# CMS VALIDATION SURVEY PROCESS

A number of accrediting organizations have deemed status from the Centers for Medicare and Medicaid Services (CMS) to accredit laboratories. These organizations are:

- COLA
- College of American Pathologists (CAP)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- American Association of Blood Banks (AABB)
- American Osteopathic Association (AOA)

Laboratories accredited by these organizations are deemed to meet all federal CLIA requirements.

As a condition of their accreditation, laboratories accredited by COLA or by the five other organizations are subject to a CMS validation survey, which is conducted by the state survey agency. The purpose of the validation survey is to verify that laboratories accredited by these organizations are meeting CLIA condition-level requirements and that the accrediting organization's inspection process assures the laboratory's continued compliance with CLIA. CMS began its validation survey process in 1995.

Laboratories are picked at random for a validation survey. The cost to the laboratory for the validation survey is five percent of what the laboratory's inspection fee would have been if it were in the government inspection program. The validation survey fee is included as part of the accreditation certificate fee the laboratory pays to CMS.

CMS may conduct a validation survey without prior notification, although they try to give two-weeks notice.

Validation surveys may be conducted up to 90 days after the accreditation survey, however most are conducted within 60 days.

Sometimes, the state surveyors accompany the accrediting agency's surveyor on a joint evaluation of a laboratory. This is called a "simultaneous validation survey."

The surveyors conducting a validation survey will follow the CMS survey protocol.

For announced surveys, a letter will be sent to the director's office of the facility indicating when the validation survey will occur. The letter will also list general records and reports, such as quality systems assessment and quality control, that should be available to the surveyor.

After the survey is complete, a report will be issued to the laboratory director listing any deficiencies found. The laboratory director must respond in writing within 10 days with a plan of correction (POC) if condition-level deficiencies are cited.

If only standard-level deficiencies are cited, laboratory directors are not required to submit a POC. However, they are encouraged to respond with a plan of action for standard level citations because of public disclosure laws.

CMS is required to disclose the findings of any validation survey to any interested party, upon request.