BIOGENIX

QUALITY MANUAL

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

A. TABLE OF CONTENT

B. REVISION HISTORY

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

C. REVIEW HISTORY

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

D. RELEASE AUTHORIZATION

This Quality Manual is released under the authority of Dr. Sally Mahmoud, **Laboratory Director,** and is the property of BIOGENIX Laboratory (unit of G42 Healthcare), Abu Dhabi, United Arab Emirates.

E. AMENDMENTS

S.No.	Page No.	Section/Clause/ Para/Line (as applicable)	Date of Amendment	Amendment Made	Reasons of Amendment	Signature of Person Authorizing Amendment

F. DISTRIBUTION

This Quality manual is prepared by the Quality Manager and approved by the Laboratory Director of BIOGENIX Laboratory and the soft copy is available to all staff of the Quality manual

G. QUALITY POLICY

At BIOGENIX Laboratory (Unit of G42 Healthcare), we are committed to provide medical laboratory services which are accurate, precise, timely and patient-centered whilst ensuring they are fulfilling the statutory national and international standards.

Dr. Sally Mahmoud
Laboratory Director
BIOGENIX LABORATORY- unit of G42 Laboratories

H. OUR MISSION

The Laboratory is committed to BIOGENIX mission to be a leader in promoting laboratory services within outstanding quality and turnaround time to all patients.

I. VISION

BIOGENIX Laboratory, through continuous quality improvement measures will provide high standard laboratory services and will go towards national recognition and international accreditation from certified organizations.

J. GOALS

On our way to achieve our vision statement we will:

- Provide a high standard service.
- Treat all patients friendly.
- Ensure safety of staff and patients.
- Assure confidentiality for the patients.
- Respect the country traditions and culture.
- Work as a team; support each other, free of blame.

K. VALUES

- We aim to provide the region with high quality services
- We are progressive and innovative by constantly seeking ways to enhance patient care
- We are committed to continuous improvement and professional development
- We approach all things through teamwork and promote learning.

L. OBJECTIVES

To maintain quality performance at the highest level, the following objectives will be pursued:

- To establish the implementation and maintenance of Quality Management System
- To be accredited by ISO 15189
- To expand the scope of the lab in molecular and core lab.
- Ensure the safety of staff and visitors by adhering to OHS and infection control guidelines.

- Define and implement appropriate test procedures as per applicable standards, guidelines and best practices. Maintain integrity of those process throughout the entire testing phase, Pre-analytical, Analytical and Post- analytical.
- Ensure that service providers, partners and other stakeholders follow the quality, competence and other statutory requirements rigorously
- Maintain confidentiality and security in the information management and electronic transaction process.
- Carry out work processes in compliance with quality management system and defined policies and procedures by qualified, competent staff that are committed to continual improvement.

1. SCOPE

The scope of this quality manual complies with the ISO 15189:2012 standard and DOH standards

The Scope of the quality management system described in this quality manual is applicable to the following clinical laboratory services offered at BIOGENIX Laboratory, United Arab Emirates.

1.1. Molecular Laboratory
1.2. Hematology,
1.3. Serology.

This Quality Manual is applicable to the various sections of laboratory as mentioned earlier for performing the tests as mentioned in our Test Summary Monitoring sheet.

The Quality manual is for use by BIOGENIX laboratory in developing the quality, administrative and technical system that governs our operations. Laboratory clients, regulatory authorities and accreditation bodies use it in confirming or recognizing the competence of laboratories.

The regulatory and safety requirements on the operation of laboratories are not covered by this Quality Manual.

Working Hours for the laboratory is 24X 7.

2. NORMATIVE REFRENCE

BIOGENIX Laboratory has developed and implemented Quality Management System that is documented in this Quality Manual as per guidelines and standards provided by:

2.1. International Standard for Medical Laboratories- Requirements for Quality and Competence.

2.2.Department of Health Abu Dhabi

2.3.ISO/IEC 17000, Conformity assessment —Vocabulary and general principles

2.4.ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories

2.5.ISO/IEC Guide 2, Standardization and related activities — General vocabulary

2.6.ISO/IEC Guide 99, International vocabulary of metrology — Basic and general concepts and associated terms (VIM).

