BIOGENIX

POLICY PROCEDURE FOR CONTINUOUS IMPROVEMENT

	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

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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 4.12 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. **Continuous Improvement:** is an **ongoing** effort to **improve** services, or processes. These efforts can seek "incremental" **improvement** over time or "breakthrough" **improvement** all at once..

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

9.1. BIOGENIX Management
9.2. BIOGENIX Staff

10. PROCEDURE

The laboratory is committed to meet the needs of users and therefore uses a quality management system which incorporates continuous quality improvement in all areas of the service. Areas for improvement are identified by:

i. Risk management
ii. Service user and staff suggestions
iii. Incidents
iv. Error logs
v. Corrective/ Preventive action
vi. Review of progress with objectives
vii. Quality management meetings
viii. Audit
ix. More complex issues may require an investigation, root cause analysis (RCA), risk assessment, an action plan. These are feed back to staff via staff meetings.

10.1. BIOGENIX laboratory has determined quality indicators as specified in ISO 15189: 2012 to support monitoring and evaluating its contribution to patient care. Whenever opportunities for improvement are identified, these are discussed, action plan developed and outcome reviewed.

10.2. The quality manager reviews regularly all the reports, corrective/ preventive actions and evaluate annually, total how many nonconformities identified, how many corrective/preventive action taken and closed in all lab areas. Quality manager discuss with lab director and Technical Manager to provide feedback for the improvement.

10.3. The lab director oversight all the management reviews on annual basis and compare the lab actual performance activities and to evaluate that quality policy and quality objectives are met/achieved.

10.4. Lab director communicate to the entire lab staff on annual improvement /achievement and related goals achieved and met.

10.5. BIOGENIX management offers educational and training opportunities for professionals in the lab and other concerned personnel to enable them to continually improve their performance.

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/051 Non-conformance form