

Subpart F - Drug Testing Laboratories

§ 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 tested as one or more of the following:

- (1) Negative;
- (2) Negative—dilute;
- (3) Rejected for testing, with remark(s);
- (4) Positive, with drug(s)/metabolite(s) noted;
- (5) Positive, with drug(s)/metabolite(s) noted—dilute;
- (6) Adulterated, with remark(s);
- (7) Substituted, with quantitative values for creatinine and specific gravity, and remarks; or
- (8) Invalid result, 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
- (M) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) You may release the laboratory results report only after review and approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report may not contain information that does not appear on the CCF.

(iii) The results report may be transmitted through any means that ensures accuracy and confidentiality. You, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage.

(2) Non-negative results: You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF that has been signed by the certifying scientist. In addition, you may provide the electronic laboratory results report following the format and procedures set forth in paragraphs (b)(1)(i) and (ii) of this section.

(c) In transmitting laboratory results to the MRO, you, as the laboratory, together with the MRO, must ensure that the information is adequately protected from unauthorized access or release, both during transmission and in storage. If the results are provided by fax, the fax connection must have a fixed telephone number accessible only to authorized individuals.

(d) You must transmit test results to the MRO in a timely manner, preferably the same day that review by the certifying scientist is completed.

(e)(1) You must provide quantitative values for confirmed positive drug and adulterated test results to the MRO when the MRO requests you to do so in writing. The MRO's request may be either a general request covering all such results you send to the MRO or a specific case-by-case request.

(2) You must also provide to the MRO quantitative values for creatinine and specific gravity for all substituted test results when the result is above your detection limit. If the result is not above your detection limit, you must report "creatinine not detected" to the MRO. You must make these reports for in all cases of substituted tests, without a request from the MRO.

(f) You must provide quantitative values for confirmed opiate results for morphine or codeine at 15,000 ng/mL or above, even if the MRO has not requested quantitative values for the test result.
[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001; 68 FR 31626, May 28, 2003]