

## How to prepare for a CLIA certification inspection

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Based on their license renewal cycle, clinicians running moderate – and high – complexity testing laboratories will undergo Clinical Laboratory Improvement Amendment (CLIA) inspections every two years.

The Centers for Medicare & Medicaid Services (CMS) regulates CLIA certification with assistance from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).<sup>1</sup> Its purpose is to protect patient safety and make sure laboratories maintain quality standards at the federal level.<sup>2</sup>

### Why CLIA certification is important

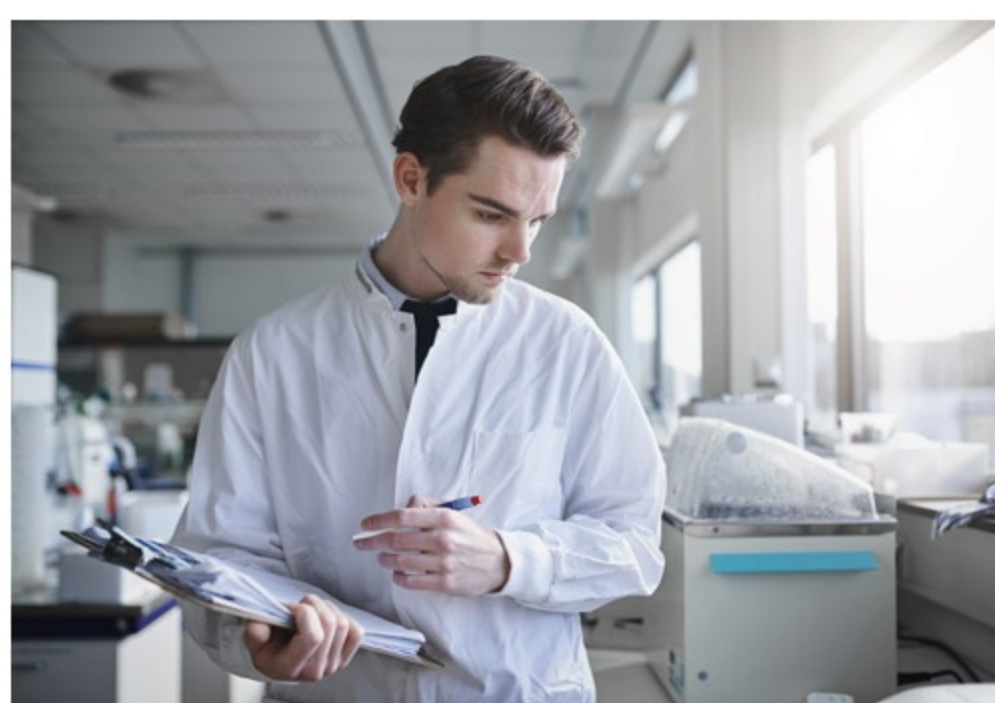
A CLIA certification is required for all types of laboratory testing – even if labs are CLIA waived. There are different types of CLIA certifications based on the diagnostic tests laboratories perform.

And though it's true that laboratories holding a Certificate of Waiver (CoW) and running CLIA waived laboratory procedures aren't routinely inspected, inspectors can still make unannounced visits to investigate any possible complaints.<sup>3</sup>

Here is a basic guide to help you prepare for a CLIA inspection.

### Always be ready for inspection with a CLIA inspection checklist

In general, CLIA inspectors give two weeks' notice for announced initial and renewal inspections – although an unannounced visit could occur at any time. And because these notices are often delivered by mail, it's possible laboratories may not receive notification until the day inspectors arrive, with possible mail delivery delays.



This explains why, "a lab should always be in a constant state of readiness for an inspection," says Lisa Bakken, director of [MedSol Laboratory Consulting Services](#).

Bakken warns:

- Representatives from any regulatory agency could show up unannounced for follow-up or look into complaints between those two years
- An unannounced visit doesn't replace a license renewal inspection
- Clinicians who know their license expires within six months can expect an inspection any time within that window

### Engage in the collaborative process

"The inspection process is designed to be collaborative," shares Bakken. If facilities have concerns, having a consultant involved can help with their CLIA inspection preparation process.

Working with a consultant with expertise in CLIA inspection preparation can help resolve concerns before they become deficiencies or, worse, put a laboratory in immediate jeopardy. "Sometimes it's worth it to invest in working with experts who can bring peace of mind throughout the process," says Bakken.

Consulting companies can also provide in-person or ongoing remote support with monthly or quarterly assistance to help clinicians stay prepared for any type of inspection. There's value in working with someone with a variety of expertise to assist with any of these inspection scenarios.

*From setup, to ongoing lab consulting, and compliance training, our MedSol program's licensed professionals can provide the support you need for your laboratory. [Learn more about MedSol >](#)*

### Schedule a mock inspection

Running a mock inspection can help laboratories find and mitigate issues before the real thing. And like actual inspections, mock inspections are a day-long process. How much time a lab needs depends on its complexity and the volume of instrumentation it uses.

According to Bakken, the facility should perform a mock inspection about three months before an expected CLIA inspection.

Laboratories perform their own mock inspections, but some facilities and physician offices may opt to contract this out, either for a stand-alone mock inspection or for ongoing support.

### Avoid common deficiencies & be prepared

"It's always important to keep consistent, legible and organized records," says Bakken, "Quality control logs and competencies of testing personnel are where most deficiencies are discovered."

If you identify any errors with your logs, it's important to develop and document your own corrective plan of action. If a deficiency is found during your inspection, and you already have a corrective action plan in place at the time of the inspection, it's possible that the inspector may not issue a citation because the risk has already been mitigated.

#### Check laboratory records

Facilities and physician offices should check they have a record of their personnel's credentials and competencies at initial hire, again at six months and then annually.<sup>4</sup>

Other areas to keep an eye on:

- Documenting any errors in a corrective action plan is essential
- Laboratory proficiency testing is another area that inspectors will frequently cite. Participants usually need to register well in advance, so clinicians should allow plenty of time to complete proficiency testing well before inspection time
- Personnel competency binders can help organize staff training documentation

#### Quality control documentation

Inspectors will choose several patients' dates from the past two years as part of a random sampling or lookback. Therefore, laboratories should always take steps to maintain accurate and consistent quality control (QC) records.

Inspectors will look at QC for those dates and patient outcomes, such as documentation of critical labs and actions taken. Again, make sure to document any errors or omissions in a corrective action plan.

### Prepare personnel for possible interviews

Occasionally, if an inspector uncovers missing competencies, concerns with QC or other deficiencies, they may interview lab personnel to better understand their testing knowledge or related background.<sup>5</sup>

Bakken explains that clinicians should encourage their personnel to respond to an inspector's questions honestly and provide answers on the items or records in question.

"Again, the point of an inspection is about collaboration and improving patient care," she says. "Anytime you find an error or something done inappropriately, it's not necessarily punitive. It's an opportunity for improvement."

*Want to learn more about CLIA? Check out our article, [CLIA 101: Answers to your most common questions about CLIA waived tests](#).*

1: <https://www.cdc.gov/cli/about.html>

2: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/cliaback.pdf>

3: <https://www.cms.gov/regulations-and-guidance/legislation/cli/downloads/howobtaincertificateofwaiver.pdf>

4: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/cliabrochure.pdf>

5: <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-Q/section-493.1773>

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