D5787

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§493.1283 Standard: Test records

(a) The laboratory must maintain an information or record system that includes the following:

(a)(1) The positive identification of the specimen.

(a)(2) The date and time of specimen receipt into the laboratory.

(a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.

(a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

Interpretive Guidelines §493.1283(a)

The regulations provide laboratories the flexibility to establish a system that ensures positive patient identification through specimen accessioning and storage, testing and reporting of test results. This may include a system that involves labeling the specimen container and request slip or the patient's medical record or chart with a unique patient identification number, but does not preclude the use of other mechanisms to assist in patient identification and tracking of specimens throughout the testing and reporting processes. The patient's name may be used as part of the identification system.

Ensure that work records reflect all the tests and dates of performance of in-house patient

testing. For example, in bacteriology, each step from media inoculation to organism isolation and identification must be documented on worksheet records either manually or in a computer system.
Corrections of laboratory results include the corrected result, incorrect result (noted as such), the date of the correction, and the initials of the person making the correction. Laboratory records should not be documented in pencil and the use of whiteout is not acceptable for making corrections.

Probes §493.1283(a)

Do the records reflect all patient testing and the dates of their performance?

If handwritten values were reported, can the laboratory demonstrate the analytic source of those results?

If the laboratory has not retained the appropriate test records, cite D3031, D3033, or D3035.