BIOGENIX

POLICY PROCEDURE FOR PREVENTIVE 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

The preventive actions for the non conformities is done as per this procedure.

5. PURPOSE

This procedure explains the activities in planning and implementing preventive actions. and is as per clause 4.11 of ISO 15189:2012 Medical Laboratories – Requirement for Quality and Competence.

6. SCOPE

6.1. This procedure is applicable to

- 6.1.1. Purchase of products,
- 6.1.2. Testing
- 6.1.3. Report preparation
- 6.1.4. Retest / resample
- 6.1.5. Clients / patients Complaints
- 6.1.6. Quality problems due to incoming materials
- 6.1.7. Test work non-conformances
- 6.1.8. Internal quality control
- 6.1.9. External Quality Control

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. **Preventive Action:** eliminate the causes of potential nonconformities in order to prevent their occurrence. It is a process for identifying opportunities for the improvement

8. ACRONYMS

N.A.

9. RESPONSIBILITIES

This is collective responsibility of BIOGENIX staff and management to do preventive action. All staffs are responsible for promoting and ensuring awareness of this procedure in their areas. Responsible sections and areas or personnel are responsible for carrying out necessary preventive actions.

10. PROCEDURE

10.1. The preventive actions are process for identifying opportunities for the improvement in two ways:

10.1.1. Once problem is identified and corrective and preventive action taken so reduce the chance that the problem will reoccur. This is reaction to the identification of the problem;

10.1.2. The other, potential problem identified to eliminate the causes of nonconformities so problem will not occur. This is proactive approach;

10.2. The below steps are taken to eliminate potential problems, so it avoid occurrence of problem:

10.2.1. The lab staff and the Lab. director who is reviewing the reports including reports released to patients and other data such as supplier agreements ,service agreement form, documents ,policy procedures, also environment safety issues, equipments, machines, reagents, inventory logs, staff training development records to determine where the potential nonconformities exist and accordingly actions are taken. The preventive actions are based on, analysis of data, including trend and risk analysis, proficiency-testing results, new technology, and problems in similar situations etc.,

10.2.2. The Quality Manager along with Lab. Director evaluates the identified areas and draws up action plans for the implementation of the preventive actions and records the same.

10.2.3. The Lab. staff is responsible for the implementation of the agreed preventive action. The proposed preventive action is to be given to the Quality Manager.

10.2.4. Based on the target date indicated, implementation of the preventive action is to be verified and the preventive action report is to be closed after review by Quality Manager.

10.2.5. The results of the preventive action are submitted for laboratory management review.

10.2.6. The effectiveness of the corrective and preventive action taken is reviewed in the Management Review Meeting.

10.2.7. Reporting to lab director so information provided to all the staffs on actions and improvement which is helpful for them to review their areas to identify and report if any potential nonconformity exist for action;

10.2.8. Quality manager is responsible to keep the record of preventive action taken;

11. CROSS REFERENCE

11.1. HAAD standard 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

12.3. BG/REC/GEN/051 Non conformance form