

## Instructions for Urine Collection Procedure (Normal/Uneventful)

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| 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.)<br><i>*Note: For FMCSA-covered drivers, you must use CDL number &amp; State instead of SSN or ID#.</i>   |
| 4  | Explain the basic collection procedure to the donor, and tell the donor that instructions for completing the CCF can be found at the HHS ( <a href="https://www.samhsa.gov/workplace">https://www.samhsa.gov/workplace</a> ) and DOT ( <a href="https://www.transportation.gov/odapc">https://www.transportation.gov/odapc</a> ) websites.  |
| 5  | Suggested: Tell donor they must stay for entire process or it <i>may</i> be considered a Refusal To Test.   |
| 6  | Ask the donor to remove unnecessary outer clothing (coats, hats, etc.) & have them empty their pockets. Ensure no items were brought that were meant to tamper with the process.  |
| 7  | Instruct the donor not to list medications that they are currently taking on the CCF.   |
| 8  | Instruct donor to wash and dry their hands while you watch them and tell them not to wash their hands again or attempt to use water until after they've returned their specimen to you.   |
| 9  | Select collection kit/cup (or allow donor to select it) and open the sealed collection kit and dump contents.   |
| 10 | <b>Instruct donor:</b> Provide at least 45mL of specimen, do not flush toilet while in restroom; be back out as soon as they are finished urinating (about 4-5 minutes at most), as it's important that the collector read the temperature ASAP (otherwise no temp reading or temp-out-of-range could result in a 2nd collection under direct observation.  |
| 11 | Allow donor time to urinate, while you wait outside restroom door. Pay close attention to the donor's conduct to ensure they are not attempting to beat the test, cheat, substitute, etc.   |
| 12 | After donor returns specimen to you: Check for-- Adequate volume, temperature reading, signs of tampering.  |
| 13 | <b><u>STEP 2 CHECKBOXES:</u></b> <ul style="list-style-type: none"> <li>• Mark the "Urine" checkbox.</li> <li>• If proper temp (32°-38°C/ 90°-100°F), check "Yes" in Step 2 Temp Box. (See Instructions under Direct Observation on this checklist if specimen is out of temperature range.)</li> </ul> And if there's at least 45 mL, check "Split" in Collection box. (See Instructions under Shy Bladder on this checklist if specimen is not within acceptable temp range.) |
| 14 | Have the donor watch you while you open the tamper-evident seals on the specimen bottles and pour their specimen into bottles.  |
| 15 | Pour at least 30mL into the first bottle. Pour at least 15mL into the 2nd bottle.   |
| 16 | Carefully place the tamper-evident seals from the CCF on the appropriate specimen bottles. (Ensure the specimen ID numbers on the labels match specimen ID number on the CCF.)  |
| 17 | <b>Collector</b> dates the seals (ON THE BOTTLES)   |
| 18 | <b>Donor</b> initials the seals (ON THE BOTTLES) -Make note in Remarks if donor will not initial.   |

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| 19 | Open to Copy 2 of the CCF (MRO's copy). Either read the Certification statement to the donor or ask them to read it.  |
| 20 | Have the donor fill out Step 5, Copy 2 / Certification Statement. (Make a note in Remarks if the donor declines to fill this out, then print their name for them in this section.)  |
| 21 | Turn back to Copy 1. Double-check that everything on form is correct so far.  |
| 22 | <b>Step 4: Collector:</b> sign your name, print your name, write today's date and the time collection. Note who will be transporting specimen to the lab.                           |
| 23 | Double-check all steps and paperwork for errors or omissions. Ensure that all copies of the CCF are legible and complete (press hard using a ballpoint pen!)                        |
| 24 | Remove Copy 1 from the CCF and place it in the bag with the specimen (in their appropriate pouches).  |
| 25 | 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. |
| 26 | The donor may now leave the collection site.  |
| 27 | Ensure that the MRO and DER receive their copy of the CCF within 24 hours or next business day. Keep your copy for at least 30 days.  |
| 28 | Place sealed specimen in secure, temporary storage.   |
| 29 | Ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case, within 24 hours or during the next business day.                          |

### **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 donor. (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 donor for prosthetic or other devices designed to carry "clean" urine and urine substitutes AND for watching the donor urinate into the collection container.
  - The collector notes the observer's name in the Remarks on the CCF.
- In the privacy of the restroom, the observer requests the donor 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 donor does not have such a device.
- If The Donor Has A Device: The observer immediately notifies the collector; the collector stops the collection and thoroughly documents the circumstances of the event in the remarks section of CCF. The regulations state that this is a refusal to test. Notify DER immediately.
- If The Donor Does Not Have A Device: The donor is permitted to return clothing to its proper position for the observed collection. The observer must watch the urine go from the donor's body into the collection container. The observer must watch as the donor takes the specimen to the collector. The collector then completes the collection process.

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- Failure of the donor to permit any part of the direct observation procedure is a refusal to test, per regulations (DER's decision).

**Documentation on the CCFs (direct observation samples):**

- On the 1<sup>st</sup> CCF, note in Remarks: *“Cold specimen. Will attempt 2<sup>nd</sup> collection under Direct Observation. 1<sup>st</sup> of 2 collections. 2<sup>nd</sup> Specimen ID#0000002”* ○ Conduct the 2<sup>nd</sup> collection using direct observation procedures, then document on 2<sup>nd</sup> CCF . . .
- *“2 of 2 Collections. Direct observation due to 1<sup>st</sup> specimen cold. 1<sup>st</sup> specimen ID# is: 0000001”*
- 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 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 1<sup>st</sup> time):*

- Note the time the 1<sup>st</sup> 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. (You will report to the DER & they will determine the refusal.)
- Encourage the donor to drink fluids. They are allowed 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. Document in Remarks.
- After a reasonable time and when the donor feels they can 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 the donor during the 3-hr period.
- 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 phone number, if they will provide it) in Step 5 on Copy 2 of CCF.
  - Collector: 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.

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- Immediately notify the DER of a “shy bladder” situation. (Note: Regulations require the DER to have the donor take a medical exam within 5 business days. The DER should consult the MRO for further guidance immediately on this situation.)

### Questionable Specimens (Insufficient & other):

- 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 1<sup>st</sup> questionable specimen.
- This applies whether the 1<sup>st</sup> specimen is sufficient or insufficient volume.
- After a questionable specimen (i.e. tampered, out-of-temp range/cold, blue/non-natural color, etc.), 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).
- Note each attempt to urinate in Remarks (just as in a ‘normal’ shy bladder situation).
- 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. Dispose of any specimen collected.
- The Collector should complete the CCF (sign, print your 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 1<sup>st</sup> specimen that was “questionable”, but also insufficient volume: *"Received insuff. specimen that was cold & blue in color. Unable to collect 2<sup>nd</sup> under direct observation due to shy bladder issues over 3-hr period."*)
  - (Example for 1<sup>st</sup> specimen that was “questionable”, but Sufficient volume: *"1<sup>st</sup> Specimen was cold & blue in color. Unable to collect 2<sup>nd</sup> under direct observation due to shy bladder issues."*)
    - ➔ Be sure to document the time of each attempt and the total amount of fluids they drank.
  - 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: The regulations state that 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.) Notify the DER immediately in all potential “refusal” situations. However, it is the DER’s final decision whether to deem a collection a “test refusal”, so we hope employers know the regulations they are supposed to follow. If not, you may wish to suggest that they complete our online DER training course.

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