2.7.DOH Clinical Laboratory Standards Version 1

2.8.Abu Dhabi Specification, ADS 8/2014, Quality Control in Medical Laboratory.

3. TERMS AND DEFINATION

As explained in clause 3 of ISO 15189:2012 the following terms and definitions are adopted in the documentation of this Manual:

3.1.**Accreditation:**

It is the procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks.

3.2.**Alert Interval Critical Interval:**

Interval of examination results for an alert (critical) test that indicates an immediate risk to the patient of injury or death.

3.3.**Automated Selection and Reporting of Results:**

Process by which patient examination results are sent to the laboratory information system and compared with laboratory defined acceptance criteria, and in which results that fall within the defined criteria are automatically included in patient report formats without any additional intervention.

3.4.**Biological Reference Interval:**

Specified interval of the distribution of values taken from a biological reference population.

3.5. **Competence:**
Demonstrated ability to apply knowledge and skills.

3.6. **Documented Procedure:**
Specified way to carry out an activity or a process that is documented, implemented and maintained.

3.7. **Examination:**
Set of operations having the object of determining the value or characteristic of a property

3.8. **Interlaboratory Comparison:**
Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

3.9. **Laboratory Director:**
Person(s) with responsibility for, and authority over, a laboratory

3.10. **Laboratory Management:**
Person(s) who direct and manage the activities of a laboratory

3.11. **Medical Laboratory:**
laboratory for the biological, microbiological, immunological, chemical, immune hematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

3.12. **Nonconformity:**
Nonfulfillment of a requirement

3.13. **Point-of-Care Testing:**
testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient

3.14. **Post-Examination Processes:**
Processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results.

3.15. **Pre-Examination Processes:**
Processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the laboratory, and end when the analytical examination begins.

3.16. **Primary Sample Specimen:**
Discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole.

3.17. **Process:**
Set of interrelated or interacting activities which transform inputs into outputs

3.18. **Quality:**
Degree to which a set of inherent characteristics fulfills requirements.

3.19. **Quality Indicator:**
Measure of the degree to which a set of inherent characteristics fulfills requirements.

3.20. **Quality Management System:**
management system to direct and control an organization with regard to quality.

3.21. **Quality Policy:**
Overall intentions and direction of a laboratory related to quality as formally expressed by laboratory management.

3.22. **Quality Objective:**
Something sought, or aimed for, related to quality.

3.23. **Referral Laboratory:**
External laboratory to which a sample is submitted for examination.

3.24. **Sample:**
One or more parts taken from a primary sample

3.25. **Turnaround Time:**
Elapsed time between two specified points through pre-examination, examination and post-examination processes.

3.26. **Validation:**
Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

3.27. **Verification:**
Confirmation, through provision of objective evidence, that specified requirements have been fulfilled.

M. MANAGEMENT REQUIREMENTS

4.1. ORGANIZATION AND MANAGEMENT RESPONSIBILITY

- **Organization**

4.1..1. GENERAL:

The laboratory director of the BIOGENIX laboratory has organized the staff into functional work groups. Each functional area of the laboratory is headed by an in-charge technologist (Team leader). The outline of the organizational structure is further described in the laboratory organization chart.

