

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

(e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.

(f) Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part.

(g) Failure to permit an inspection or reinspection. Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

Interpretive Guidelines §493.1773(e-g)

If for any reason a facility denies entry to or does not permit you to conduct a survey, the following steps should be taken:

- Explain your authority to conduct the survey and the consequences of failure to permit a survey;
- If necessary, consult with your supervisor or the RO; and
- For failure to permit entry into or inspection of the laboratory, use D8101.

If the laboratory continues to refuse a survey, refer to Subpart R – Enforcement Procedures beginning at §493.1800 and the Adverse Action section of the SOM at 6250.

Conduct complaint surveys on an unannounced basis.

The CLIA application will solicit the laboratory's hours of operation. For complaint or revisit surveys, you may phone the laboratory to confirm the hours of testing prior to a survey without revealing your identity or the scheduled date.

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, e.g., physician's offices, clinics, residential care facilities, hospitals, respect patient privacy and do not interrupt or interfere with patient care. Be well prepared, courteous and make requests, not demands.

Maintain documentation for all on-site follow-up surveys in the laboratory's official file.

§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.

Interpretive Guidelines §493.1775(a)

To cite deficiencies related to an inspection of a laboratory holding a certificate of waiver or a certificate of provider performed microscopy procedures, use D8100, D8101 and D8103, as appropriate.