D8103

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§493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following:

Interpretive **Guidelines §493.1773(b)-(c)**

The regulations **do not** require a laboratory to maintain records on-site. During the survey, the laboratory must be able to retrieve copies of all records and necessary information upon request. Determine what constitutes a reasonable timeframe based on the information requested.

(b)(1) Test samples, including proficiency testing samples, or perform procedures.

(b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.

(b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following:

(b)(4)(i) Specimen procurement and processing areas.

(b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(b)(4)(iii) Testing and reporting areas.

(b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires.

(c) Accessible Records and Data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) Requirement to Provide Information and Data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.