4.1..2. LEGAL ENTITY

The Legal name of the Organization is "G42 Laboratories" and is registered under Department of Health Abu Dhabi (DOH) with a Registration Certificate No: MF5712 and the organization is headed by its Chief executive officer Mr. Hamed Al Shamsi. The certificate is issued under the authority of DOH, Abu Dhabi. The current operating location: BIOGENIX Laboratories, Masdar City

دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

ترخيص مركز تشخيصي
LICENSE FOR DIAGNOSTIC CENTRE

License No. :	MF5712	MF5712	رقم المنشأة :
Date of Issue:	22/04/2020	2020/04/22	تاريخ الإصدار:
Date of Expiry:	21/04/2021	2021/04/21	تاريخ الإنتهاء :
Region:	Abu Dhabi	أبو ظبي	المنطقة :
Name of Facility:	G42 LABORATORY L.L.C	مختبر جي 42 الطبي ذ.م.م	إسم المنشأة :
Facility Owner:	GROUP 42 HOLDING LTD G42 COMPANIES MANAGMENT RSC LTD	جروب 42 هولدنج ليمتد جي 42 كومبانيس ريسترکتد ليمتد	مالك المنشأة :

4.1..3. ETHICAL CONDUCT

It is the responsibility of BIOGENIX Laboratory management to ensure that code of medical ethics and professional conduct are followed in the day to day work in BIOGENIX Laboratory.

The management has arrangements in place to ensure the following:

4.1..3.1. There is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity;

4.1..3.2. Management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work;

4.1..3.3. Where potential conflicts in competing interests may exist, they will be openly and appropriately declared;

4.1..3.4. There are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;

4.1..3.5. Confidentiality of information is maintained.

Refer to the following Policy Procedure

- **Code of medical ethics and professional conduct (BG/PP/GEN/020)**
- **Confidentiality (BG/PP/GEN/001)**
- **Confidentiality Form (BG/REC/GEN/008)**
- **Disclaimer for Conflict of Interest (BG/REC/GEN/020)**

4.1..4. LABORATORY DIRECTOR

The Laboratory Director in BIOGENIX Laboratory has overall responsibility for the technical operation and the provision of resources needed to ensure the required quality of laboratory procedures.

The responsibilities of the laboratory director include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory.

The laboratory director will delegate selected duties and/or responsibilities to qualified personnel: however, the laboratory director will maintain the ultimate responsibility for the overall operation and administration of the laboratory.

The duties and responsibilities of the laboratory director are documented in her job description. The laboratory director (or the designates for the delegated duties) have the necessary competence, authority and resources in order to fulfil the requirements of the ISO 15189:2012.

The laboratory director

The chief laboratory technologist and laboratory technologist team leaders supervise the technical operations of their departments and provide adequate resources for ensuring quality in laboratory procedures.

The laboratory director (or designee/s) will:

4.1..4.1. Provides effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities

4.1..4.2. Relates and functions effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required.

4.1..4.3. Ensures that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users.

4.1..4.4. Ensures the implementation of the quality policy.

4.1..4.5. Implements a safe laboratory environment in compliance with good practice and applicable requirements.

4.1..4.6. Serves as a contributing member of the medical staff for those facilities served, if applicable and appropriate.

4.1..4.7. Ensures the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results.

4.1..4.8. Selects and monitors laboratory suppliers.

4.1..4.9. Selects referral laboratories and monitors the quality of their service.

4.1..4.10. Provides professional development programs for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations.

4.1..4.11. Defines, implements and monitors standards of performance and quality improvement of the medical laboratory service or services.

4.1..4.12. Monitors all work performed in the laboratory to determine that clinically relevant information is being generated.

4.1..4.13. Addresses any complaint, request or suggestion from staff and/or users of laboratory services;

4.1..4.14. Designs and implements a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable

4.1..4.15. Plans and directs research and development, where appropriate.

