Lab Setup and Compliance Checklist (5 stages: planning, design, acquisition, installation, validation)

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Done	#	Stage	Task	Suggested owner	Reference
[ ]	1	1. Planning	Define test menu and CLIA complexity for each test	Lab director / owner	42 CFR 493.5, 493.15, 493.20, 493.25
[ ]	2	1. Planning	Forecast volume, specimen types and turnaround needs	Lab leadership	
[ ]	3	1. Planning	Map 6 to 12 month timeline backward from go-live date	Project manager	
[ ]	4	1. Planning	Name project team: lab leadership, facilities, EHS, IT/LIS, purchasing, finance	Owner	
[ ]	5	1. Planning	Budget by category: construction, casework, HVAC/electrical, water, safety equipment, instruments, LIS/LIMS, reagents/QC, PT, fees, staffing, training	Finance	
[ ]	6	1. Planning	Add 10-15% contingency reserve	Finance	
[ ]	7	1. Planning	Check state lab license and personnel license rules; confirm zoning for lab use	Owner / consultant	State law; soundlabconsult.com/states-that-require-a-clinical-laboratory-license
[ ]	8	2. Design	Floor plan with unidirectional workflow (receiving > processing > testing > reporting)	Architect / lab director	42 CFR 493.1101
[ ]	9	2. Design	Separate pre-amplification, amplification and detection areas for open molecular testing	Architect / lab director	42 CFR 493.1101(a)(3)
[ ]	10	2. Design	Physical barriers, pass-throughs, splash shields; Class II biosafety cabinets per risk assessment	EHS	CDC/NIH BMBL
[ ]	11	2. Design	Chemical storage with segregation of incompatibles (acids/bases, oxidizers/flammables)	EHS	29 CFR 1910.1450; 1910.1200
[ ]	12	2. Design	Eyewash stations and safety showers where corrosives are used	EHS / facilities	29 CFR 1910.151(c); ANSI/ISEA Z358.1
[ ]	13	2. Design	Chemical fume hood for volatile or toxic chemicals	Facilities	
[ ]	14	2. Design	Utilities: dedicated circuits, UPS, water purity, HVAC temperature/humidity, network drops, monitored cold storage	Facilities / IT	
[ ]	15	2. Design	Biohazard and sharps waste path; hand-wash sinks	EHS	29 CFR 1910.1030; state waste rules
[ ]	16	3. Acquisition	Select instruments on reliability, service coverage, warranty, reagent supply and menu fit	Lab director / purchasing	
[ ]	17	3. Acquisition	Confirm FDA status of each assay (cleared/approved vs modified/LDT)	Lab director	42 CFR 493.1253
[ ]	18	3. Acquisition	Select LIS/LIMS; scope instrument and EHR/billing interfaces	IT / lab leadership	

Done	#	Stage	Task	Suggested owner	Reference
[ ]	19	3. Acquisition	Order reagents, calibrators and QC material (two levels for quantitative tests)	Supervisor	42 CFR 493.1256
[ ]	20	3. Acquisition	Enroll in proficiency testing for regulated analytes	Supervisor	42 CFR 493 Subpart H
[ ]	21	3. Acquisition	File CMS-116 for correct CLIA certificate type	Owner / consultant	CMS-116
[ ]	22	3. Acquisition	Apply for state license and accreditation (CAP, COLA or TJC) if chosen	Owner / consultant	
[ ]	23	4. Installation	Installation Qualification (IQ) for each instrument	Vendor / supervisor	
[ ]	24	4. Installation	Operational Qualification (OQ) for each instrument	Vendor / supervisor	
[ ]	25	4. Installation	Temperature, water and environment checks recorded	Supervisor	
[ ]	26	4. Installation	LIS build, report template and interface testing end to end	IT / supervisor	42 CFR 493.1291
[ ]	27	4. Installation	Hire qualified director, supervisors/consultants and testing personnel; build qualification files	Owner	42 CFR 493 Subpart M
[ ]	28	4. Installation	Document training on each test, instrument, LIS and safety	Supervisor	
[ ]	29	4. Installation	Write procedure manual; director approves, signs and dates	Lab director	42 CFR 493.1251
[ ]	30	4. Installation	Exposure control plan, Chemical Hygiene Plan, hepatitis B vaccination offer, safety training	EHS	29 CFR 1910.1030; 1910.1450
[ ]	31	4. Installation	QC plan / IQCP, PT plan, quality assessment plan, document control and record retention	Supervisor	42 CFR 493.1256; 493.1105
[ ]	32	5. Validation	Performance Qualification (PQ)	Supervisor	
[ ]	33	5. Validation	Verify accuracy, precision, reportable range, reference intervals (unmodified FDA tests)	Supervisor / director	42 CFR 493.1253(b)(1)
[ ]	34	5. Validation	Full validation incl. analytical sensitivity, specificity, interferences (modified tests/LDTs)	Director	42 CFR 493.1253(b)(2)
[ ]	35	5. Validation	Calibration and calibration verification schedule set	Supervisor	42 CFR 493.1255
[ ]	36	5. Validation	Initial competency assessment, six elements, per test system	Technical consultant / supervisor	42 CFR 493.1413, 493.1451
[ ]	37	5. Validation	Mock survey against CLIA and accreditor checklist	Consultant	
[ ]	38	5. Validation	Director sign-off on validation reports; go-live approval	Lab director	

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