

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

**Oral Fluid Specimen Collection Handbook
for
Federal Agency Workplace Drug Testing Programs**

EFFECTIVE OCTOBER 10, 2023

Note: This handbook 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 handbook 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).

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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 and drug testing facilities for federally regulated drug testing. Testing must be performed at facilities certified by SAMHSA under the National Laboratory Certification Program (NLCP). HHS has maintained oversight of federally regulated drug testing through this program since it began in 1988. 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.

The **HHS Urine Specimen Collection Handbook** provides information and guidance for the collection of urine specimens for Federal agency workplace drug testing programs, based on the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG).¹

The **HHS Oral Fluid Specimen Collection Handbook** provides information and guidance for the collection of oral fluid specimens for Federal agency workplace drug testing programs, based on the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG).²

All federally regulated oral fluid specimens must be sent to an HHS-certified laboratory for testing. IITFs are not allowed to test oral fluid specimens.

This document and additional specimen collection resources are available on the SAMHSA website: <https://www.samhsa.gov/workplace/resources>.

¹ Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine, Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, 88 FR 70768, effective 02/01/2024.

² Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid, Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, 88 FR 70814, effective 10/10/2023.

Chapter 1. The Collector

A collector is the person trained to instruct and assist a donor in providing a specimen.

The following restrictions apply:

- The immediate supervisor of an employee may only collect that donor's specimen when no other collector is available. A supervisor serving as a collector must be a trained collector. The supervisor must maintain an explanatory memorandum to explain why they collected their employee's specimen.
- The hiring official of a Federal agency applicant may only collect that Federal agency applicant's specimen when no other collector is available. A hiring official serving as a collector must be a trained collector. The hiring official should maintain an explanatory memorandum to explain why they collected the applicant's specimen.
- A coworker who is in the same testing pool or who works with an employee on a daily basis must not serve as a collector when that employee is tested.
- An applicant or employee must not serve as the collector by collecting their own specimen.
- An individual working for an HHS-certified test facility may not serve as a collector if that individual can link the donor with the specimen drug test result or the report from the test facility.
- An individual who has a personal relationship with the employee (e.g., spouse, ex-spouse, relative, personal friend) must not serve as the collector.

To qualify as an oral fluid specimen collector for a Federal agency program, an individual must:

1. Be knowledgeable of the collection procedure described in the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG).
2. Be knowledgeable of any guidance provided by the Federal agency's Drug-Free Workplace Program and additional information provided by HHS relating to the collection procedure described in the OFMG.
3. Be knowledgeable of the manufacturer instructions for each oral fluid collection device that will be used by the collector for Federal agency specimens. See **Appendix B** requirements for devices used to collect diluted and undiluted (neat) oral fluid specimens.
4. Receive training from a qualified trainer for oral fluid specimen collectors on the following topics for each oral fluid collection device:
 - a. All steps to correctly perform an oral fluid specimen collection in accordance with this Specimen Collection Handbook and the manufacturer's instructions for the collection device.

- b. Completion and distribution of the Federal Custody and Control Form (CCF). (See **Note** below.)
 - c. Problem collections.
 - d. Fatal flaws and correctable flaws and how to correct problems during collections.
 - e. Collector responsibilities to maintain 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.
5. Demonstrate proficiency in oral fluid collections by successfully completing five consecutive error-free mock collections that 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.
 - a. The 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. When training on multiple collection devices, the trainer may revise the proficiency demonstration to require two uneventful additional collection scenarios using each collection device type and use only one of the device types for the remaining three scenarios (i.e., insufficient specimen, donor refusal to sign the Federal CCF, donor refusal to initial the tamper-evident seal on the specimen tube).
 6. Document their completed training as a collector in accordance with the above requirements before collecting any specimens for a Federal agency.
 7. Maintain training documentation and provide it to a Federal agency upon request.

Note: The collector training outlined above must be conducted using a paper Federal CCF. To use an electronic Federal CCF (ECCF) for federally regulated specimen 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. See also ECCF definitions and requirements in **Chapter 5, Section A**.

A trained oral fluid specimen collector must:

1. Before using an additional or revised collection device for a Federal agency program, complete training that includes initial training in items 4 and 5 above. A minimum of two mock uneventful collection scenarios using the device is required for the proficiency demonstration. The trainer may also choose to require the three additional error-free mock collections described in item 5 above.

2. At least every five years from the date of initial training, complete refresher training that includes all initial training items (items 1-6 above).
3. Document training in accordance with the above requirements before collecting any Federal agency specimens using the additional/revised collection device or collecting any Federal agency specimens more than five years after initial training.
4. Maintain training documentation and provide it to a Federal agency upon request.

To qualify as a trainer for oral fluid collectors to use a specific collection device for a Federal agency program, an individual must:

1. Be qualified as a trained collector and have regularly conducted oral fluid drug test collections using that collection device for a period of at least one year OR have successfully completed a “train the trainer” course given by an organization (e.g., oral fluid collection device manufacturer, private entity, contractor, Federal agency).
2. Complete refresher training in accordance with collector requirements (see above) at least every five years from the date of the individual’s initial training.
3. Maintain records documenting trainer qualification (e.g., original records for initial and refresher collector training, “train the trainer” course certificate, employment records) and provide copies to a Federal agency or to a Federal agency’s Medical Review Officer (MRO) upon request.

Before a collector is permitted to collect an oral fluid specimen for a Federal agency, the agency must:

1. Ensure that the collector has satisfied the oral fluid specimen collector requirements described in the OFMG.
2. Ensure that the collector, who may be self-employed, or an organization (e.g., third party administrator that provides a collection service, collector training organization, Federal agency that employs its own collectors) maintains a copy of the collector’s training documentation.
3. Provide the collector with the name and telephone number of the Federal agency’s designated representative.

The collector should have identification with their name and their employer’s name, address, and telephone number. The collector is required to provide their identification (employee badge or employee list) if requested by the donor. There is no requirement for the collector to have identification (ID) with their photo or to provide their driver's license with an address.

Chapter 2. Collector/Collection Site Records

The collector must maintain their original collector training records (i.e., for initial, additional, and refresher training) and provide copies to their employer and, as requested, to the Federal agency.

Collection site records must be stored at a secure site designated by the collector or the collector's employer for a minimum of two years. Collection site records include the collector copies of the Office of Management and Budget-approved Federal CCF for each specimen. Both hardcopy and electronic collection records must be stored and disposed of in a manner that ensures donor confidentiality is maintained. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Personally identifiable information (PII) is information that can be used to distinguish or trace an individual's identity alone or when combined with other personal identifying information which is linked or linkable to a specific individual. PII that may be on the Federal CCF includes the donor's Social Security Number (SSN), name, date of birth, telephone numbers, and employment status. All federally regulated employers and drug testing service providers (including collectors) must implement procedures and administrative, technical, and physical controls to ensure donor privacy by restricting access to PII on hardcopy and electronic collection records (e.g., on Federal CCFs, in information entered into a computer system or database). Access to donor PII must be limited to those individuals requiring access to fulfill job duties. Such individuals must receive training to make them aware of their responsibilities for protecting the information. The confidentiality must be maintained from the time the donor PII is obtained through transmission/transport of the Federal CCF copies and record handling (i.e., storage, retrieval, and final destruction). Both hardcopy and electronic collection records must be stored and disposed of in a manner that ensures donor confidentiality is maintained.

The collector must not solicit or record a donor's medical information during the collection process.

Chapter 3. The Collection Site

A collection site may be a permanent or temporary facility, located either at the work site or at a remote site, where donors present themselves for the purpose of providing a specimen for a drug test. When there is an immediate need to collect a specimen (e.g., a post-accident investigation) and there is no agency-designated site available, another site may be used for the collection. The site must have all necessary personnel, supplies, equipment, facilities, and supervision to provide for specimen collection, security, and temporary storage until the specimen is transferred to an HHS-certified laboratory, and must have arrangements for the transfer of the specimens to a certified laboratory.

A facility used as an oral fluid collection site must have:

1. Provisions to ensure donor privacy during the collection. Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.
2. A suitable clean surface inaccessible to the donor for the collector to handle the specimen and complete the paperwork.
3. A secure temporary storage area for maintaining specimens until they are transferred to an HHS-certified laboratory. Specimens must be shipped within 24 hours or no later than the next business day. **Specimens that will not be shipped within 24 hours (e.g.,**

collected on a Friday for shipment on Monday) should be kept in secure refrigerated storage.

Note: Specimens should NOT be exposed to high temperatures for an extended time. These conditions may affect the test results of an oral fluid specimen.

4. Provisions 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).
5. Provisions for the collector to:
 - a. Restrict access to collection supplies before, during, and after the collection,
 - b. Store collection site records securely, and
 - c. Restrict donor access to items that could be used to adulterate or substitute the specimen, or otherwise adversely affect the oral fluid collection.

Chapter 4. Federal Agency Blind Samples

The OFMG require each Federal agency to have blind samples (i.e., negative and positive samples) submitted to each HHS-certified laboratory that tests donor specimens for its workplace drug testing program. The blind samples may be purchased and supplied to the collector by the Federal agency or the agency's external service provider, or purchased by the collector and submitted to each HHS-certified laboratory that the collector sends the agency's specimens. The OFMG specify the approximate percentage of each type (i.e., 75 percent negative, 25 percent positive for one or more drugs). At a minimum, each Federal agency must submit 3 percent blind samples 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. The collector should distribute blind samples randomly with donor specimens rather than submitting blind samples as one group.

Each oral fluid blind sample must meet the following requirements:

1. Drug-positive and -negative blind samples must be validated by the supplier as to their content using appropriate initial and confirmatory drug tests. The samples to be validated must be in the specimen tubes for the selected oral fluid collection device(s), along with the diluent for that device.
2. The supplier must provide the blind samples as matched A and B pairs, along with information on their content, validation, expected results, and stability to the collection site/collector that will send the blind samples to the laboratory. The supplier must also provide the information upon request to the MRO, the Federal agency for which the blind sample was submitted, or the HHS Secretary. If the collector purchases the samples for the Federal agency's blind program, the collector must send the supplier's information (e.g., the content and concentration of the blind samples) to the MRO to enable the

MRO to interpret the results and report them to the agency. The MRO will contact the supplier and/or collector as needed when investigating discrepant results.

3. Negative and positive blind samples must be prepared using artificial or human oral fluid at the same volume as that collected in the collection device and be added to the manufacturer's specimen tubes with the same pad and volume of diluent that would be present in a donor's specimen.
4. Drug-positive blind samples must be fortified with one or more of the drugs or metabolites listed in the OFMG, and the concentration should be 1.5 to 2 times the initial drug test cutoff concentration in "neat" oral fluid prior to any dilution in the collection device.
5. Drug-negative blind samples (i.e., certified to contain no drugs) must be validated by the supplier as negative using the appropriate initial and confirmatory tests.
6. The collector must submit blind samples to the laboratory in the same type of oral fluid collection device(s) used by the laboratory for the Federal agency's specimens.

Each blind sample must be submitted as a split specimen (specimens A and B) with a current Federal CCF (paper or electronic) that the HHS-certified laboratory uses for donor specimens.

1. The collector provides the required information to ensure that the Federal CCF has been properly completed, including fictitious donor identification in Step 1c of the Federal CCF and fictitious donor initials on the A and B specimen tube labels/seals.
2. The collector indicates that the sample is a "blind sample" on the MRO copy where the donor would normally provide a signature (Step 5 on Copy 2 of the Federal CCF).
3. The collector may either discard Copies 4 and 5 of a paper Federal CCF (the employer copy and the donor copy) or maintain them with Copy 3 of the Federal CCF (the collector copy).