Refer to Job Description of Laboratory Director: BG/JD/HR/005

4.1..5. MANAGEMENT RESPONSIBILITY

4.1..6. Management Commitment

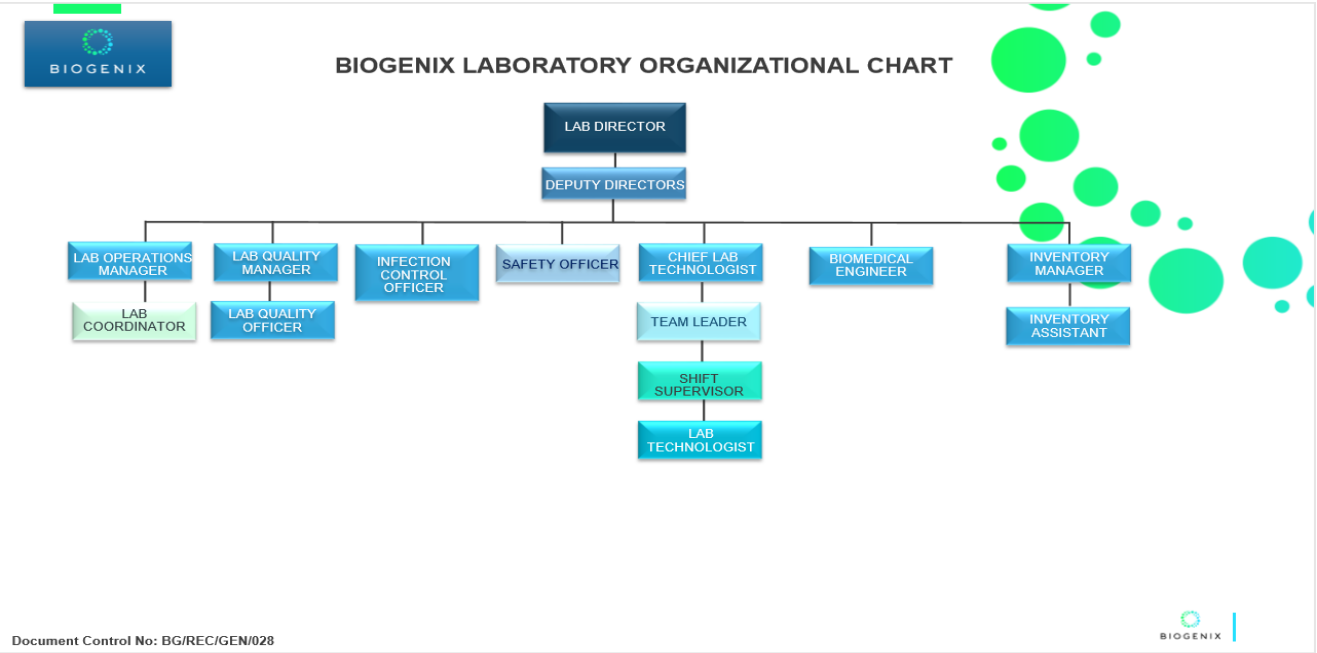
BIOGENIX laboratory management provides evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:

4.1..6.1. Communicating to laboratory personnel the importance of meeting the needs and requirements of users (4.1.2.2) as well as regulatory and accreditation requirements; Refer to **Policy Procedure for Communication (BG/PP/GEN/002)**

4.1..6.2. Establishing the quality policy (4.1.2.3); **Refer to section G of this Quality Manual**

4.1..6.3. Ensuring that quality objectives and planning are established; **Refer to section L of this Quality Manual**

4.1..6.4. Defining responsibilities, authorities and interrelationships of all personnel; BIOGENIX management supports all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties. Team leaders are assigned for overseeing key functions in each section of the lab. They are responsible for ensuring technical operations such as functioning of lab equipment, quality control checks (internal and external), and maintenance of work area.



4.1..6.5. **Establishing communication processes;**
BIOGENIX Laboratory has established communication processes within the laboratory enabling information flow between sections.

