BIOGENIX

# POLICY PROCEDURE FOR EVALUATION AND AUDITS

| | NAME | DESIGNATION | SIGNATURE | DATE |
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| **Prepared by** | MS. PREETY RAHEJA | QUALITY MANAGER |  | 30/06/2020 |
| **Reviewed by** | DR. JULIET TEDDY | DEPUTY DIRECTOR |  | 01/07/2020 |
| **Approved by** | DR. SALLY ABDULLA IBRAHIM | LABORATORY DIRECTOR |  | 01/07/2020 |

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## 2. REVISION HISTORY

| # | Version | Date | Changes Made by | Reason for Changes | Clause Changed |
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| 1 | 1.0 | | | | |
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## 4. POLICY STATEMENT

The Evaluation and audit is done as per this procedure.

## 5. PURPOSE

The purpose of this procedure is to enable BIOGENIX Laboratory to identify processes which are weak and may violate the regulation as well as slow down the customer services. Accordingly Conduct audits and review the audit reports to ensure that the corrective, preventive actions have been taken to strengthen these processes which ultimately improve the effectiveness of the overall BIOGENIX Laboratory system. This procedure is with accordance to clause no: 4.14 of ISO 15189:2012 Medical Laboratory –Requirements for quality and competence.

## 6. SCOPE

6.1. All departments of BIOGENIX laboratory

6.2. Target Audience

6.2.1. BIOGENIX Management

6.2.2. BIOGENIX Staff

## 7. DEFINITIONS

**7.1.** **Audit:** an official inspection of an organization typically by an independent body.

**7.2.** **External Audit**: An external audit is an independent examination of an organization. It is usually conducted for statutory purposes (because the requirement of the standard). An audit results in an audit opinion about whether the statements given and documentation are 'true and fair' and according to the standards.

**7.3.** **Internal Audit:** Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. Internal auditing provides value to governing bodies and senior management as an objective source of independent advice. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.

**7.4.** **Auditee:** a person or organization that is audited.

## 8. ACRONYMS

**8.1.** **CPAP:** Corrective Preventive action plan
**8.2.** **DOH:** Department of Health AbuDhabi

## 9. RESPONSIBILITIES

9.1. The Management is responsible for approving the annual internal audit plan,
9.2. The Quality Manager is responsible for ensuring that internal audits are planned and carried out in accordance with this procedure. The Quality Manager is responsible for reporting the audits finding in timely manner - within three working days of the last day of the audit,
9.3. The Auditee(s) are responsible for rectifying all identified nonconformance raised by an auditor by applying all necessary corrective action in a reasonable time frame.

## 10. PROCEDURE

**10.1. Periodic Review of Requests and Suitability of procedures and sample requirements:** Laboratory director reviews sample volume, collection device and preservative requirements for blood, urine, other body fluids and other sample types. In our laboratory technical staff checks the volume and requirement of the tests on regular basis as the sample received in the laboratory and entered in the LIS before starting the processing technical staff has to accept the sample which means the staff has reviewed the request and the procedure is suitable as per the test and sample is also acceptable. If any sample has to be rejected it is mentioned in the sample rejection form.

**10.2. Assessment of user feedback & Staff Suggestion** is as per our communication procedure.

**10.3. INTERNAL AUDIT:**

The lab conducts internal audits in planned intervals to determine that all the activities working smoothly, requirement of international standard are maintained. The audits are conducted as developed and planned schedule. All the clauses as per ISO 15189 standards are audited once in a year as per audit plan. Audit is conducted by the trained and competent person to assess the performance of managerial and technical processes. Before conducting audit the previous reports of the audit and action plan is reviewed. The opening and closed audit meeting is called to inform the staff about the audit results. After each audit the report is submitted to the responsible staff for the area been audited and ensures that action is promptly under taken.

