BIOGENIX

POLICY PROCEDURE FOR CORRECTIVE ACTION

	NAME	DESIGNATION	SIGNATURE	DATE
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1. TABLE OF CONTENT

2. REVISION HISTORY

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

3. REVIEW HISTORY

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

4. POLICY STATEMENT

5. PURPOSE

The purpose of this procedure is to define the method of determining the root cause for the non-conformities and to ensure effective corrective action is taken at the appropriate time occurring during implementation quality management system including those related to technical operations and testing of samples. The procedure is in accordance with clause 4.10 of ISO 15189:2012 Medical Laboratories –Requirement for Quality and Competence

6. SCOPE

6.1. This procedure is applicable to all kinds of Nonconformities.

6.2. Target Audience:

6.2.1. BIOGENIX Management

6.2.2. BIOGENIX Staff.

7. DEFINITIONS

7.1. Non-conformance Nonconformity (also known as a defect) is a deviation from a specification, a standard, or an expectation.

7.2. Corrective/preventive action: are improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations

8. ACRONYMS

8.1. PDCA: Plan Do Check Act

9. RESPONSIBILITIES

9.1. The BIOGENIX staff are responsible for the implementation of the agreed corrective action.

9.2. Quality Manager is responsible for verification and closure of non-conformance and to assess the effectiveness of corrective action.

9.3. The laboratory director is responsible to monitor the results of any corrective action taken, in order to ensure that they have been effective in overcoming the identified problems

10. PROCEDURE

10.1. Once nonconformities are identified and prioritized, the quality manger determines the action to eliminate the causes of nonconformities. The nonconformities are documented with staff responsible for action and time frame of each action.

10.2. Corrective actions are initiated based on non-conformances reported or noted during routine testing of patient samples, Sample rework, results of Internal Quality Control, proficiency of test results, Complaints and suggestion received from patients / Staff/ other Labs, feedback from referral doctor's/Referral lab. /suppliers, Result of Proficiency testing Programmed / Results of Inter Lab Comparison, non-conformance reports generated during internal as well as external audits.

10.3. The critical nonconformities which need immediate action after discussion with lab. director the root cause analysis is performed by using the quality model, PDCA and quality tool, cause and effect diagram.

10.4. After analysis, develop a corrective and preventive action plan, discuss with the concerned staff for their action and ensure that nonconformities do not recur;

10.5. Quality Manager reports to the lab director so information provided to all the staffs on these actions which is helpful for them to learn lesson to avoid mistake;

10.6. All the corrective action records are kept;

10.7. The effectiveness of the corrective action taken on regular basis is being reviewed.

10.8. All corrective actions are reviewed in Management review.

10.9. Disposition details, root cause for nonconformity and corrective actions planned or proposed are to be outlined.

10.10. The proposed corrective action is to be verified by Quality Manager, if the proposed corrective action is adequate or not.

10.11. After the implementation of the corrective action as per the target date, a re-audit is to be organized by the Quality manager to verify the effectiveness of corrective actions implemented.

10.12. Where implementation is completed on or before the target date the Quality manager is to be informed.

10.13. The nonconformity report is to be closed if implementation of corrective action is found satisfactory.

10.14. Types of corrective/ Preventive actions include:

10.14.1. Meeting actions
10.14.2. Individual Staff actions
10.14.3. Equipment error logs and issues requiring investigation / engineer support
10.14.4. Improvement suggestions
10.14.5. Staff Trainings
10.14.6. Performance Development Review (Appraisal) actions.

11. CROSS REFERENCE

11.1. HAAD standards for Clinical Laboratory

11.2. ISO 15189:2012 Medical Laboratories –Requirement for Quality and Competence

12. RELEVANT DOCUMENTS & RECORDS

12.1. BG/REC/GEN/052 Corrective and preventive action report form

12.2. BG/REC/GEN/053 Action Plan