WELLNESS & CARE GROUP OF TEXAS
YOUR PARTNER IN SUCCESS

TEXAS FREESTANDING EMERGENCY ROOM
LABORATORY SURVEY-READINESS CHECKLIST
CLIA • COLA • TEXAS HHSC • JOINT COMMISSION

Facility: _____ **CLIA #:** _____ **Laboratory Directo** _____ **Review Month/Yea** _____

Reviewed By: _____ **Date:** _____ **Status Key:** ☐ C = Compliant ☐ D = Deficient ☐ N/A = Not Applicable

PAGE 1 - REGULATORY & TECHNICAL READINESS

#	Survey-Readiness Item	CLIA	COLA	HHSC	TJC	C	D	N/A	Corrective Action / Finding	Due
1	Current CLIA certificate is available and displayed/maintained as required. Certificate type matches actual testing complexity.	X	X	X	X	☐	☐	☐		
2	Laboratory does not perform testing exceeding the complexity authorized by its CLIA certificate.	X	X	X	X	☐	☐	☐		
3	Current COLA accreditation certificate/status is available when COLA is the laboratory accreditor.		X			☐	☐	☐		
4	Laboratory Director designation is current and qualifications are documented for the testing performed.	X	X		X	☐	☐	☐		
5	Current laboratory test menu identifies test, method/instrument, specimen, and CLIA complexity.	X	X	X	X	☐	☐	☐		
6	FSER has required emergency laboratory capability available on premises, including cardiac markers, hematology, chemistry, and pregnancy testing.	X	X	X		☐	☐	☐		
7	Current written procedure is available for every laboratory test performed.	X	X		X	☐	☐	☐		
8	Procedures have appropriate Laboratory Director/authorized approval and review documentation.	X	X		X	☐	☐	☐		
9	Current manufacturer Instructions for Use are readily accessible to personnel.	X	X		X	☐	☐	☐		
10	Testing is performed according to required manufacturer IFU instructions; unauthorized modifications are not being made.	X	X		X	☐	☐	☐		
11	Patient identification process uses required identifiers before specimen collection/testing.	X	X		X	☐	☐	☐		
12	Specimens are labeled accurately and traceable to the correct patient.	X	X		X	☐	☐	☐		
13	Written specimen collection, handling, transport, storage, stability, and rejection criteria are available and followed.	X	X		X	☐	☐	☐		
14	Required Quality Control is performed at the correct frequency and documented.	X	X		X	☐	☐	☐		
15	QC results are reviewed for acceptability before affected patient results are released.	X	X		X	☐	☐	☐		
16	Failed/out-of-range QC is investigated and corrective action is documented before patient testing resumes.	X	X		X	☐	☐	☐		
17	Calibration/calibration verification and required function checks are current for applicable analyzers.	X	X		X	☐	☐	☐		
18	Required analyzer maintenance and preventive maintenance are current and documented.	X	X		X	☐	☐	☐		
19	Reagents, controls, cartridges, and kits are within expiration date and stored according to requirements.	X	X		X	☐	☐	☐		
20	Refrigerator/freezer/room-temperature logs are current; excursions have documented investigation and disposition.	X	X		X	☐	☐	☐		
21	Lot numbers and expiration dates can be correlated with QC and/or patient testing when required.	X	X		X	☐	☐	☐		
22	Laboratory can trace patient testing to operator, instrument/method, date/time, result, and associated QC.	X	X		X	☐	☐	☐		
23	Proficiency Testing enrollment covers applicable regulated nonwaived analytes.	X	X		X	☐	☐	☐		
24	PT samples are tested appropriately, with attestations and required records maintained.	X	X		X	☐	☐	☐		
25	Unacceptable/unsatisfactory PT performance receives documented investigation, corrective action, and follow-up.	X	X		X	☐	☐	☐		
26	IQCP is complete and current for any eligible test system operating under an Individualized Quality Control Plan.	X	X		X	☐	☐	☐		
27	Reference/contract laboratories have current appropriate CLIA certification and applicable credentials.	X	X	X	X	☐	☐	☐		
28	Laboratory downtime plan addresses analyzer failure, LIS/EMR failure, power failure, reagent shortage, and backup testing.	X	X	X	X	☐	☐	☐		

IMMEDIATE-ATTENTION FINDINGS

Critical Finding(s): _____ **Immediate Action:** _____ **Owner:** _____ **Due:** _____