Refer to Communication Policy Procedure BG/PP/GEN/002

4.1..6.6. **Appointing a quality manager, however named;**
The Quality Manager appointed has delegated responsibility and authority to oversee compliance with the requirements of the Quality Management System. Quality Manager is responsible for ensuring routine implementation of Quality systems such as documentation and implementation of Quality improvement systems. Quality Manager reports to the Laboratory Director who makes the decision on laboratory policy and resources

4.1..6.7. Conducting management reviews;

4.1..6.8. Ensuring that all personnel are competent to perform their assigned activities;

Refer to Job Description of Quality Manager BG/JD/HR/010

Supporting Documents:

Clause No.	Document Name	Reference Number
4.1.1.1.	Lab Facility Scope of Service	BG/PP/GEN/006
4.1.1.1.	Flow Process of Molecular Lab	BG/FP/GEN/001
4.1.1.1.	Flow Process of Core Lab	BG/FP/GEN/002
4.1.1.2.	DOH License	EX DOC 1
4.1.1.3.	Code of medical ethics and Professional Conduct	BG/PP/GEN/020
4.1.1.3.	Disclaimer (Conflict of Interest)	BG/REC/GEN/020
4.1.1.3.	Confidentiality Procedure	BG/PP/GEN/001
4.1.1.3.	Confidentiality Statement	BG/REC/GEN/008
4.1.1.4.	Laboratory Director Job Description	BG/JD/HR/005
4.1.2.1/4.1.2.5	Organization Chart (Designation)	BG/REC/GEN/028
4.1.2.1	Organization Chart with names	BG/REC/GEN/029
4.1.1.4.	Delegation of Authority Procedure	BG/PP/GEN/024
4.1.2.7	Job Description for Quality Manager	BG/JD/HR/010
4.1.2.3 & 4.1.2.4	Quality Manual consist Quality Policy & Objectives	BG/QM/GEN/001
4.1.2.6	Communication Policy and Procedure	BG/PP/GEN/002
4.1.2.6	Endorsement Register	BG/REC/GEN/030
4.1.2.6	Minutes of Meeting	BG/REC/GEN/034
4.1.2.6	Event Attendance sheet	BG/REC/GEN/001

4.2. Quality management system

4.2.1. General Requirements

BIOGENIX Laboratory has established, documented, implemented and maintains a quality management system and continually improves its effectiveness in accordance with the requirements of the ISO 15189:2012 Standard.

The quality management system provides for the integration of all processes required to fulfil its quality policy and objectives and meet the needs and requirements of the users.

The laboratory

- determines the processes needed for the quality management system and ensure their application throughout the laboratory;
- determines the sequence and interaction of these processes;
- determines criteria and methods needed to ensure that both the operation and control of these processes are effective:
- ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- monitor and evaluate these processes;
- implement actions necessary to achieve planned results and continual improvement of these processes.

4.2..1. DOCUMENTATION REQUIREMENTS:

4.2.2. General:

The quality management system documentation includes:

4.2.2.1.1. statements of a quality policy and quality objectives

4.2.2.1.2. a quality manual (see 4.1.2.4)

4.2.2.1.3. procedures and records required by ISO 15189:2012

4.2.2.1.4. documents, and records determined by the laboratory to ensure the effective planning, operation and control of its processes.

4.2.2.1.5. copies of applicable regulations, standards and other normative documents.

4.2..2. QUALITY MANUAL

BIOGENIX laboratory established and maintains a quality manual that includes:

4.2.2.1.6. the quality policy (4.1.2.3);
4.2.2.1.7. a description of the scope of the quality management system;
4.2.2.1.8. a presentation of the organization and management structure of the laboratory and its place in BIOGENIX Laboratory;
4.2.2.1.9. a description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with the International Standard (15189);
4.2.2.1.10. a description of the structure and relationships of the documentation used in the quality management system;
4.2.2.1.11. The documented policies established for the quality management system and reference to the managerial and technical activities that support them.

All laboratory staff have access to and be instructed on the use and application of the quality manual and the referenced documents.

