






BIOGENIX

POLICY PROCEDURE FOR CONTINUOUS IMPROVEMENT

	NAME	DESIGNATION	SIGNATURE	DATE
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DOCUMENT CONTROL: BG/PP/GEN/010

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VERSION: 1.0

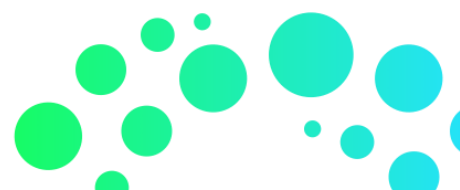
DATE OF EFFECTIVITY:
01/07/2020

PAGE: 2 of 7

NEW REVIEW DATE: 30/06/2022

1. TABLE OF CONTENT

1. TABLE OF CONTENT	2
2. REVISION HISTORY	3
3. REVIEW HISTORY	4
4. POLICY STATEMENT	5
5. PURPOSE	5
6. SCOPE	5
7. DEFINITIONS	5
8. ACRONYMS	5
9. RESPONSIBILITIES	6
10. PROCEDURE	6
11. CROSS REFERENCE	6
12. RELEVANT DOCUMENTS & RECORDS	7





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DOCUMENT CONTROL: BG/PP/GEN/010

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VERSION: 1.0

DATE OF EFFECTIVITY:
01/07/2020

PAGE: 3 of 7

NEW REVIEW DATE: 30/06/2022

2. REVISION HISTORY

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





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DOCUMENT CONTROL: BG/PP/GEN/010

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VERSION: 1.0

DATE OF EFFECTIVITY:
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PAGE: 4 of 7

NEW REVIEW DATE: 30/06/2022

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PAGE: 5 of 7

NEW REVIEW DATE: 30/06/2022

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

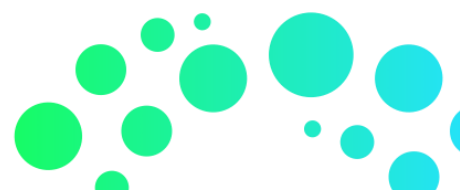
- 6.1. This procedure is applicable to
 - 6.1.1. Purchase of products,
 - 6.1.2. Testing
 - 6.1.3. Report preparation
 - 6.1.4. Retest / resample
 - 6.1.5. Clients / patients Complaints
 - 6.1.6. Quality problems due to incoming materials
 - 6.1.7. Test work non-conformances
 - 6.1.8. Internal quality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





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VERSION: 1.0

DATE OF EFFECTIVITY:
01/07/2020

PAGE: 6 of 7

NEW REVIEW DATE: 30/06/2022

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





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PAGE: 7 of 7

NEW REVIEW DATE: 30/06/2022

- 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](#)

