



BIOGENIX

POLICY PROCEDURE FOR LABORATORY DIRECTOR RESPONSIBILITIES

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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

The HAAD regulation is very specific and defines the qualifications of the laboratory Head - Clinical Services and assigns numerous responsibilities to Head - Clinical Services of laboratories. HAAD holds the director responsible for the "overall operation and administration of the lab" and lists areas of responsibility included within that operation and administration. The laboratory Head - Clinical Services must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

5. PURPOSE

Policy outlines the responsibilities of the laboratory director of BIOGENIX laboratory.

6. SCOPE

6.1 Scope: The scope of this policy extends to define the responsibilities of the Laboratory Director.

6.2 Target Audience: All BIOGENIX laboratory staff

7. DEFINITIONS

N.A.

8. ACRONYMS

8.1 DOH: Department of Health Abu Dhabi

8.2 EHSMSS: Environments, Health and Safety Management System

8.3 CME: Continuing Medical Education

9. RESPONSIBILITIES

9.1 BIOGENIX Laboratory, provide laboratory services to the population served by the BIOGENIX laboratory who refer various samples for analysis. Laboratory Director is available 24 hours per day, 7 days per week. If the Laboratory Director is not available, the interim period is managed by deputy director.

9.2 The laboratory director must meet the qualifications defined in the standards issued by the Health Authority of Abu Dhabi (HAAD). The director of the laboratory





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is a professional licensed pathologist with appropriate training, education, and experience to direct the laboratory services provided by the laboratory.

10. PROCEDURE

- 10.1** The laboratory director is ultimately responsible for every task required to assure accurate, reliable, timely, and relevant test results in the **molecular and core lab**. This includes pre-analytic, analytic, and post-analytic processes. Therefore, the director must implement processes to assure consistent performance of testing activities. In addition, processes to monitor for test variances and provide timely corrective action, when required, must be in place.
- 10.2** This job is occupied by a consultant or a senior specialist pathologist. He/she is responsible in front of the Head - Clinical Services for the quality of Laboratory Service provided to all patients.
- 10.3** He/she is responsible for all the laboratory staff: Medical and non-medical.
- 10.4** He/she has two types of duties:
 - 10.4.1** Administrative duties as Head of Laboratory department.
 - 10.4.2** Medical duties as a consultant or a senior specialist physician.
- 10.5** The duties of the Laboratory Director are listed below and may be delegated to qualified individuals with oversight by the laboratory director. The laboratory director is responsible for and will ensure that:
 - 10.5.1** The laboratory provides for the type and scope of services to meet the needs of ordering clinicians and the patient population served. Management and supervision of overall performance of the Laboratory with regard to Quality of performance, productivity and tests availability.
 - 10.5.2** The laboratory provides for required services either directly or through referral to another laboratory.
 - 10.5.3** The director assures the consistent performance of reference and contract laboratory services in accordance with DOH laboratory standards, when they are used.
 - 10.5.4** Inspect, recommend and monitor outside sources for laboratory services.
 - 10.5.5** All reference and/or contract laboratory's used meets applicable laws and regulation.
 - 10.5.6** The director plans and provides adequate resources for the provision of laboratory services. These resources include:
 - 10.5.6.1** A budget and fiscal resources for operating the laboratory;
 - 10.5.6.2** Required personnel in numbers and qualifications to meet the goals of the laboratory;
 - 10.5.6.3** Physical structure and spaces to facilitate efficient, effective, and safe delivery of laboratory services;





