appropriate) as adulterated and provide the numerical value that supports the adulterated result.

[73 FR 35970, June 25, 2008]

§ 40.96 What criteria do laboratories use to establish that a specimen is invalid?

(a) As a laboratory, you must use the invalid test result criteria for the initial and confirmation testing as required by the HHS Mandatory Guidelines, and you must use two separate aliquots—one for the initial test and another for the confirmation test.

(b) As a laboratory, for a specimen having an invalid result for one of the reasons outlined in the HHS Mandatory Guidelines, you must contact the MRO to discuss whether sending the specimen to another HHS certified laboratory for testing would be useful in being able to report a positive or adulterated result.

(c) As a laboratory, you must report invalid results in accordance with the invalid test result criteria as required by the HHS Guidelines and provide the numerical value that supports the invalid result, where appropriate, such as pH.

(d) As a laboratory, you must report the reason a test result is invalid.

[73 FR 35970, June 25, 2008]

§ 40.97 What do laboratories report and how do they report it?

(a) As a laboratory, you must report the results for each primary specimen. The result of a primary specimen will fall into one of the following three categories. However, as a laboratory, you must report the actual results (and not the categories):

(1) Category 1: Negative Results. As a laboratory, when you find a specimen to be negative, you must report the test result as being one of the following, as appropriate:

(i) Negative, or

(ii) Negative-dilute, with numerical values for creatinine and specific gravity.

(2) Category 2: Non-negative Results. As a laboratory, when you find a specimen to be non-negative, you must report the test result as being one or more of the following, as appropriate:

(i) Positive, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s).

(ii) Positive-dilute, with drug(s)/metabolite(s) noted, with numerical values for the drug(s) or drug metabolite(s) and with numerical values for creatinine and specific gravity;

(iii) Adulterated, with adulterant(s) noted, with confirmatory test values (when applicable), and with remark(s);

(iv) Substituted, with confirmatory test values for creatinine and specific gravity; or

(v) Invalid result, with remark(s). Laboratories will report actual values for pH results.

(3) Category 3: Rejected for Testing. As a laboratory, when you reject a specimen for testing, you must report the result as being Rejected for Testing, with remark(s).

(b) As a laboratory, 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 a service agent (*e.g.*, C/TPA).

(1) Negative results: 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, or you may provide the laboratory results report electronically (*i.e.*, computer data file).

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;

(B) Employer's name (you may include I.D. or account number);

(C) Medical review officer's name;

(D) Specimen I.D. number;

(E) Donor's SSN or employee I.D. number, if provided;

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) Date received at the laboratory;

(J) Date certifying scientist released the results;

(K) Certifying scientist's name;

(L) Results (e.g., positive, adulterated) as listed in paragraph (a) of this section; and