BIOGENIX

POLICY PROCEDURE FOR ONGOING MONITORING OF LABORATORY PROCESSES

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2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3. REVIEW HISTORY

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4. POLICY STATEMENT

4.1 All laboratory procedures and processes shall be monitored on daily, weekly or monthly basis to ensure compliance, commitment, and adequate control.

4.2 This includes but not limited to the following:

- 4.2.1. Monitoring of daily processes:
  - 4.2.1.1. Pre - analytical
  - 4.2.1.2. Analytical
  - 4.2.1.3. Post - analytical
- 4.2.2. Inventory management
- 4.2.3. Equipment management
- 4.2.4. Proficiency testing (External quality control)
- 4.2.5. Staff training and competency assessment
- 4.2.6. Laboratory information system (LIS) management
- 4.2.7. Monitoring laboratory performance
- 4.2.8. Management for incidents
- 4.2.9. Waste management and spill management

5. PURPOSE

This policy and procedure describe the continuous monitoring of laboratory activities and processes in all sections of BIOGENIX Laboratory to ensure compliance and meet requirement of accreditation programs and satisfy customer needs and expectations.

6. SCOPE

Scope of this policy covers all the processes and procedures at BIOGENIX Laboratory.

7. DEFINITIONS

N.A.

8. ACRONYMS

8.1 POCT - Point of Care Testing
8.2 KPI - Key Performance Indicators
8.3 TAT - Turnaround Time
8.4 SOPs - Standard Operating Procedures
8.5 IQC - Internal Quality Control
8.6 EQC - External Quality Control
8.7 QC - Quality Control
8.8 IT - Information Technology

8.9 BME - Biomedical Engineer
8.10 PPM - Periodic Preventive Maintenance
8.11 CAP - College Of American Pathologist
8.12 CME - Continue Medical Education
8.13 LIS - Laboratory Information System
8.14 MSDS - Material Safety Data Sheet

9. RESPONSIBILITIES

9.1 It's the responsibility of the laboratory director / Deputy Director assigned to ensure that all procedures and processes were controlled and done appropriately according to defined policies and written procedures.

9.2 It is the responsibility of Technologist/ technicians and all laboratory staff to follow the laboratory director's instructions, complete all assigned procedures, and comply with hospital policies and procedures.

10. PROCEDURE

10.1 Monitoring of daily processes and procedures:

10.1.1 Pre-analytical

10.1.1.1 Test Order

a. To ensure that complete request and correct specimen / sample sent to the lab, this includes proper patient identification, correct number of specimens, correct collection tubes, and adequate specimen. Unsatisfactory request or specimen shall be rejected and documented in the specimen rejection form.
b. The laboratory director / Deputy Director assigned review all specimen rejection forms daily.
c. Quality department follows specimen rejection as laboratory KPI and perform analysis and corrective action if needed.

10.1.1.2 Specimen collection and transportation

a. Daily review of specimen collection, transportation, and temperature logs, by quality co-ordinator/Team leaders and monthly by Laboratory director.
b. Daily inspection of disposal of waste, storage and expiry of consumables to ensure safety procedures and minimize risk of exposure to incidents.

10.1.2 Analytical

It is the responsibility of laboratory director to ensure that all analytical procedures done according to written SOP's. This is monitored by reviewing daily, weekly and monthly all instrument records by laboratory director / Deputy Director assigned, and Team Leader/quality co-ordinator and section in-charges this includes:

10.1.2.1 Daily, weekly, and monthly instrument maintenance records (Reviewed monthly by laboratory director, daily by shift leaders and Team Leaders)

10.1.2.2 Calibration records (reviewed daily by shift leaders and Team Leaders)

10.1.2.3 IQC records (reviewed daily by shift leaders and Team Leaders and Quality Manager/ laboratory director (if needed))

10.1.2.4 EQC reports and corrective action (Quality Manager and Laboratory director review all CAP reports after receiving and approve corrective action reports)

10.1.2.5 Monthly QC charts (Prepared monthly by section in-charge or senior technologist, and reviewed by laboratory director/ Deputy Director/ quality Manager)

10.1.2.6 Critical result notification and documentation (Daily reviewed by laboratory director / Deputy Director)

10.1.2.7 STAT test result notification and documentation (Daily reviewed by laboratory director / Deputy Director)

10.1.3 Post-analytical

The laboratory director / Deputy Director or technologist assigned daily validates all patients result after technologist review in the department.

