

Instructions for Collection Procedure (Normal/Uneventful)

Provided by Certified Training Solutions

1	Secure collection site (bluing in toilet, no running or clear water in restroom, etc.)
2	Donor Arrives: Get donor's proper photo ID
3	Fill out Step 1 of the CCF (donor ID or SSN, Employer info, reason for test, etc.) <i>*Note: For FMCSA-covered drivers, you must use CDL number & State for instead of SSN or ID#.</i>
4	Show donor the Instructions on the back of the CCF and explain collection process.
5	Tell donor s/he must stay for entire process or it <i>may</i> be considered a Refusal To Test.
6	Have employee/donor remove unnecessary outer clothing (coats, hats, etc.)
7	Have donor empty their pockets
8	Instruct donor to wash and dry their hands while you watch them
9	Select collection kit/cup (or allow donor to select it)
10	Collector opens sealed collection kit and dump contents
11	Instruct donor: Provide at least 45mL of specimen, do not flush toilet while in restroom, and do not wash hands again or use water until after the specimen is brought to the collector; be back out in 4-5 minutes at most, as it's important that the collector read the temperature ASAP (otherwise no temp reading could result in a 2nd collection under direct ob.)
12	Allow donor time to urinate, while you wait outside restroom door
13	After donor returns specimen to you: Check for-- Adequate volume, temperature reading, signs of tampering
14	If proper temp, check "Yes" in Step 2 Temp Box. And if there's at least 45 mL, check "Split" in Collection box
15	Have the donor watch you while you open the tamper-evident seals on the specimen bottles and pour their specimen into bottles.
16	Pour at least 30mL into the first bottle
17	Pour at least 15mL into the 2nd bottle
18	Place the tamper-evident seals from the CCF on the appropriate specimen bottles
19	Collector dates the seals (ON THE BOTTLES)
20	Donor initials the seals (ON THE BOTTLES)
21	Open to Copy 2 of the CCF. Either read the Certification statement to the donor or ask them to read it.
22	Have the donor fill out Step 5, Copy 2 / Certification Statement
23	Turn back to Copy 1. Double-check that everything on form is correct so far
24	Step 4: Collector may now sign their name, print their name, write today's date and the time collection. Note who will be transporting specimen to the lab.
25	Double-check all Steps and paperwork for errors or omissions.
26	Remove Copy 1 from the CCF and place it in the bag with the specimen (in their appropriate pouches).

27	Give Copy 5 of the CCF to donor. Tell them they may list any medications they may be taking on their copy only, to refresh their own memory, in case the MRO needs to contact them.
28	The donor may now leave the collection site.
29	Ensure that the MRO and DER receive their copy of the CCF within 24 hours or next business day.
30	Place sealed specimen in secure, temporary storage.

Direct Observation Collection:

(This will be necessary if the first specimen is out of temperature range or tampered/adulterated; OR if the reason for the test is Return-To-Duty or Follow-up; OR if ordered by the MRO).

- The observer must be the same gender as the employee. (Note: If gender is in question, the guidance is that the observer should be the same gender as the gender that the donor identifies with).
- If the collector is not the observer, the collector must instruct the observer about the procedures for checking the employee for prosthetic or other devices designed to carry “clean” urine and urine substitutes AND for watching the employee urinate into the collection container.
- In the privacy of the restroom, the observer requests the employee to raise his or her shirt, blouse or dress / skirt, as appropriate, above the waist, just above the navel; and lower clothing and underpants to mid-thigh and show the observer, by turning around, that the employee does not have such a device.
- If The Employee Has A Device: The observer immediately notifies the collector; the collector stops the collection; and the collector thoroughly documents the circumstances surrounding the event in the remarks section of CCF. The collector notifies the DER. This is a refusal to test.
- If The Employee Does Not Have A Device: The employee is permitted to return clothing to its proper position for the observed collection. The observer must watch the urine go from the employee’s body into the collection container. The observer must watch as the employee takes the specimen to the collector. The collector then completes the collection process.
- Failure of the employee to permit any part of the direct observation procedure is a refusal to test.

Documentation on the CCFs (samples):

- On the 1st CCF, note in Remarks: *“Cold specimen. Will attempt 2nd collection under Direct Observation. 1st of 2 collections. 2nd Specimen ID#0000002”* ○ Conduct the 2nd collection using direct observation procedures, then document on 2nd CCF . . .
- *“2 of 2 Collections. Direct observation due to 1st specimen cold. 1st specimen ID# is: 000001”*
- Don’t forget to check the “Observed” box in Step 2.
- Complete the rest of the CCF, completing all steps in the correct order, just as in a normal collection.

