



## SEEKING ACCREDITATION FROM A CMS-APPROVED PROGRAM

The CLIA '88 regulations allow laboratories to seek private accreditation as an alternative to the federal CLIA inspection process. Accreditation provides an additional option to achieve quality laboratory testing and demonstrate compliance with the federal CLIA standards.

Accreditation must be obtained from an organization approved by the Centers for Medicare and Medicaid Services (CMS). To be approved, organizations must demonstrate that their standards meet or exceed the CLIA standards. This ensures that accredited laboratories comply fully with all CLIA requirements.

To date, six national accreditation organizations are recognized and approved by CMS. A list of these organizations is given in the box on the right.

Accredited laboratories are not routinely inspected by a state survey agency acting on behalf of CMS. Instead, they will be inspected (often called "surveyed") by the accrediting organization. Accredited laboratories will still pay a CLIA certificate fee for an initial Certificate of Registration and later a Certificate of Accreditation (COA), but will not pay a compliance fee (the cost of the federal inspection). It remains the responsibility of the laboratory, not the accrediting organization, to maintain a valid CLIA certificate and to pay the appropriate CLIA certificate fees.

Laboratories seeking accreditation must apply to CMS for a COA. The cost of this certificate will vary depending on the annual test volume and number of specialties of testing. Follow up by enrolling with the accrediting organization that best meets your needs and paying the organization the accreditation fee. Accredited laboratories also pay CMS a validation fee that equals five percent of what the federal inspection would have cost. Validation fees are pooled to cover the cost of validation surveys to verify that accrediting organizations are meeting quality standards. Accredited laboratories have a five percent chance of being selected for a validation survey during any two-year period.

Federally inspected laboratories can switch to private accreditation. Contact your local state survey agency in writing to inform them of your plan to switch to private accreditation. You are expected to provide documentation to your state survey agency that you have enrolled in an approved accreditation program.

### National Accreditation Organizations

#### COLA

9881 Broken Land Parkway  
Suite 200  
Columbia, MD 21046-1195  
800.981.9883  
[www.colaprof.org](http://www.colaprof.org)

#### College of American Pathologists Laboratory Accreditation Program

325 Waukegan Road  
Northfield, IL 60093  
800.323.4040  
[www.cap.org](http://www.cap.org)

#### Joint Commission on Accreditation of Healthcare Organizations

One Renaissance Boulevard  
Oakbrook Terrace, IL 60181  
630.792.5800  
[www.jcaho.org](http://www.jcaho.org)

#### American Society for Histocompatibility & Immunogenetics

17000 Commerce Parkway  
Suite C  
Mt. Laurel, NJ 80854  
856.638.0428  
[www.ashi-hla.org](http://www.ashi-hla.org)

#### American Association of Blood Banks

8101 Glenbrook Road  
Bethesda, MD 20814-2749  
301.907.6977  
[www.aabb.org](http://www.aabb.org)

#### American Osteopathic Association

142 East Ontario Street  
Chicago, IL 60611  
312.202.8070  
[www.aoa-net.org](http://www.aoa-net.org)