Post analytical procedures monitored daily and periodically to ensure:

10.1.3.1 Accurate Reporting of results.

10.1.3.2 Adequate reporting format, by periodic review of patient's reports and communication with IT department to update and design new templates (IF NEEDED).

10.1.3.3 Documentation of all amended and corrected reports

10.2 Inventory management:

The laboratory director and chief technologist ensures availability of reagents to provide the service without delaying any patient's results. This includes

10.2.1 Daily material consumption (Inventory logs)

10.2.2 Maintenance of minimum stock

10.2.3 Checking expiry, documentation for expired items

10.2.4 Placing orders, at the beginning of each month and when needed.

10.2.5 Reagent receiving and labelling

10.2.6 New reagent number verification

10.2.7 Daily checking refrigerator temperature and store room temperature and humidity to ensure proper storage conditions

10.3 Equipment management

The laboratory director ensures adequate functioning equipment to provide the service. BME departments maintain PPM, and corrective action maintenance for all laboratory equipment's.

Laboratory director maintain all records and perform periodic review for the following procedure:

10.3.1 Selection of new equipment
10.3.2 Completing Purchasing request and refer it to BME department for approval
10.3.3 Documentation of all validation experiments when new equipment or test is introduced.
10.3.4 Training of the staff on new equipment and documentation of training.
10.3.5 Complete maintenance records and schedule
10.3.6 Decommissioning or transfer of equipment by BME.

10.4 External quality control

The laboratory director and quality manager shall ensure participation in external QC programme for all laboratory tests. All aspects of the process from ordering to reporting should be controlled and monitored by laboratory director to ensure compliance. This includes:

10.4.1 Receiving of CAP survey specimens
10.4.2 Ensuring integrity of the samples when received
10.4.3 Distribution to appropriate section
10.4.4 Result entry online to CAP website
10.4.5 Validation of result by laboratory director
10.4.6 Report analysis and corrective action

10.5 Staff training and competency assessment

The laboratory director ensures proper staff training and competency assessment by reviewing all staff training and competency records, this includes:

10.5.1. New staff job specific training
10.5.2. Competency assessment
10.5.3. Continues training and CME

10.6 Laboratory information system management

The laboratory director and chief technologist ensures that LIS is functioning on 24 hours daily without any interruption or problems. Laboratory information management includes:

10.6.1 Training of new staff
10.6.2 Procedure when system is down
10.6.3 Mapping of new tests and retrieval of patients reports
10.6.4 Trouble shooting problems

10.7Monitoring laboratory performance

The laboratory director, and quality department selects appropriate KPI's that covers all laboratory phases. The laboratory director responsibilities include:

10.7.1 Laboratory KPI analysis
10.7.2 Reporting to quality department
10.7.3 Root cause analysis for unacceptable performance

10.8 Management for incident

The laboratory director reviews all laboratory incidents, this includes:

10.8.1 Documentation of laboratory incident
10.8.2 Reporting to quality department
10.8.3 Corrective action for specific problems

10.9 Waste management, spill management, and safety in the laboratory

In order to maintain safe environment for both customers and staff the laboratory director ensure compliance with all safety procedures and waste management in the laboratory, this includes:

10.9.1. Identifying laboratory wastes
10.9.2. Availability of MSDS
10.9.3. Management of Spills
10.9.4. Documentation of all incidents
10.9.5. Adherence to standard precautions

11. CROSS REFERENCE

11.1. HAAD clinical laboratory standards version I.
11.2. ISO 15189 Third Edition 2012-11-01 corrected version 2014-08-15, Medical laboratories- Requirements for quality and Competence

12. RELEVANT DOCUMENTS & RECORDS

12.1 BG/REC/GEN/058 Template for KPI Reports

	WHAT	WHO	WHEN	CORRECTIVE ACTION
1. Monitoring of daily processes and procedures **<u>1.1. Pre-analytical</u>** **Sample Collection**	1. Regular update of Sample Collection, policies and procedures (Policy and Procedures)	Sample collection Team Leader Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	As needed or when revision date is due	Update Policy And Procedures, and release of new versions. Distribution of new Policy And Procedures to collection areas Staff awareness if new Policy And Procedures implemented.
	2. Review of Sample Collection Techs competency assessment	Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Twice biannually and then annually	Re-assessment if deficiency reported
	3. Ensure availability of HAAD license	Chief Laboratory Technologist Laboratory Director / Designee	Monthly Quarterly review of availability of HAAD licenses	Refer to Chief Laboratory Technologist Refer to HR department to complete license.
	13 Checking proper inventory maintenance: ”expiry, stock, consumption, staff initials, …”	Sample Collection Team Leader / Assigned staff	Daily	Ensure compliance with standard procedures. Train staffs how to do consumption, check expiry, and document all actions.

