D3041
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1105 Standard: Retention requirements

(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:

Interpretive Guidelines §493.1105(a)(6)

A copy, either paper or electronic, of the original report includes all information sent to recipients, and includes the name and address of the laboratory performing the test. The copy need not be paper, but may be retrieved from a computer system, microfilm or microfiche record, as long as it contains the exact information as sent to the individual ordering the test or utilizing the test results. The laboratory copy of the report should contain information that provides an accurate, complete, display of previously reported data retained or retrieved from the laboratory's record system.

For test reports from histopathology, oral pathology, or cytology that require personnel identifiers or an authorized signature (which may be electronic), the copy must include evidence of the identifiers or signature(s).

A "preliminary report" means a test result that has been reported directly to the

authorized person or laboratory that initially requested the test, directly or through an electronic health record provider or health information exchange **prior to the issuance of** the final test result(s). Frequently, a preliminary report will contain significant, but not definitive information (e.g., a urine culture preliminary report of >100,000 Gram-negative bacilli after 24 hours incubation or a beta subunit preliminary report of >200 miu/ml). It should be noted on the report when the result is a preliminary result and that a final report will follow.

A "partial report" means multiple tests are ordered on the same specimen or patient. If partial reports are issued for only those tests that have been completed, then the report date will be the date when all tests have been completed. However, the laboratory should be able to identify the date that each new test is appended to the report.

The laboratory must have a system for retaining copies of all reports, including original, preliminary, corrected, and final reports. This includes computer-generated reports.

Probes §493.1105(a)(6)

How has the laboratory verified that its record retrieval system functions appropriately?

(a)(6)(i) Immunohematology reports as specified in 21 CFR 606.160(d).

Interpretive Guidelines §493.1105(a)(6)(i)

Refer to the current version of 21 CFR Part 600.160 for the specified section.

Transfusion-related Immunohematology test reports, including but not limited to, donor processing [§493.1271(b)], compatibility testing, and transfusion reaction investigations, must be retained for the time frame stated at 21 CFR §606.160(d).

All Immunohematology test reports not subject to 21 CFR §606.130(d) must be retained for at least 2 years

(a)(6)(ii) Pathology test reports for at least 10 years after the date of reporting.