§ 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory’s hours of operation to do the following:

1. Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.
2. Evaluate a complaint from the public.
3. Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

(c) The laboratory must comply with the basic inspection requirements of §493.1773.

[63 FR 26737, May 14, 1998]

§ 493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance.

(a) Initial inspection. (1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory’s compliance with the requirements of this part before CMS issues a certificate of compliance.

2. The inspection may occur at any time during the laboratory’s hours of operation.

(b) Subsequent inspections. (1) CMS or a CMS agent may conduct subsequent inspections on a biennial basis or with such other frequency as CMS determines to be necessary to ensure compliance with the requirements of this part.

2. CMS bases the nature of subsequent inspections on the laboratory’s compliance history.

(c) Provider-performed microscopy procedures. The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

(d) Compliance with basic inspection requirements. The laboratory must comply with the basic inspection requirements of §493.1773.

[63 FR 26738, May 14, 1998]

§ 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.

(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.