identification of the donor, and documentation of the testing process and transfers of custody of the specimen.

(e) Each time a specimen is handled or transferred within the laboratory, laboratory personnel shall document the date and purpose on the custody-and-control form and every individual in the chain shall be identified. Authorized technicians are responsible for each urine specimen or aliquot in their possession and shall sign and complete custody-and-control forms for those specimens or aliquots as they are received.

(f) If a specimen is to be transferred to a second HHS-certified laboratory, laboratory personnel shall ensure that a copy of the custody-and-control form is packaged with the aliquot of a single specimen or Bottle B of a split specimen, as appropriate. Sealed and labeled specimen bottles and aliquots, with their associated custody-and-control forms, being transferred from one laboratory to another must be placed in a second, tamper-evident shipping container designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are inaccessible without breaking a tamper-evident seal.

(g) Couriers, express carriers, and postal service personnel do not have direct access to the custody-and-control forms or the specimen bottles. Therefore, such personnel are not required to document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

(h) Specimens that do not receive an initial test within 7 days of arrival at the laboratory must be placed in secure refrigeration units for short-term storage. Temperatures may not exceed 6°C (42.8°F). The laboratory shall ensure proper storage conditions in the event of a prolonged power failure.

(i) Long-term frozen storage at a temperature of −20°C (−68°F) or less ensures that positive, adulterated, substituted, and invalid urine specimens and Bottle B of a split specimen will be available for any necessary retests. Unless otherwise authorized in writing by the licensee or other entity, laboratories shall retain and place in properly secured long-term frozen storage all specimens reported as positive, adulterated, substituted, or invalid. At a minimum, such specimens must be stored for 1 year. Within this 1-year period, a licensee, other entity, or the NRC may ask the laboratory to retain the specimen for an additional period of time. If no retention request is received, the laboratory may discard the specimen after the end of 1 year. However, the laboratory shall retain any specimens under review or legal challenge until they are no longer needed.

(j) The laboratory shall discard a valid specimen that tests negative on initial or confirmatory drug tests or may pool such specimens for use in the laboratory’s internal quality control program after certifying that the specimens are negative and valid. The laboratory may not retain any information linking donors to specimens that are pooled for use in the internal quality control program.

§ 26.161 Cutoff levels for validity testing.

(a) Validity test results. Each validity test result for a specimen that the HHS-certified laboratory reports to the MRO as adulterated, substituted, dilute, or invalid must be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot. Licensees and other entities shall ensure that the HHS-certified laboratory is capable of conducting, and conducts, confirmatory testing for at least one oxidizing adulterant and any other adulterants specified by the licensee’s or other entity’s testing program. If initial validity test results indicate that the specimen is valid under the criteria in paragraphs (c) through (f) of this section, the HHS-certified laboratory need not perform confirmatory validity testing of the specimen.

(b) Initial validity testing. The HHS-certified laboratory shall perform initial validity testing of each specimen as follows:
(1) Determine the creatinine concentration;
(2) Determine the specific gravity of every specimen for which the creatinine concentration is less than 20 mg/dL;
(3) Determine the pH;
(4) Perform one or more initial validity tests for oxidizing adulterants; and
(5) Perform additional validity tests, the choice of which depends on the observed indicators or characteristics below, when the following conditions are observed:
   (i) Abnormal physical characteristics;
   (ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of internal standards, unusual response); or
   (iii) Possible unidentified interfering substance or adulterant.
(c) Results indicating an adulterated specimen. The laboratory shall report a specimen as adulterated when the specimen yields any one or more of the following validity testing results:
   (1) The pH is less than 3, or equal to or greater than 11, using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;
   (2) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;
   (3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOD of the confirmatory test on the second aliquot;
   (4) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a halogen colorimetric test (halogen concentration equal to or greater than the LOD) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOD of the confirmatory test on the second aliquot;
   (5) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a pyridine colorimetric test (pyridine concentration equal to or greater than the LOD) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with specific pyridine concentration equal to or greater than the LOD of the confirmatory test on the second aliquot;
   (6) The presence of glutaraldehyde is verified by using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a glutaraldehyde colorimetric test (glutaraldehyde concentration equal to or greater than the LOD) for the initial test on the first aliquot and GC/MS for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOD of the analysis on the second aliquot;
   (7) The presence of a surfactant is verified by using a surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent on the second aliquot; or
(8) The presence of any other adulterant not specified in paragraphs (c)(3) through (c)(7) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(d) Results indicating a substituted specimen. The laboratory shall report a specimen as substituted when the specimen’s creatinine concentration is less than 2 mg/dL and its specific gravity is less than or equal to 1.0010, or equal to or greater than 1.0200, on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

(e) Results indicating a dilute specimen. The laboratory shall report a specimen as dilute when the specimen’s creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and its specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(f) Results indicating an invalid specimen. The laboratory shall report a specimen as invalid when the laboratory obtains any one or more of the following validity testing results:

(1) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is equal to or greater than 3 and less than 4.5, or equal to or greater than 9 and less than 11, using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(3) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test, or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial test and the confirmatory test, or, using either initial test, the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL using a different confirmatory test (e.g., spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(4) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial test and the confirmatory test on two separate aliquots;

(5) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOD for both the initial test and the confirmatory test on two separate aliquots or relying on the odor of the specimen as the initial test;

(6) The possible presence of glutaraldehyde is determined using the same aldehyde test (aldehyde present) or the characteristic immunoassay response is observed on one or more drug immunoassay tests for both the initial test and the confirmatory test on two separate aliquots;

(7) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with cutoffs equal to or greater than 200 mcg/mL nitrite-equivalents, equal to or greater than 50 mcg/mL chromium (VI)-equivalents, or a halogen concentration equal to or greater than the LOD) for both the initial test and the confirmatory test on two separate aliquots;

(8) The possible presence of a surfactant is determined using the same surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent for both the initial test and the confirmatory test on two separate aliquots or a foam/shake test for the initial test;

(9) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained).
(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:

<table>
<thead>
<tr>
<th>Drug or metabolites</th>
<th>Cutoff level (nanograms/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marijuana metabolite</td>
<td>50</td>
</tr>
<tr>
<td>Cocaine metabolite</td>
<td>300</td>
</tr>
<tr>
<td>Opiate metabolite</td>
<td>2000</td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>25</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>1000</td>
</tr>
</tbody>
</table>

(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.

<table>
<thead>
<tr>
<th>Drug or metabolites</th>
<th>Cutoff level (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marijuana metabolite</td>
<td>15</td>
</tr>
<tr>
<td>Cocaine metabolite</td>
<td>150</td>
</tr>
<tr>
<td>Opiates:</td>
<td></td>
</tr>
<tr>
<td>Morphine</td>
<td>2000</td>
</tr>
<tr>
<td>Codeine</td>
<td>2000</td>
</tr>
<tr>
<td>6-acetyl morphine</td>
<td>10</td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>25</td>
</tr>
<tr>
<td>Amphetamines:</td>
<td></td>
</tr>
<tr>
<td>Amphetamine</td>
<td>500</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>500</td>
</tr>
</tbody>
</table>

1. As delta-9-tetrahydrocannabinol-9-carboxylic acid.
2. As benzoylcegonine.
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...