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

Collection Site Checklist

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

Effective October 10, 2023

Note: This checklist 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 checklist 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).

Table of Contents

References

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

1. Federal Custody and Control Form (Federal CCF)

2. HHS Oral Fluid Specimen Collection Handbook for Federal Agency Workplace Drug Testing Programs (HHS Oral Fluid Collection Handbook)

3. *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid* (OFMG). Published October 12, 2023 (88 FR 70814), effective October 10, 2023.

Instructions

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

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

Checklist

Each question in the *Collection Site Checklist for Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs* is designed to address the requirements in OFMG subparts D, E, F, G and H. Answer each question based on these requirements and your review of the collection site standard operating procedures, practice, and records.

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

Section Evaluation

Each checklist section contains a section evaluation page. Use the section evaluation to summarize and classify the seriousness of identified deficiencies.

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

Collection Site Evaluation Form

1. In the Overall Section Summary, assign a numerical “score” for each checklist section, based on the section evaluation:
   - Record a “0” on the evaluation form for each section summary where serious deficiencies were identified.
   - Record a “1” for each section summary where deficiencies were identified but do not require immediate corrective action.
   - Record a “2” for each section summary where no deficiencies were identified.

2. In the appropriate “Inspector/Collection Site Reviewer” columns under “Overall Summary of Serious Deficiencies,” list the sections identified as having serious deficiencies and those with no serious deficiencies.

3. Add the individual section scores to determine the rating and record the total in the “Rating” space for “Inspector/Collection Site Reviewer” under “Inspection Outcome.”

4. Sign and date in the appropriate space at the bottom of the form. Inspectors sign the “Onsite Inspection by” line; Collection Site Reviewers sign the “Self-Evaluation by” line.

A. Collection Site

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

A-2. Does the collection site have the following? YES NO

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

____ a. A means for washing hands

____ b. A suitable clean surface, inaccessible to the donor, for the collector to use as a work area

____ c. A secure temporary storage area for maintaining specimens until they are transferred to an HHS-certified laboratory

A-3. Does the collection site have procedures or restrictions to prevent the following? YES NO

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

____ a. Unauthorized access to the site during the collection

____ b. Unauthorized access to the collection materials/supplies

____ c. Unauthorized access to collection site records

____ d. Donor access to items that could be used to adulterate or substitute the specimen, or otherwise adversely affect the oral fluid collection

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

A-5. Is access to collection supplies restricted to authorized personnel? YES NO

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

If **YES**,

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

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

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

____ a. Hiring official or donor's immediate supervisor unless there is no feasible alternative and the individual is a trained collector

____ b. Co-worker in the same testing pool or who works with the donor on a daily basis

____ c. The applicant or employee (i.e., the specimen donor)

____ d. Employee of an HHS-certified laboratory who can link the donor with the specimen drug test results

____ e. Relatives or personal friends of the donor

Section Evaluation

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

____ Serious deficiencies were identified
____ Deficiencies were identified
____ No deficiencies were identified

Note: Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

B. Personnel

Collectors

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

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

_____

B-2. Was documentation of training for each collector provided for review during the inspection? YES NO

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

_____

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

B-3. Does each collector maintain their training documentation? YES NO

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

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

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

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

____ a. The steps to correctly perform a collection using each type of collection device to be used for Federal agency specimens

____ b. The proper completion and distribution of the Federal CCF

____ c. Problem collections

____ d. Fatal and correctable flaws and how to correct problems in collections

____ e. Collector responsibilities to maintain the integrity of the collection process, to protect the privacy of donors, to ensure the security and integrity of specimens, and to maintain proper conduct

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

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

____ a. Two uneventful scenarios

____ b. One insufficient specimen quantity scenario

____ c. One scenario in which the donor refuses to sign the Federal CCF

____ d. One scenario in which the donor refuses to initial the tamper-evident tube label/seal

B-8. Do the initial and refresher training records for each collector include the following? YES NO

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

____ a. Documentation that the training was conducted in person or by means allowing real-time observation and interaction between trainer and trainee.

