



Microbiology Quality Control

The Clinical Laboratory Improvement Amendments (CLIA) regulations at 493.1256 and 493.1261 state a laboratory must perform quality control on microbiology reagents and test systems. The results of the quality control must meet the laboratory's and manufacturer's criteria for acceptability. The laboratory must document the actual measurement, reaction or observation of quality control testing. The quality control records should include lot numbers, date prepared or opened, and expiration dates.

The laboratory must check each batch of in-house prepared or lot number and shipment of commercially prepared reagents, disks and identification systems for positive and negative reactivity. Examples of reagents, disks and test procedures used for identification purposes include:

- ◆ Bacitracin.
- ◆ Catalase.
- ◆ Cefinase™.
- ◆ Coagulase plasma.
- ◆ ONPG (ortho-phenol beta-galactosidase).
- ◆ Optochin.
- ◆ Oxidase.
- ◆ Spot indole.

Mycology germ tube tests and X and V factor strips or disks need to be checked only for positive reactivity.

The laboratory must perform controls to check both positive and negative reactivity of staining materials to ensure proper staining characteristics each day of use. An exception is Gram stain which must be checked each week of use. Another exception is fluorescent and immunohistochemical stains which must be checked for positive and negative reactivity each time of use.

The laboratory must check each batch of in-house prepared or lot number and shipment of commercially prepared microbiological antisera and once every six months afterward.

Beta-lactamase methods other than Cefinase™ must have positive and negative reactivity checked each day of use.

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If you would like to receive CLIA Bits electronically, please send your e-mail address to Bridget Weidner at bweidner@nd.gov.

Requirements for CLIA Certificate Changes

The requirements for making changes to your CLIA certificate are as follows:

- Name of laboratory — written notice
- Location — written notice
- Mailing address — written notice
- Tax identification number — written notice
- Testing performed — written notice
- Telephone and fax numbers — written notice
- Adding or deleting multiple sites — written notice
- Voluntary closure — written notice
- Laboratory Director for Provider Performed Microscopy Procedures (PPMP), Compliance, or Accreditation — new CMS-116 (CLIA application form) and evidence of qualifications
- Laboratory Director for Certificate of Waiver — written notice
- Certificate type — new CMS-116
- Ownership — contact our office for instructions

Notification time requirements for changes are as follows:

- Name — within 30 days
- Location — within 30 days
- Director — within 30 days
- Technical supervisor — within 30 days
- Ownership — within 30 days
- Testing performed — within six months



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Questions and Answers (Q & A)

CMS provides specialized CLIA training courses for state surveyors. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. The Q & A is a regular feature of the CLIA Bits newsletter. We hope you find this information interesting and useful. Readers are welcome to submit questions to bweidner@nd.gov or sheilman@nd.gov.

Q. In response to the Winter 2009 issue of CLIA Bits, must the laboratory perform end-user quality control on chocolate agar?

A. No, this media is listed on the Clinical and Laboratory Standards Institute (CLSI) document M22-A3 as exempt from end-user quality control. However, this department does recommend end user quality control for media used to grow fastidious organisms (e.g., *Neisseria gonorrhoeae* and *Hemophilus influenzae*) to ensure optimum recovery. For more information regarding CLSI, visit their website at www.clsi.org.

Q. Can laboratory records be stored off-site?

A. Yes, if records can be retrieved in a reasonable amount of time. The laboratory must establish and follow policies ensuring security, confidentiality and ability to retrieve off-site records.

Sources for this article: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; State Operations Manual, Chapter 6 - Special Procedures for Laboratories; CLIA Basic and Beyond Training Sept. 2006; and CLSI document M22-A3.



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