10.3.1. **Planning the Audit**

Quality Manager is responsible to prepare an "Annual Internal audit plan" which includes the following information:

10.3.1.1. Objectives of the Audit,

10.3.1.2. Audit Scope,

10.3.1.2.1. Personnel/employee audits eg, staff planning as per requirement, staff training, and staff Annual evaluation, Staff satisfaction survey;

10.3.1.2.2. Lab Equipments/ Machines and consumable audits;

10.3.1.2.3. Environment health and safety audits;

10.3.1.2.4. Risk Management Audit, Contingency and Emergency preparedness audit;

10.3.1.2.5. Patient care audits, (Review of requests and suitability procedures and samples requirements, Complaint, patients satisfaction survey);

10.3.1.2.6. Documentation audit;

10.3.1.2.7. Outsource supplier & agreement audit;

10.3.1.2.8. Management review audit. (KPI audits, corrective preventive follows up actions)

10.3.1.3. Assigned Auditors: Internal auditors are trained by DAC, for auditing skills before being appointed as internal auditors. The Auditor is responsible for the planning, implementing and reporting of the audit.

10.3.1.4. Date and Time of Audit.

The Plan is approved by the lab director. These areas elaborate more as per schedule.

**10.3.2. Audit Process**

**10.3.2.1. Audit tool**:

**10.3.2.1.1.** DOH audit Checklist

**10.3.2.1.2.** Questionnaires (Staff Suggestions, Customer Feedback),

**10.3.2.1.3.** ISO checklist for 15189:2012 Medical Laboratories requirements for quality and competence, also other HAAD requirements.

**10.3.2.2. Sample size**

**10.3.2.2.1.** Depend on the specific audit;

**10.3.2.2.2.** To maintain the reliability and validity, the sample size is from 30%

**10.3.2.3. Audit team**

**10.3.2.3.1.** Competent for specific audit

**10.3.2.4. Methodology during audit is:**

**10.3.2.4.1.** Observation;

**10.3.2.4.2.** Review of documents;

**10.3.2.4.3.** Interviews.

A notice of audit in the form of a memorandum (or e-mail) is prepared by the Quality Manager, with the attached "Audit Plan". This is distributed and/or posted at least one week before the scheduled audit for the general information of all departments and personnel concerned.

10.4. **Conducting and Reporting the Audit**

Internal audits are carried out through a process of review of documents, records and interviews with people within the area being audited. The focus is on compliance as well as adequacy of the system. Also, the audit focuses on assessing the system performance over a longer period of time to help top management with better decision making.

10.4.1. An opening meeting is conducted by the Auditor to explain the objectives, scope and itinerary specified in the "Audit Plan". Only then the audit be carried out;

10.4.2. On completion of the audit, the auditor discusses the findings with the auditees and agrees with the identified non-conformances, observations and corrective actions needed along with target closing dates for the identified non-conformances;

10.4.3. All detected nonconformance, including opportunities for improvement is discussed by the Internal Auditor to all the auditees in the closing meeting;

10.4.4. The report is issued to the Laboratory Director who records it such that it can be tracked and monitor the progress on the open non-conformances;

10.4.5. The Quality Manager monitor the status of all identified nonconformance by reviewing the CPAP on a monthly basis and request the respective auditor to verify effective closure of non-conformances through follow-up audit;

10.4.6. The results of evaluation and improvement activities are included in the input to the management review.

10.5. **External audits:**

10.5.1. External Audit includes reports for Proficiency Test Survey and also periodical review from DOH and ISO 15189 team.

10.5.2. BIOGENIX laboratory takes corrective and preventive action and compliance with the non-conformities, record of the review and corrective preventive actions are maintained regularly.

**10.6. Follow-up Audit and Verification of Corrective and/or Preventive Action**

The Quality Manager verifies and closes out the non-conformance(s) upon notification of completed work by concerned department.

## 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/055 Annual Internal Audit Plan
12.2. BG/REC/GEN/054 Internal Audit Checklist
12.3. Evaluation plan