Chapter 5. The Federal Drug Testing Custody and Control Form (Federal CCF)

Federal agencies are required to use the Office of Management and Budget (OMB)-approved Federal CCF when collecting specimens for their workplace drug testing programs. Federal CCFs are available from a number of different sources (e.g., laboratories, collectors, third party administrators, MROs, ECCF providers). The same Federal CCF is used for urine and oral fluid specimens. **Note:** References to instrumented initial test facilities (IITFs) in this chapter apply to urine specimens only.

2023 Federal CCF: OMB approved the use of the 2023 Federal CCF as of May 1, 2023, for urine and oral fluid specimens. The 2023 Federal CCF may be used as a paper or electronic form. Acceptable formats are described in **Section A** below.

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, and no MFR is required.
- 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.

See **Section B.1** below regarding use of an incorrect CCF.

Employers are prohibited from using the Federal CCF for:

1. Private-sector employee drug testing, with the exception of transportation industry urine testing conducted under the Department of Transportation (DOT) regulations.
2. State workplace drug testing programs
3. Department of Justice drug testing programs

A. Acceptable Formats for a Federal CCF

A Federal agency may use the Federal CCF as:

1. A paper form: a five-part form that is either preprinted or printed at the collection site before the collection, or
2. An electronic form (ECCF): either a digital (paperless) form or a combination electronic and paper form. All ECCFs must be the functional equivalent of a paper Federal CCF with respect to integrity, accuracy, and accessibility.

The two types of combination electronic and paper ECCF systems are:

- a. **Type 1**: The collector uses an ECCF system to document the collection process, then prints Copy 1 and Copies 2–5 (without signatures). The donor signs in Step 5 of Copies 2–5 using a wet-ink signature and the collector signs in Step 4 of Copies 1–5 using a wet-ink signature. The electronic form is not signed.
- b. **Type 2**: The collector uses an ECCF system to document the collection process, the collector and donor sign using electronic signatures (the donor uses a digitized signature), and the collector prints Copy 1 with his or her electronic signature. The printout of ECCF Copy 1 must be designated as the single authoritative copy of the ECCF.

HHS-certified test facilities must receive approval from HHS before accepting regulated specimens collected using an ECCF system. SAMHSA maintains the list of HHS-certified test facilities (laboratories and IITFs) approved to use an ECCF, with the ECCF system(s) that each is authorized to use, on the SAMHSA website: <https://www.samhsa.gov/workplace>.

If a laboratory or IITF receives a specimen that was collected using an ECCF system whose use has not been approved by SAMHSA for that test facility, **they will reject the specimen.**

All collection sites must maintain a supply of paper Federal CCFs. A paper Federal CCF must 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).

Federally regulated employers and drug testing service providers (e.g., collectors, test facilities, MROs) who use an ECCF must implement procedures and administrative, technical, and physical controls to ensure the authenticity, integrity, and confidentiality of electronic records, and to ensure that electronic signatures are the legally binding equivalent of traditional handwritten signatures. These procedures and controls include, but are not limited to:

1. System validation.
2. The ability to generate accurate and complete copies of records in both human-readable and electronic form suitable for inspection, review, and copying upon request of authorized parties (e.g., the MRO, Federal agency, or SAMHSA).
3. Protection of records to enable accurate and ready retrieval throughout the records retention period.
4. Limiting system access to authorized individuals (e.g., trained collectors). Procedures must be in place for managing the user authentication system (e.g., assignment, review, revocation).
5. Secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete records from the time of initiation of the Federal CCF (changes should be evident when reviewing the original record, and any electronic or paper copy of the original record).
6. Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

B. Federal CCF Problems

See also **Appendix A: Federal CCF Decision Trees for Collectors.**

1. Use of an Incorrect CCF

- a. As noted above, if a laboratory or IITF receives a specimen that was collected using an ECCF system whose use has not been approved by SAMHSA for that test facility, they must reject the specimen.
- b. In rare cases, a collector may use a non-Federal CCF or an expired Federal CCF (2017 or earlier) for a Federal agency collection by mistake or as the only means to conduct a collection under unusual circumstances (e.g., post-accident test with insufficient time to obtain an OMB-approved Federal CCF).
 - If the collector realizes an incorrect CCF was used, they must include remarks on the CCF noting that it is a Federal agency specimen or that an expired Federal CCF was used, provide the reason that the incorrect form was used, and include all collection information required on the current Federal CCF for that specimen type (urine or oral fluid). (Instructions for using the current Federal CCF are in **Section D** below.)
 - If the CCF used for the collection does not include space for all collection information required on the current Federal CCF, the collector must include the missing information in a signed memorandum for the record (MFR) sent to the test facility with the specimen.
 - If a laboratory or IITF discovers or is notified that a Federal agency specimen was collected using an incorrect CCF and the collector did not provide explanatory collector remarks and required 2023 Federal CCF information on the CCF or on a signed MFR sent with the specimen, the test facility will contact the collector for an MFR to recover the missing information, with the following exception.
 - **For an oral fluid collection device with diluent**, if a laboratory receives an oral fluid specimen with an incorrect CCF and no collector documentation that they observed the device volume indicator(s) during the collection (i.e., on the CCF or a signed MFR sent with the specimen), the laboratory will reject the specimen. **An MFR cannot be used to recover this missing information after the collection.**
 - If an MRO discovers the use of a non-Federal or expired Federal CCF(2017 or earlier), the collector is notified to provide an MFR to the MRO with the reason for using the incorrect form and with other information required on the 2023 Federal CCF, with the following exception.
 - **For an oral fluid collection device with diluent**, if the collector did not document that they observed the device volume indicator(s) at the time of the collection on the CCF or on a signed MFR sent to the laboratory with the specimen, the MRO must cancel the test. **An MFR cannot be used to recover this missing information after the collection.**
- c. The collector must take **immediate** steps to provide an MFR when notified. A laboratory or IITF holds specimens for a short time (i.e., a minimum of five business days) after notifying the collector, before reporting a “rejected for testing” result to the MRO, who will cancel the test.

- In the case of an expired (urine-only) CCF for a urine specimen, if the collector is not available, the collection site supervisor may sign the MFR.

2. Incorrect CCF Copy

Section E below describes proper distribution of Federal CCF Copies 1–5. The collector sends the **Test Facility Copy (Copy 1)** with the specimen to the laboratory or IITF.

- If the collector sends an incorrect CCF copy (i.e., Copy 2–5) with the specimen, the laboratory or IITF will not test the specimen until the collector provides documents to recover the error. The collector must send a signed explanatory MFR and the original Federal CCF Copy 1 signed by the collector using a wet-ink signature. The collector must send the Federal CCF Copy 1 with their wet-ink signature by courier or mail to the test facility (i.e., it is not acceptable to send a fax or pdf copy).
- The collector must take **immediate** steps to provide an MFR when notified. In the case of an ECCF reprint error, if the collector no longer works at the collection site, the collection site supervisor may sign the MFR. A laboratory or IITF holds specimens for a short time (i.e., a minimum of five business days) after notifying the collector, before reporting a rejected for testing result to the MRO, who will cancel the test.

3. Reprint ECCF Copy 1

For a Combination Electronic and Paper Federal CCF that has been signed by the collector and donor using electronic signatures, the collector must send the printout of Copy 1 designated as the single authoritative copy of the ECCF with the specimen.

- The ECCF system will distinguish the authoritative copy from subsequent printed copies of Copy 1 (e.g., identifying subsequent copies as “Reprint”). If there is a problem with printing the authoritative copy (e.g., a printer error):
 - The collector must sign the reprinted Copy 1 (in the presence of the donor) using a wet-ink signature in Step 4 (near their printed name and electronic signature) to designate this copy as the single authoritative copy.
 - The collector (or the ECCF system) must include a remark in Step 2 of the ECCF reprint noting the reason for reprinting Copy 1. Alternatively, the collector must send a signed MFR to the laboratory or IITF with the specimen, including the reason that a reprinted Copy 1 was sent with the specimen.
 - If the collector fails to sign the ECCF reprint using a wet-ink signature and/or fails to provide an explanatory remark or an MFR, the laboratory or IITF will not test the specimen, but will hold the specimen pending receipt of collector documents to recover the error(s). The collector must reprint the ECCF Copy 1 for the specimen, sign using a wet-ink signature, and provide an explanatory MFR. The collector must send the reprint ECCF with their wet-ink signature by courier or mail to the test facility (i.e., it is not acceptable to send a fax or pdf copy).

- b. The collector must take **immediate** steps to provide an MFR when notified. In the case of an ECCF reprint error, if the collector no longer works at the collection site, the collection site supervisor may sign the MFR. A laboratory or IITF holds specimens for a short time (i.e., a minimum of five business days) after notifying the collector, before reporting a rejected for testing result to the MRO, who will cancel the test.

C. Federal CCF Content Requirements

1. Test Facility Identification

At the top of the Federal CCF, the test facility (i.e., HHS-certified laboratory or IITF) must be identified by one of the following:

- a. The name and address of the specific test facility,
- b. A list of addresses with checkboxes to allow the collector to check the box for the specific laboratory or IITF to which the specimen will be shipped, or
- c. A corporation name and telephone number. **Note:** Either the collector will annotate the address of the specific test facility within the corporation to which the specimen will be shipped, or the test facility that receives the specimen for testing will annotate its address.

2. Labels/Seals

The tamper-evident labels/seals for the specimen bottles/tubes may be at the bottom of Copy 1 or may be separate from the form:

- a. There must be two labels/seals: one marked with the letter "A" to designate the primary specimen and the other marked with the letter "B" to designate the split specimen.
- b. Each label/seal must have:
 - The same specimen ID number that is at the top of the Federal CCF,
 - A place for the collector to annotate the date of the collection, and
 - A place for the donor to initial the label/seal after it is placed on the specimen bottle/tube.
 - **For oral fluid specimens:** The label/seal must not cover the expiration date on the oral fluid specimen tube and must allow visual assessment of the contents of the tube.

3. Required Statements and Instructions

Wording of required statements must be identical to that on the OMB-approved Federal CCF. Instructions and statements must be provided as follows:

a. Instructions for Completing the Federal Drug Testing Custody and Control Form for Urine and Oral Fluid Specimen Collections

- Separate Instructions for Completing the Federal CCF (for urine specimens and for oral fluid specimens) are available for downloading on the SAMHSA website: <https://www.samhsa.gov/workplace/resources>.
- The collector must provide the instructions to the donor (e.g., hardcopy, onscreen, posted at the collection site).

b. Public Burden Statement

- Paper Federal CCF: The Public Burden Statement is printed on each Federal CCF copy (i.e., on the back of Copies 1 through 5).
- Electronic Federal CCF (Digital or Combination Electronic and Paper): The Public Burden Statement is provided to employers and donors on the printed or electronically transmitted ECCF (Copies 4 and 5) and to collectors on the ECCF (Copy 3) maintained in collector/collection site records. The statement must be provided to test facilities and MROs on a separate page (hardcopy or electronic).

c. Privacy Act Statement (For Federal Employees Only)

- Paper Federal CCF: The Privacy Act Statement is printed on the back of the donor copy (Copy 5).
- Electronic Federal CCF (Digital or Combination Electronic and Paper): The Privacy Act Statement is provided to donors on the printed or electronically transmitted Federal CCF (Copy 5).

D. Federal CCF Instructions for Use with Oral Fluid Collections

Note: Chapter 7, Section C includes step-by-step instructions for oral fluid collections, including instructions for collector and donor entries on the Federal CCF.

Step 1. To be completed by the collector or Federal agency representative prior to the donor providing a specimen.

