

Eligibility for a Multiple-Site Laboratory 42 CFR 493.35(b), 493.43(b) and 493.55(b)

An owner of a clinical laboratory may request multiple site laboratory status if the laboratory meets the following definition and requirements:

Criteria for One Certificate for Multiple Sites

Each location where laboratory tests are performed must file a separate application, unless it meets one of the following exceptions as outlined in 42 CFR 493.35(b), 493.43(b) and 493.55(b):

(1) Laboratories that are not at a fixed location, i.e., laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the CLIA certificate and address of the designated primary site or home base.

(2) A not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 types of moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for CLIA certificate(s) for the laboratory sites within the same physical location or street address.

Additional Requirements for 493.35(b)(2) and 493.43(b)(2) as follows:

(493.55 - Accredited multiple site laboratory refers to accrediting organization for guidance)

- There must be a common director legally responsible for all of the laboratory testing performed at all of the locations.
- No high complexity testing may be performed at any of the locations.
- The parent laboratory must identify in writing all locations where laboratory testing occurs by completing the form(s) provided by the Laboratory Compliance Section.
- Additional satellite locations may not be added without approval of the laboratory director and notification to Laboratory Compliance.
- All locations must have common laboratory policies and procedures. The parent laboratory must keep a master copy of all policies and

- procedures with director signature. Each satellite location must keep a copy of applicable procedures in the area where testing occurs.
- There should be a uniform training policy for laboratory personnel including a form for documentation of individual training and proof of competency.
 - There must be one general quality assurance (QA) plan with unique monitors specific to each location if moderate complexity testing is performed. Although it is recommended, sites performing waived tests only are not required to participate in QA activities.
 - All laboratory testing locations should use identical equipment and test kits, when possible.
 - Test reports must identify the laboratory name and specific location of test performance.
 - Tracking of 'reference tests' (send outs) must be site specific.
 - All locations performing moderate complexity tests must participate in applicable proficiency testing (PT). PT is to be rotated but only one site performs all specimens each testing event.
 - The laboratory director or qualified designee must routinely review all applicable records of quality control, instrument maintenance, proficiency testing and quality assurance at a minimum of every three or four months. Delegation of responsibilities to site supervisors or managers must be in writing.
 - The original clinical laboratory CLIA Certificate must be posted in the parent laboratory and a copy of the Certificate must be displayed at each satellite laboratory test location. The Certificate must be posted in the area where specimens are collected in full view of patients or clients.

Certificate and Fees

- The Certificate shall indicate the highest complexity level of testing performed (moderate, PPM or waived).
- The Certificate fee shall be based on the total test volume of all moderate complexity tests performed at all locations.

Application for Multiple Site Status

Entities who believe they qualify for 'Multiple Site' status must submit their request using the forms provided by the Laboratory Compliance Section.

Essentially the information must contain the following:

- Name and ownership of the laboratories

- Tax identification number
- Site address of the parent laboratory and site addresses of each satellite facility where laboratory tests are performed.
- List of all personnel performing laboratory tests
- What test each individual performs
- The educational status or college degree of each testing personnel
- Proof of non-profit status

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