

CDPH Branch Laboratory Training Assessment of Quality Assurance Processes

Employee: Dr. Adam Rosendorff

Section/Unit: Quality Management

Responsibility	Proficient? (Yes/No)	Needs Improvement
Have a working knowledge of beginning to end sample testing process.	Yes	No
Understand the procedure of initiating and completing quality exception reports (QERs) and corrective and preventative actions (CAPAs), root cause analysis (RCA) and effectivity of change.	Yes	No
Have a working knowledge of the overall Quality Management Plan	Yes	No
Monitor and present key performance indicators as required at Monthly and Quarterly QA Meetings	Presents at CHHS/CDPH Level	No
Knowledge of the Audit Process, acknowledge the Audit Schedule and potential role as participant, auditor or responder.	Yes	No
Access test requisitions from the Color Genomics system (request or direct access)	Yes, indirect, request access.	No
Access patient test reports from the Color Genomics system (request or direct access)	Yes, indirect, request access	No
Receive communication from the LIMC Admin regarding issues with LIMC function or transmission problems.	Yes	No
Receive and review the laboratory update email sent nightly by the project manager; flag deviations to the attention of the Laboratory Director to determine if additional follow-up is needed.	Yes	No
Communicate with laboratory groups (VALQA, Laboratory Management, IT) via email as appropriate.	Yes	No

Signature (Employee): Self, Adam Rosendorff

Signature (Laboratory director): 

Date: 5/24/21

CDPH Branch Laboratory Training Assessment of Quality Assurance Processes

Employee: [REDACTED]

Section/Unit: Quality Management

Responsibility	Proficient? (Yes/No)	Needs Improvement
Have a working knowledge of beginning to end sample testing process.	Yes: Tracer Auditor for Mar End to End	No
Understand the procedure of initiating and completing quality exception reports (QERs) and corrective and preventative actions (CAPAs), root cause analysis (RCA) and effectivity of change.	Yes: Primary resource for monitoring & tracking Personnel documentation and interface with supervisors/managers.	No
Have a working knowledge of the overall Quality Management Plan	Yes	No
Monitor and present key performance indicators as required at Monthly and Quarterly QA Meetings	Yes: Primary resource for QMR monthly metrics for Personnel targets; See QMR April 2021 quality targets conducted 20 May2021	No
Knowledge of the Audit Process, acknowledge the Audit Schedule and potential role as participant, auditor or responder.	Yes; participates in scheduling monthly audits and documents observations, following audit plan, in the role of auditor (Personnel, Equipment Maintenance)	No
Access test requisitions from the Color Genomics system (request or direct access)	Not Assigned at this time	No
Access patient test reports from the Color Genomics system (request or direct access)	Not Assigned at this time	No
Receive communication from the LIMC Admin regarding issues with LIMC function or transmission problems	Not Assigned at this time	No
Receive and review the laboratory update email sent nightly by the project manager; flag deviations to the attention of the Laboratory Director to determine if additional follow-up is needed.	Not Assigned at this time	No
Communicate with laboratory groups (VALQA, Laboratory Management, IT) via email as appropriate.	Yes	No

Signature, Hershey Edwards: [REDACTED]

Date: 05/24/2021

Signature, Dr Adam Rosendorff, Laboratory director: 

Date: 5/24/21

CDPH Branch Laboratory Training Assessment of Quality Assurance Processes


Employee: [REDACTED]

Section/Unit: Quality Management

Responsibility	Proficient? (Yes/No)	Needs Improvement
Have a working knowledge of beginning to end sample testing process.	Yes: Tracer Auditor for Feb, Mar, Apr End to End Audits	No
Understand the procedure of initiating and completing quality exception reports (QERs) and corrective and preventative actions (CAPAs), root cause analysis (RCA) and effectivity of change.	Yes: Primary resource for Pre and Post Analytical Processes as well as Maintenance and Reagent documentation; interfaces with supervisors/managers	No
Have a working knowledge of the overall Quality Management Plan	Yes	No
Monitor and present key performance indicators as required at Monthly and Quarterly QA Meetings	Yes: compiled all WorkFlow Process targeted quality metrics for April 2021 QMR reviewed on 20 May 2021	No
Knowledge of the Audit Process, acknowledge the Audit Schedule and potential role as participant, auditor or responder.	Yes: participates in scheduling monthly audits and documents observations in creation of audit plans and the role of auditor (all types of audits); proficient as audit report writer	No
Access test requisitions from the Color Genomics system (request or direct access)	Yes – Access COLOR database; indirect request when interface is not working.	No
Access patient test reports from the Color Genomics system (request or direct access)	Yes – Access COLOR database; indirect request when interface is not working.	No
Receive communication from the LIMC Admin regarding issues with LIMC function or transmission problems.	Not Assigned at this time	No
Receive and review the laboratory update email sent nightly by the project manager; flag deviations to the attention of the Laboratory Director to determine if additional follow-up is needed.	Not Assigned at this time	No
Communicate with laboratory groups (VALQA, Laboratory Management, IT) via email as appropriate.	Yes	No


