



12 STEPS TO OPENING YOUR NEW LAB

This checklist will assist you in opening a new diagnostic laboratory. Laboratories that perform testing on human specimens for the diagnosis, prevention, or treatment of disease, or for the assessment of health must comply with all applicable CLIA '88 regulations. These regulations, which were finalized in 2003, establish standards to help ensure the quality and accuracy of laboratory testing. Steps that include this symbol t have additional resources provided at the end of this fact sheet.

1. Determine the complexity of the tests you will perform in the laboratory. ▼

- **Waived Tests**
Fingerstick glucose and dipstick urinalysis are just a few of the simple tests classified as waived. No inspection or proficiency testing (PT) is required, but you must follow the manufacturer's directions for the test. (Waived labs can skip steps 5-11 below.)

- **Provider Performed Microscopy Procedures (PPMP)**

A provider (must be a physician, physician's assistant, nurse practitioner, nurse midwife, or dentist) performs specified microscopy procedures, usually during the exam of a patient. These special tests are moderate complexity. There are no routine inspections, but certain CLIA requirements apply, including proficiency testing (PT). (PPMP labs can skip step 5 and steps 8-11 below.)

- **Non-waived (Moderate or High Complexity) Tests**

Non-waived testing (other than PPMP) requires an on-site inspection of the laboratory every two years and compliance with all the applicable CLIA requirements. You must meet specific personnel standards for moderate complexity testing and even more stringent ones for high complexity testing.

2. Obtain a CMS-116 form to apply for a CLIA certificate. ▼

These forms are available on-line, or by calling COLA or your local state agency. If your state has its own

laboratory licensure laws instead of, or in addition to CLIA, you will need to obtain that paperwork from your state agency.

3. Complete the CMS-116 form, applying for the appropriate certificate type. ▼

Directions are provided with the form. Here are some hints for certain sections:

Section I

- Indicate that the application is for a new laboratory by marking the box next to Initial Application. In the future, should you wish to change your certificate type, use another CMS-116 form and check the box next to Change in Certification Type.

Section II

Select the certificate type that matches the highest level of testing performed and the choice of inspection agency, if applicable.

- For waived testing only, select Certificate of Waiver.
- For PPMP testing, select Certificate for PPMP. Remember, this certificate allows a limited list of microscopic tests that must always be performed by the provider. A PPMP certificate will also allow anyone in the facility to perform waived tests.
- For moderate or high complexity testing, select:
 - Certificate of Compliance if you choose a government inspection
 - Certificate of Accreditation if you choose to

enroll with an accrediting agency and participate in their program

- Mark the box next to the accrediting agency you choose

Sections VI and VII

- Using the instructions provided, estimate the expected annual test volume for:
- Waived tests
- Non-waived tests (including PPMP)

4. Submit the completed CMS-116 form (as well as any state-specific paperwork) to your local state agency. ▼

Upon receipt of your completed application, you will be mailed a bill for your CLIA certificate. Be sure to pay this bill promptly! As of 2004:

- Certificate of Waiver labs will be billed \$150.
- Certificate of PPMP labs will be billed \$200.
- Certificate of Compliance or Certificate of Accreditation labs will be billed \$100 for an interim Certificate of Registration. This certificate serves as a valid CLIA certificate until the laboratory has successfully passed an on-site inspection. The lab will be billed later by CMS for the actual certificate and inspection.

5. If you selected Certificate of Accreditation, then enroll your laboratory with that agency now. ▼

- Accredited labs are still required to pay CMS to maintain a valid CLIA certificate. This remains your responsibility, and not the responsibility of the accrediting agency.

6. Enroll in an approved proficiency testing program for all regulated analytes on your test menu. ▼

7. Set up your laboratory using the applicable CLIA requirements. For non-waived testing, establish a policy and procedure manual and a quality assessment plan, perform test method validation, train employees, and prepare for inspection. ▼

- Government-inspected laboratories may consult the Code of Federal Regulations to view the laboratory requirements or contact their local state agency for assistance in setting up the laboratory.

- COLA-accredited laboratories may consult their Accreditation Manual or call for assistance. COLA will also provide technical support to non-members, but cannot address specific requirements of other accrediting agencies.
- Laboratories enrolled with other accrediting agencies should consult any reference materials provided to them or contact the agency for assistance.

8. Pay any inspection fees owed to the state/CLIA program or your accrediting agency when you receive a bill.

- Government inspection fees are based on your estimated annual test volume, which will be verified at the time of inspection.
- An accredited laboratory's inspection fees will vary, based upon the agency's fee schedule (which may or may not be based on annual test volume).

9. Schedule your on-site inspection.

- Your local state agency or accrediting agency will contact you to schedule your inspection. Unannounced inspections are also allowed, so be prepared!

10. Complete the inspection process and correct any deficiencies within the required time-frame.

11. When your laboratory has successfully completed the inspection process, CMS will issue a bill for the Certificate of Compliance or Certificate of Accreditation. ▼

- The cost of the CLIA certificate is based on the verified annual test volume of the laboratory.
- Accredited labs also pay a validation fee. This fee is 5 percent of the cost of the government inspection and covers the cost of CMS validation surveys.

12. Maintain a valid and current CLIA certificate that matches the level of testing performed.

- You must renew your CLIA certificate every two years for as long as you perform testing.
- Use the CMS-116 form to change your certificate type if you change the level of testing performed.

Additional Resources for Opening Your New Lab ▼

1. Current list of waived tests–
www.cms.hhs.gov/clia/downloads/cr5083.waivetbl.pdf
(Link changes whenever this document is updated. If link is outdated, go to www.cms.hhs.gov/clia and then click on “Categorization of Tests” from the left menu and scroll down to the “Downloads” section for the latest list.)
2. List of PPM Procedures –
www.cms.hhs.gov/clia/downloads/ppmp.list.pdf
3. To determine the complexity of a test, use this searchable CLIA test complexity database –
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
(Type in as much information as you have and click the Search button.)
4. Personnel requirements for non-waived testing – www.phppo.cdc.gov/clia/regs/subpart_m.aspx
5. How to apply for a CLIA certificate (Includes a link to a printable CMS-116 form and a list of state agencies.) –
http://www.cms.hhs.gov/CLIA/o6_How_to_Apply_for_a_CLIA_Certificate_Including_Foreign_Laboratories.asp
6. List of states with their own laboratory licensure programs – www.cms.hhs.gov/clia/downloads/Exempt.States.List.pdf
7. CLIA certificate fee schedule – http://www.cms.hhs.gov/CLIA/11_CLIA_Certificate_Fee_Schedule.asp
8. List of CLIA-approved Accrediting Organizations – <http://www.cms.hhs.gov/CLIA/downloads/AO.List.pdf>
9. List of CLIA-approved Proficiency Testing Programs – <http://www.cms.hhs.gov/CLIA/downloads/ptlist.pdf>
10. List of regulated analytes (proficiency testing is required) – See Fast Facts #10 at: www.cola.org/fastfacts.html
11. View the current CLIA laboratory requirements – www.phppo.cdc.gov/clia/regs/toc.aspx
12. On-line Education, including a course on CLIA '88 – www.LabUniversity.org
13. COLA Accreditation - www.cola.org/whycola.html