____ b. Written attestation by the trainer that the mock collections were error-free.

____ c. Documentation of the trainer's qualifications at the time of the training.

Collector Trainers

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

B-9. During interview by the inspection team, did each collector trainer demonstrate a working knowledge of the collection procedures described in the OFMG, the HHS Oral Fluid Collection Handbook, the manufacturer instructions for the specific collection device(s) and any

other guidance provided by the Federal agency related to the collection procedures? YES NO

B-10. Was documentation of training for each trainer provided for review during the inspection? YES NO

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

B-11. Does each trainer maintain their training documentation? YES NO

B-12. Do the training records for each collector trainer document <u>at least one</u> of the following qualifications? YES NO

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

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

Section Evaluation

B-14. *For the Personnel Section*:

____ Serious deficiencies were identified
____ Deficiencies were identified
____ No deficiencies were identified

Note: Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

C. Specimen Collection Procedures

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

C-2. Does the collector begin the collection without delay once the donor arrives at the collection site? YES NO

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

C-4. Does the collector perform only one specimen collection at a time? YES NO

C-5. Does the collector properly verify donor identity? YES NO

Proper forms of identification include:

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

C-6. Does the collector provide identification to the donor when requested? YES NO

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

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

C-9. Does the collector complete the required information in Step 1 of the Federal CCF? YES NO

C-10. Does the collector take the following steps to deter specimen tampering? YES NO

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

____ a. Ask the donor to remove any unnecessary outer clothing (e.g., coat, jacket)

____ b. Ask the donor to leave all other personal belongings (e.g., briefcase, purse) with the outer clothing

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

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

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

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

____ e. Begin 10-minute wait period after inspection of the donor oral cavity prior to beginning specimen collection

____ f. If the donor removes an item from their mouth as instructed, has abnormally colored saliva, or indicates they have “dry mouth”, provide water to the donor to rinse. Begin 10-minute wait period after donor has rinsed their mouth

____ g. Direct the donor to wash and dry their hands under the collector’s supervision

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

C-12. Does the collector review the procedures for a successful oral fluid specimen collection as detailed in the device-specific manufacturer’s

instructions? YES NO

C-13. Are unauthorized personnel prohibited from entering the collection site during the collection procedure? YES NO

C-14. Are only the collector and the donor allowed to handle the unsealed specimen? YES NO

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

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

____ a. Ensure the donor has positioned the specimen collection device properly for collection

____ b. Ensure the collection is performed correctly

____ c. Ensure collection device is working properly

Completion of a Collection

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

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

____ a. Two specimens collected simultaneously using two separate collection devices

____ b. Two specimens collected serially with two separate collection devices

____ c. Two specimens collected simultaneously using a single collection device that splits the specimen into two separate collection tubes

____ d. A single specimen collected using a single collection device that is subdivided into two specimen tubes.

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

C-18. Does the collector complete the required information in Step 2 of the Federal CCF? YES NO

C-19. Does the collector report a refusal if the donor refuses to complete the collection? YES NO

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

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

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

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

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

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

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

C-27. Does the collector provide Copy 5 of the Federal CCF to the donor? YES NO

C-28. Does the collector prepare the sealed tamper-resistant package containing the specimen tubes and Federal CCF for transport to the

HHS-certified laboratory? YES NO

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

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

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

Section Evaluation

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

____ Serious deficiencies were identified
____ Deficiencies were identified
____ No deficiencies were identified

Note: Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

D. Collection Problems

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

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

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

____ a. Requests that the donor follow the instructions for the specific collection device and attempt to provide an oral fluid specimen

____ b. Provides a drink (up to 8 oz.) when the donor indicates they may provide a specimen after drinking fluids

____ c. Allows a wait period up to 1 hour for the donor to provide a sufficient oral fluid specimen

____ d. Directs the donor to remain at the collection site (in an area designated by the collector) during the wait period

