



# 21 Audit Schedule \_January - July

MONTH	AREA	SYSTEM/PROCESS	REPORT OWNER
January	Extraction	On site walkthrough review of compliance with technical Procedures, Safety, Reagents, Instrumentation and Workflow	Operations Director, Wet Lab Managers, Extraction Supervisors
	All Technical	Available and Signed Personnel Training Records for Regulatory Compliance	Operations Director Wet Lab Managers Supervisors
February	All Technical	Testing Processes for Proficiency Testing Regulatory Compliance (Complete Attestations Fall 2020)	Quality Manager
	All Areas	End to End Sample Tracer Audit for preanalytical, analytical and post analytical processes covering sample receipt, equipment qualification, maintenance GDP documentation, QC personnel qualification, training, competency documents, result reporting and corrected reports.	OPS Director, Wet Lab Managers, Supervisors
	All Areas	Reagent Labeling Compliance	OPS Director, Wet Lab Managers, Supervisors
	All Areas	Equipment Maintenance Logs: GDP compliance and regulatory compliance	OPS Director, Wet Lab Managers, Supervisors
March	All Areas	Document Control: Director Approval of Documents Employee Review of Documents	Lab Director, OPS Director, Wet Lab Managers, Supervisors
	Pre/Post PCR W-F/Day	On site walkthrough review of compliance with technical Procedures, Safety, Instrumentation and Workflow	Operations Director, Wet Lab Managers, PCR Supervisors
	All Areas	End to End Sample Tracer Audit for preanalytical, analytical and post analytical processes covering sample receipt, equipment qualification, maintenance GDP documentation, QC personnel qualification, training, competency documents, result reporting and corrected reports.	OPS Director, Wet Lab Managers, Supervisors
	Result Reporting	Corrected Reports: Review all instances and verify that original and amended versions are retained and available to the lab	Lab Director, Quality Manager
	Specimen Acceptability	Delayed Receipt Cancellation Report (LIMC Function) Request to IT	Lab Director, Quality Manager
	All Areas	Reagent Labeling Compliance	OPS Director, Wet Lab Managers, Supervisors
	All Areas	Equipment Maintenance Logs: GDP compliance and regulatory compliance	OPS Director, Wet Lab Managers, Supervisors
April	Accessioning	Specimen Receipt/Manifest Date/Time Stamp Audit	OPS Director, OPS Managers, Accession Supervisors
	Extraction W-F/Night	On site walkthrough review of compliance with technical Procedures, Safety, Reagents, Instrumentation and Workflow	OPS Director, Wet Lab Managers, Extraction Supervisors

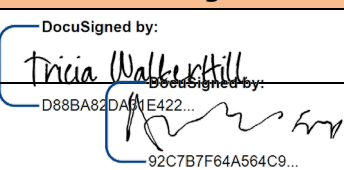
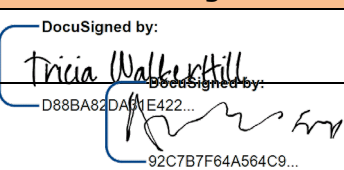


