

§ 40.71

§ 40.71 How does the collector prepare the specimens?

(a) All collections under DOT agency drug testing regulations must be split specimen collections.

(b) As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you. You must take these steps in the presence of the employee.

(1) Check the box on the CCF (Step 2) indicating that this was a split specimen collection.

(2) You, not the employee, must first pour at least 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.

(3) You, not the employee, must then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.

(4) You, not the employee, must place and secure (*i.e.*, tighten or snap) the lids/caps on the bottles.

(5) You, not the employee, must seal the bottles by placing the tamper-evident bottle seals over the bottle caps/lids and down the sides of the bottles.

(6) You, not the employee, must then write the date on the tamper-evident bottle seals.

(7) You must then ensure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the specimens he or she provided. If the employee fails or refuses to do so, you must note this in the "Remarks" line of the CCF (Step 2) and complete the collection process.

(8) You must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: you may use excess urine to conduct clinical tests (*e.g.*, protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT agency regulation. Neither you nor anyone else may conduct further testing (such as adulteration testing) on this excess urine and the employee has no legal right to de-

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mand that the excess urine be turned over to the employee.

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§ 40.73 How is the collection process completed?

(a) As the collector, you must do the following things to complete the collection process. You must complete the steps called for in paragraphs (a)(1) through (a)(7) of this section in the employee's presence.

(1) Direct the employee to read and sign the certification statement on Copy 2 (Step 5) of the CCF and provide date of birth, printed name, and day and evening contact telephone numbers. If the employee refuses to sign the CCF or to provide date of birth, printed name, or telephone numbers, you must note this in the "Remarks" line (Step 2) of the CCF, and complete the collection. If the employee refuses to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

(2) Complete the chain of custody on the CCF (Step 5) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory.

(3) Ensure that all copies of the CCF are legible and complete.

(4) Remove Copy 5 of the CCF and give it to the employee.

(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(6) Secure both pouches of the plastic bag.

(7) Advise the employee that he or she may leave the collection site.

(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(i) Place the sealed plastic bag in a shipping container (*e.g.*, standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

(9) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations.

(b) As a collector or collection site, you must 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.

Subpart F—Drug Testing Laboratories

§ 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.

(b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory certification standards or deemed your laboratory fully equivalent to a laboratory meeting HHS laboratory certification standards for all testing required under this part; or

(2) The DOT, based on a written recommendation from HHS, has recognized a Canadian or Mexican certifying organization as having equivalent laboratory certification standards and procedures to those of HHS, and the Canadian or Mexican certifying organization has certified your laboratory under those equivalent standards and procedures.

(c) As a laboratory participating in the DOT drug testing program, you must comply with the requirements of this part. You must also comply with

all applicable requirements of HHS in testing DOT specimens, whether or not the HHS requirements are explicitly stated in this part.

(d) If DOT determines that you are in noncompliance with this part, you could be subject to PIE proceedings under Subpart R of this part. If the Department issues a PIE with respect to you, you are ineligible to participate in the DOT drug testing program even if you continue to meet the requirements of paragraph (a) or (b) of this section.

§ 40.83 How do laboratories process incoming specimens?

As the laboratory, you must do the following when you receive a DOT specimen:

(a) You are authorized to receive only the laboratory copy of the CCF. You are not authorized to receive other copies of the CCF nor any copies of the alcohol testing form.

(b) You must comply with applicable provisions of the HHS Guidelines concerning accessioning and processing urine drug specimens.

(c) You must inspect each specimen and CCF for the following “fatal flaws:”

(1) The specimen ID numbers on the specimen bottle and the CCF do not match;

(2) The specimen bottle seal is broken or shows evidence of tampering, unless a split specimen can be redesignated (see paragraph (g) of this section);

(3) The collector’s printed name *and* signature are omitted from the CCF; and

(4) There is an insufficient amount of urine in the primary bottle for analysis, unless the specimens can be redesignated (see paragraph (g) of this section).

(d) When you find a specimen meeting the criteria of paragraph (c) of this section, you must document your findings and stop the testing process. Report the result in accordance with § 40.97(a)(3).

(e) You must inspect each CCF for the presence of the collector’s signature on the certification statement in Step 4 of the CCF. Upon finding that the signature is omitted, document the flaw and continue the testing process.