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 Urine Specimens for
Federal Agency Workplace Drug Testing Programs

Effective January 2022

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 (82 FR 7920) dated January 23, 2017 (effective October 1, 2017). 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).

Previous Versions of this Checklist are Obsolete

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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* (UrMG) published on January 23, 2017 (effective October 1, 2017).

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

Checklist

Each question in the *Collection Site Checklist for Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs* is designed to address the requirements in UrMG 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. Check 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 test facility

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, substitute, or dilute the specimen (e.g., soap, disinfectants, cleaning agents, water)

A-4. Does the collection site have the required supplies for federally regulated urine 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 Instrumented Initial Test Facility (IITF) or HHS-certified laboratory who can link the donor with the specimen drug test results

☐ e. Relatives or close 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 UrMG, the HHS Urine Specimen Collection Handbook, 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 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? ☐ 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 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. One uneventful scenario
- ☐ b. One insufficient specimen quantity scenario
- ☐ c. One temperature is out of range scenario
- ☐ d. One scenario in which the donor refuses to sign the Federal CCF
- ☐ e. One scenario in which the donor refuses to initial the tamper-evident bottle 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 UrMG, the HHS Urine Collection Handbook, 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.

Complete the remaining Section B questions for the records provided.

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,*
- *The trainer successfully completed a "train the trainer" course given by an organization (e.g., manufacturer, private entity, contractor, or federal agency)*

B-13. Has each trainer (as applicable) completed refresher training at least every five years from the date of initial training? ☐ 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 restroom to deter the dilution or substitution of a specimen? ☐ YES ☐ NO

Required steps:

- *Placing bluing agent in the toilet or turning off the water supply and flushing the toilet*
- *Securing any other water source in the enclosure where urination occurs*

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, hat, etc.)
- ☐ b. Ask the donor to leave all other personal belongings (e.g., briefcase, purse) with the outer clothing or in another secured location
- ☐ 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
- ☐ e. 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 give the donor the following collection instructions? ☐ YES ☐ NO

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

- ☐ a. Provide at least 45 mL of urine
- ☐ b. Do not flush the toilet
- ☐ c. Provide the specimen in a reasonable time (set by the collector)
- ☐ d. Return with the specimen as soon as they have finished providing the specimen

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. Do both the collector and the donor maintain visual contact with the specimen from the time the specimen is transferred to the collector until specimen bottles have been sealed for shipment? ☐ YES ☐ NO

Completion of a Collection

C-16. After receiving the specimen from the donor, whenever practical, does the collector allow the donor to wash their hands and to flush the toilet? ☐ YES ☐ NO

C-17. Does the collector check the specimen temperature within four minutes after receiving the specimen from the donor and check the appropriate box in Step 2 of the Federal CCF? ☐ YES ☐ NO

C-18. Does the collector inspect the specimen for adulteration or substitution by examining the physical characteristics of the urine? ☐ YES ☐ NO

C-19. Does the collector check the specimen volume to ensure that the specimen contains at least 45 mL of urine? ☐ YES ☐ NO

C-20. In the presence of the donor, does the collector pour at least 30 mL into “Bottle A” and at least 15 mL into “Bottle B”? ☐ YES ☐ NO

C-21. Does the collector discard excess urine (unless it is used for a clinical test as part of a physical examination required by a federal agency)? ☐ YES ☐ NO

C-22. 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 bottle to ensure that the lid/cap cannot be removed without destroying the label/seal? ☐ YES ☐ NO

C-23. If the tamper-evident label/seal does not adhere to the bottle or is damaged, does the collector apply the unacceptable label/seal to the bottle, and apply a second, separate tamper-evident seal to seal the specimen bottle? ☐ YES ☐ NO

C-24. Does the collector record the date of the collection on the bottle seals after placing them on the bottles? ☐ YES ☐ NO

C-25. Does the collector ask the donor to initial the specimen bottle seals after placing them on the bottles? ☐ YES ☐ NO

C-26. 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-27. Does the collector complete the collector chain of custody section in Step 4 on Copy 1 of the Federal CCF? ☐ YES ☐ NO

C-28. Does the collector place the sealed specimen bottles 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 bottles)? ☐ YES ☐ NO

C-29. Does the collector provide Copy 5 of the Federal CCF to the donor? ☐ YES ☐ NO

C-30. Does the collector prepare the sealed tamper-resistant package containing the specimen bottles and Federal CCF for transport to the HHS-certified test facility (i.e., IITF or laboratory)? ☐ YES ☐ NO

C-31. Are the specimen bottles and Federal CCF appropriately safeguarded until they are retrieved for transport to the HHS-certified test facility (i.e., IITF or laboratory)?
☐ YES ☐ NO

C-32. 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 within 24 hours after the collection or during the next business day? ☐ YES ☐ NO

C-33. Are specimens submitted to an HHS-certified test facility (i.e., IITF or laboratory) within 24 hours after the collection or during the next business day? ☐ YES ☐ NO

Section Evaluation

C-34. 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

Direct Observed Collections

D-1. Does the collector initiate a direct observed collection in the following situations? ☐ YES ☐ NO

