

§ 40.177

following items to the second laboratory:

(1) The split specimen in its original specimen bottle, with the seal intact;

(2) A copy of the MRO's written request; and

(3) A copy of Copy 1 of the CCF, which identifies the drug(s)/metabolite(s) or the validity criteria to be tested for.

(e) You must not send to the second laboratory any information about the identity of the employee. Inadvertent disclosure does not, however, cause a fatal flaw.

(f) This subpart does not prescribe who gets to decide which HHS-certified laboratory is used to test the split specimen. That decision is left to the parties involved.

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) detected in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.87 .

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported positive in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.91 .

(d) In addition, if the test fails to reconfirm the presence of the drugs/drugs metabolites or validity criteria that were reported in the primary specimen, you may transmit the specimen or an aliquot of it to another HHS-certified laboratory that will conduct another reconfirmation test.

§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the

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primary specimen, using the criteria of § 40.95 just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing the split specimen, you must test the split specimen using the criteria of § 40.93(b), just as you would do for a primary specimen. The result of the primary specimen is reconfirmed if the split specimen meets these criteria.

§ 40.183 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the "Reconfirmed" box or the "Failed to Reconfirm" box (Step 5(b)) on Copy 1 of the CCF.

(b) If you check the "Failed to Reconfirm" box, one of the following statements must be included (as appropriate) on the "Reason" line (Step 5(b)):

(1) "Drug(s)/Drug Metabolite(s) Not Detected."

(2) "Adulterant not found within criteria."

(3) "Specimen not consistent with substitution criteria [specify creatinine, specific gravity, or both]"

(4) "Specimen not available for testing."

(c) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

§ 40.185 Through what methods and to whom must a laboratory report split specimen results?

(a) As the laboratory testing the split specimen, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or another service agent (*e.g.*, a C/TPA).

(b) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF, which has been signed by the certifying scientist.

(c) You must transmit the laboratory result to the MRO immediately, preferably on the same day or next business day as the result is signed and released.

§ 40.187 What does the MRO do with split specimen laboratory results?

As an MRO, you must take the following actions when a laboratory reports the following results of split specimen tests:

(a) *Reconfirmed.* (1) In the case of a reconfirmed positive test for a drug or drug metabolite, report the reconfirmation to the DER and the employee.

(2) In the case of a reconfirmed adulterated or substituted result, report to the DER and the employee that the specimen was adulterated or substituted, either of which constitutes a refusal to test. Therefore, "refusal to test" is the final result.

(3) In the case of a reconfirmed substituted result, in which the creatinine concentration for the primary specimen was less than 2 mg/dL and the creatinine concentration of the split specimen is between 2 and 5 mg/dL, inclusive, report the result to the employer as "dilute" and instruct the employer to conduct an immediate recollection under direct observation.

(b) *Failed to Reconfirm: Drug(s)/Drug Metabolite(s) Not Detected.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(c) *Failed to Reconfirm: Adulteration or Substitution (as appropriate) Criteria Not Met.* (1) Report to the DER and the employee that both tests must be cancelled.

(2) Using the format in Appendix D to this part, inform ODAPC of the failure to reconfirm.

(d) *Failed to Reconfirm: Specimen not Available for Testing.* (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement

until immediately before the collection.

(3) Using the format in Appendix D to this part, notify ODAPC of the failure to reconfirm.

(e) *Failed to Reconfirm: Specimen Results Invalid.* (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) Using the format in Appendix D to this part, notify ODAPC of the failure to reconfirm.

(f) *Failed to Reconfirm: Split Specimen Adulterated.* (1) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated.

(2) Follow the procedures of § 40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration.

(3) If you determine that there is a legitimate medical explanation for the adulterated test result, report to the DER and the employee that the test is cancelled. Using the format in Appendix D to this part, notify ODAPC of the result.

(4) If you determine that there is not a legitimate medical explanation for the adulterated test result, take the following steps:

(i) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen also is present in the primary specimen.

(ii) Except that the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of §§ 40.153, 40.171, 40.173, 40.179, and 40.185.

(iii) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen, report your result to the MRO on a photocopy (faxed,