

D8303

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(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.

(b)(2) CMS bases the nature of subsequent inspections on the laboratory's compliance history.

Interpretive Guidelines §493.1777(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.