

D8401

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§493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation

(a) Validation inspection. CMS or a CMS agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

***Interpretive* Guidelines §493.1780**

Validation surveys of accredited laboratories will be conducted by the State survey agencies. Refer to special procedures for accredited laboratories in the SOM. The RO is responsible for conducting validations of CLIA-exempt laboratories.

(b) Complaint inspection. CMS or a CMS agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of this part.

***Interpretive* Guidelines §493.1780(b)**

In **any** laboratory holding a CLIA certificate, tests listed on the waived list **are not** subject to routine surveys. A survey for waived tests may be conducted **only** when authorized by the RO in one of the following instances:

- To collect information on waived tests;
- To determine whether the laboratory is testing beyond its certificate;
- If a complaint is alleged; or
- You have information that the performance of such tests poses an imminent and serious risk that adversely affects patient test results.

When authorized to perform a survey of waived tests, in addition to the requirements in this subpart, refer to the requirements at §493.15, subpart A, and §§493.35, 493.37 and 493.39, subpart B, of these guidelines.

Section 493.35(d) requires that laboratories performing only waived tests and no other tests must agree to permit inspections by HHS in order to receive a certificate of waiver.

Make every effort to minimize the impact of the survey on the laboratory operations and patient care activities. Be flexible, accommodate staffing schedules and workloads as much as possible. In facilities providing direct patient care, (i.e., physician's offices, clinics, residential care facilities, hospitals, etc.), respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

(c) Noncompliance determination. If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

(c)(1) A laboratory issued a certificate of accreditation is subject to a full review by CMS, in accordance with subpart E of this part and §488.11 of this chapter.

(c)(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program.

(d) Compliance with basic inspection requirements. CLIA-exempt laboratories and

laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in §493.1773.