1. The employer's name, address, telephone and fax numbers, and employer ID number (if applicable).
2. The specific MRO or MRO company name, address, telephone number, and fax number.
3. Donor identification (e.g., SSN, employee ID number, or commercial driver's license number and state). The collector enters the donor identification after verifying the donor's identity. If the donor refuses to provide their SSN or ID number, the collector enters a remark in Step 2 on Copy 1.

4. The testing authority box indicating under which Federal agency the specimen is being collected. The HHS box is checked for a Federal agency employee or pre-employment specimen.
5. The appropriate box indicating the reason for the drug test. If the test is to be performed for a reason other than those listed on the Federal CCF, the "Other" box is checked and the specific reason is recorded.
6. The appropriate box for the drug tests to be performed. If the test is to be performed for a drug other than those listed on the Federal CCF, the "Other" box is checked and each specific drug is recorded.
7. The collection site address.
8. Collector contact information including telephone number, fax number, and other (e.g., email address).

Step 2. To be completed by the collector.

1. Specimen type. Check the **ORAL FLUID** checkbox at the top of Step 2.
2. Collection type: Check the appropriate box to indicate whether the collection was a split specimen or single specimen collection. **Note:** Split specimens are required for all Federal agency collections. If no specimen was provided, check the None Provided box and enter a remark and print your name in Step 2. You may, but are not required to, sign the Step 2 Remarks.
3. **ORAL FLUID** entries:
 - a. **Split Collection Type.** Check the appropriate box.
 - **Serial:** A and B specimens collected one after the other using two devices.
 - **Concurrent:** A and B specimens collected simultaneously using two devices.
 - **Subdivided:** A and B specimens collected using one device that directs the oral fluid into two separate specimen tubes OR a single specimen collected using a single device, that is subsequently divided into A and B specimens.
 - b. **Expiration Date.** Inspect each device to be used for the collection to verify that the expiration date has not been exceeded.
 - If each device is within its expiration date, check the YES box in Step 2. If a device is outside its expiration date (and no acceptable device is available for use), check the NO box and stop the oral fluid collection.
 - **Note:** the same human-readable expiration date must be on the collection device and the specimen tube(s) that will contain the oral fluid collected using that device.

- **Note:** The collector must record the manufacturer's expiration date on the A specimen tube as the Primary/Single Specimen Device Expiration Date in Step 4 of the Federal CCF and record the manufacturer's expiration date on the B specimen tube as the Split Specimen Device Expiration Date in Step 4 of the Federal CCF. **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.
- c. **Volume Indicator(s) Observed.** Observe the volume indicator on each device to verify that sufficient oral fluid has been collected. After collecting the A and B specimens, check the box to document that the volume indicator(s) were observed. For devices without a diluent (i.e., neat oral fluid specimens), inspect the volume markings on the specimen tubes after the specimen is collected to verify that at least 1 mL of oral fluid was collected for each of the A and B specimens (i.e., excluding any foam or bubbles above the oral fluid).
4. **Remarks:** Enter collector remarks and take action as needed (e.g., unusual behavior or appearance of the donor; failed collection attempts; unusual color, presence of foreign objects or material in the specimen).

Step 3. This section lists actions to be performed by the collector and donor at the end of the collection, after the primary (A) and split (B) specimens have been collected. The collector assists the donor with completing the donor section of the Federal CCF in **Step 5 on Copy 2.**

1. Record or instruct the donor to record the donor's information:
 - a. Printed name
 - b. Date of collection
 - c. Email address, daytime, and evening telephone numbers
 - d. Date of birth
2. Instruct the donor to:
 - a. Review information transcribed by the collector on the CCF
 - b. Read the donor certification statement and information in Step 5 on possible MRO requests for donor medication information (i.e., based on MRO review of test results)
 - c. Sign and date the certification statement
3. If the donor refuses to provide their information or to sign the certification statement, enter a remark in Step 2 on Copy 1.

For ECCFs: if the donor refuses to sign electronically but is willing to sign a paper CCF with a wet-ink signature, print the ECCF, Copies 1–5. The donor must sign in Step 5 of Copies 2–5 using a wet-ink signature and the collector must sign in Step 4 of Copies 1–5 using a wet-ink signature.

Step 4. To be initiated by the collector and completed at the test facility.

1. Sign the collector certification statement in Step 4 on Copy 1 to certify that the specimen was collected, labeled, sealed, and released for shipment to the HHS-certified laboratory in accordance with Federal requirements.
2. Include your printed name.
3. Record the following:
 - a. Date of collection
 - b. Time of collection
 - c. The specific name of the delivery service to which the specimen tubes are released for shipment to the HHS-certified laboratory

Note: Copy 1 entries in Step 4 below the first bold line and in the subsequent steps are made at the HHS-certified laboratory, with one exception. As described under CCF Step 2 entries above (i.e., item 3.b), the collector may transcribe the expiration date from each specimen tube (A and B) to Step 4 of the Federal CCF. In this case, the laboratory accessioner will verify the recorded expiration date vs. that on the specimen tube upon receipt.

E. Federal CCF Distribution

Note: Employers, collectors, test facilities, and MROs who send or receive CCFs electronically are responsible for ensuring the security of data transmissions and limiting access to any data transmission, storage, and retrieval systems.

Paper CCFs and Combination Electronic and Paper CCFs

1. Copy 1 (Test Facility Copy)

The collector sends the signed Copy 1 with the specimen to the HHS-certified laboratory. Copy 1 is placed in the package with the specimen (i.e., in a compartment separate from the specimen tubes).

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-ink signature.

2. Copy 2 (MRO Copy)

The collector sends Copy 2 signed by the donor to the MRO via courier, mail, fax, or other electronic transmission method.

For a Paper Federal CCE: If a copy of Copy 2 is sent to the MRO via fax or provided electronically, the collector maintains the original Copy 2 in the collection site records.

3. Copy 3 (Collector Copy)

Copy 3 is maintained in the collection site records.

4. Copy 4 (Employer Copy)

The collector sends Copy 4 to the Federal agency employer via courier, mail, fax, or other electronic transmission method.

5. Copy 5 (Donor Copy)

The collector gives Copy 5 to the donor as a hardcopy after the collection is complete or sends it electronically.

Digital Federal CCFs

1. Copy 1 (Test Facility Copy)

a. Copy 1 signed by the collector is electronically provided to the HHS-certified laboratory.

b. In addition, the collector must either:

- Include a printed copy of the Test Facility Copy (Copy 1) in the package with the specimen (i.e., in a compartment separate from the specimen tubes), or
- Apply a label to the outside of the specimen package, with the specimen ID number, test facility name and contact information, and collection site name and contact information.

2. Copies 2 through 5

a. Copy 2 signed by the donor is electronically provided to the MRO.

b. Copy 3 is maintained in the collection site records.

c. Copy 4 is provided electronically to the employer.

d. Copy 5 is provided to the donor as a hardcopy or electronically.

Chapter 6. Verification of Donor Identity

The donor must provide appropriate identification to the collector upon arrival at the collection site.

Acceptable forms of identification are:

1. A photo ID (e.g., driver's license, employee badge issued by the employer, or an alternative photo ID issued by a Federal, state, or local government agency), or
2. Positive identification by the supervisor of the donor or by a Federal agency representative.

If the identity of the donor cannot be established, the collector must not proceed with the collection.

Unacceptable forms of identification are:

1. Identification by a co-worker,
2. Identification by another donor,
3. Non-photo ID (e.g., social security card, credit card, union or other membership cards, pay vouchers, voter registration card), or
4. A faxed copy or photocopy of an identification document.

Chapter 7. Oral Fluid Specimen Collection

A. Collection Site Security

The collection site must have a restricted access area to prevent unauthorized access to specimens, collection supplies, and collection site records. A permanent site that is used solely for specimen collections must be secured at all times. At facilities that are not dedicated specimen collection sites, the area of the site used for specimen collections must be secured as a restricted access area during the time a specimen is collected.

A collector must:

1. Prohibit unauthorized personnel from entering the collection site during the collection.
2. Ensure the privacy of the donor.
3. 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 item C.13 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.
4. Restrict access to collection supplies before, during, and after the collection.
5. Ensure that only the collector and the donor are allowed to handle the unsealed specimen.
6. Ensure that chain of custody is maintained and documented from the time of collection until the labeled and sealed specimen tubes are sealed in the specimen package for transport to the laboratory.

7. Ensure that the Federal CCF is completed and CCF Copies 1–5 are distributed as required.
8. Ensure that specimens are transported to the laboratory in a sealed and secure transport container to minimize the possibility of damage during shipment and to prevent undetected tampering.

B. Collection Supplies

The following items must be available at the collection site to conduct proper oral fluid collections. Collection supplies should be individually packaged for each collection. **Appendix B** describes oral fluid collection device requirements.

1. **Collection Device:** a single-use device that has been cleared by the Food and Drug Administration (FDA) and validated by an HHS-certified laboratory as acceptable to collect Federal agency oral fluid specimens. Many current devices consist of a stick with a pad that is placed in the donor's oral cavity to collect oral fluid. However, oral fluid may also be collected without a pad, by expectoration into a device.
 - a. If the device contains a diluent, the device must have an indicator that signals when a sufficient volume of oral fluid has been collected.
 - b. If the collection device does not contain a diluent:
 - The volume of undiluted (i.e., neat) oral fluid collected should be at least 1 mL for each primary (A) and split (B) specimen; and
 - The A and B specimen tubes (defined below) must each have a volume marking clearly noting 1 mL.
2. **Specimen Tube:** a sealable, non-leaking container to hold the collected oral fluid specimen [i.e., one tube for the (A) primary specimen and one tube for the (B) split specimen].
3. **Collection Device Instructions:** Device-specific instructions for the collection must be available at the time of the collection. The instructions may be provided to the donor as a hardcopy, displayed onscreen, or posted at the collection site. The collector may also offer a copy of the instructions to the donor at the end of the collection (e.g., a hardcopy, an electronic file, a website link sent via email).
4. **Federal CCFs:** An OMB-approved Federal CCF as described in **Chapter 5** must be used for the collection. All collection sites, including those using ECCFs (digital and/or combination electronic and paper Federal CCFs), should maintain a supply of paper Federal CCFs.
5. **Tamper-evident labels/seals:** Tamper-evident labels/seals are used to identify and seal the specimen tubes containing the primary (A) and split (B) specimens. Occasionally, a tamper-evident label/seal will not properly adhere to the specimen tube (e.g., due to moisture, temperature, or specimen tube material). If this occurs, follow instructions in **Chapter 8, Section G** for using another tamper-evident seal.
6. **Leak-resistant container:** A container (e.g., plastic bag) that is leak-resistant and large enough to hold two specimen tubes.

7. **Specimen package**: The sealed, tamper-resistant container (e.g., plastic bag, box) that contains the specimen tube(s) and Federal CCF from an oral fluid drug test collection. **Note:** When an electronic Federal CCF was used for the collection, the collector must either (1) include a printed copy of the Federal CCF (for informational purposes only) in the specimen package or (2) apply a label to the outside of the specimen package with the specimen identification number, test facility name and contact information, and collection site name and contact information.
8. **Absorbent material**: The absorbent material is placed inside the leak-resistant container with the specimen tubes in case a specimen tube leaks during shipment. The U.S. Postal Service and other express carriers require the use of absorbent material when shipping biological materials.
9. **Shipping container**: The container (e.g., box, mailer, bag) in which the collector places one or more specimen packages for transport to a laboratory. The shipping container must be securely sealed to prevent loss of a specimen during transport. It is not necessary to use a shipping container if a courier hand-delivers the specimen package directly from the collection site to the laboratory.