SUPPORTING DOCUMENTS:

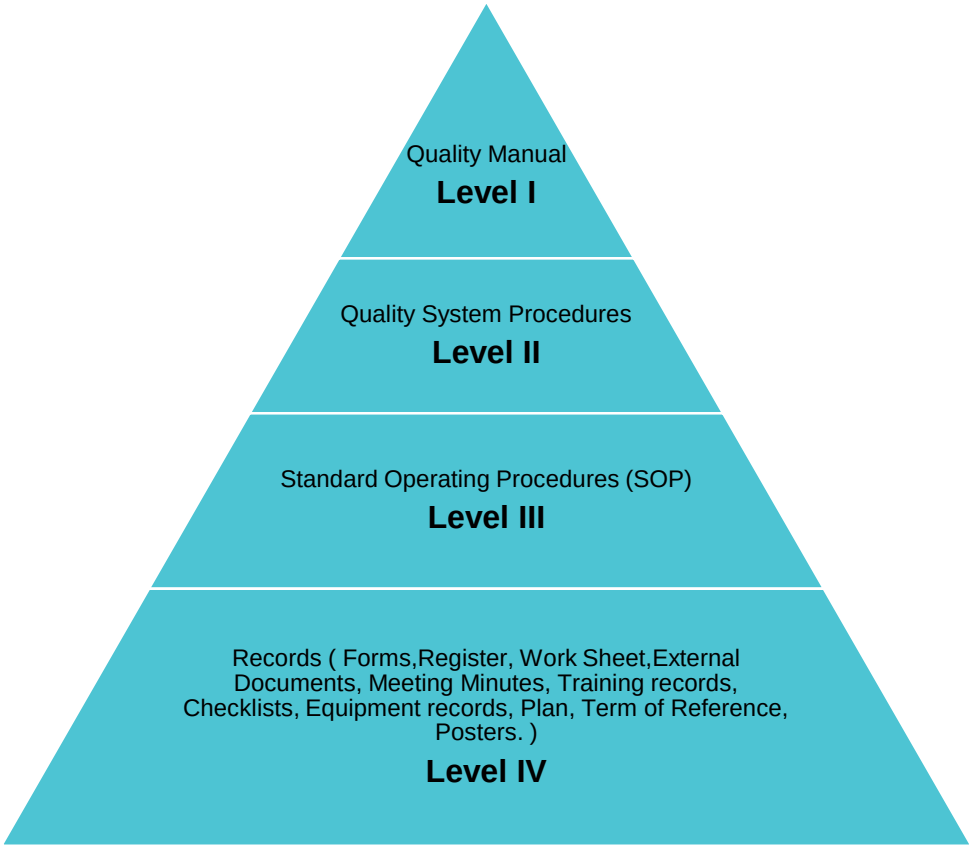
Clause No.	Document Name	Reference Number
4.2	**QUALITY MANUAL**	BG/QM/GEN/001
4.2.2.1	• Copy of ISO 15189:2012 Medical Laboratories-Requirements for Quality and Competence, Corrected Version 2014-08-15, • DOH Clinical Laboratory Standards Version 1 • Abu Dhabi Specification, ADS 8/2014, Quality Control in Medical Laboratory	EX DOC 2

4.3. DOCUMENT CONTROL

BIOGENIX Laboratory has controlled documents required by the quality

management system and ensures that unintended use of any obsolete document is prevented. The document control policy procedure ensures that the following conditions are met:

4.3.1 Documents are controlled by dividing in different levels as follows



4.3.2 Document review and approval, issue system- all documents, including those maintained in a computerized system, issued as part of the quality management system will be reviewed and approved by authorized personnel before issue.

4.3.3 All documents relevant to the Quality Management System are uniquely identified, to include

- a title;
- a unique identifier on each page;
- the date of the current edition and/or edition number;
- page number to total number of pages;

4.3.4 BIOGENIX Laboratory maintains a list of documents available as part of Quality Management System in the form of a Document Control Log which identifies the current authorized editions, control and version numbers and their distribution.