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PAGE 2 - PERSONNEL, PATIENT SAFETY, QUALITY & QAPI

#	Survey-Readiness Item	CLIA	COLA	HHSC	TJC	C	D	N/A	Corrective Action / Finding	Due
29	Qualifications of all laboratory/testing personnel are documented and appropriate for tests performed.	X	X		X	☐	☐	☐		
30	Testing personnel receive documented training before independent testing.	X	X		X	☐	☐	☐		
31	Initial and ongoing competency assessments are current and documented as applicable to test complexity.	X	X		X	☐	☐	☐		
32	Competency assessments use the required number and types of assessment methods for applicable testing.	X	X		X	☐	☐	☐		
33	Staff performing instrument-based waived testing have documented training and required ongoing competency.		X		X	☐	☐	☐		
34	Only authorized and competent personnel have access to perform/report laboratory tests.	X	X		X	☐	☐	☐		
35	Critical-value list is formally established/approved by medical staff or appropriate leadership.	X	X	X	X	☐	☐	☐		
36	Critical laboratory values are communicated promptly to the physician/LIP and communication is documented.	X	X	X	X	☐	☐	☐		
37	Process addresses critical results discovered after patient discharge.		X	X	X	☐	☐	☐		
38	Laboratory reports contain required patient/result information and are integrated into the medical record.	X	X	X	X	☐	☐	☐		
39	Corrected/amended result process preserves the original result and documents reason, date/time, and notification when applicable.	X	X		X	☐	☐	☐		
40	Appropriate reference intervals/ranges are available to clinicians interpreting results.	X	X		X	☐	☐	☐		
41	Laboratory turnaround time is monitored for key emergency tests.		X		X	☐	☐	☐		
42	Delays in critical/emergency testing are analyzed and corrected when performance falls outside facility goals.	X	X		X	☐	☐	☐		
43	Mislabeled, unlabeled, rejected, contaminated, hemolyzed, and recollected specimens are tracked.	X	X		X	☐	☐	☐		
44	Laboratory-related incidents, errors, near misses, and complaints are reported and investigated.	X	X		X	☐	☐	☐		
45	Laboratory Quality Assessment addresses preanalytic, analytic, and postanalytic processes.	X	X		X	☐	☐	☐		
46	Laboratory QA/QAPI activities identify measurable problems, interventions, responsible owners, and outcomes.	X	X	X	X	☐	☐	☐		
47	Previous corrective actions are followed through to determine whether they were effective and sustained.	X	X	X	X	☐	☐	☐		
48	Monthly laboratory quality indicators are reported to facility Quality/QAPI leadership as applicable.		X	X	X	☐	☐	☐		
49	Chemical safety policies, SDS access, PPE, exposure response, and hazardous-material practices are current.	X	X	X	X	☐	☐	☐		
50	Sharps/bloodborne-pathogen practices and biohazard-waste handling are compliant with facility policy and applicable requirements.		X	X	X	☐	☐	☐		
51	Emergency eyewash/safety equipment is accessible and checked according to policy when required by laboratory hazards.		X	X	X	☐	☐	☐		
52	Blood/blood components, if maintained, meet required storage, temperature, emergency power, transfusion, and documentation requirements.	X	X	X	X	☐	☐	☐		
53	New instruments/test methods receive required verification/validation before reporting patient results.	X	X		X	☐	☐	☐		
54	New reagent/kit lots receive required verification before routine use where applicable.	X	X		X	☐	☐	☐		
55	Records are retained for the required period and can be produced promptly during a survey.	X	X	X	X	☐	☐	☐		
56	Previous CLIA/COLA/HHSC/Joint Commission laboratory citations have documented correction and evidence preventing recurrence.	X	X	X	X	☐	☐	☐		

MONTHLY LABORATORY QUALITY DASHBOARD

Indicator	Current	Goal	Prior	Trend / Action
Specimen identification errors		0		
Specimen rejection/recollection rate		Facility Goal		
QC failures		Facility Goal		
Unresolved QC failures		0		
PT score / deficiencies		100% / 0		
Critical-value notification compliance		100%		
Critical-value notification turnaround		Facility Goal		
Troponin turnaround time		Facility Goal		
CBC turnaround time		Facility Goal		
Chemistry turnaround time		Facility Goal		
Analyzer downtime		Facility Goal		
Temperature excursions		0 unresolved		
Staff competency compliance		100%		
Expired reagent/supply findings		0		
Laboratory incidents / near misses		Trend review		

CORRECTIVE ACTION & EFFECTIVENESS TRACKER

Finding	Immediate	Root Cause	Corrective Action	Owner	Due	Effectiveness	Status

MONTHLY LEADERSHIP REVIEW

HIGH - What went well?

LOW - What did not meet expectations?

BLOCKER - What is preventing compliance or improvement?

DECISION NEEDED - What requires leadership action?

SURVEY-READINESS STATUS

☐ Survey Ready ☐ Minor Corrective Actions ☐ Corrective Action Required ☐ Immediate Leadership Review

SIGN-OFF

Laboratory Lead / Manager _____ **Laboratory Director** _____

Facility Administrator _____ **Medical Director** _____

CLOSING STANDARD: FINDING → IMMEDIATE CORRECTION → ROOT CAUSE → CORRECTIVE ACTION → MEASUREMENT → EFFECTIVENESS VERIFIED → CLOSED

References: CLIA / 42 CFR Part 493; Texas HHSC 26 TAC Chapter 509, including §509.49; current COLA Accreditation Manual; current Joint Commission standards/guidance applicable to the organization and testing scope. Internal readiness tool only; does not replace current manuals or manufacturer IFUs.