C. Collection Procedure

1. Prepare the collection site to collect oral fluid specimens.
2. Assemble supplies.
3. Provide a means for the donor to wash their hands under your direct observation. If there is not a restroom or a sink within the collection area, provide another means (e.g., waterless cleanser, moist towelette).
4. Begin the collection process without delay when the donor arrives at the collection site. For example, the collection should not be delayed because an authorized employer or employer representative is late in arriving.
 - a. If a donor fails to arrive at the collection site at the assigned time for the drug test, follow the Federal agency policy or contact the Federal agency representative to obtain guidance on the appropriate action to be taken.
5. Verify the donor's identity with a photo identification (see **Chapter 6**). If the donor requests, you must provide identification (e.g., employee badge, employee list).

See Chapter 5, Section D for step-by-step instructions for completing the Federal CCF.

Instructions below apply to all Federal CCF formats (see ECCF definitions and requirements in Chapter 5, Section A).

6. Obtain the paper Federal CCF or log onto the Federal ECCF system for the collection.
7. Ensure that the specimen identification number on the Federal CCF matches the identification number printed on each specimen tube label/seal and on the specimen package label (if any).

Note: Some ECCF systems require the collector to scan the barcoded specimen ID number on each tube label/seal and add that specimen ID number to the ECCF. This step may be later in the collection process (as directed by the ECCF system).

8. Verify the preprinted laboratory information (e.g., name and address) at the top of the Federal CCF, including the laboratory account number (if applicable).
9. Record and verify the information in Step 1 of the Federal CCF. Edit entries as needed. For a paper CCF, line through incorrect information, handwrite the correct information, and initial and date the change.
10. To deter adulteration or substitution of the specimen:
 - a. Ask the donor to remove any unnecessary outer clothing (e.g., coat, jacket, hat) that could be used to conceal items or substances that could be used to adulterate or substitute the oral fluid specimen.
 - The donor is not required to remove any items worn for faith-based reasons.
 - It is not necessary for the donor to remove their footwear, unless you suspect that they are concealing something that may be used to adulterate or substitute the specimen.
 - b. Take steps to safeguard the donor's outer clothing and other personal belongings (e.g., briefcase, purse). The donor may retain their wallet.
 - The belongings may be left unsecured if they remain within the line of sight of the collector and the donor, and out of the donor's reach, until the end of the collection, or
 - The belongings may be secured (e.g., in a lockable cabinet with access controlled by the donor, in a sealed bag with a tamper-evident seal).

→→→ If the donor will be under your direct observation from this point until the end of the collection, **skip to Step 11.** ←←←

→→→ If the donor will **not** be under your direct observation from this point until the end of the collection (including the entire 10-minute wait period described in Step 12 below), **continue with item c below.** ←←←

Note: If the donor fails to follow any of the instructions in item c below, skip to Step 11 and keep the donor under your direct observation until the end of the collection.

- c. Ask the donor to empty their pockets and display the items.
 - If there are no items that can be used to adulterate a specimen, instruct the donor to return the items to their pockets and continue the collection procedure (i.e., with Step 8).

- If an item is present whose purpose is to adulterate, substitute, or dilute the specimen or otherwise affect the collection (e.g., a commercial drug culture product; a collection device, pad, or stick that mimics that to be used for an oral fluid collection; or other substance for which the donor has no reasonable explanation), this is considered a refusal to test. You must stop the collection and report the refusal to test to the Federal agency to ensure immediate notification is received (see **Chapter 8, Section F**). Create a MFR to document the item (e.g., written description, photograph), and sign and date the MFR.
- If an item that could be used to adulterate or substitute a specimen (e.g., common personal care products such as mouthwash, lozenges, capsules, breath mints, breath spray) appears to have been inadvertently brought to the collection site, document the item in an MFR (e.g., written description, photograph), sign and date the MFR, safeguard the item with the donor's belongings, and continue the collection procedure (i.e., with Step 8).

11. Ask the donor to open their mouth, so you can inspect the oral cavity.

- a. If the donor claims that they have a medical condition that prevents opening their mouth for inspection, follow the Federal agency policy or contact the Federal agency representative for authorization to collect another authorized specimen matrix (e.g., urine).
- b. When you inspect the donor's oral cavity:
 - If an item in the donor's oral cavity is present for the purpose of adulterating, substituting, or diluting the specimen or otherwise affecting the collection, this is considered a refusal to test.
 - Stop the collection and report the refusal to test to the Federal agency to ensure immediate notification is received (see **Chapter 8, Section F**).
 - Create an MFR to document the item (e.g., written description, photograph), and sign and date the MFR.
 - If an item (e.g., candy, gum, food, tobacco) is present that could be used to adulterate, substitute, or dilute the specimen, but may not be present for that purpose, instruct the donor to remove the item.
 - If the donor removes the item(s), give 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 an item or refuses to rinse their mouth, this is a refusal to test. Stop the collection and report the refusal to test to the Federal agency to ensure immediate notification is received (see **Chapter 8, Section F**).
 - If the donor's oral fluid is abnormally colored or if the donor claims to have "dry mouth," give the donor water (e.g., up to 4 oz.) to rinse their mouth. The donor may drink the water.

- If the donor refuses to rinse their mouth, this is a refusal to test. Stop the collection and report the refusal to test to the Federal agency to ensure immediate notification is received (see **Chapter 8, Section F**).
- The donor is not required to remove a dental appliance (e.g., a retainer).

12. Start the 10-minute wait period. During the wait period:

- a. Describe the basic collection procedure to the donor and inform the donor that the collection device-specific instructions and Instructions for Completing the Federal Custody and Control Form for an Oral Fluid Collection are available upon request. **Note:** You may allow the donor to review these documents during the 10-minute wait period.
- b. Answer any reasonable and appropriate questions that the donor has about the collection process.
- c. Inform the donor that they must remain at the collection site (i.e., in the area that you designate) during the wait period. If the donor fails to follow these instructions, you must report a refusal to test to the Federal agency (see **Chapter 8, Section F**).

If the donor will not be under your direct observation from this point until the end of the collection, as time permits, you may start the collection process for other donors during the remainder of the 10-minute wait period.

Note: The collector must work with only one donor at a time and must protect each donor's privacy. Only authorized personnel and the donor may be present in the restricted access area where the collection takes place. In addition, the collector must maintain the security and confidentiality of donor information on the Federal CCF for each donor.

13. Prepare for the collection:

- a. Instruct the donor to wash and dry their hands under your observation.
 - After washing their hands, the donor must remain in your presence. Instruct the donor to keep their hands within view and avoid touching items or surfaces.
 - If the donor refuses to wash their hands when instructed, this is considered a refusal to test. You must stop the collection and report the refusal to test to the Federal agency.
- b. Provide or allow the donor to select the packaged collection device(s) to be used for the collection.
 - Only you (the collector) may open the package.
 - Once you have opened a package, both you and the donor must keep the unwrapped device in view at all times until the donor's specimen collected using the device has been sealed and labeled.
- c. Review the device manufacturer's instructions for the collection with the donor.

- d. Inspect each device for obvious defects prior to starting the collection. You must discard a defective device and replace it with a compliant device for the collection.
- For devices with a diluent: the collector must check that the diluent volume in each device is not visibly different from the standard volume for that device. **Note:** It is suggested that the collector/collection site maintain an unopened device/tube to use for this comparison.
 - When two devices with a diluent are to be used for the A and B specimens, the collector must visually compare the volume of fluid in the two devices before they are used to collect the donor's oral fluid. A visible difference in diluent volumes is evidence of a defective product that can affect the test.
- e. Check that each collection device is within its expiration date and mark the checkbox in Step 2 of the Federal CCF.

Special instructions for serial split collections:

Note: The B specimen collection must begin within two minutes after the A specimen has been collected.

- a. Instruct the donor to place the A specimen device into the tube (with diluent) immediately when you direct them to remove the device from their mouth.
- b. When the donor removes the A specimen device from their mouth, record the time on the Federal CCF (Step 4).
- c. The donor is not allowed to drink or rinse their mouth between the two collections.
- d. Cap the A specimen tube, then give the collection device for the B specimen to the donor and instruct them to position the device in their mouth while you record the start time on the Federal CCF (Step 4).

If the time between the end of the A specimen collection and the beginning of the B specimen collection is within two minutes: proceed to label and seal the A specimen tube in the presence of the donor.

If the time between the end of the A specimen collection and the beginning of the B specimen collection exceeds two minutes:

- a. Discard the first specimen collected, and continue to collect the second specimen as the A specimen.
- b. Follow the specimen collection instructions above to collect a third specimen as the B specimen.

Using the same Federal CCF, document disposal of the first specimen and reason in the Remarks line in Step 2. Line through the original collection time and record the new collection time in Step 4, and initial the edit.

Note: If the donor refuses to provide a specimen, delays providing the B specimen within 2 minutes of the A specimen, or leaves the collection site before the collection process is completed, this is considered a refusal to test (see **Chapter 8, Section F**). Discard any collected oral fluid and unpackaged devices, document the refusal to test on the Federal CCF, and send all copies of the Federal CCF to the Federal agency's designated representative.

14. Perform the oral fluid collection:

- a. **You must be present and maintain visual contact with the donor for the entire collection.** Follow the device-specific instructions provided by the collection device manufacturer for the proper use of the device.

Note: The following instructions are written for collection devices that are placed in the donor's mouth. For oral fluid specimens collected by expectoration, follow the same/similar steps as applicable. See **Special Instructions for Serial Split Collections** above for routine specimen collection and A and/or B recollection.

- b. Give the collection device to the donor. The donor is responsible for positioning the collection device in their mouth as you watch. Verify the positioning and provide further instructions as needed. The device must stay in the donor's mouth for the manufacturer's specified time or until a sufficient volume of oral fluid has been collected as shown by the device volume indicator or by the volume markings on the specimen tubes.
 - For specimen tubes with 1 mL volume markings: if a specimen has air bubbles or froth, ensure that at least 1 mL of oral fluid was collected by requiring the donor to provide oral fluid above the 1 mL mark for each of the A and B specimens.
- c. If there is a failure to collect a specimen, discard the collection device with the insufficient specimen and begin the process again, using a new collection device (see **Chapter 8, Section A, and Appendix E**). Note the failed collection attempt on the Remarks line in Step 2 of the Federal CCF. If multiple devices fail to collect an oral fluid specimen, record the lot number(s) of the devices separately (not on the Federal CCF) for troubleshooting purposes and report the problem to the HHS-certified oral fluid laboratory. (If the laboratory is not the form supplier, also notify the supplier and obtain additional devices/different lots as needed).
- d. Once the required volume of oral fluid has been collected, receive the device from the donor, inspect the condition of the device for any abnormal appearance (e.g., abnormal color, foreign material, evidence of chewing on collection pad or stick). If a device's appearance is abnormal, take actions as described in **Chapter 8, Section C** and/or **Appendix C**. If there are no abnormal characteristics, follow the manufacturer's instructions for completing the collection (e.g., inserting the pad into the specimen tube, capping the specimen tube). **Carefully handle all open tubes containing diluent.** If any diluent is spilled (i.e., before or after combining with the collected oral fluid), recollect the specimen using a new device.
- e. Mark the checkbox in Step 2 of the Federal CCF to document that you observed the volume indicator(s) during the collection.
- f. For collection devices with a diluent, visually compare the volumes (i.e., oral fluid plus diluent) of the A and B specimens. A visible difference in volumes could be evidence of a problem with the collection or with a device. If A and B volumes are different, take action as described in **Chapter 8, Section D** and/or **Appendix C**.
- g. Inspect the specimen for any abnormal appearance (e.g., unusual color, presence of foreign objects or material). If there are no abnormal characteristics, proceed with the collection. If a specimen's appearance is abnormal, take actions as described in **Chapter 8, Section C** and/or **Appendix C**.

