






BIOGENIX

POLICY PROCEDURE FOR IDENTIFICATION OF NON CONFORMITIES

	NAME	DESIGNATION	SIGNATURE	DATE
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DOCUMENT CONTROL: BG/PP/GEN/007

BIOGENIX

VERSION: 1.0

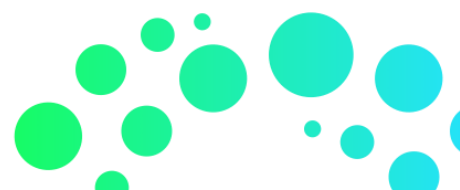
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2. REVISION HISTORY

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





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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

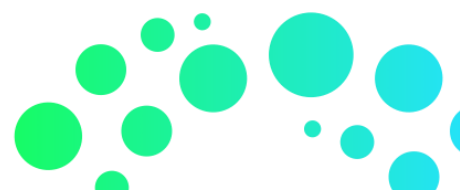
- 6.1. This procedure is applicable to:
 - 6.1.1. Purchase of products,
 - 6.1.2. Testing
 - 6.1.3. Report preparation
 - 6.1.4. Retest / resample
 - 6.1.5. Clients / patients Complaints
 - 6.1.6. Quality problems due to incoming materials
 - 6.1.7. Test work non-conformances.
 - 6.1.8. Internal quality 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.





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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.





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- 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.](#)