If the direct observation collection is conducted for another reason, be sure to note the reason in Remarks, such as:

- *“Direct observation conducted due to test reason follow-up (or return-to-duty),” as appropriate.*
- *“Direct observation conducted as directed by MRO.”*

Remember: In any situation in which TWO collections are conducted and in which both specimens are being sent to the laboratory, you must fill out a separate CCF for EACH collection and bag/seal each split specimen and respective CCF separately. (You must not document two separate collections on one CCF.)

Shy Bladder:

(If the donor does not provide a sufficient specimen the 1st time):

- Note the time the 1st insufficient specimen was received in Remarks/Step 2. (This is the time the 3-hour clock begins.) ○ Example: *“Insuff. Spec. at 1:30pm, approx. 15ml”*
- Explain to the donor that the DOT requires a specimen of at least 45ml, and that donor will be required to stay at the collection site, under observation for up to 3 hours, or until they can provide a specimen of sufficient volume. Warn the donor that they cannot leave the collection site or this may be considered a refusal to test under Federal regulations.
- Offer the donor fluids. They may have up to 40 ounces of fluids (spread reasonably over the 3 hour period). You or a designated person should watch the donor, provide the fluids, and record the fluids given. If the donor declines to drink fluids, this is not a refusal to test.
- After a reasonable time and when the donor feels they are able to provide a specimen, provide them with a new collection cup and give them all restroom instructions again.
- Repeat the process if the donor again provides an insufficient specimen (Note the time in Remarks and note “insufficient specimen”. Continue offering fluids and observing donor.
- If the donor provides a sufficient specimen at any time, proceed with preparing the specimen for shipping to the laboratory and complete the CCF.
- If the donor has not provided a sufficient specimen after 3 hours, ○ Check “None Provided” in Step 2.
 - Print the donor’s name (and telephone number, if s/he will provide it) in Step 5 on Copy 2 of CCF.
 - Collector should complete Step 4: Sign and Print Collector Name, Date, but leave Time of Collection blank.
 - Discard/shred lab copy (Copy 1) of the CCF. ○ Distribute ALL other copies of the CCF to appropriate parties.
 - Immediately notify the DER of this “shy bladder” situation. (Note: Regulations require the DER to have the employee take a medical exam within 5 business days. The DER should consult the MRO for further guidance immediately on this situation.)

NEW – January 1, 2018: “Questionable Specimens”

- If the donor provides a specimen that is also out of temperature range (if it’s enough to get a fair temp reading) **OR** if the specimen shows signs of adulteration, substitution, or tampering, you will follow the Direct Observation procedures immediately following receipt of the 1st questionable specimen. ○ This applies whether or not the 1st specimen is sufficient or insufficient volume.
- If the donor does **not** provide a sufficient specimen within the 3-hour time period after the first questionable specimen is received, you will NOT send anything to the lab.
- In this case, you will dispose of the 1st specimen, and you will complete the CCF (Collector signs, prints name, and date in Step 4).
 - Collector must PRINT the donor’s name in Step 5, Copy 2 of the CCF (Certification Statement). ○ You will shred the lab’s copy of the CCF and distribute the other copies.
 - Be sure to document the situation in Remarks before signing
 - (Example for 1st specimen that was “questionable”, but also insufficient volume: “Received insuff. specimen that was cold & blue in color. Unable to collect 2nd under direct observation due to shy bladder issues.”)
 - (Example for 1st specimen that was “questionable”, but Sufficient volume: “1st Specimen was cold & blue in color. Unable to collect 2nd under direct observation due to shy bladder issues.”)
 - -Be sure to note each attempt to urinate in Remarks (just as in a ‘normal’ shy bladder situation).
 - ✦ The Observer must accompany the donor into the restroom each time the donor makes an attempt to urinate and must complete the direct observation procedure with each attempt (“Up, down, turn-around” with the clothing).
 - The employer will then handle this situation as a “shy bladder” (i.e. The donor must be evaluated by a physician within 5 business days to determine if there was a medical reason why s/he could not provide a sufficient specimen within a 3-hour period.)
- Report the situation as a “shy bladder/unable to collect a sufficient specimen” to the employer. However, be sure to report the details of the situation to the DER.

Remember: It is a Refusal at any time if the donor will not cooperate -- (Example: The donor provides a “questionable” specimen, but then refuses to stay and attempt to provide additional/sufficient specimen under direct observation, or refuses to follow the instructions or cooperate with the required direct observation collection.)