

must be available to the laboratory at the time of testing and available to HHS upon request. The laboratory must assure that the requisition or test authorization includes—

(a) The patient's name or other unique identifier;

(b) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values;

(c) The test(s) to be performed;

(d) The date of specimen collection;

(e) For Pap smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy; and

(f) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.1107 Standard; Test records.

The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. These records must identify the personnel performing the testing procedure. Records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years. Immunohematology records and transfusion records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). The record system must provide documentation of information specified in § 493.1105 (a) through (f) and include—

(a) The patient identification number, accession number, or other unique identification of the specimen;

(b) The date and time of specimen receipt into the laboratory;

(c) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and

(d) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s), which are necessary to assure proper identification and accurate reporting of patient test results.

[57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993]

§ 493.1109 Standard; Test report.

The laboratory report must be sent promptly to the authorized person, the individual responsible for using the test results or laboratory that initially requested the test. The original report or an exact duplicate of each test report, including final and preliminary report, must be retained by the testing laboratory for a period of at least two years after the date of reporting. Immunohematology reports and transfusion records must be retained by the laboratory for a period of no less than five years in accordance with 21 CFR part 606, subpart I. In addition, records of blood and blood product testing must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d). For pathology, test reports must be retained for a period of at least ten years after the date of reporting. This information may be maintained as part of the patient's chart or medical record which must be readily available to the laboratory and to HHS upon request.

(a) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner, and, ensure patient confidentiality throughout those parts of the total testing process that are under the laboratory's control.