

Preparing for a CLIA Inspection The 30-Day Countdown

A timeline-based guide to getting inspection-ready

Article 16 of 22

5-minute read

30 Days

Structured preparation
countdown

6 Elements

Of competency per
test system required

Day 1

Designate one point
of contact for inspector

CLIA inspections should not be stressful—if you run your lab properly, the inspection validates what you already do. But even well-run labs benefit from a structured preparation process.

1 Days 30–21: Document Review

Verify all SOPs reviewed within 12 months. Check CLIA certificate is current and posted. Verify director qualifications on file. Review PT records for 2 years including corrective actions for failures.

2 Days 20–11: Personnel and Training

Confirm every employee has documented qualifications, competency assessments (6mo/12mo/annual), and all six competency elements: direct observation, monitoring, specimen assessment, QC/PT review, problem-solving, and written assessment.

3 Days 10–4: Equipment and QC

Review maintenance logs. Verify preventive maintenance on schedule. Check thermometer and pipette calibrations. Review QC data for the past month—Levey-Jennings current, out-of-range events with corrective actions.

QUICK TIP: Check every instrument maintenance log for gaps.

4 Days 3–1: Physical Environment

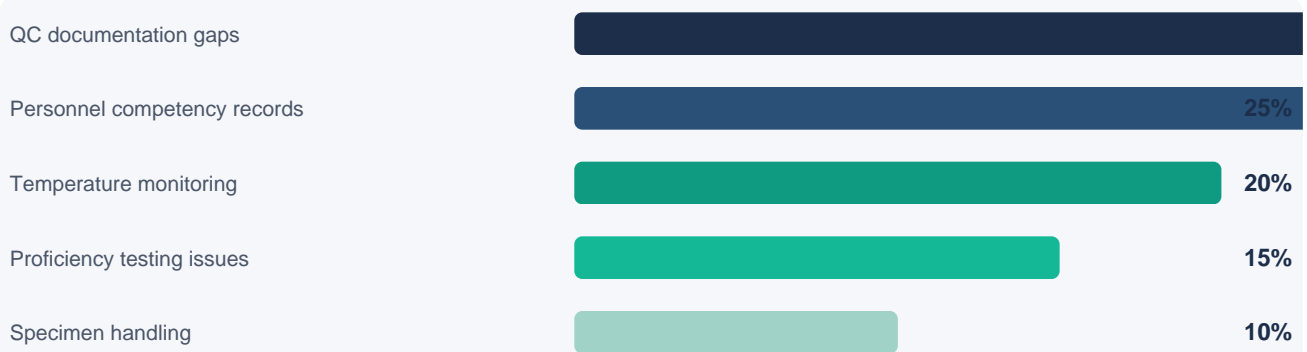
Walk through with fresh eyes: reagent storage temps documented, expired reagents removed, lab clean, SDS accessible, fire extinguisher charged, PPE available and worn, biohazard containers labeled.

5 Day of Inspection

Designate one primary contact. Make all records accessible. Answer honestly. If something is not done, say so and explain your plan. Inspectors appreciate transparency.

QUICK TIP: Print this countdown and start working through it now.

TOP CLIA CITATION CATEGORIES



Common CLIA inspection citation areas

BOTTOM LINE: Print this countdown and work through it step by step. The best time to start is now, not when you get the inspection notification.

FREE TOOLS TO GET STARTED

Template	What It Does
CLIA Inspection 30-Day Checklist	Complete checklist with phases, status tracking, and due dates

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