

§ 40.199

additional test because the result was dilute.

(4) If the result of the test you directed the employee to take under paragraph (b)(2) of this section is also negative and dilute, you are not permitted to make the employee take an additional test because the result was dilute. Provided, however, that if the MRO directs you to conduct a recollection under direct observation under paragraph (b)(1) of this section, you must immediately do so.

(5) If the employee declines to take a test you directed him or her to take under paragraph (b) of this section, the employee has refused the test for purposes of this part and DOT agency regulations.

[68 FR 31626, May 28, 2003, as amended at 69 FR 64867, Nov. 9, 2004; 73 FR 35974, June 25, 2008]

§ 40.199 What problems always cause a drug test to be cancelled?

(a) As the MRO, when the laboratory discovers a “fatal flaw” during its processing of incoming specimens (see § 40.83), the laboratory will report to you that the specimen has been “Rejected for Testing” (with the reason stated). You must always cancel such a test.

(b) The following are “fatal flaws”:

- (1) There is no CCF;
- (2) In cases where a specimen has been collected, there is no specimen submitted with the CCF;
- (3) There is no printed collector’s name and no collector’s signature;
- (4) Two separate collections are performed using one CCF;
- (5) The specimen ID numbers on the specimen bottle and the CCF do not match;
- (6) The specimen bottle seal is broken or shows evidence of tampering (and a split specimen cannot be re-designated, see § 40.83(h)); or
- (7) Because of leakage or other causes, there is an insufficient amount of specimen in the primary specimen bottle for analysis and the specimens cannot be re-designated (see § 40.83(h)).
- (8) For an oral fluid collection, the collector used an expired device at the time of collection.
- (9) For an oral fluid collection, the collector failed to enter the expiration

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date in Step 4 of the CCF and the laboratory confirmed that the device was expired.

(c) You must report the result as provided in § 40.161.

[65 FR 79526, Dec. 19, 2000, as amended at 82 FR 52245, Nov. 13, 2017; 88 FR 27648, May 2, 2023]

§ 40.201 What problems always cause a drug test to be cancelled and may result in a requirement for another collection?

As the MRO, you must cancel a drug test when a laboratory reports that any of the following problems have occurred. You must inform the DER that the test was cancelled. You must also direct the DER to ensure that an additional collection occurs immediately, if required by the applicable procedures specified in paragraphs (a) through (e) of this section.

(a) The laboratory reports an “Invalid Result.” You must follow applicable procedures in § 40.159 (recollection under direct observation may be required).

(b) The laboratory reports the result as “Rejected for Testing.” You must follow applicable procedures in § 40.161 (a recollection may be required).

(c) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results because the drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/or substitution criteria were not met. You must follow the applicable procedures in § 40.187(b)—no recollection is required in this case, unless the split specimen creatinine concentration for a substituted primary specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/ dL, or the primary specimen had an invalid result which was not reported to the DER. Both these cases require recollection under direct observation.

(d) The laboratory reports that the split specimen failed to reconfirm all of the primary specimen results, and that the split specimen was invalid. You must follow the procedures in § 40.187(c)(1)—recollection under direct observation is required in this case.

(e) The laboratory reports that the split specimen failed to reconfirm all of

the primary specimen results because the split specimen was not available for testing or there was no split laboratory available to test the specimen. You must follow the applicable procedures in § 40.187(e)—recollection under direct observation is required in this case.

(f) The examining physician has determined that there is an acceptable medical explanation of the employee's failure to provide a sufficient amount of specimen. You must follow applicable procedures in § 40.193(d)(1) (no recollection is required in this case).

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35974, June 25, 2008; 88 FR 27648, May 2, 2023]

§ 40.203 What problems cause a drug test to be cancelled unless they are corrected?

(a) As the MRO, when a laboratory discovers a “correctable flaw” during its processing of incoming specimens (see § 40.83), the laboratory will attempt to correct it. If the laboratory is unsuccessful in this attempt, it will report to you that the specimen has been “Rejected for Testing” (with the reason stated).

(b) The following is a “correctable flaw” that laboratories must attempt to correct: The collector's signature is omitted on the certification statement on the CCF.

(c) As the MRO, when you discover a “correctable flaw” during your review of the CCF, you must cancel the test unless the flaw is corrected.

(d) The following are correctable flaws that you must attempt to correct:

(1) The employee's signature is omitted from the certification statement, unless the employee's failure or refusal to sign is noted on the “Remarks” line of the CCF.

(2) The certifying scientist's signature is omitted on Copy 1 of the CCF for a positive, adulterated, substituted, or invalid test result.

(3) The collector uses a non-Federal form or an expired CCF for the test. This flaw may be corrected through the procedure set forth in § 40.205(b)(2), provided that the collection testing process has been conducted in accordance

with the procedures in this part in an HHS-certified laboratory.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41954, Aug. 9, 2001; 75 FR 59108, Sept. 27, 2010; 76 FR 59578, Sept. 27, 2011; 82 FR 52246, Nov. 13, 2017]

§ 40.205 How are drug test problems corrected?

(a) As a collector, you have the responsibility of trying to successfully complete a collection procedure for each employee.

(1) If, during or shortly after the collection process, you become aware of any event that prevents the completion of a valid test or collection (*e.g.*, a procedural or paperwork error), you must try to correct the problem promptly, if doing so is practicable. You may conduct another collection as part of this effort.

(2) If another collection is necessary, you must begin the new collection procedure as soon as possible, using a new CCF and a new collection kit.

(b) If, as a collector, laboratory, MRO, employer, or other person implementing these drug testing regulations, you become aware of a problem that can be corrected (see § 40.203), but which has not already been corrected under paragraph (a) of this section, you must take all practicable action to correct the problem so that the test is not cancelled.

(1) If the problem resulted from the omission of required information, you must, as the person responsible for providing that information, supply in writing the missing information and a statement that it is true and accurate. For example, suppose you are a collector, and you forgot to make a notation on the “Remarks” line of the CCF that the employee did not sign the certification. You would, when the problem is called to your attention, supply a signed statement that the employee failed or refused to sign the certification and that your statement is true and accurate. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

(2) If the problem is the use of a non-Federal form or an expired Federal form, you must provide a signed statement (*i.e.*, a memorandum for the