	14 Checking all sample receiving logs and sheets	Chief Laboratory Technologist Sample receiving and collection Team leaders Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Weekly Daily Weekly Monthly	Regular monitoring by In-charge Phlebotomist Train staff how to fill all log and sheets Document training attendance sheet Competency re-assessment
	6 Checking Sample collection incident and error monitoring logs	Sample receiving and collection Team leaders Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Daily Weekly Monthly	Investigate possible causes of errors. Implement recommendations (e.g. staff training, material change…)
	7 Review of specimen rejection logs	Sample receiving and collection Team leaders Chief Laboratory Technologist Laboratory Director / Deputy Director	Daily	Collect and analyze data. Perform root cause analysis. Co-ordinate with concerned departments to implement remedial actions

	8 Review of waste segregation and management in the section	Sample collection Team leader / Assigned staff Chief Laboratory Technologist	Daily Random	Train and monitor the staff

	WHAT	WHO	WHEN	CORRECTIVE ACTION
1. Monitoring of daily processes and procedures	1 Ensure Correct Sample identification procedure followed by Lab sample reception counter that includes; correct specimen type, complete order, and correct labels. (By observation only)	Chief Laboratory Technologist Laboratory Director / Deputy Director	Daily If needed	Observe staff if properly matching and checking specimens, and labels. Train staff if deficiency reported Review of policy and procedures
1.1. Pre-analytical **1.1.2. Laboratory "sample accession"**	2. Check specimen rejection log	Chief Laboratory Technologist Laboratory Director / Deputy Director	Daily	Collect and analyze data Perform root cause analysis Co-ordinate with concerned departments to

				implement remedial actions
	3. Proper specimen handling transport, and storage (Observation)	Chief Laboratory Technologist Laboratory Director / Deputy Director	Daily Random	Staff training and re-assessment
	Daily review of laboratory specimen logs	Chief Laboratory Technologist Laboratory Quality Manager	Daily Random	Staff training and instruct to complete all logs to ensure compliance
	Review of all specimen reception logs (By observation only)	Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy director	Daily Monthly	Instruct staff to comply with standard laboratory procedures

	WHAT	WHO	WHEN	CORRECTIVE ACTION
1. Monitoring of daily processes and procedures	1. Review all instrument maintenance record (daily, weekly, and monthly)	Staff Assigned /Team Leader Chief Laboratory Technologist	Daily	Train and instruct staff to perform and document all maintenance procedures. Investigate recurrent problems with BME and service engineers

		Laboratory Quality Manager Laboratory Director / Designee	Monthly	
1.2. Analytical **1.2.1. General procedure**	2. Review of calibration report	Staff Assigned /Team Leader Chief Laboratory Technologist	Daily	Instruct staff to comply with calibration requirement.
	3. Review of IQC reports	Staff Assigned /Team Leader Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Daily Monthly	Train and instruct staff to comply with IQC procedures. Ensure corrective action is documented
	4. Review of IQC corrective action logs	Staff Assigned /Team Leader Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Daily Monthly	Train the staff how to do IQC corrective action and document their results.
	5. Review of specimen rejection forms	Chief Laboratory Technologist Laboratory Director / Deputy Director	Daily	Collect and analyze data Perform root cause analysis

				Co-ordinate with concerned departments to implement remedial actions
	6. Review of critical result notification forms and log sheet	Chief Laboratory Technologist Laboratory Director / Deputy Director	Daily	Follow KPI and emphasize on staff awareness in case of failure to notify within acceptable time

	WHAT	WHO	WHEN	CORRECTIVE ACTION
1. Monitoring of daily processes and procedures	1. Approve patient's reports in the LIS after primary review	Deputy Director Laboratory Director	Daily	Ensure availability of Lab pathologists to approve all patient reports
1.3. Post-analytical	2. Ensure accurate reporting of patient results and no pending tests (No clerical error/pending result) (correlate result to clinical data)	Lab Coordinator; review only clerical errors.	Daily	Instruct staff to review all tests according to our TAT.
		Laboratory Director / Designee	Daily	Investigate causes for delaying patients specimens

