(10) Interference with the drug confirmation assay occurs on at least two separate aliquots of the specimen, and the laboratory is unable to identify the interfering substance;

(11) The physical appearance of the specimen indicates that testing may damage the laboratory's equipment; or

(12) The physical appearances of Bottles A and B (when a split specimen collection is used) are clearly different, and either the test result for Bottle A indicated it is an invalid specimen or the specimen in Bottle A was screened negative for drugs, or both.

(g) *Additional testing by a second laboratory.* If the presence of an interfering substance/adulterant is suspected that could make a test result invalid, but it cannot be identified (e.g., a new adulterant), laboratory personnel shall consult with the licensee's or other entity's MRO and, with the MRO's agreement, shall send the specimen to another HHS-certified laboratory that has the capability to identify the suspected substance.

(h) *More stringent validity test cutoff levels are prohibited.* Licensees and other entities may not specify more stringent cutoff levels for validity tests than those specified in this section.

§ 26.163 Cutoff levels for drugs and drug metabolites.

(a) *Initial drug testing.* (1) HHS-certified laboratories shall apply the following cutoff levels for initial testing of specimens to determine whether they are negative for the indicated drugs and drug metabolites, except if validity testing indicates that the specimen is dilute or the licensee or other entity has established more stringent cutoff levels:

INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drug or metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2000
Phencyclidine (PCP)	25
Amphetamines	1000

(2) At the licensee's or other entity's discretion, as documented in the FFD program policies and procedures, the licensee or other entity may require the HHS-certified laboratory to conduct special analyses of dilute specimens as follows:

(i) If initial validity testing indicates that a specimen is dilute, the HHS-certified laboratory shall compare the responses of the dilute specimen to the cutoff calibrator in each of the drug classes;

(ii) If any response is equal to or greater than 50 percent of the cutoff, the HHS-certified laboratory shall conduct confirmatory testing of the specimen down to the LOD for those drugs and/or drug metabolites; and

(iii) The laboratory shall report the numerical values obtained from this special analysis to the MRO.

(b) *Confirmatory drug testing.* (1) A specimen that is identified as positive on an initial drug test must be subject to confirmatory testing for the class(es) of drugs for which the specimen initially tested positive. The HHS-certified laboratory shall apply the confirmatory cutoff levels specified in this paragraph, except if the licensee or other entity requires the special analysis of dilute specimens permitted in paragraph (a)(2) of this section or the licensee or other entity has established more stringent cutoff levels.

CONFIRMATORY TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drug or metabolites	Cutoff level (ng/mL)
Marijuana metabolite [1]	15
Cocaine metabolite [2]	150
Opiates:	
Morphine	2000
Codeine	2000
6-acetylmorphine [3]	10
Phencyclidine (PCP)	25
Amphetamines:	
Amphetamine	500
Methamphetamine [4]	500

[1] As delta-9-tetrahydrocannabinol-9-carboxylic acid.
[2] As benzoylecgonine.
[3] Test for 6–AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/mL.
[4] Specimen must also contain amphetamine at a concentration equal to or greater than 200 ng/mL.

(2) Each confirmatory drug test must provide a quantitative result. When the concentration of a drug or metabolite exceeds the linear range of the standard curve, the laboratory may record the result as ''exceeds the linear range of the test'' or as ''equal to or greater

than <insert the value for the upper limit of the linear range>,'' or may dilute an aliquot of the specimen to obtain an accurate quantitative result when the concentration is above the upper limit of the linear range.

§ 26.165 Testing split specimens and retesting single specimens.

(a) *Testing split specimens.* (1) If a specimen has been split into Bottle A and Bottle B at the collection site, and the specimen was not initially tested at a licensee testing facility, then the HHS-certified laboratory shall perform initial and confirmatory validity and drug testing, if required, of the specimen in Bottle A.

(2) If a specimen was initially tested at a licensee testing facility and positive or questionable validity test results were obtained, then the HHS-certified laboratory shall perform initial and confirmatory testing, if required, of the specimen in Bottle A.

(3) At the licensee's or other entity's discretion, Bottle B must either be forwarded to the HHS-certified laboratory or maintained in secure storage at the licensee testing facility, as required by § 26.135(a) and (c), as applicable. If the specimen in Bottle A is free of any evidence of drugs or drug metabolites, and is a valid specimen, then the licensee testing facility or HHS-certified laboratory may discard the specimens in Bottles A and B.

(b) *Donor request to MRO for a retest of a single specimen or testing Bottle B of a split specimen.* (1) For a confirmed positive, adulterated, or substituted result reported on a single specimen of 30 mL or more, or a specimen in Bottle A of a split specimen which the donor submitted to the licensee or other entity, a donor may request (through the MRO) that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory. For an invalid test result, a donor may not request that an aliquot from the single specimen or the split specimen in Bottle B be tested by a second HHS-certified laboratory.

(2) The MRO shall inform the donor that he or she may, within 3 business days of notification by the MRO of the confirmed positive, adulterated, or substituted test result, request the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen. The MRO shall provide the donor with specific instructions for making this request (i.e., providing telephone numbers or other contact information). The MRO shall have the ability to receive the donor's calls at all times during the 3-day period (e.g., by use of an answering machine with a ''time stamp'' feature when there is no one in the MRO's office to answer the phone). The donor's request may be oral or in writing.

(3) The donor shall provide his or her permission for retesting an aliquot of the single specimen or the testing of Bottle B. Neither the licensee, MRO, NRC, nor any other entity may order retesting of the single specimen or testing of the specimen in Bottle B without the donor's written permission, except as permitted in § 26.185(l).

(4) If the donor has not requested a retest of an aliquot of a single specimen or a test of the split specimen (Bottle B) within 3 business days, the donor may present to the MRO information documenting that serious injury, illness, lack of actual notice of the confirmed test result, inability to contact the MRO (e.g., there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented the donor from making a timely request. If the MRO concludes from the donor's information that there was a legitimate reason for the donor's failure to contact the MRO within the 3 business days permitted, the MRO shall direct the retesting of an aliquot of the single specimen or the test of the split specimen (Bottle B) take place, as if the donor had made a timely request.

(5) As soon as reasonably practical and not more than 1 business day following the day of the donor's request, as permitted in paragraph (b)(3) or (b)(4) of this section, the MRO shall ensure that the HHS-certified laboratory forwards an aliquot of a single specimen, or that the HHS-certified laboratory (or licensee testing facility, as appropriate) forwards Bottle B of a split specimen, to a second HHS-certified