15. Seal the A and B specimen tubes one at a time while the donor watches, using the tamper-evident A and B specimen labels/seals with the same specimen ID number as the Federal CCF. For each specimen:
 - a. Place the label/seal on the tube and over the cap. The label/seal must be positioned to:
 - Provide a tamper-evident seal (i.e., the lid/cap cannot be removed without breaking the label/seal);
 - Not cover the expiration date on the tube; and
 - Allow visual assessment of the contents of the tube.
 - b. Date the label/seal on each tube.
 - c. Instruct the donor to verify that the specimen ID number on A and B tubes match that on the Federal CCF, and to initial the two labels.
 - If the donor fails or refuses to initial the seals, note this on the Remarks line in Step 2 of the Federal CCF and complete the collection process. This is not considered a refusal to test.
16. Complete the Federal CCF.

See Chapter 5, Section D for step-by-step instructions for completing the Federal CCF.

Instructions below apply to all Federal CCF formats (see ECCF definitions and requirements in Chapter 5, Section A).

- a. Assist the donor in completing the donor section of the Federal CCF (Copy 2, Step 5)
 - Record (or instruct the donor to record) donor information indicated on the CCF. The collector must not solicit any donor medical information, and medical information must not be recorded on the Federal CCF or other record maintained or distributed by the collector. See Step 18 regarding a donor-recorded list of medications.
 - Instruct the donor to read the donor certification statement, and to sign and date the certification statement.
 - If the donor refuses to provide their information or to sign the form, make a comment on the Remarks line in Step 2 of the Federal CCF to that effect. This is not considered a refusal to test.
 - b. Complete the collector chain of custody portion in Step 4 on Copy 1 of the Federal CCF.
17. Prepare the specimen package for shipment.
 - a. Place the sealed specimen tubes in a leak-resistant container (e.g., plastic bag) including the absorbent material.

- b. Place the Test Facility Copy (Copy 1) and any collector MFRs in the container with the specimen (i.e., in a compartment separate from the specimen tubes).

Note: For a digital Federal CCF, the collector must either (1) include a printed copy of the Federal CCF (for informational purposes only) in the specimen package or (2) apply a label to the outside of the specimen package with the specimen identification number, test facility name and contact information, and collection site name and contact information. Any collector MFRs for the specimen must be included in the package (i.e., in a compartment separate from the specimen tubes) or sent electronically to the laboratory using established procedures (e.g., secure fax, email).

- c. Seal the bag so both compartments are sealed.

18. Provide the Donor Copy of the Federal CCF to the donor.

- a. Remind the donor that they may list any prescription and over-the-counter medications on a separate sheet or on the back of the donor's copy of the Federal CCF. This information may help the donor to remember what medications they may have taken if they are contacted by the MRO.

Note: This information must not be recorded on any other copy of the Federal CCF or other record maintained or distributed by the collector.

19. Inform the donor that they may leave the collection site.

20. Send the specimen package to the HHS-certified laboratory **within 24 hours after the collection or during the next business day**. Specimens that will not be shipped within 24 hours (e.g., collected on a Friday for shipment on Monday) should be kept in secure refrigerated storage. If the specimen package is not shipped immediately, the collector is responsible for ensuring its security:

- a. For specimens in a sealed specimen package that has not been placed in a shipping container, take necessary steps to prevent tampering or access by unauthorized personnel.
- b. For specimen packages in a sealed shipping container, take necessary steps to protect the container from damage or theft prior to pick-up by the designated delivery service.
- c. If the tamper-evident label/seal is broken on a specimen tube after the donor leaves the collection site, **the collection must be cancelled**.
 - Notify the agency's designated representative that the label/seal was broken on the specimen tube, and send all copies of the Federal CCF to the Federal agency's designated representative.

21. Distribute the MRO and employer copies of the Federal CCF. **Chapter 5, Section E describes proper distribution of Federal CCF Copies 1–5.**

- a. The collection site and the MRO must coordinate the Federal CCF distribution process to ensure that procedures meet the MRO's and Federal agency's requirements.

- b. The collection site or the MRO must maintain the original Copy 2 with the donor's signature (i.e., paper Copy 2 with the donor's wet-ink signature, if signed).

Chapter 8. Miscellaneous Collection Issues

A. Inability to Provide a Sufficient Specimen

If the donor states that they are unable to provide an oral fluid specimen during the collection process, request that the donor follow the device instructions and attempt to collect a specimen. The donor demonstrates their inability to provide a specimen when there is insufficient oral fluid after 15 minutes of using the device or after multiple failures to collect the specimen. **Appendix E** provides flowcharts for collector actions.

Note: 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. (See **Special Instructions for Serial Split Collections** in **Chapter 7, Section C.**)

1. If the donor states that they may be able to provide a specimen after drinking some fluids, give the donor a drink (up to 8 oz.) and wait an additional 10 minutes before the next collection attempt.
 - a. You must provide a period of up to 1 hour for the donor to attempt to provide a sufficient oral fluid specimen.
 - b. Inform the donor that they must remain at the collection site (in the area that you designate) during the wait period.
 - c. The donor is not required to drink any fluids between collection attempts.
 - d. At a minimum, the donor must be under your observation during the final 10 minutes of the wait period before the collection attempt.
2. If the donor is unable to provide a specimen:
 - a. Record the reason for not collecting an oral fluid specimen on the Federal CCF.
 - b. Follow the Federal agency policy or contact the Federal agency representative for authorization to collect another authorized specimen matrix (e.g., urine).
 - c. Send the appropriate copies of the Federal CCF to the MRO and to the Federal agency representative.

B. Donor Conduct

The collector should pay close attention to the donor's conduct during the entire collection process and take the following actions as necessary:

1. Note any unusual behavior or appearance of the donor in the Remarks line in Step 2 of the Federal CCF.
 - a. If the conduct clearly indicates an attempt to tamper with a specimen (e.g., an attempt to prevent the device from collecting sufficient oral fluid), report a refusal to test immediately to the Federal agency in accordance with **Section F** below.
 - b. If the donor's actions may have affected a collected oral fluid specimen but do not clearly indicate an attempt to tamper with a specimen (e.g., possible misunderstanding of collection instructions), stop the collection procedure, discard that specimen, and perform a second split oral fluid specimen collection using the same Federal CCF.
 - Record an appropriate comment on the Remarks line in Step 2 of the Federal CCF.
 - Proceed with the second split specimen collection as described in **Chapter 7, Section C**.
 - If you did not follow Step 7 (i.e., instructing the donor to remove unnecessary outer clothing and display their pocket contents) prior to the first collection, start with Step 7 to deter adulteration or substitution of the specimen.
 - If you followed Step 7 prior to the first collection, start with Step 8.
2. If the donor fails to arrive at the assigned time within a reasonable time, as determined by the Federal agency, this is considered a refusal to test. Report the refusal to test to the Federal agency in accordance with **Section F** below.

Note: If the donor refuses to provide an additional specimen or leaves the collection site before the split specimen collection process is completed, this is considered a refusal to test (see **Section F** below).

C. Specimens with Abnormal Physical Characteristics

The collector must inspect each oral fluid specimen for abnormal physical characteristics that may interfere with testing and/or be indicative of the donor's attempt to adulterate or substitute the specimen. Supporting evidence of donor tampering includes, but is not limited to, an item in the donor's oral cavity that could have affected the collection; evidence of chewing on the collection pad or stick; foreign material in the tube that could have been introduced only by the donor; and a donor admission to tampering with the specimen. **Appendix C** provides flowcharts for collector actions for specimens with abnormal color and for specimens with abnormal physical characteristics other than color (e.g., foam, chemical smell, foreign material in the tube). **Appendix D** provides some Example Donor Attempts to Subvert an Oral Fluid Collection.

D. Diluent Volume Issues

The collector must evaluate the volume of diluent present in the tube(s) to be used before beginning a collection. The collector must check that the diluent volume in each device is not visibly different from the standard volume for that device (e.g., using an unopened tube for comparison). The collector must also compare the volumes (i.e., oral fluid plus diluent) of the A

and B specimens after collection. If A and B volumes are different, take action as described in **Appendix C**.

E. Multiple Collectors for a Specimen Collection

The procedures for collecting a Federal agency drug testing specimen, as required by the HHS Mandatory Guidelines and detailed in this Specimen Collection Handbook, are designed to be performed from start to finish by one trained collector. Collection sites and Federal agencies are expected to schedule collections accordingly.

In the rare event when the collector who began a collection cannot complete all steps (e.g., when a collection coincides with a shift change), a second trained collector may assume responsibility for the collection at certain specific steps during the collection, as follows:

1. At any step up to the end of the 10-minute wait period prior to the collection (see **Chapter 7, Oral Fluid Specimen Collection, Step 10**); or
2. When there is an issue that requires the collector to restart the split collection (e.g., insufficient specimen volume, one or more specimens with an abnormal physical characteristic).

Note: The same collector must collect both A and B specimens from the donor and complete the collection.

Prior to changing collectors:

1. The first collector must document their name, the time, and the reason for the change in Step 2 of the Federal CCF. The first collector may, but is not required to, sign in addition to printing their name in Step 2.
2. Before assuming responsibility for the collection, the second collector must:
 - Verify the donor's identity with a photo identification (see **Chapter 6**). If the donor requests, you must provide identification (e.g., employee badge, employee list).
 - Verify the donor ID number recorded on the Federal CCF.
 - Ensure that Step 1 of the Federal CCF is complete.
 - Review and verify any information in Step 2 of the CCF recorded by the first collector.

F. Refusal to Test

A Federal agency will take adverse action against an employee whose drug test specimen is reported as a refusal to test. The collector reports a "refusal to test" when:

1. The donor fails to appear for a collection within a reasonable time as determined by the Federal agency, consistent with Federal agency regulations.

2. The donor fails to remain at the collection site until the collection is complete.
3. The donor admits to the collector that they have adulterated or substituted their specimen.
4. The donor fails to cooperate with any part of the testing process or disrupts the collection process. Examples include, but are not limited to:
 - a. Failing to open their mouth for inspection when directed
 - b. Failing to remove a foreign object from their mouth when directed
 - c. Failing to rinse their mouth when directed
 - d. Refusing to wash their hands
 - e. Failing to provide a specimen (i.e., oral fluid or other authorized alternate specimen type) for a drug test required by the Mandatory Guidelines or Federal agency regulations.
 - f. Failing or declining to participate in an alternate specimen collection (e.g., urine) as directed by the Federal agency or collector
 - g. Bringing materials to the collection site for the purpose of adulterating, substituting, or diluting their specimen, or otherwise affecting the collection.
 - h. Delaying more than two minutes between collection of the A and B specimens during a serial specimen collection
 - i. Conduct that clearly indicates an attempt to adulterate, substitute, or dilute the specimen, or otherwise prevent collection of a sufficient oral fluid specimen as described in item B above. Examples of donor attempts to subvert an oral fluid collection are included in **Appendix D**.

When reporting a “refusal to test,” the collector must:

1. Notify the agency’s designated representative by a means (e.g., telephone, secure fax, email) that ensures immediate receipt of the refusal notification,
2. Document the refusal to test on the Federal CCF with appropriate comments, signature, and date in the Remarks line of Step 2 of the Federal CCF, discards any oral fluid, and
3. Send all copies of the Federal CCF to the Federal agency’s designated representative.

