CLINICAL LABORATORY AUDIT TOOL

Unit: _____Lab: _____ Date: _____ Auditor: _____

1. Organization				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Design of organization structure to ensure quality	The Unit/lab organizational chart is accurate and available. Duties of personnel in the chart are defined.	□ Yes □ No		
Additional comments:				

2. Personnel				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Qualifications	Education records for new personnel demonstrate that they meet the CLIA requirements for their testing or supervisory position.	□ Yes □ No		
Management of personnel training	Training records for new hires have complete dates and initials and are neatly maintained.	□ Yes □ No		
Assessment of competence	Records for competency assessment indicate assessments at “6” months (new hires) and annual.	□ Yes □ No		
	Records for competency assessment follow CLIA requirement for all 6 procedures on each test.	□ Yes □ No		
Additional comments:				

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3. Documents and Records				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Process for identification and control of documents	All posted quick reference notes (i.e. job aides are referenced to the procedure manual.	□ Yes □ No		
Procedure Manual is current, accurate and approved by lab director.	All technical procedures are in current template approved by Lab Director.	□ Yes □ No		
	All technical procedures are accurate for testing performed.	□ Yes □ No		
	Procedures are available for using Starlims other computer programs if required for testing.	□ Yes □ No		
Product Inserts/assay sheets	Product inserts/assay sheets used for tes are stored for 2 years and available.	□ Yes □ No		
Additional comments:				

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Unit: _____Lab: _____ Date: _____ Auditor: _____

4. Equipment and Reagents				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Maintenance logs and records	Maintenance manual and maintenance records are current. Record keeping is consistent and complete. Supervisor review is evident.	□ Yes □ No		
Ancillary equipment	Preventative maintenance is performed and records are available for pipets, balances, etc.	□ Yes □ No		
Temperature records	Temperature records are complete and reviewed. Temp and humidity are monitored as required for testing.	□ Yes □ No		
Reagents and Supplies	If prepared in house, are QC records available and are reagents labeled with lot # and expiration date.	□ Yes □ No		
	Do purchased reagents & media match SOP? Are containers dated when open?	□ Yes □ No		
	Are all reagents and supplies stored at correct temperature and used within expiration date?	□ Yes □ No		
Additional comments:				

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5. Process Control				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Pre-Analytic	Information available to clients is current (Directory/Website) for specimen collection, labeling, and shipping.	□ Yes □ No		
	Lab follows policy for handling Unsats and Unsats are not tested.	□ Yes □ No		
Analytic	Testing is performed per SOP.	□ Yes □ No		
	Quality Control testing meets CLIA requirement. Lot #s are in date and use meets insert instructions.	□ Yes □ No		
	QC values are monitored for trends/shifts. Testing not reported if QC outside limits. Corrective action documented for OOR QC.	□ Yes □ No		
	Calibrations performed and documented if required. Cal. Verification/linearity @6mo if applicable.	□ Yes □ No		
	If multiple instruments, correlations performed @ 6 mos.	□ Yes □ No		
	Validation/verification performed for tests added w/in 2 years.	□ Yes □ No		

	Records document date of testing and who performed test.	□ Yes □ No		
Post-Analytic	Computer generated report complies with Regulatory requirements and disclaimers are present when required.	□ Yes □ No		
	Procedure for corrected reports. Corrected reports have required information and labeled as such.	□ Yes □ No		
	Samples, requisitions, and work records are stored appropriate and for required time period.	□ Yes □ No		
	Documentation of appropriate notification for "critical" values	□ Yes □ No		
Additional comments:				

6. Information Management				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Starlims and web reporting	Procedures are available and followed for using LIMS throughout process.	□ Yes □ No		
	Calculations are verified at least once / year.	□ Yes □ No		
	Web reporting checked periodically for availability and accuracy.	□ Yes □ No		

	If manual entry, how are results verified?	□ Yes □ No		
Additional comments:				

7. Nonconforming Event (NCE) Management				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Documentation of problems/occurrences/NCEs	Staff have access to and are aware of how to document NCEs.	□ Yes □ No		
	Customers are notified of significant testing delays.	□ Yes □ No		
	Laboratory documents problems and NCEs.	□ Yes □ No		
Additional comments:				

8. Proficiency Testing (Internal Assessment)				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Proficiency Testing performance and records	Lab/Unit is enrolled in PT for all analytes when it is available.	□ Yes □ No		
	PT records are complete: include raw data, submitted results, attestation, evaluation, reviews, corrected action.	□ Yes □ No		

	QA/correlation testing performed 2x year for all tests w/out PT.	□ Yes □ No		
Internal Audits and other assessments	Is there evidence that the laboratory has participated in internal audits or other assessments and, if so has taken and documented corrective actions when indicated.	□ Yes □ No		
Additional comments:				

9. Continual Improvements				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Quality Indicators	Quality Indicators are monitored and investigated when trends, outliers are found.	□ Yes □ No		
Quality Assessment	Is there documentation of supervisory review of QC and other work processes?	□ Yes □ No		
	Is there any evidence of QA Studies or other QA activities in the lab/Unit?	□ Yes □ No		
Additional comments:				

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10. Facilities and Safety				
QSE Requirement	Evidence of Compliance	Compliant	Comments	Response
Work Practices	Staff are using appropriate PPE for testing and adequate supplies are available for use.	□ Yes □ No		
Bio-Hazard	Observation: Bio-hazard materials are handled appropriately; safety procedures followed for test method.	□ Yes □ No		
Additional comments:				