Platinum Accreditation Process

1

Requirement Check & Development of Quality Mgmt. System

a. Before beginning the application process, review CLIA and State requirements to ensure your laboratory is meeting the CLIA requirements based on the complexity of testing.
b. R102 requires your laboratory to own a copy of ISO 15189. Read the standard, become familiar with it, and begin to develop a quality management system encompassing CLIA and ISO 15189 requirements.

2

CLIA Certificate through CMS

a. Apply for a CLIA Certificate of Accreditation through CMS by:
   i. Completing the CMS116 form with A2LA being selected as the Accreditation Organization under a Certificate of Accreditation
   ii. Providing all of the required information including organization details, personnel details, and testing information
   iii. Submitting the completed form and required documents to the local state agency (contact details are on the CMS website)

3

Apply for A2LA Platinum Accreditation with Customer Care Representative and AcO Assistance

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

4

A2LA Assessor Assigned

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

5

Laboratory Assessment Conducted

a. The assessment begins with a review of your laboratory including quality and technical review. The length of the assessment will depend on the length of scope, specialties/subspecialties, and the size of the assessment team.

6

Review Nonconformances Found

a. At the end of the assessment, your assessor provides you with a list of nonconformances found during the assessment. For CLIA specific nonconformances, each nonconformance will be listed as either Standard or Condition level. The assessor may not add any additional nonconformances at this point, and they must deliver their full report to A2LA within one week of the exit meeting. Your AcO will ensure that each nonconformance is valid.

7

Complete the Corrective Action Process

a. You must respond to each nonconformance 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.

8

The Accreditation Council (AC) Votes on Accreditation

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

9

Accreditation Awareded

a. Once the AC approves your laboratory, you are awarded an A2LA Scope of Accreditation, ISO 15189 Certificate, and CLIA Certificate. A2LA notifies CMS of the accreditation that is granted. Then, display your certificate and share the news with customers, staff, and stakeholders.