



WHAT TO EXPECT DURING YOUR CLIA SURVEY

CLIA requires all laboratories performing moderate and high complexity testing to be surveyed (inspected) once every two years. The focus of the survey is to assess how the laboratory monitors its operations and ensures the quality of testing.

The survey may be performed by a state survey agency, CMS regional office, or a CMS-approved private, non-profit accrediting organization.

The following process describes what you might expect to happen during an on-site survey conducted by the state survey agency or CMS regional office.

On-site Survey

In most cases, you will be contacted in advance by your state survey agency to inform you of your date of survey. On the day of your survey, the first step will be the entrance interview. Your surveyor will present identification and introduce any accompanying team members. The surveyor will inform the facility's administrator, director, or supervisor of the purpose of the survey, the anticipated time schedule, and explain the survey process. This is an opportunity to ask any questions you may have about the survey process.

The surveyor will make every effort to minimize the impact of the survey on laboratory operations and patient care activities.

The survey will include a tour of the facility, record review, observation, and interviews with personnel involved in the pre-analytic, analytic, and post-analytic phases of the testing process. The surveyor will request the information and records required to complete the survey.

To facilitate the survey process, the following information should be accessible and retrievable at the time of survey:

- Procedure manuals
- Safety information
- QC records
 - Statistical limits
 - Remedial actions
 - Calibration and calibration verification records
- Instrument maintenance and function checks records
- Quality assessment plan and documentation of reviews for each phase of testing (pre-analytic, analytic, post-analytic)
- Records of tests referred to other laboratories and the client service manuals for those reference laboratories
- Proficiency testing reports and records
- Personnel records
 - Education, training, and experience documentation
 - Continuing education
 - Competency assessment
 - Duties and responsibilities
 - Personnel changes since the last survey

- Patient testing records
 - Requisitions
 - Worksheets and instrument printouts
 - Patient test reports

The survey is an outcome-oriented process, with emphasis placed on the laboratory's quality system as well as the structures and processes throughout the entire testing process that contribute to quality test results. The surveyor selects a cross-section of information from all aspects of the laboratory's operation for review to assess the laboratory's ability to produce accurate, timely, and reliable results. The selected information is reviewed to verify that the laboratory has established and implemented appropriate ongoing mechanisms for monitoring its practices, and identifying and resolving problems effectively.

At the end of the survey there will be an exit conference that is a continuation of the educational survey process. The purpose of the exit conference is to give the surveyor the opportunity to inform laboratory staff of the findings and to solicit any additional information in response to the findings.

Any requirements that are not in compliance and the findings that substantiate these deficiencies will be described. It is the laboratory's responsibility to determine the corrective actions necessary to remedy any problems. The surveyor will provide instructions and the timeframe expected for submitting any needed plan of correction. Based on the level of compliance, the surveyor will inform the laboratory staff of the intended recommendation to certify, re-certify, or deny certification to the laboratory.

THE SURVEY IS AN OUTCOME-ORIENTED PROCESS, WITH EMPHASIS PLACED ON THE LABORATORY'S QUALITY SYSTEM AS WELL AS THE STRUCTURES AND PROCESSES THROUGHOUT THE ENTIRE TESTING PROCESS THAT CONTRIBUTE TO QUALITY TEST RESULTS.