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

- ☐ a. Specimen temperature is outside the acceptable range
- ☐ b. Specimen appearance indicative of tampering (abnormal physical characteristic such as unusual color, excessive foaming when shaken, unusual odor)
- ☐ c. Donor conduct indicates an attempt to adulterate or substitute the specimen, and the donor has already provided a specimen

D-2. Does the collector take the following steps before conducting a direct observed collection? ☐ YES ☐ NO

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

- ☐ a. Contact a collection site supervisor for concurrence with the collector's decision for a direct observed collection
- ☐ b. Explain to the donor why a direct observed collection is being conducted
- ☐ c. Inform the donor that the gender of the observer will match the donor's gender, which is determined by the donor's gender identity

D-3. Before an individual is allowed to serve as the observer for a direct observed collection, does a collector/collection site supervisor provide training on the following subjects? ☐ YES ☐ NO

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

- ☐ a. The steps necessary to perform a direct observed collection correctly
- ☐ b. Maintaining visual contact with the collection container throughout the collection process, to maintain the integrity and security of the specimen
- ☐ c. Ensuring the privacy of the donor
- ☐ d. Observing the collection in a professional manner, to minimize discomfort of the donor
- ☐ e. Avoiding conduct that could be interpreted as offensive or inappropriate

D-4. Does the collector ensure that the observer for each direct observed collection meets the following requirements? ☐ YES ☐ NO

- *Trained in direct observed specimen collection procedures*
- *Same gender as the donor*

D-5. Does the collector properly document the direct observed collection in Step 2 of the Federal CCF? ☐ YES ☐ NO

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

☐ a. Mark the checkbox for an observed collection

☐ b. Record the name and gender of the observer on the Remarks line

☐ c. Record the reason for the observed collection on the Remarks line

Monitored Collections

D-6. Does the collector initiate a monitored collection in the following situations? ☐ YES ☐ NO

- *The collection is being conducted in a public restroom*
- *The restroom used for the collection has a water source that cannot be disabled or secured*

D-7. Does the collector ensure that the monitor for each monitored collection meets <u>at least one</u> of the following requirements? ☐ YES ☐ NO

- *Same gender as the donor*
- *A trained medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician) who is licensed or certified to practice where the collection occurs*

D-8. Does the collector record the name of the monitor (if not the collector) on the Remarks line in Step 2 on Copy 1 of the Federal CCF? ☐ YES ☐ NO

Insufficient Specimen

D-9. When the donor has demonstrated that they are unable to provide a sufficient specimen, does the collector offer the donor a reasonable amount of fluid to drink (e.g., an 8 ounce glass of water every 30 minutes, not to exceed 40 ounces over a period of 3 hours)? ☐ YES ☐ NO

D-10. Does the collector allow the donor up to three hours to provide a sufficient specimen? ☐ YES ☐ NO

D-11. Do collection procedures prohibit combining urine collected from separate voids to create a specimen of sufficient volume? ☐ YES ☐ NO

D-12. Does the donor remain under the direct observation of the collector to prevent the donor from possibly compromising the collection process? ☐ YES ☐ NO

D-13. Does the collector record the time of each attempt to provide a sufficient volume of specimen (e.g., on the Remarks line of the Federal CCF)? ☐ YES ☐ NO

D-14. Does the collector discontinue the collection procedure in the following situations? ☐ YES ☐ NO

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

D-15. When the donor has not provided a sufficient specimen, does the collector end the collection procedure and 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 urine 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-16. 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 (except a pre-employment test) within a reasonable time as determined by the federal agency
- ☐ b. The donor fails to provide a specimen (e.g., urine or another authorized alternate specimen type)
- ☐ c. The donor fails to cooperate with any part of the testing process (e.g., refuses to empty pockets, disrupts the collection process, fails to wash hands when directed by the collector)
- ☐ d. The donor fails to allow a direct observed collection when required
- ☐ e. The donor fails to follow the observer's instructions related to the direct observed collection
- ☐ f. The donor fails to allow a monitored collection when required
- ☐ g. The donor brings materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen
- ☐ h. The donor attempts to adulterate, substitute, or dilute the specimen
- ☐ i. The donor leaves the collection site before completion of the collection (except for leaving before the collection has begun for a pre-employment test)
- ☐ j. The donor possesses or wears a prosthetic or other device that could be used to interfere with the collection process
- ☐ k. The donor admits to the collector that they have adulterated or substituted their specimen

D-17. 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 urine 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-18. When the collector realizes that an incorrect or expired Federal CCF is used prior to packaging the specimen bottles, 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-19. Does the collector provide a memorandum for the record (MFR) when requested by the HHS-certified test facility (i.e., laboratory, IITF), or MRO? ☐ YES ☐ NO

Section Evaluation

D-20. 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)

	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:**	Acceptable

Additional Comments:

Acceptable Outcome for Inspection: ☐ Yes ☐ No

Self-Evaluation by: Date:

Onsite Inspection by: Date:

Approved by: Date:

Position/Title:

Reset