Signature, Paven Gahir: [REDACTED]

Date: 24 May 2021

Signature, Dr. Adam Rosendorff, Laboratory director: 

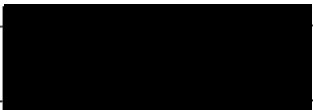
Date: 5/24/21

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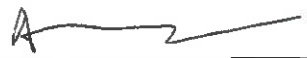
Employee: 

Section/Unit: Quality Management

Responsibility	Proficient? (Yes/No)	Needs Improvement
Have a working knowledge of beginning to end sample testing process.	Yes: Tracer Auditor for Apr End to End	No
Understand the procedure of initiating and completing quality exception reports (QERs) and corrective and preventative actions (CAPAs), root cause analysis (RCA) and effectivity of change.	Yes: Primary resource for monitoring & tracking QER/CAPA and interface with the supervisors/managers.	No
Have a working knowledge of the overall Quality Management Plan	Yes	No
Monitor and present key performance indicators as required at Monthly and Quarterly QA Meetings	Yes: Primary resource for QMR monthly metrics for QER/CAPA; See QMR April2021 conducted 20May2021	No
Knowledge of the Audit Process, acknowledge the Audit Schedule and potential role as participant, auditor or responder.	Yes – participates in scheduling monthly audits and documents observations in the role of auditor (Personnel and Equipment Maintenance).	No
Access test requisitions from the Color Genomics system (request or direct access)	Not Assigned at this time	No
Access patient test reports from the Color Genomics system (request or direct access)	Not Assigned at this time	No
Receive communication from the LIMC Admin regarding issues with LIMC function or transmission problems.	Not Assigned at this time	No
Receive and review the laboratory update email sent nightly by the project manager; flag deviations to the attention of the Laboratory Director to determine if additional follow-up is needed.	Not Assigned at this time	No
Communicate with laboratory groups (VALQA, Laboratory Management, IT) via email as appropriate.	Yes	No

Signature, Victor Militoysyan: 

Date: 24 MAY 2021

Signature, Dr. Adam Rosendorff, Director: 

Date: 5/24/21

CDPH Branch Laboratory Training Assessment of Quality Assurance Processes


Employee: [REDACTED] _____

Section/Unit: Quality Management

Responsibility	Proficient? (Yes/No)	Needs Improvement
Have a working knowledge of beginning to end sample testing process.	Yes: Tracer Auditor for Feb, Mar, Apr End to End Audits	No
Understand the procedure of initiating and completing quality exception reports (QERs) and corrective and preventative actions (CAPAs), root cause analysis (RCA) and effectivity of change.	Yes: Primary resource for monitoring & tracking Equipment Qualifications, Maintenance, Safety, Computer Software and Analytical Workflow Process & interface with supervisors/managers.	No
Have a working knowledge of the overall Quality Management Plan	Yes	No
Monitor and present key performance indicators as required at Monthly and Quarterly QA Meetings	Not Assigned at this time	No
Knowledge of the Audit Process, acknowledge the Audit Schedule and potential role as participant, auditor or responder.	Yes – Documents observations in the role of auditor (Equipment, Maintenance Log, Tracer Audits).	No
Access test requisitions from the Color Genomics system (request or direct access)	Yes – Indirect request	No
Access patient test reports from the Color Genomics system (request or direct access)	Yes – Indirect request	No
Receive communication from the LIMC Admin regarding issues with LIMC function or transmission problems.	Yes – primary problem solver/RCA with IT Admin for PQ, validations and tracer studies.	No
Receive and review the laboratory update email sent nightly by the project manager; flag deviations to the attention of the Laboratory Director to determine if additional follow-up is needed.	Not Assigned at this time	No
Communicate with laboratory groups (VALQA, Laboratory Management, IT) via email as appropriate.	Yes	No

Signature, Lynn Deng: [REDACTED] _____

Date: 24 May 2021 | 9:49 PM EDT

Signature, Dr. Adam Rosendorff, Laboratory director:  _____

Date: 5/24/21