

Subpart F - Drug Testing Laboratories

§ 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 Copy 1 of the CCF. You are not authorized to receive other copies of the CCF or 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 (h) 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 (h) 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.

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the flaw.

(2) You must then attempt to correct the flaw by following the procedures of §40.205(b)(1).

(3) If the flaw is not corrected, report the result as rejected for testing in accordance with §40.97(a)(3).

(f) If you determine that the specimen temperature was not checked and the “Remarks” line did not contain an entry regarding the temperature being outside of range, you must then attempt to correct the problem by following the procedures of §40.208.

(1) In such a case, you must continue your efforts to correct the problem for five business days, before you report the result.

(2) When you have obtained the correction, or five business days have elapsed, report the result in accordance with §40.97(a).

(g) If you determine that a CCF that fails to meet the requirements of §40.45(a) (e.g., a non-Federal form or an expired Federal form was used for the collection), you must attempt to correct the use of the improper form by following the procedures of §40.205(b)(2).

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the problem.

(2) If the problem(s) is not corrected, you must reject the test and report the result in accordance with §40.97(a)(3).

(h) If the CCF is marked indicating that a split specimen collection was collected and if the split specimen does not accompany the primary, has leaked, or is otherwise unavailable for testing, you must still test the primary specimen and follow appropriate procedures outlined in §40.175(b) regarding the unavailability of the split specimen for testing.

(1) The primary specimen and the split specimen can be redesignated (i.e., Bottle B is redesignated as Bottle A, and vice-versa) if:

(i) The primary specimen appears to have leaked out of its sealed bottle and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(ii) The primary specimen is labeled as Bottle B, and the split specimen as Bottle A; or

(iii) The laboratory opens the split specimen instead of the primary specimen, the primary specimen remains sealed, and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing; or

(iv) The primary specimen seal is broken but the split specimen remains sealed and the laboratory believes a sufficient amount of urine exists in the split specimen to conduct all appropriate primary laboratory testing.

(2) In situations outlined in paragraph (g)(1) of this section, the laboratory shall mark through the “A” and write “B,” then initial and date the change. A corresponding change shall be made to the other bottle by marking through the “B” and writing “A,” and initialing and dating the change.

(i) A notation shall be made on Copy 1 of the CCF (Step 5a) and on any laboratory internal chain of custody documents, as appropriate, for any fatal or correctable flaw.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 71 FR 49384, Aug. 23, 2006; 73 FR 35970, June 25, 2008; 75 FR 59107, September 27, 2010]