New License Application Checklist

Prepare the following requirements before creating an account and applying for a new testing site.
Note: Additional requirements may be requested upon review.

A — For Certificate Type: REGISTRATION (Waiver or PPMP)

1 INFORMATION:

- ☐ Business Tax ID number
- ☐ Contact person, phone, email
- ☐ Business address (Mailing address)
- ☐ Testing site address (Address that will appear on the printed certificate)
- ☐ VIN/Vehicle ID Number (if mobile lab)
- ☐ Name(s) and professional license numbers of Laboratory Director
- ☐ Name(s) and professional license numbers of Testing Personnel

2 TO BE UPLOADED:

- ☐ Form LAB 182 Attestation of each Owner
- ☐ Form LAB 183 Attestation of each Laboratory Director
- ☐ Form LAB 116 Laboratory Personnel Report (if PPMP, or Moderate/High Complexity)
- ☐ Form CMS 116 CLIA Application for Certification
- ☐ Proof of accreditation or letter of enrollment from accrediting agency (if applicable)

B — For Certificate Type: LICENSE (Moderate/High Complexity)

1 INFORMATION:

- ☐ **All requirements found in A1, plus...**
- ☐ List of tests performed at the site (names, specialties, complexity level, and analyte)
- ☐ Laboratory testing equipment make, model, and serial number
- ☐ Estimated Annual Volume of Tests
- ☐ Education information of Directors and Testing Personnel (if out-of-state)
- ☐ Training information of Director and Testing Personnel (if out-of-state)

2 TO BE UPLOADED:

- ☐ **All requirements found in A2, plus...**
- ☐ Form LAB 144A Lab Testing Declaration (upload only if not entering individual tests online)
- ☐ Form CMS 209 CLIA Laboratory Personnel Report (not required if out-of-state)
- ☐ Documentation of Laboratory Director's qualifications
- ☐ Articles of Incorporation (if POL)
- ☐ Proficiency Testing, Facility Administration, and Quality Systems Requirements (upon request)
- ☐ Form LAB 116 OS Laboratory Personnel Report (if out-of-state)
- ☐ Form LAB 168 OS Laboratory Personnel Qualification (if out-of-state)
- ☐ CLIA Certification, SOP and Validation Summaries (if out-of-state)