# CLIA Guidelines Quick Reference

Where the official CLIA rules and guidance PDFs live, which regulation covers each topic, and the core items surveyors check. Prepared by Sound Lab Consultants, an independent clinical laboratory consulting firm. Not affiliated with CMS, CDC or FDA. Always confirm against the current official documents linked below. Updated November 2026.

## 1. Official CLIA documents (free PDFs)

| Document | What it is | Link |
|---|---|---|
| 42 CFR Part 493 | The CLIA regulations themselves (eCFR, always current) | ecfr.gov Part 493 |
| SOM Appendix C | Survey procedures and interpretive guidelines surveyors use, organized by D-tag (Rev. 233, issued 09-12-2025) | som107ap-c-lab.pdf |
| QSO-25-10-CLIA (revised 06-23-2025) | CMS memo on the Appendix C revisions | qso-25-10-clia PDF |
| Form CMS-116 | CLIA application for certification and changes | cms116.pdf |
| How to Obtain a CLIA Certificate | CMS brochure on certificate types and the process | HowObtainCLIACertificate.pdf |
| Certificate of Waiver brochure | Rules for labs doing only waived tests | howobtaincertificateofwaiver.pdf |
| Proficiency Testing and PT Referral | CMS brochure (October 2024) | PT brochure PDF |
| CLIA Laboratory Quick Start Guide | CMS starter guide for new labs | Quick start guide PDF |
| PPM procedures list | Tests allowed under a PPM certificate | ppmplist.pdf |
| State agency contacts | CLIA state survey agency contacts | CLIASA.pdf |
| Exempt states | States with CLIA-exempt licensure programs | exemptstateslist.pdf |

## 2. Which rule covers what

| Topic | 42 CFR 493 | Appendix C (starting D-tag) |
|---|---|---|
| Certificate types and test complexity | §493.5, §493.15, §493.19 | D1000 (waived) |
| Proficiency testing | §493.801 | D2000 |
| Facility administration | §493.1101 | D3000 |
| General quality systems | §493.1200 | D5000 |
| Personnel competency policies | §493.1235 | D5209 |
| Analytic systems | §493.1250 | D5400 |
| Verifying performance specifications | §493.1253 | D5421 |
| Quality control | §493.1256 | D5445 |
| Test report | §493.1291 | Postanalytic, D5800 series |
| Lab director, moderate complexity | §493.1407 | D6000 |
| Lab director, high complexity | §493.1445 | D6076 |

D-tags are the numbers surveyors cite on Form CMS-2567. Confirm the exact tag in the current Appendix C before quoting it in a plan of correction.

## 3. Certificate types at a glance

| Certificate | Who needs it | Routine survey |
|---|---|---|
| Certificate of Waiver | Labs doing only FDA-waived tests | No routine survey; may be surveyed for complaints or projects |
| Provider-Performed Microscopy (PPM) | Physicians and mid-level practitioners doing listed microscopy, plus any waived tests | No routine survey |
| Certificate of Compliance | Moderate or high complexity labs surveyed by the state agency | Every two years by the state survey agency |
| Certificate of Accreditation | Moderate or high complexity labs accredited by CAP, COLA, The Joint Commission or another approved accreditor | Every two years by the accreditor |

## 4. Survey-readiness essentials

[ ] Current CLIA certificate posted and matching your test menu, director and address.

[ ] Written procedure manual approved and signed by the laboratory director.

[ ] Performance verification (or establishment for modified and laboratory developed tests) on file before patient testing.

[ ] QC run, reviewed and documented at the required frequency, with corrective action records.

[ ] Calibration and calibration verification at least every six months where required.

[ ] Proficiency testing enrolled for regulated analytes, handled like patient samples, never referred, results reviewed.

[ ] Personnel files with qualifications, training and six required competency elements: initially, at six months, then annually.

[ ] Temperature, maintenance and reagent lot records complete and reviewed.

**Need help with CLIA?** Sound Lab Consultants sets up labs, provides laboratory director and technical consultant coverage, and prepares labs for surveys in all 50 states. soundlabconsult.com · (602) 874-1311 · 25 Arizona Pl, Chandler, AZ 85225. Book a free 30-minute consultation.

General information, not legal advice. CLIA, state and accreditor requirements change; check the official sources above.