

§ 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.