples to HHS-certified laboratories?

(a) Each Federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory that the collector sends employee specimens.

(b) Each Federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative and 25 percent must be positive for one or more drugs.

### Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier in the selected manufacturer’s collection device as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must contain one or more of the drugs or metabolites listed in the drug testing panel.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff.

(b) Drug negative blind samples (i.e., certified to contain no drugs) must be validated by the supplier in the selected manufacturer's collection device as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory, and must provide the information upon request to the MRO, the Federal agency for which the blind sample was submitted, or the Secretary.

#### Section 10.3 How is a blind sample submitted to an HHS-certified laboratory?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

#### Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory reports a result for a blind sample that is inconsistent with the expected result (e.g., a laboratory reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory and attempt to determine if the laboratory made

an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the Federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the Federal agency. The Secretary shall ensure notification of the finding as appropriate to other Federal agencies and coordinate any necessary actions to prevent the recurrence of the error.