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§493.1291 Standard: Test report

(i) If a laboratory refers patient specimens for testing--

> **(i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory;**

Interpretive Guidelines §493.1291(i)(1)

If the laboratory transcribes results from the reference laboratory report, the test results, interpretation and information directly related to the interpretation must be copied exactly as reported by the reference laboratory. The report must adhere to the requirements in §§493.1291(c)(1)–(c)(7) and 493.1291(d).

> **(i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and**

Interpretive Guidelines §493.1291(i)(2)

An "exact duplicate" is an exact copy of the information sent to the individual requesting the test or using the test result(s), and includes the name and address of the laboratory performing the test. The exact copy need not be paper, it 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 duplicate laboratory report must contain information positioned such that it is clear and includes all original interpretive information. For tests requiring an authorized signature or containing personnel identifiers (e.g., Pathology), the exact duplicate must include the signatures or identifiers. "Pathology" includes all of its subspecialties (i.e., Histopathology, Oral pathology, Cytology).

A "preliminary report" means a test result that has been reported to the authorized person or laboratory that initially requested the test before the final test result is completed. 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.

(i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

Interpretive Guidelines §493.1291(i)(3)

Test report forms may include codes to identify the name and address of the laboratory that performed the test, provided the interpretations of the codes are available to the authorized person using the test results.