G. Problems with Specimen Tube Labels/Seals

If the tamper-evident label/seal does not adhere properly to the specimen tube (e.g., due to moisture, temperature, specimen tube material) or is accidentally broken or damaged during the collection process:

1. Apply the unacceptable label/seal (i.e., printed with the same specimen identification number as the Federal CCF) to the tube, and
2. Apply a second, separate tamper-evident seal to seal the specimen tube.
 - a. Place the additional seal perpendicular to the original label/seal. Position the seal so it does not cover information on the original label/seal or the expiration date on the tube, and will allow visual assessment of the tube contents.
 - b. Initial and date the second seal.
 - c. Ask the donor to initial the second seal.
 - d. Provide a comment on the Remarks line in Step 2 of the Federal CCF explaining why the second seal was used.

Note: If the donor refuses to initial the second seal, the collector should note this on the Remarks line in Step 2 and continue with the collection process. This is not considered a refusal to test.

Chapter 9. Collector Errors and Corrective Actions

The Federal CCF is a forensic, legal document and will be part of the litigation package if a specimen comes under legal challenge. Federal agencies will investigate reported collection site deficiencies (e.g., specimens rejected for testing due to collector/collection errors).

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 ID 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 line through the erroneous information, leaving the original 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 line 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.

There are three categories of collector errors:

1. Fatal flaws that result in an HHS-certified laboratory rejecting a specimen or an MRO canceling a test,

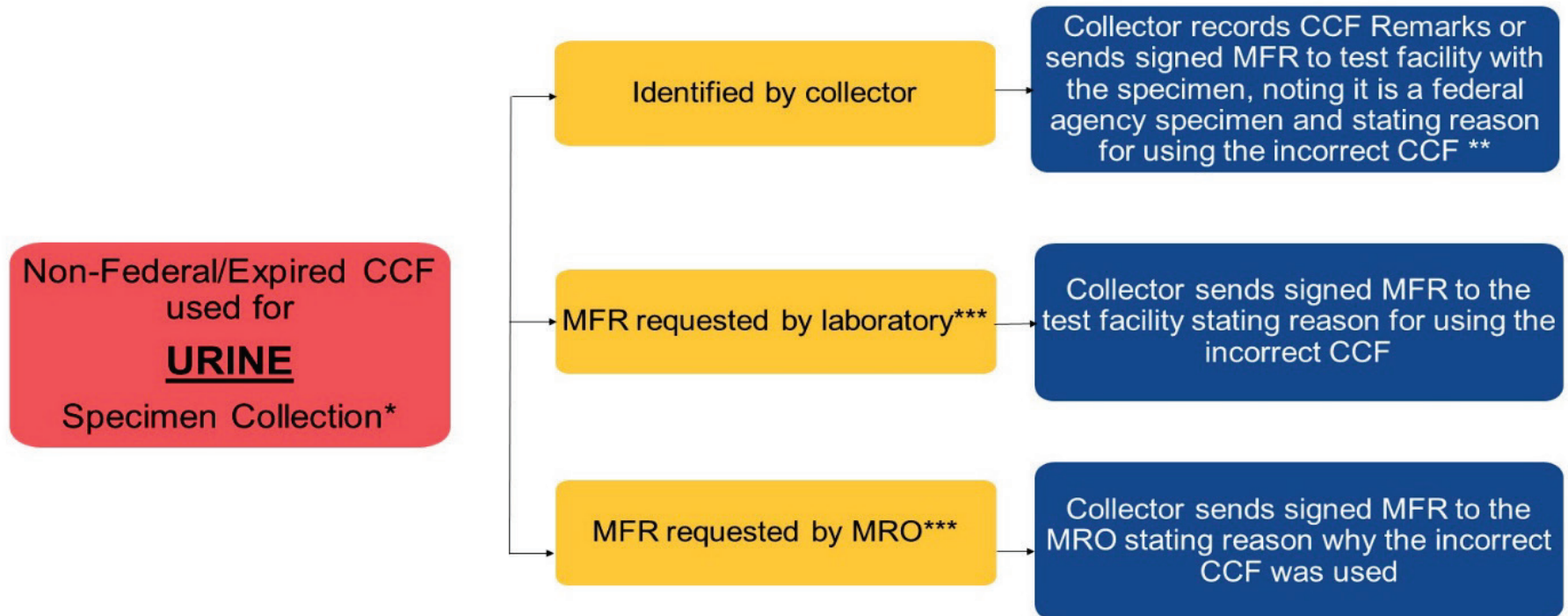
2. Correctable flaws that result in an HHS-certified laboratory rejecting a specimen or an MRO canceling a test unless the flaw is corrected by an MFR from the collector, and
3. Omissions and discrepancies on the Federal CCF that do not require rejection by the HHS-certified laboratory or cancellation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

The collector should not access the Federal CCF or the specimen tubes after the package has been sealed in the presence of the donor. If the collector realizes they have made a correctable flaw or omission after the Federal CCF Copy 1 has been sealed in the specimen package, the collector should proactively send an explanatory MFR to the HHS-certified laboratory.

Chapter 5 includes instructions for when an incorrect CCF is used for a Federal agency specimen or an incorrect CCF copy is sent with the specimen. See also Appendix A: Federal CCF Decision Trees for Collectors.

The collector must take **immediate** steps to provide an MFR to the HHS-certified laboratory or the MRO when notified of an error. A laboratory holds specimens for a short time (i.e., a minimum of five business days) after the collector has been notified, before reporting the specimen as rejected for testing and discarding the specimen.

Appendix A: Federal CCF Decision Trees for Collectors

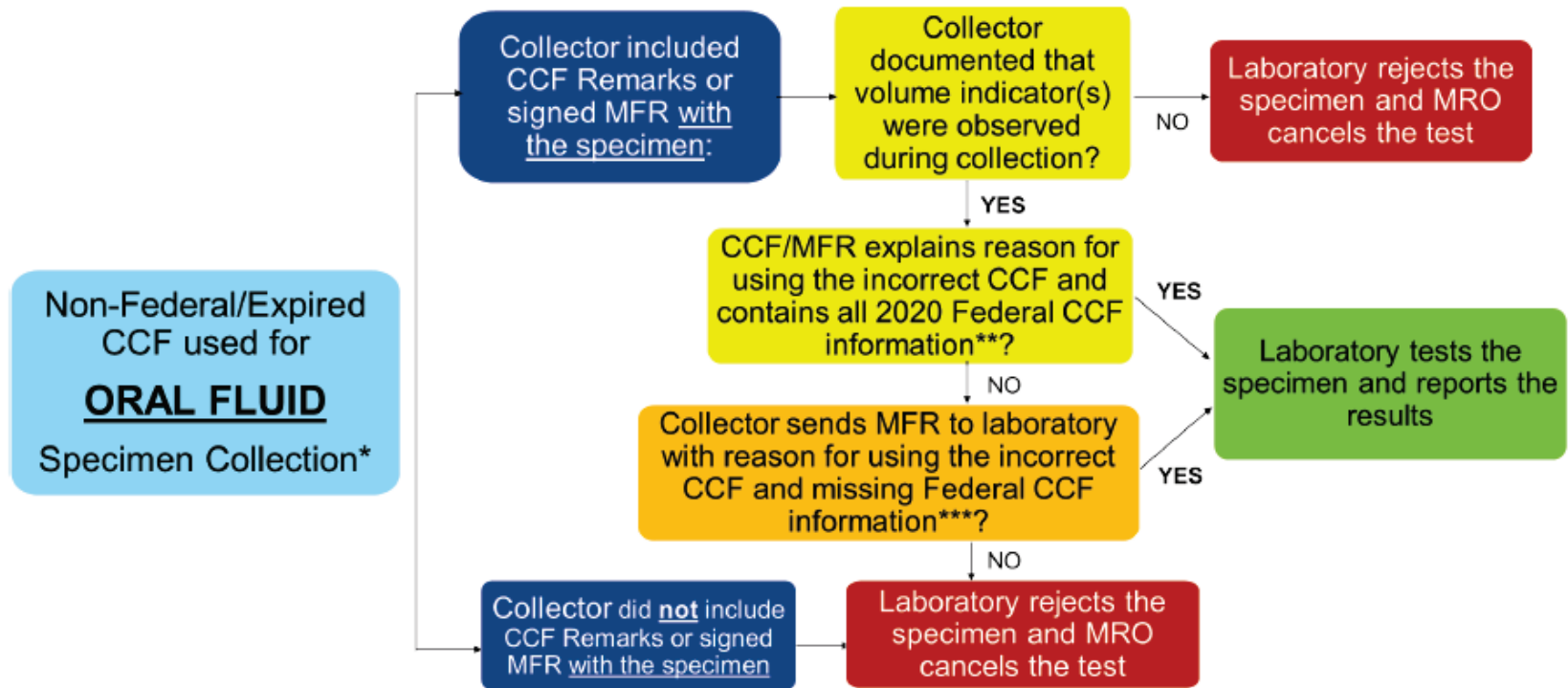


* The laboratory will reject a specimen that was collected using an ECCF system not approved by SAMHSA for the test facility

** If the non-federal CCF does not include all information required on a Federal CCF, the collector must also include the missing information in the MFR (MFR not required if collector includes the explanatory remarks in Step 2 of the CCF Copy 1).

*** The collector must take **immediate** steps to provide an MFR when notified. If the collector no longer works at the collection site, the collection site supervisor may sign the MFR.

Appendix A: Federal CCF Decision Trees for Collectors



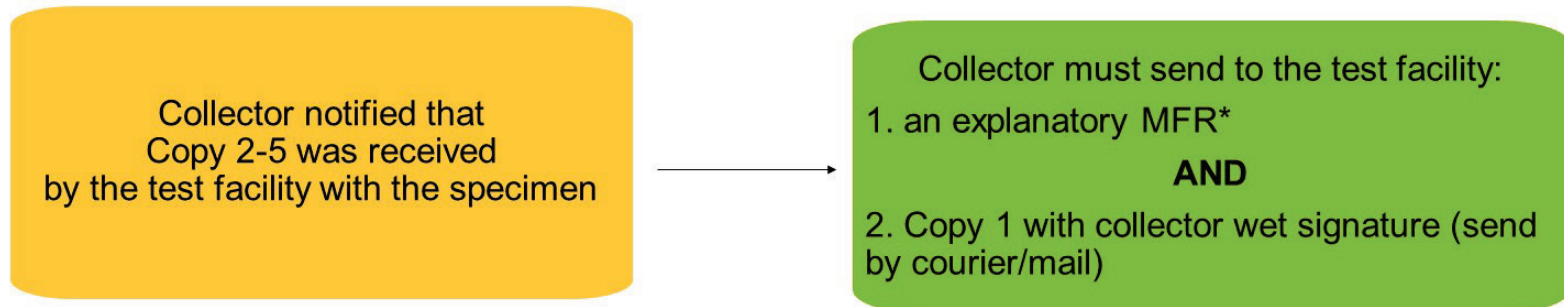
* The laboratory will reject a specimen that was collected using an ECCF system not approved by SAMHSA for the test facility

** If the non-federal CCF does not include all information required on a Federal CCF, the collector must also include the missing information in the MFR (MFR not required if collector includes the explanatory remarks in Step 2 of the CCF Copy 1).

***The collector must take **immediate** steps to provide an MFR when notified. If the collector no longer works at the collection site, the collection site supervisor may sign the MFR.