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

D-3. Does the collector discontinue the collection procedure in the following situations? YES NO

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

D-4. When discontinuing a collection, does the collector take the following steps? YES NO

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

____ a. Mark the "None Provided" checkbox in Step 2 of the Federal CCF

____ b. Record the reason for not collecting the specimen on the Remarks line in Step 2 of the Federal CCF

____ c. Notify the agency's designated representative for authorization to collect an alternate specimen or follow the standard protocol from the Federal agency

____ d. Discard the oral fluid collected (if any)

____ e. Discard Copy 1 of the Federal CCF (no valid specimen was collected) and maintain Copy 3 in the collection records

____ f. Distribute the remaining Federal CCF copies within 24 hours or the next business day:

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

Refusal to Test

D-5. Does the collector report a "refusal to test" in the following situations? YES NO

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

____ a. The donor fails to appear for any test within a reasonable time as determined by the Federal agency

____ b. The donor leaves the collection site before completion of the collection

____ c. The donor fails to provide a specimen (e.g., oral fluid or another authorized alternate specimen type)

____ d. The donor fails to cooperate with any part of the testing process (e.g., refuses to empty pockets, disrupts the collection process, fails to rinse mouth when directed by the collector, refuses to provide a split specimen)

____ e. The donor brings materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen

____ f. The donor attempts to adulterate, substitute, or dilute the specimen

____ g. The donor admits to the collector that they have adulterated or substituted their specimen

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

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

____ a. Discard the oral fluid collected (if any)

____ b. Immediately notify the agency’s designated representative of the refusal (e.g., by telephone, secure fax machine, e-mail)

____ c. Document the refusal to test with appropriate comments, signature, and date in the Remarks line of Step 2 of the Federal CCF

____ d. Send all copies of the Federal CCF to the Federal agency’s designated representative

Collector Errors

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

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

Section Evaluation

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

____ Serious deficiencies were identified
____ Deficiencies were identified
____ No deficiencies were identified

Note: Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

E. Collection Site Records

E-1.	Are collection site records including Copy 3 of the Federal Custody and Control Form (Federal CCF) stored for a minimum of two years?	YES	NO
E-2.	Are collection site records stored and disposed of in a manner that ensures donor confidentiality?	YES	NO
E-3.	Have collectors properly completed the Federal CCF?	YES	NO
E-4.	Are edits to the Federal CCF properly made, initialed, and dated?	YES	NO

Section Evaluation

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

____ Serious deficiencies were identified
____ Deficiencies were identified
____ No deficiencies were identified

Note: Serious deficiencies require immediate corrective action by the collection site to maintain the integrity of the collection process, to maintain the security and integrity of the specimens collected, and to ensure the privacy of the donors.

Describe basis for the above selection:

Collection Site Evaluation Form

Overall Section Summary

Checklist Sections		Serious Deficiencies Identified (0)	Deficiencies Identified (1)	No Deficiencies Identified (2)
A. Collection Site				
B. Personnel				
C. Specimen Collection Procedures				
D. Collection Problems				
E. Collection Site Records				

Overall Summary of Serious Deficiencies

(List Sections)

Reviewer	***Serious Deficiencies were identified***	***No Serious Deficiencies were identified***
Inspector / Collection Site Reviewer		
Federal Agency/ Designee		

Inspection Outcome

Rating (out of 10)		Acceptable: *rating ≥ 5 and no more than one section with serious deficiencies* Unacceptable: *rating < 5 or more than one section with serious deficiencies*	
Inspector / Collection Site Reviewer	___/10		
Federal Agency/ Designee	___/10	**Outcome:**	

Additional Comments: _____

_____

_____

Acceptable Outcome for Inspection: Yes _____ No _____

Self-Evaluation by: _____ Date:_____

Onsite Inspection by: _____ Date:_____

Approved by: _____ Date:_____

Position/Title: _____