

## **D8101**

**(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)**

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

**(a) A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections.**

#### **Interpretive Guidelines §493.1773(a)**

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.