	Technical Employees	Personnel: Complete Competency documentation for employees trained in September (include compliance with GDP)	OPS Director, Wet Lab Managers, Supervisors
	All Areas	End to End Sample Tracer Audit for preanalytical, analytical and post analytical processes covering sample receipt, equipment qualification, maintenance GDP documentation, QC personnel qualification, training, competency documents, result reporting and corrected reports.	OPS Director, Wet Lab Managers, Supervisors
	Results Reporting	Corrected Reports: Review all instances and verify that original and amended versions are retained and available to the lab	Lab Director, Quality Manager
	Specimen Acceptability	Delayed Receipt Cancellation Report (LIMC Function) Request to IT	Lab Director, Quality Manager
	All Areas	Reagent Labeling Compliance	OPS Director, Wet Lab Managers, Supervisors
	All Areas	Equipment Maintenance Logs: GDP and Regulatory Compliance	OPS Director, Wet Lab Managers, Supervisors
May	Accessioning W-F/Nights	On site walkthrough review of compliance with technical Procedures, Safety, Reagents, Instrumentation and Workflow	OPS Director, OPS Managers, Accession Supervisors
	All Areas	Safety Compliance: Personnel Training Documentation LMS/Media Lab; HSO walkthroughs, Fire Extinguishers, Showers, Eye Wash Logs	OPS Director, OPS & Wet Lab Managers
	All Employees	Information Management: LIMC User Security Access and Rights	IT Director, OPS Director, HR
	Technical Employees	Personnel: Complete Competency Documentation for employees trained in October (incl compliance with GDP)	Operations Director Wet Lab Managers Supervisors
	All Areas	End to End Sample Tracer Audit for preanalytical, analytical and post analytical processes covering sample receipt, equipment qualification, maintenance GDP documentation, QC personnel qualification, training, competency documents, result reporting and corrected reports.	OPS Director, Wet Lab Managers, Supervisors
	Result Reporting	Corrected Reports: Review all instances and verify that original and amended versions are retained and available to the lab	Lab Director, Quality Manager
	Specimen Acceptability	Delayed Receipt Cancellation Report (LIMC Function) Request to IT	Lab Director, Quality Manager
	All Areas	Reagent Labeling Compliance	OPS Directors, Wet Lab Managers, Supervisors
	All Areas	Equipment Maintenance Logs: GDP and Regulatory Compliance	OPS Directors, Wet Lab Managers, Supervisors
Jun	All technical Areas	Type A/B Equipment Maintenance Review (Pipettes, centrifuges, etc)	Operations Director Wet Lab Managers Supervisors
	Technical Employees	Personnel: Complete Competency Documentation for employees trained in November (incl compliance with GDP)	Operations Director Wet Lab Managers Supervisors
	All Areas	End to End Sample Tracer Audit for preanalytical, analytical and post analytical processes covering sample receipt, equipment qualification, maintenance GDP documentation, QC personnel qualification, training, competency documents, result reporting and corrected reports.	OPS Director, Wet Lab Managers, Supervisors

	Result Reporting	Corrected Reports: Review all instances and verify that original and amended versions are retained and available to the lab.	Lab Director, Quality Manager
	Specimen Acceptability	Delayed Receipt Cancellation Report (LIMC Function) Request to IT	Lab Director, Quality Manager
	All Areas	Reagent Labeling Compliance	OPS Directors, Wet Lab Managers, Supervisors
	All Areas	Equipment Maintenance Logs: GDP and Regulatory Compliance	OPS Directors, Wet Lab Managers, Supervisors
	Accessioning S-T/Nights	On site walkthrough review of compliance with technical Procedures, Safety, Reagents, Instrumentation and Workflow	OPS Director, OPS Managers, Accession Supervisors
JUL	Software	Automated Temperature Monitoring Audit	OPS Director, Wet Lab Managers, Supervisors
	Extraction S-W/Day	On site walkthrough review of compliance with technical Procedures, Safety, Reagents, Instrumentation and Workflow	OPS Director, Wet Lab Managers, Extraction Supervisors
	Technical Employees	Personnel: Complete Competency Documentation for employees trained in December (incl compliance with GDP)	OPS Director, Wet Lab Managers, Supervisors
	All Areas	End to End Sample Tracer Audit for preanalytical, analytical and post analytical processes covering sample receipt, equipment qualification, maintenance GDP documentation, QC personnel qualification, training, competency documents, result reporting and corrected reports.	OPS Director, Wet Lab Managers, Supervisors
	Result Reporting	Corrected Reports; Review all instances and verify that original and amended versions are retained and available to the lab.	Lab Director, Quality Manager
	Specimen Acceptability	Delayed Receipt Cancellation Report (LIMC Function) Request to IT	Lab Director, Quality Manager
	All Areas	Reagent Labeling Compliance	OPS Directors, Wet Lab Managers, Supervisors
	All Areas	Equipment Maintenance Logs: GDP and Regulatory Compliance	OPS Directors, Wet Lab Managers, Supervisors

Pre-Scheduled Audits for 1<sup>st</sup> half of 2021 approved as written. Additional audits may be added to the schedule based on review of non-conforming events and continuous improvement actions. Audit Schedule is reviewed and updated every 6 months.

**Reviewed and Approved:**

		Signature	Date
Quality Manager	Tricia Walker-Hill	 DocuSigned by: Tricia Walker-Hill	01 March 2021   1 : 14
Laboratory Director	Dr. Adam Rosendorff	 DocuSigned by: D88BA82DAD1E422... 92C7B7F64A564C9...	01 March 2021   1 : 14



