D8201
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

(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:

Interpretive Guidelines §493.1775(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.

(b)(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.

(b)(2) Evaluate a complaint from the public.

(b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

Interpretive Guidelines §493.1775(b)(3)

When a laboratory has failed to obtain a registration certificate before performing and reporting patient results for nonwaived testing, notify the RO of a possible action by the Office of the Inspector General (OIG) if the laboratory does not obtain the appropriate certificate or cease the nonwaived testing.

(b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.