



CLIA Accreditation Process

1

Requirement Check

Before beginning the application process, review CLIA and State requirements to ensure your laboratory is meeting CLIA requirements based on the complexity of testing.

4

Assessor Assigned

You'll work with an AcO to match you with an expert or team to perform your lab assessment. The assessor will provide your lab with at most two-week notice prior to the assessment start date of the assessment occurring.

7

Complete Corrective Action Process

Each nonconformance must have a response with a cause analysis, corrective action, and objective evidence of the implemented corrective action. You will have 30 days from the exit meeting to respond to each nonconformance.

2

CLIA Accred. Application

Apply through CMS:

- Complete CMS116: A2LA selected as Accreditation Org. under a Certificate of Accreditation
- Provide required information: organization, personnel, and testing details
- Submit completed form and required documents to local state agency

5

Laboratory Assessment

The assessment begins with a review of your lab including quality and technical review. The length of the assessment will depend on length of scope, specialties/subspecialties, and the size of the assessment team. Nonconformances are provided at the end of the assessment/during the exit briefing.

8

Accreditation Voting

After all nonconformances have been closed, your final application moved to the Accreditation Council (AC) for voting. AC members have 15 days to review and submit their votes. Accreditation is finalized when all positive votes have been received.

3

A2LA Cert. Application

During the A2LA accreditation application process, you'll work with a customer care representative and Accreditation Officer (AcO) to complete the application by submitting lab information, quality documentation, and completed checklist.

6

Nonconformance Review

Each nonconformance found during your assessment will be listed as either Standard or Condition level. Additional nonconformances may not be added now. Your AcO ensures each nonconformance is valid. The assessor must deliver their full report to A2LA within one week of the exit meeting.

9

Accreditation Awarded

Once the AC approves your laboratory, you are awarded an A2LA CLIA Certificate of Accreditation. A2LA notifies CMS of the accreditation that is granted. Then, display your certificate and share the news with customers, staff, and stakeholders.