	3. Typing and consolidating the patient reports	Lab. Coordinator Deputy Director Laboratory Director	Daily	Train and instruct about the reporting formats.
	3. Ensure adequate reporting format	Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Co-ordinate with IT when needed	Investigate the causes
	4. Approve amended and corrected results, and ensure comments are added. (amended/corrected)	Chief Laboratory Technologist / Assigned staff Laboratory Quality Manager Laboratory Director / Deputy Director	When incident documented	Investigate the incident. Communicate with treating doctor to relay amended result.
	5. Document and archive amended reports	Chief Laboratory Technologist Laboratory Quality Manager	After approval by Lab Director / Deputy Director	Availability of tracking system for amended report Document amended reports

		Laboratory Director / Deputy Director		
	6. Monitoring of TAT	Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Daily	Investigate causes for delay

	WHAT	WHO	WHEN	CORRECTIVE ACTION
2. Inventory management	1. Review of daily material consumption (Inventory logs)	Assigned Lab Tech / Team Leader Chief Laboratory Technologist	Daily	Assign staff to do material consumption and maintain inventory records for each section
	2. Maintain minimum reagent stock	Assigned Lab Tech / Team Leader Chief Laboratory Technologist	Daily	Forecast monthly demand based on consumption
	3. Check expiry, documentation for expired items	Assigned Lab Tech / Team Leader	Daily	Order reagent with long expiry date Use near to expire first (FIFO)

		Chief Laboratory Technologist		
	4. Place orders, at the beginning of each month	Team Leader Chief Laboratory technologist	Monthly	Instruct In-charge staff to prepare their reagent demand on time
	5. Approve monthly demands	Laboratory Director / Deputy Director	Monthly	Order enough stock to maintain monthly balance.
	5. Verify new reagent lot number	All Laboratory staff Team Leader Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Designee	When new reagent lot is used	Train staff to do new reagent verification for each new lot
	6. Check refrigerator temperature, room temperature and humidity records and charts	Team Leader Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Daily Monthly	Instruct staff to check temperature daily. Contact BME if problems encountered

	WHAT	WHO	WHEN	CORRECTIVE ACTION

3. Equipment management	1. Purchase new equipment	Laboratory Director	As needed	Place order according to demand to Stores through BME department
	2. Perform verification study	Team Leader Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	New test/Analyzer	Plan for the validation study.
	3. Review of verification study	Laboratory Quality Manager Laboratory Director / Deputy Director	When new method introduced	Contact service engineer if failure reported
	4. Perform Calibration verification and linearity experiment (CVL)	Team Leader Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Twice a year	Review manufacturer specifications Repeat experiment under controlled condition
	5. Review of CVL and linearity study	Laboratory Quality Manager Laboratory Director /	Twice a year	Contact service engineer if failure reported

		Deputy Director		
	6. Approve Training on new equipment	Chief Laboratory Technologist Laboratory Director / Deputy Director	As needed	Reschedule training if needed
	7. Approve daily maintenance records	Chief Laboratory Technologist Laboratory Director / Deputy Director	monthly	Instruct staff to perform and document all maintenance procedures.
	8. Review of PPM and corrective maintenance.	Team Leader Chief Laboratory Technologist BME Laboratory Director / Deputy Director	As scheduled or needed	BME contact and arrange for PPM and corrective maintenance
	9. Approve Disposing or transferring of Lab equipment	Laboratory Director / Deputy Director BME	As needed	Co-ordinated with BME
	10. Decommissioning /transferring of Lab equipment	BME	As needed	BME coordinates with service engineer
	11. Review of equipment and maintenance policy	Laboratory Quality Manager	As scheduled	Update Policy And Procedures, and release of new versions.

		Laboratory Director / Deputy Director		Document staff awareness if new Policy And Procedures implemented.

	WHAT	WHO	WHEN	CORRECTIVE ACTION
4. External quality control	1. Order CAP survey	Laboratory Quality Manager Laboratory Director / Designee	Annual, or if needed	Place order for all in-house tests
	1. Receiving of CAP survey specimens	Staff assigned Laboratory Quality Manager Laboratory Director / Deputy Director	According to CAP calendar	Contact on-line CAP customer service
	2. Distribution to appropriate section	Staff assigned Laboratory Quality Manager Laboratory Director / Deputy Director	When new survey received	Staff training on EQC material handling and processing
	3. On-line result entry	Staff assigned	After testing has	Contact on-line CAP customer service.

	into CAP website	Laboratory Quality Manager Laboratory Director / Deputy Director	completed and before due date	
	4. Validation of CAP result	Laboratory Director / Deputy Director	After on-line result entry and before due date	Edit reports before due date. Contact on-line CAP customer service
	5. Report analysis and corrective action	Staff assigned /Team leader Laboratory Quality Manager Laboratory Director / Deputy Director	After receiving CAP report	Fill PT failure Investigation Checklist Contact service engineer if needed
	6. Approval of CAP reports and corrective action	Laboratory Director / Deputy Director	After reviewing and completing corrective action	Contact service engineer
	7. Review of all EQC policies and documents	Laboratory Quality Manager Laboratory Director / Deputy Director	As scheduled	Update Policy And Procedures, and release of new versions. Document staff awareness if new Policy And Procedures implemented.