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- 10.5.6.4** Necessary equipment, new tests and technologies;
- 10.5.6.5** Accessibility of services and provisions for specimen collection, storage, and transport; and
- 10.5.6.6** Safe use, maintenance, and supervision of space, equipment, and other Environmental elements, such as required utilities.
- 10.6** The director ensures that there is effective communication of laboratory daily activities.
- 10.7** The director requires practices that respect the needs of patients, including providing for privacy, security, and confidentiality of information.
- 10.8** The director provides for consultation to those who request tests about the choice of tests, the use of the laboratory's services, and the interpretation of test results.
- 10.9** The director is responsible for developing, implementing, revising and maintaining policies and procedures that guide and support the provision of services. Ensure that work is done according to the policies and procedures stated by the laboratory. This includes policies and procedures for the pre-analytic, analytic, and post-analytic phases of testing. These procedures include:
 - 10.9.1** Specimen collection procedures provided to all those who collect specimens to be sent to the laboratory;
 - 10.9.2** All procedures related to performing laboratory tests; and
 - 10.9.3** Procedures for the review and reporting of laboratory test results.
- 10.10** All lab procedure manuals are accessible to all staff. All new procedures and changes in procedures are approved, signed, and dated by the Laboratory Director.
- 10.11** The director is responsible for defining and maintaining necessary quality control programs.
- 10.12** He/she is actively involved in the design, implementation, and oversight of the quality management system.
- 10.13** The director is responsible for determining and defining in writing, the qualifications and competence of staff required to meet the laboratory's goals.
- 10.14** The director provides an adequate number of qualified, competent staff by participating in the recruitment.
- 10.15** The director requires new employees to be oriented to all job responsibilities, and to be assessed as competent before performing these responsibilities independently.
- 10.16** The director provides ongoing, in-service training and education (CME) when required to update staff on new procedures or instrumentation or to maintain staff competence in current procedures.
- 10.17** Establishes an effective working relationship with the clinical staff, the organization's administration, and other departments/services. Represents the Laboratory at various hospital wide meetings.





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- 10.18** Must ensure compliance with EHSMS and state/local regulations, as well as other applicable safety regulations and ensure that the lab has a safe environment to work in.
- 10.19** Review's the lab's organizational chart
- 10.20** Hold regular monthly meetings with the laboratory staff to discuss and resolve outstanding laboratory issues and maintain minutes of the same.
- 10.21** The laboratory director assures ongoing monitoring of quality control and other processes to ensure the efficient provision of consistently reliable quality services. These monitoring activities are to be documented and include:
 - 10.21.1** Day to day review of internal quality control results and at least monthly review of cumulative quality control results.
 - 10.21.2** The lab's testing systems provide quality lab services and testing methods used in the lab provide quality test results.
 - 10.21.3** Overall monitoring and reviewing of all laboratory services within and outside the laboratory.
 - 10.21.4** The lab uses verification procedures that adequately measure the accuracy of its testing methods.
 - 10.21.5** Staff perform tests as required to yield accurate and reliable results.
 - 10.21.6** Monthly review of analytical equipment problems to determine if there are any recurring problems.
 - 10.21.7** Acceptable performance levels for each test system are established. The lab takes and documents remedial action when performance specifications go unmet.
 - 10.21.8** The lab reports patient results only when systems work properly.
 - 10.21.9** Test reports include all required information.
 - 10.21.10** Review of customer complaints as they occur, along with a response to the customer in accordance with the organization's policy.
 - 10.21.11** Prompt review of external quality control reports to determine if actions need to be taken.
 - 10.21.12** Periodic (at least quarterly) review of data for unacceptable requests and specimens to identify trends from specific areas or clinicians, and the need to communicate with that area or clinician in order to improve the services provided.
 - 10.21.13** Periodic monitoring and review of turn-around-times for laboratory tests.
 - 10.21.14** Annual review of the above parameters to allow planning for the following year.
 - 10.21.15** Annual review of customer satisfaction through a customer-satisfaction survey, in conjunction with a cumulative review of the year's customer complaints to identify any problematic trends. If the laboratory is part of a larger health-care organization, this should be done as part of the organization's customer satisfaction process.





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10.22 Work Contacts:

10.22.1 Laboratory staffs

11. CROSS REFERENCE

- 11.1 HAAD clinical laboratory standards, Version 1.0, Health policy and regulation, Health Authority of Abu Dhabi.
- 11.2 Clinical Laboratory Improvement Amendments, laboratory director responsibilities.
- 11.3 JCI 5th Standards Edition, AOP 5.1, GLD 9, GLD 6, GLD 6.1
- 11.4 ISO 15189:2012 Medical laboratories – Requirements for Quality and Competence.

12. RELEVANT DOCUMENTS & RECORDS

- 12.1. BG/JD/HR/005 Laboratory Director Job Description

