CLIA Mock Inspection Checklist

Sound Lab Consultants · soundlabconsult.com/clia-mock-inspection · Last reviewed November 25, 2026. General information, not legal advice; confirm current rules with CMS, your state agency and your accreditor. A mock inspection does not replace an official survey. Book a free consultation: https://calendar.app.google/9Cb6LrwFMurwbTJRA

Done	#	Section	Task	Suggested owner	Reference
[ ]	1	1. Timing and scope	Confirm the expected official survey or inspection window and schedule the mock 3 to 6 months beforehand	Lab director / owner	
[ ]	2	1. Timing and scope	Also schedule a focused mock after a new test or instrument, a leadership change, a move, a complexity change, or a prior deficiency	Lab director	
[ ]	3	1. Timing and scope	Plan at least a full day on site or a full-day remote review; add time for high complexity, multiple instruments or several specialties	Project lead	
[ ]	4	1. Timing and scope	Select at least one test or patient specimen to trace end to end (order, handling, testing, QC records, reporting)	Technical consultant / supervisor	
[ ]	5	2. Certificate and general (Subparts A–D, J)	CLIA certificate type, number and site address match the tests performed and the testing location	Lab director / owner	42 CFR 493.43–493.63; 493.35–493.39
[ ]	6	2. Certificate and general (Subparts A–D, J)	CMS-116 updates filed for director, name, address, ownership or test-menu changes	Owner / consultant	CMS-116; certificate-change rules
[ ]	7	2. Certificate and general (Subparts A–D, J)	State clinical laboratory license current, if the state requires one	Owner	State law
[ ]	8	2. Certificate and general (Subparts A–D, J)	Facility, space, utilities and safety support the testing performed (ventilation, sinks, storage, emergency equipment)	Lab director	42 CFR 493.1101
[ ]	9	2. Certificate and general (Subparts A–D, J)	Record retention schedule meets 42 CFR 493.1105 (and longer immunohematology/pathology periods)	Supervisor	42 CFR 493.1105
[ ]	10	3. Preanalytic systems	Written requisition / order procedures; required elements present on a sample of recent orders	Supervisor	42 CFR 493.1241
[ ]	11	3. Preanalytic systems	Specimen collection, labeling, transport, accessioning and storage procedures in use at the bench	Supervisor	42 CFR 493.1242
[ ]	12	3. Preanalytic systems	Written rejection criteria applied and documented when specimens are unacceptable	Supervisor	42 CFR 493.1242
[ ]	13	3. Preanalytic systems	Preanalytic quality assessment performed and problems corrected	Supervisor	42 CFR 493.1249
[ ]	14	4. Procedures and test systems	Written procedure manual for every test, approved, signed and dated by the laboratory director before use	Lab director	42 CFR 493.1251
[ ]	15	4. Procedures and test systems	Procedures accessible to testing personnel; discontinued procedures retained 2 years	Supervisor	42 CFR 493.1251; 493.1105
[ ]	16	4. Procedures and test systems	Test systems, reagents, materials and supplies stored and used as required; expired reagents removed	Supervisor	42 CFR 493.1252
[ ]	17	4. Procedures and test systems	Manufacturer instructions followed for unmodified FDA-cleared or approved tests	Supervisor	42 CFR 493.1253; 493.1251

