

# Facts about laboratory accreditation

The Joint Commission has been evaluating and accrediting hospital laboratory services since 1979 and freestanding laboratories since 1995. Today, The Joint Commission accredits about 1,500 organizations providing laboratory services. These organizations represent almost 2,000 laboratories with Clinical Laboratory Improvement Amendment (CLIA) certification. Laboratories eligible for accreditation include:

- Laboratories in hospitals, clinics, long term care facilities, home care organizations, behavioral health care organizations, ambulatory sites and physician offices
- Reference laboratories
- Freestanding laboratories, such as assisted reproductive technology laboratories
- Blood transfusion and donor center laboratories
- Public health laboratories, including Indian Health Service laboratories
- Laboratories in federal health care facilities, such as the Department of Veterans Affairs
- Point-of-care test sites in patient care areas which may include blood gas laboratories providing services to patients in emergency rooms, surgical suites, and cardiac catheterization laboratories

### **Standards**

Requirements for laboratory accreditation are contained in the *Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB)*. The standards emphasize the results a laboratory should achieve, not the specific methods of compliance, and were developed with input from professional laboratory organizations. In compliance with CLIA regulations, Joint Commission standards address processes that follow laboratory specimens through the laboratory from the time of specimen collection to the time of result reporting, focusing on the provision of high quality, safe laboratory services.

### **Survey process**

Joint Commission accreditation concentrates on operational systems critical to the safety and quality of patient care. The objective of the survey is not only to evaluate the laboratory, but to provide education and "good practice" guidance to staff on continuous performance improvement. The survey process evaluates actual care processes by tracing the care, treatment and services provided to a patient in an organization, and analyzing the quality and safety of diagnostic services provided to that patient.

Surveys are conducted by Joint Commission-employed medical technologists. Surveyors must have a bachelor's degree, certification from the American Society for Clinical Pathology (ASCP), clinical work experience in three or more technical specialty areas of laboratory medicine, and five years of laboratory management experience. Surveyors complete a one-week training course and up to six preceptoral surveys with a veteran surveyor. Surveyors receive comprehensive, continuing education throughout the year. Full-time surveyors conduct 60 to 70 laboratory surveys annually. Pathologist surveyors are available by request.

#### **Deemed status**

The Centers for Medicare & Medicaid Services (CMS) officially recognizes The Joint Commission Laboratory Accreditation program as meeting the requirements of CLIA. CLIA regulations require that all laboratories be surveyed on a two-year cycle. CLIA regulations also require that there be an on-site survey or inspection by an approved agency such as The Joint Commission, **for all tests of moderate or high complexity**. The main categories of laboratory testing, as defined by CLIA regulation, are:

- Waived tests simple procedures with little chance of negative outcomes if performed inaccurately (surveyed only if non-waived testing is being performed).
- Moderately complex tests more complex than waived tests but usually automated, such as blood counts or routine chemistry tests.
- **Provider-performed microscopy (PPM)** a subset of moderately complex tests performed by licensed mid-level providers or physicians.

• **Highly complex tests** – usually non-automated or complicated tests requiring considerable clinical judgment, such as microbiology tests or crossmatching of blood.

## **Proficiency testing**

Joint Commission standards and CLIA regulations require that a laboratory be enrolled in a CMS-approved proficiency testing program for all regulated tests conducted by the laboratory. Annually, laboratories must report verification of annual enrollment in a proficiency testing program to The Joint Commission. CLIA requires that a laboratory's proficiency testing results be monitored on an ongoing basis by The Joint Commission.

## Lab Advantage™

To meet accreditation, proficiency testing and education requirements, laboratories can participate in Lab Advantage<sup>TM</sup>, a collaboration between The Joint Commission, the American Proficiency Institute (a CMS-approved proficiency testing provider), and the American Society for Clinical Pathology. Lab Advantage combines the strengths of these three nationally known organizations to provide a product that offers value, efficiency and cost savings to laboratories nationwide. Customers receive a 5 percent discount on accreditation fees and a 10 percent discount on educational programs. To sign up for Lab Advantage services or for more information, go to the <u>Lab Advantage website</u>, call 800-333-0958, ext. 3013, or e-mail info@labadvantage.org.

### Cost of accreditation

The on-site survey fee is paid at the end of the on-site survey and covers survey-related direct costs. The on-site survey fee starts at \$2,110 for one surveyor per day. The additional annual fee, which is based on an organization's volume and type of services provided, is due every January and covers Joint Commission accreditation-related services. The annual fee starts at \$1,450 for a small lab and increases based on the number of CLIA specialties, subspecialties, and locations for which testing is performed. For more information about pricing, contact The Joint Commission Pricing Unit at 630-792-5115.

## For more information

- The names of accredited laboratories are available to the public on Quality Check<sup>®</sup> at www.qualitycheck.org.
- Questions or comments about the Laboratory Accreditation Program: Stacy Olea, executive director, 630-792-5214 or solea@jointcommission.org.
- Questions about seeking laboratory accreditation for the first time: Sharon Hibbe, project manager, 630-792-5817 or <a href="mailto:shibbe@jointcommission.org">shibbe@jointcommission.org</a>.
- Questions about laboratory standards: Standards Interpretation Group, 630-792-5920 or use the online form.
- Questions about unsuccessful proficiency testing and corrective plans of action: Eileen Stawczyk, laboratory specialist, 630-792-5248 or <a href="mailto:estawczyk@jointcommission.org">estawczyk@jointcommission.org</a>.
- Specific questions about your organization's accreditation: Accredited organizations may contact their assigned account executive at his or her extension or by calling 630-792-3007.
- Laboratory Accreditation Services web page