BIOGENIX

POLICY PROCEDURE FOR IDENTIFICATION OF NON CONFORMITIES

	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

Identification and control of Non conformities are done as per following procedure.

5. PURPOSE

The purpose of this procedure is to establish, implement and maintain a documented process in all areas of laboratory for dealing with actual and potential nonconformities by identification and control. The procedure is in accordance with clause 4.9 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. Nonconformities are classified as critical, major, or minor.

8. ACRONYMS

N.A.

9. RESPONSIBILITIES

9.1. This is collective responsibility of BIOGENIX staff and management to identify the problem.

9.2. All staffs are responsible for promoting and ensuring awareness of this procedure at their areas.

9.3. However, Quality Manager is overall responsible for the development of audit plan implementation and corrective /preventive actions with regular follow up till nonconformity is not closed. Also responsible for present the result of audit and corrective /preventive action plans to the lab director for input and actions

10. PROCEDURE

This procedure is detailed step by step for **Identification of the Non Conformities:**

10.1. Nonconformities may be identified in many ways; these include:

- 10.1.1. QC failures
- 10.1.2. Instrument problems
- 10.1.3. Problems with consumables - reagents, calibrators, QC materials or supplies
- 10.1.4. Complaints from clinics, including physicians, nurses and lab staff, and from patients
- 10.1.5. Near misses
- 10.1.6. Opportunity / suggestion for improvement
- 10.1.7. Employee safety reports
- 10.1.8. Results of internal audits
- 10.1.9. Results of external audits (e.g. proficiency testing)
- 10.1.10. Quality indicators

The BIOGENIX Laboratory has developed an audit plan to identify the nonconformities; this plan is scheduled as per dates and time with the responsibilities of audit and area of audit.

10.2. All the problems are reported to the Laboratory Director/quality manager.

10.3. The other ways are Customer complaints and customer satisfaction survey, also assists to identify problems;

10.4. Review of regular reports; inter laboratory comparison as well as key performance indicators.

10.5. Once nonconformity or potential nonconformity is identified, Root cause analysis by the quality manager is done.

10.6. The priority list of critical nonconformities is prepared which need immediate action including clinical nonconformity such as release of results to recall etc.

10.7. The timeline for initiation of a corrective action depends on the nonconformity. Nonconformities that involve errors in reporting patient results require immediate action (remedial action and correction).

10.8. These nonconformities are reported to the lab director for their immediate attention and action.

10.9. Potentially non-conforming tests if suspended can be resumed only after review by the Lab. Director.

10.10. Each nonconformity or potential nonconformity is discussed with the staff and documented, recorded to detect the trend and initiate corrective action.

10.11. The details of any nonconformance raised / observed during the audit are recorded by the Auditor in the Non-Conformance Report.

10.12. After identification of Non conformity the concerned staff has to fill up Nonconformance form and update the quality manager.

10.13. Quality manager follow up the Nonconformance and do corrective preventive action and update lab. director.

11. CROSS REFERENCE

11.1 HAAD standard for clinical Laboratory

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

11.3 CLSI guidelines QMS 11 -A Management of Non-Conforming Laboratory events

12. RELEVANT DOCUMENTS & RECORDS

12.1. BG/REC/GEN/051 Nonconformance form.