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[ ]	18	5. Method verification and validation	Performance specifications verified for unmodified FDA-cleared or approved tests (accuracy, precision, reportable range, reference intervals)	Lab director / supervisor	42 CFR 493.1253(b)(1)
[ ]	19	5. Method verification and validation	Performance specifications established for modified tests and LDTs (including analytical sensitivity, specificity and interferences as applicable)	Lab director	42 CFR 493.1253(b)(2)
[ ]	20	5. Method verification and validation	Director review and sign-off on each verification or validation file before patient testing	Lab director	42 CFR 493.1253
[ ]	21	6. Maintenance, calibration and QC	Maintenance and function checks documented on the required schedule	Supervisor	42 CFR 493.1254
[ ]	22	6. Maintenance, calibration and QC	Calibration and calibration verification performed at least every 6 months and when otherwise required	Supervisor	42 CFR 493.1255
[ ]	23	6. Maintenance, calibration and QC	Control procedures meet 42 CFR 493.1256, or a complete IQCP is in use where permitted	Supervisor	42 CFR 493.1256
[ ]	24	6. Maintenance, calibration and QC	QC reviewed, signed and acted on; patient results not reported when QC is unacceptable	Supervisor	42 CFR 493.1256; 493.1282
[ ]	25	6. Maintenance, calibration and QC	Corrective action documented when controls, calibration or instruments fail	Supervisor	42 CFR 493.1282
[ ]	26	6. Maintenance, calibration and QC	Specialty QC procedures followed (for example microbiology media and stains, blood bank, etc.)	Supervisor	42 CFR 493.1261–493.1278
[ ]	27	7. Proficiency testing (Subpart H)	Enrollment in an HHS-approved PT program for each regulated analyte	Supervisor	42 CFR 493.801
[ ]	28	7. Proficiency testing (Subpart H)	PT samples tested like patient specimens, by routine testing personnel, on routine instruments	Testing personnel / supervisor	42 CFR 493.801
[ ]	29	7. Proficiency testing (Subpart H)	No interlaboratory communication or referral of PT samples before the due date	Lab director	42 CFR 493.801
[ ]	30	7. Proficiency testing (Subpart H)	Attestation signed; results reviewed; unsuccessful events investigated with corrective action	Lab director / supervisor	42 CFR 493.801; 493.807–493.861
[ ]	31	7. Proficiency testing (Subpart H)	Twice-yearly alternative assessment documented for analytes without a PT program	Supervisor	42 CFR 493.1236
[ ]	32	8. Personnel (Subpart M)	Laboratory director qualified for the certificate complexity, with diploma/transcript and license on file	Owner / director	42 CFR 493.1405, 493.1443
[ ]	33	8. Personnel (Subpart M)	Technical consultant (moderate complexity) or technical supervisor (high complexity) qualified and on file	Lab director	42 CFR 493.1409–493.1411; 493.1447–493.1449
[ ]	34	8. Personnel (Subpart M)	Clinical consultant, general supervisor and testing personnel qualified for assigned duties	Lab director	42 CFR 493 Subpart M
[ ]	35	8. Personnel (Subpart M)	Written duties and delegations current; director responsibilities not over-delegated	Lab director	42 CFR 493.1407, 493.1445
[ ]	36	8. Personnel (Subpart M)	Training documented before independent testing on each test system	Technical consultant / supervisor	
[ ]	37	8. Personnel (Subpart M)	Competency assessment uses all six elements, is test-system specific, semiannual in year one and annual thereafter	Technical consultant / supervisor	42 CFR 493.1413(b)(8); 493.1451(b)(8)

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[ ]	38	8. Personnel (Subpart M)	Competency repeated when methods or instruments change; unsuccessful competency has documented follow-up	Technical consultant / supervisor	42 CFR 493.1413(b)(8); 493.1451(b)(8)
[ ]	39	9. Reporting and postanalytic systems	Test reports include required elements and go only to authorized persons	Supervisor	42 CFR 493.1291
[ ]	40	9. Reporting and postanalytic systems	Critical-value (alert) notification procedure followed and documented	Supervisor	42 CFR 493.1291
[ ]	41	9. Reporting and postanalytic systems	Amended or corrected reports issued and the original identified as corrected	Supervisor	42 CFR 493.1291
[ ]	42	9. Reporting and postanalytic systems	Postanalytic quality assessment performed and problems corrected	Supervisor	42 CFR 493.1299
[ ]	43	10. Quality assessment	Ongoing QA covers preanalytic, analytic and postanalytic systems	Lab director	42 CFR 493.1200; 493.1239
[ ]	44	10. Quality assessment	Complaints, errors, delayed reports and communication failures logged and investigated	Supervisor	42 CFR 493.1239
[ ]	45	10. Quality assessment	Comparison of test results when a lab uses different methods or sites for the same analyte	Supervisor	42 CFR 493.1281
[ ]	46	10. Quality assessment	Document control: current versions in use; obsolete forms and SOPs removed from benches	Supervisor	42 CFR 493.1105; 493.1251
[ ]	47	11. Day-of tracer and interviews	Opening conference: certificate, org chart, test menu, recent changes, PT events, prior deficiencies	Project lead	
[ ]	48	11. Day-of tracer and interviews	Laboratory tour: workflow, labeling, reagent storage, expired-material control, safety	Project lead	42 CFR 493.1101
[ ]	49	11. Day-of tracer and interviews	Staff can locate the SOP, current lot, today's QC and the procedure for failed QC or instrument flags	Testing personnel	
[ ]	50	11. Day-of tracer and interviews	Personnel file and method-validation file pulled for the person and test used in the tracer	Technical consultant / supervisor	
[ ]	51	11. Day-of tracer and interviews	Closing conference: preliminary findings reviewed with the director and supervisors	Lab director	
[ ]	52	12. Findings, plan of correction and follow-up	Each finding cited to 42 CFR 493 (and D-tag) or the accreditor checklist item	Consultant / project lead	SOM Appendix C; accreditor checklist
[ ]	53	12. Findings, plan of correction and follow-up	Condition-level concerns separated from standard-level findings	Consultant / lab director	42 CFR 493 Subpart R
[ ]	54	12. Findings, plan of correction and follow-up	Plan of correction for each finding: action, owner, due date and monitoring so it does not recur	Lab director	Form CMS-2567 practice
[ ]	55	12. Findings, plan of correction and follow-up	Corrective evidence collected (signed SOP, training, QC, PT, validation) and retained	Supervisor	
[ ]	56	12. Findings, plan of correction and follow-up	High-risk findings re-checked before the official survey window	Lab director / consultant	

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