Appendix A: Federal CCF Decision Trees for Collectors

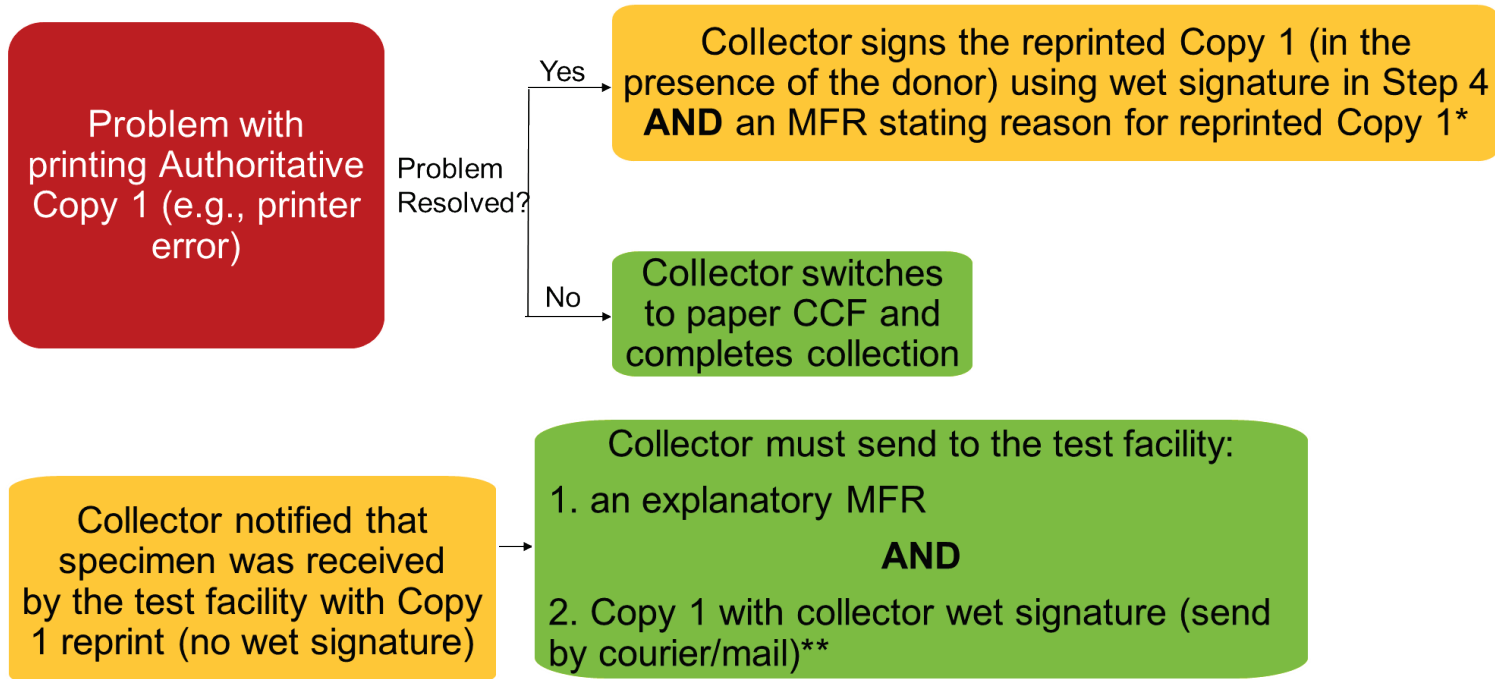
Incorrect CCF Copy (Copy 2-5) for Urine or Oral Fluid



*The collector must take **immediate** steps to provide an MFR when notified. If the collector no longer works at the collection site, the collection site supervisor may sign the MFR.

Appendix A: Federal CCF Decision Trees for Collectors

Reprint ECCF Copy 1 for Urine or Oral Fluid



* MFR not required if collector includes the explanatory remarks in Step 2 of the CCF Copy 1.

The collector must take **immediate steps to provide an MFR when notified. If the collector no longer works at the collection site, the collection site supervisor may sign the MFR.

Appendix B: Oral Fluid Collection Device Requirements

Collection Device: a single-use device that has been cleared by the Food and Drug Administration (FDA) and validated by an HHS-certified laboratory as acceptable to collect Federal agency oral fluid specimens. Many current devices consist of a stick with a pad that is placed in the donor's oral cavity to collect oral fluid; however, oral fluid may be collected by (unstimulated) expectoration into the device. The FDA-approved collection device must be used in accordance with manufacturer instructions and program requirements. **No modification of the FDA-cleared device is allowed.**

1. A collection device must not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen, and must:
 - a. Ensure pre-analytical drug and drug metabolite stability, and
 - b. Include an indicator that demonstrates to the collector the adequacy of the volume of the oral fluid specimen collected.
2. If the device contains a diluent (or other component, process, or method that modifies the volume of the collected specimen):
 - a. The volume of undiluted oral fluid collected should be at least 1 mL \pm 10 percent of the target volume for each primary (A) and split (B) specimen;
 - b. The volume of diluent in the device should be within \pm 2.5 percent of the diluent target volume; and
 - c. The device must have a volume indicator visible to the collector, which demonstrates when an adequate volume of oral fluid has been collected.
3. If the collection device does not contain a diluent (or other component, process, or method that modifies the volume of the collected specimen):
 - a. The volume of undiluted (neat) oral fluid collected should be at least 1 mL for each primary (A) and split (B) specimen; and
 - b. The A and B specimen tubes (defined below) must each have a volume marking clearly noting 1 mL.

Specimen Tube: a sealable, non-leaking container approved by FDA with the collection device, used to hold the collected oral fluid specimen (i.e., one tube for the primary specimen and one tube for the split specimen).

1. A specimen tube must not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen, and must:
 - Ensure pre-analytical drug and drug metabolite stability,

- Maintain the integrity of the specimen during storage and transport so that the specimen can be tested for drugs and drug metabolites,
- Display device expiration date:
 - The manufacturer must include the expiration date on the tube (i.e., the expiration date cannot be printed or transcribed on the label/seal applied by the collector);
 - The expiration date must be the date of the key component (i.e., the diluent expiration date if a diluent is used); and
 - The expiration date must be human-readable and readily visible to the collector and laboratory staff.
- Be designed so that the required tamper-evident label/seal from the Federal CCF is not damaged when initialed by the donor, and
- Be sufficiently transparent to enable a visual assessment of the contents (i.e., oral fluid, diluent, collection pad) for identification of abnormal physical characteristics without opening the tube.

2. Specimen tubes must be supplied as:

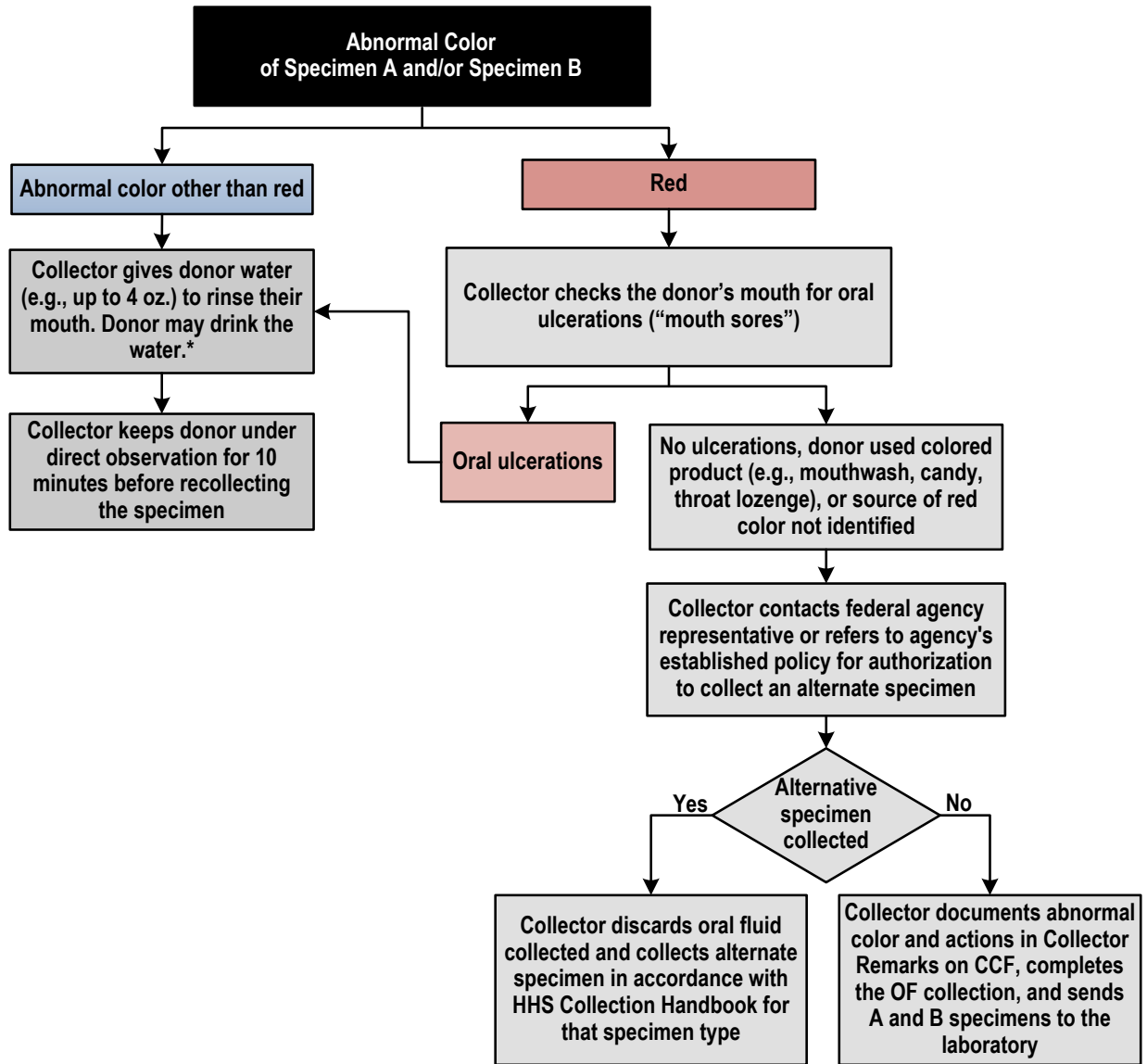
- a. An individual tube for a single oral fluid specimen (i.e., primary or split specimen) collected using a single collection device (i.e., two collection devices are used simultaneously or serially for a split specimen collection), or
- b. Paired tubes for the primary and split specimens, when one collection device is used to collect a single oral fluid specimen that is subdivided into primary and split specimens.

Analyte Stability and Recovery

Stability: (recoverable concentrations ≥ 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

Recovery: ≥ 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.

