StaffReady

CAP Inspection Readiness Checklist

Use this checklist to identify and close compliance gaps based on the Top 10 CLIA deficiencies. Each section corresponds to a known risk area during inspections.

1	Personnel Competency Assessment
☐	6-month and 12-month competency assessments completed for all new staff
☐	All 6 CAP-required elements documented per test system
☐	Records stored by employee and test System

2	Reagent and Control Storage Conditions
☐	Temperature logs maintained with date/time/initials
☐	Storage conditions meet manufacturer specifications
☐	Evidence of daily review implemented for temperature excursions

3	Twice-Yearly Verification of Test Performance
☐	Scheduled QC review every 6 months
☐	Review documented with signatures, dates, and summary of findings
☐	Corrective actions implemented if trends or biases are identified

4	Verification of Performance Specifications for New Tests
☐	New tests validated before use
☐	Verification includes accuracy, precision, and reportable range
☐	Validation records centrally stored

5	Personnel Testing: Mishandling, Documentation, and Follow-Up
☐	PT samples handled as patient specimens
☐	Lab director reviews all PT results
☐	Corrective actions documented for all PT failures

6	Incomplete or Inaccurate Procedure Manuals
☐	SOPs reviewed and acknowledged annually
☐	Procedures match current practices and obsolete versions are properly controlled.
☐	Electronic audit trail maintained for all SOPs

7	Test System Failures Not Documented or Investigated
☐	Failures logged immediately upon occurrence
☐	Root cause analysis conducted for each event
☐	CAPA process documented and tracked

8	QC Review Not Performed Twice Per Year
☐	QC data reviewed twice per year
☐	Apply Westgard Rules to analyze trends
☐	Documentation of findings and decisions

9	Proficiency Testing Results Not Reviewed or Acted Upon
☐	All PT reviewed by the lab director
☐	Failures investigated and corrected
☐	Follow-up actions documented

10	Incomplete or Missing Test Records
☐	All test records include timestamps, initials, with corrective actions not obscuring original entry
☐	Logs stored consistently across departments
☐	Internal audits performed to confirm completeness