	WHAT	WHO	WHEN	CORRECTIVE ACTION
5. Staff training and competency assessment	1. Conduct new staff training	Team Leader Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	At beginning of employment	Training and re-assessment
	2. Approves new staff training	Laboratory Director / Deputy Director	At end of training period	Training and re-assessment
	3. Competency assessment	Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Initial competency after 1 month Re-assessment after 6 month Then annual reassessment	Training and re-assessment Instruct staff to read Policy And Procedures
	4. Continues training and CME	All Lab staff Laboratory Director / Deputy Director	Monthly lectures	Instruct staff to attend CME and lectures
	5. Documentation of all training	Chief Laboratory Technologist	After laboratory Director /	Complete all competency assessment on time

	and competency records	Laboratory Quality Manager	Deputy Director approval	
	6. Review of staff training and competency policies	Laboratory Director / Deputy Director	As scheduled or if needed	Update Policy And Procedures, and release of new versions. Document staff awareness if new Policy And Procedures implemented.

	WHAT	WHO	WHEN	CORRECTIVE ACTION
6. Laboratory Information System	1.Training of new staff	Team Leader Chief Laboratory Technologist	After joining of new staff	Arrange IT training for the staff
	2. Procedure followed when system down	Chief Laboratory Technologist	When system down	Contact IT department
	3. Mapping of new tests and retrieval of patients reports	Chief Laboratory Technologist Laboratory Quality Manager	As needed	Contact IT department
	4. Trouble shooting IT problems	All Lab staff	If encountered	Contact IT department
7. Monitoring laboratory performance	1. Laboratory KPI data collection	Staff assigned Chief Laboratory Technologist	Monthly	Investigate delay in processing KPI data with Laboratory Director / Designee

		Laboratory Quality Manager Laboratory Director / Deputy Director		
	2. Approval of KPI results	Laboratory Director / Designee	Monthly	Review data collected
	2. Reporting to quality department	Laboratory Quality Manager Laboratory Director / Deputy Director	Monthly	Contact quality department
	3. Root cause analysis for unacceptable performance	Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	Monthly	Investigate possible causes of failure

	WHAT	WHO	WHEN	CORRECTIVE ACTION
8. Management for incident	1. Description of laboratory incident	All Laboratory Staffs	When incident occurred	Co-ordinate with quality department

	(OVR)	Laboratory Quality Manager Laboratory Director / Deputy Director		Discuss contributing factors Root cause analysis if frequently reported
	2. Reporting to quality department	Chief Laboratory Technologist Laboratory Quality Manager Laboratory Director / Deputy Director	When incident reported	Review action taken and recommendation
	3. Closing the incident (OVR)	Laboratory Director / Deputy Director Quality department	After completing all recommendation and corrective action	Ensure implementation of recommendations

	WHAT	WHO	WHEN	CORRECTIVE ACTION
Waste management and spill management	1. Identifying laboratory wastes	All Lab Staff Laboratory EHSMS representative	Daily	Review Waste management policy Arrange waste disposal training

		Laboratory Director / Deputy Director		Ensure Staff awareness is documented
	2. Ensure the availability of MSDS (periodic review of MSDS files)	Team Leader Chief Laboratory Technologist Laboratory EHSMS representative Laboratory Quality Manager Laboratory Director / Deputy Director	Yearly	Complete all MSDS document Contact vendors to supply MSDS
	3. Management of Spills	All Laboratory staff Hospital Safety Officer Laboratory EHSMS representative Laboratory Director / Deputy Director	When incident reported	Review procedures for handling of biological and chemical spill Conduct staff Training and drills
	4. Filling incident report (OVR) (describe the incident)	All Laboratory staff Laboratory EHSMS representative Laboratory Director / Deputy Director	When incident reported	Action taken to contain and handle he spill

	5. Document actions and recommendation on incident report (OVR)	Quality Department Laboratory Quality Manager Laboratory Director / Deputy Director	When incident reported and after filling incident	Ensure proper handling and decontamination of spill Closure of OVR