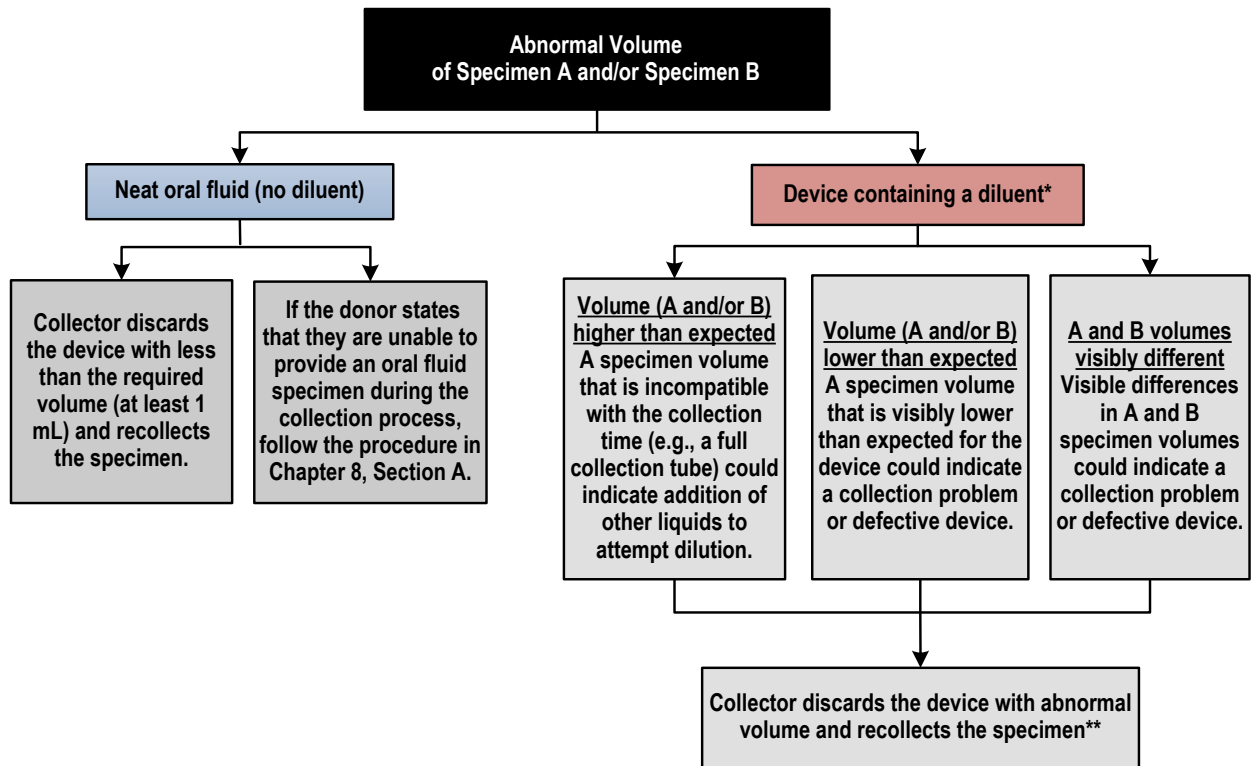
Appendix C: Abnormal Physical Characteristics Flowcharts



*Serial split collections: Donor is not allowed to rinse or drink water between A and B specimen collection. If time between the end of Specimen A collection and beginning of Specimen B collection exceeds two minutes, discard all collected oral fluid and recollect both A and B specimens.

Recollection: If donor states that they are unable to provide an oral fluid specimen during the collection process, follow the procedure in **Appendix E, Insufficient Specimen**.

Refusal to test: Stop the collection and report a refusal to test when donor fails to follow instructions (e.g., refuses to remove an item from their mouth, refuses to rinse), admits that they have adulterated or substituted their specimen, or donor conduct clearly indicates an attempt to subvert the collection. See **Appendix D, Example Donor Attempts to Subvert an Oral Fluid Collection**.



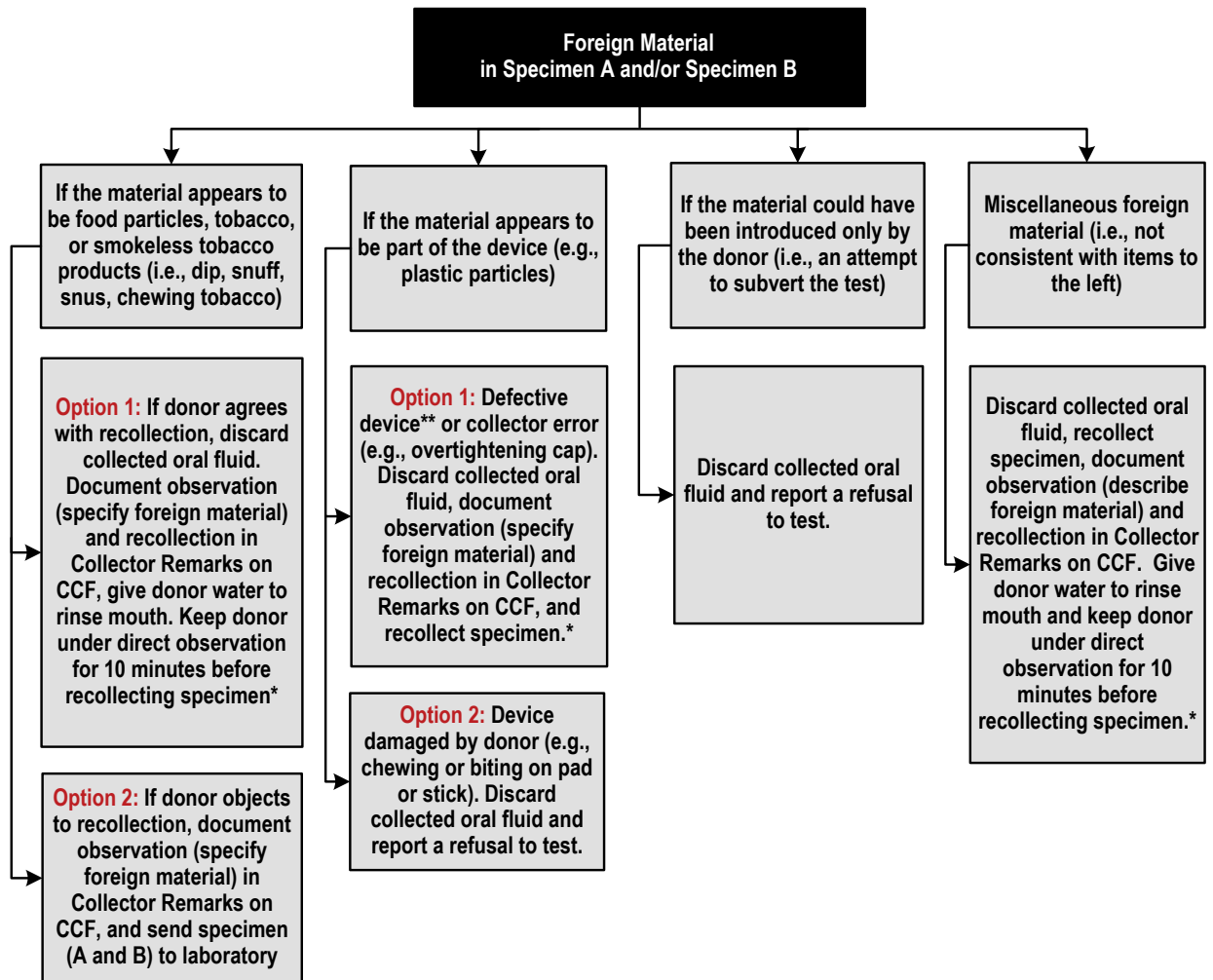
* The collector should have checked diluent volumes for A and B devices during device selection. If **any** diluent is spilled (before or after combining collected specimen with diluent): discard the device and use a new device to collect/recollect the specimen.

**Serial split collections: Donor is not allowed to rinse or drink water between A and B specimen collection. If time between the end of Specimen A collection and beginning of Specimen B collection exceeds two minutes, discard all collected oral fluid and recollect both A and B specimens.

If multiple devices appear defective (e.g., fail to collect any oral fluid, device particles indicative of defect): record the lot number(s) of the devices separately (not on the CCF) and report the problem to the HHS-certified oral fluid laboratory. If the laboratory is not the form supplier, also notify the supplier and obtain additional devices/different lots as needed.

Recollection: If donor states that they are unable to provide an oral fluid specimen during the collection process, follow the procedure in **Appendix E, Insufficient Specimen**.

Refusal to test: Stop the collection and report a refusal to test when donor fails to follow instructions (e.g., refuses to remove an item from their mouth, refuses to rinse), admits that they have adulterated or substituted their specimen, or donor conduct clearly indicates an attempt to subvert the collection. See **Appendix D, Example Donor Attempts to Subvert an Oral Fluid Collection**.



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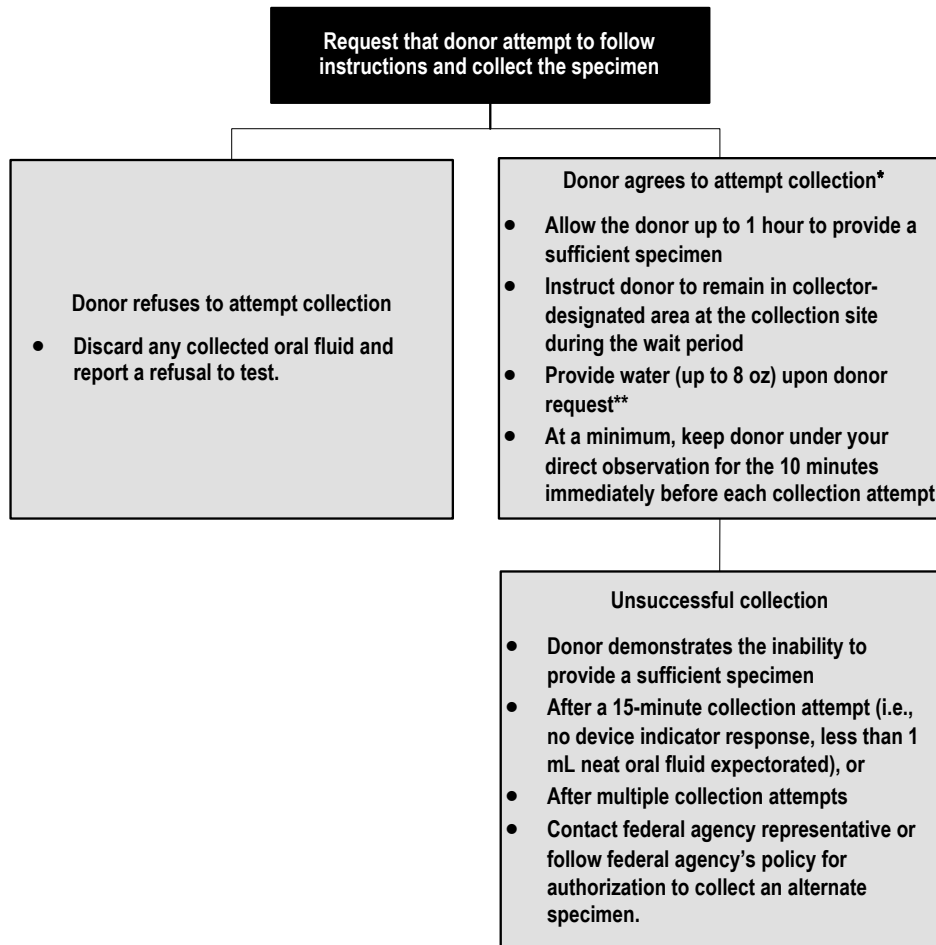
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Appendix D: Example Donor Attempts to Subvert an Oral Fluid Collection

- Attempting to rinse their mouth or gargle with mouthwash or other liquid (e.g., detox products, hydrogen peroxide, lemon juice, vinegar) immediately before or during the collection
- Chewing gum, using dental products (e.g., dental floss), or holding items (e.g., lozenges, capsules) in their mouth before collection
- Attempting to hold a portion of collector-provided water in their mouth to dilute their specimen
- Attempting to cause bleeding (e.g., biting/chewing their cheek)
- Biting/chewing the collection device
- Sucking the fluid out of the collection device, attempting to direct oral fluid away from collection pad, or swallowing excessively during collection process.
- Not positioning the collection device correctly in their mouth
- Attempting to conceal a foreign object (e.g., mint, breath strip, toothpaste, ice, liquid capsule, cough drop) in their mouth
- Attempting to detach, rip, eat, swallow, or destroy the collection pad while in the mouth

Appendix E. Insufficient Specimen



***Serial split collection.** If time between the end of Specimen A collection and beginning of Specimen B collection exceeds two minutes, discard all collected oral fluid and recollect both A and B specimens.

****Donor is not required to drink any fluids.** For serial split collections, donor is not allowed to rinse mouth or drink water between A and B specimen collection.