D5801
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1291 Standard: Test report

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:

Interpretive Guidelines §493.1291(a)

The regulations apply to manual as well as automated record systems (e.g., a laboratory information system or LIS). Regardless of the means used to transmit laboratory results, routine checks should be conducted to verify that transmissions are being accurately and reliably conveyed to the final report destination.

For CLIA purposes, the final report destination for test results is considered to be the authorized person and/or their designated personal representative (a personal representative is generally a person authorized under applicable law to make health care decisions for the individual. See 45 CFR §164.502(g). Additional individuals or entity(s) who are responsible for using the test results may also receive test results from the laboratory if they are designated by the authorized person on the test requisition. As of

April 7, 2014 a new CLIA regulation was added at §493.1291(l) in order to provide patients with more access to laboratory test report(s). In accordance with amendments to the HIPAA Privacy Rule, the new regulation states: "Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient". The HIPAA Privacy Rule preempts contrary state laws on patient access to laboratory test report(s), but where a HIPAA-covered laboratory can continue to comply with both the HIPAA Privacy Rule and state law, it must frame its policies and procedures in a way that complies with both laws. Further, the HIPAA Privacy Rule does not preempt more stringent state laws, even if contrary to the Privacy Rule. CLIA laboratories that are not subject to HIPAA will have discretion to provide patients with direct access to their laboratory test reports, subject to any applicable state laws that may constrain access.

To ensure the accurate, timely, confidential, and easily understood reporting of patient test results to the authorized person, their personal representative (if applicable) and others who are identified as responsible for using the test results on the requisition, a laboratory may contract with another entity to assist in the delivery of patient reports in a manner that complies with all applicable laws, including the CLIA regulatory and statutory requirements. Please note that if the laboratory is subject to HIPAA and the entity with which it contracts meets the HIPAA definition of a business associate, see 45 CFR §160.103 (definition of "business associate"), the laboratory's contract or other written arrangement with its business associate must contain the elements specified at 45 CFR §164.504(e).

Note: An example of an electronic system that a laboratory or health care provider can contract with is Direct, which provides secure, authenticated, encrypted transport of laboratory test results to an authorized person, their personal representative, and others responsible for using the test results. Laboratories utilizing Direct, in addition to fully supporting the Direct Implementation Guide for Delivery Notification, and meeting all other relevant CLIA requirements, would meet the CLIA regulations for an adequate electronic system for sending test results to the final report destination (§493.1291(a)).

Probes §493.1291(a)

How does the laboratory ensure that transmitted reports are legible and the information received at the final destination was the same data sent by the laboratory?

If the laboratory uses a LIS or facsimile, what security measures have been instituted to ensure that transmitted reports go directly from the device sending reports to the authorized person, their personal representative (if applicable), and others who are identified as responsible for using the test results on the requisition?

§493.1291 Standard: Test report

(a)(1) Results reported from calculated data.

(a)(2) Results and patient-specific data electronically reported to network or interfaced systems.

(a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

Interpretive Guidelines §493.1291(a)(3)

Manually transcribed or electronically transmitted results from an outside referral laboratory or from within the laboratory system (e.g., satellite or point-of-care testing locations) must be periodically verified for accuracy and timely reporting.