4.3.5 Only current, authorized editions of applicable documents are available at points of use.

4.3.6 BIOGENIX laboratory's document control system does not allow for amendment of documents by hand.

4.3.7 Changes to documents are identified in the revision history of each document.

4.3.8 All the documents are legible.

4.3.9 Documents are periodically reviewed and updated at a frequency that they remain fit for purpose and is documented in the Review History of each document.

4.3.10 Obsolete controlled documents are dated and marked as obsolete.

4.3.11 At least one copy of an obsolete controlled document is retained for a specified time period or in accordance applicable specified requirements.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.3	Policy and Procedure for Document control	BG/PP/GEN/003
4.3/ 4.13	Policy and Procedure for Control of Records	BG/PP/GEN/011
4.3	Document Master List	BG/REC/GEN/036
4.3	Document Change Form	BG/REC/GEN/037
4.3	Distribution List	BG/REC/GEN/038

4.4. SERVICE AGREEMENTS

4.4.1. ESTABLISHMENT OF SERVICE AGREEMENTS

BIOGENIX laboratory has documented procedures for the establishment and review of agreements for providing medical laboratory services.
Each request accepted by our laboratory for examination(s) is considered as an agreement.
Agreements to provide medical laboratory services takes into account the request, the examination and the report. The agreement specifies the information needed on the request to ensure appropriate examination and result interpretation.
The following conditions are met when the laboratory enters into an agreement to provide medical laboratory services.

a) The requirements of the customers and users, and of the provider of the laboratory services, including the examination processes used, are defined, documented and understood.
b) The laboratory has the capability and resources to meet the requirements.
c) Laboratory personnel have the skills and expertise necessary for the performance of the intended examinations.
d) Examination procedures selected are appropriate and able to meet the customers' needs.
e) Customers and users are informed of deviations from the agreement that impact upon the examination results.
f) Reference is made to any work referred by the laboratory to a referral laboratory or consultant.

4.4.2. REVIEW OF SERVICE AGREEMENTS

Reviews of agreements to provide medical laboratory services includes all aspects of the agreement. BIOGENIX Laboratory maintains records of reviews, including any significant changes and pertinent discussions. When an agreement has to be amended after the work has commenced, the same agreement review process is repeated and the details of amendments are communicated to all affected parties.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.4.1 & 4.4.2	Policy Procedure for Service Agreement	BG/PP/GEN/025
4.4.1.	Test Request Form	BG/REC/GEN/039

4.5. EXAMINATION BY REFERRAL LABORATORIES

4.5.1. SELECTING AND EVALUATING REFERRAL LABORATORIES AND CONSULTANTS:

BIOGENIX Laboratory has documented procedure for evaluating & selecting referral lab as well as consultants to get second opinion.

The procedure ensures that the following conditions are met.

- BIOGENIX Laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the quality of performance and ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations.
- Arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of the International Standard ISO 15189:2012 are met.
- Records of periodic reviews are maintained.
- A register of all referral laboratories, and consultants from whom opinions are sought, is maintained.
- Requests and results of all samples referred are kept for a pre-defined period.

4.5.1.1. PROVISION OF EXAMINATION RESULTS

BIOGENIX Laboratory ensures that referral laboratory examination results and findings are provided to the person making the request.

BIOGENIX Laboratory doesn't modify the reports received from the referral laboratory. Downloaded report are directly attached to the patient request so it includes all essential elements of the results reported by the referral laboratory without alterations that could affect clinical interpretation as required by National, Regional and Local Regulations.

All the referral lab reports are verified by the Laboratory Director to confirm their accuracy. If any errors identified the referral lab is informed to issue an amended report. As the interpretative remarks are provided by the referral

laboratories, none will be added to them. In case the clinician requires any additional information, the referral lab is instructed to interact with that particular physician without any hindrance by commercial or financial considerations.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.5	Procedure for Selection And Evaluation Of Referral Laboratories	BG/PP/GEN/026
4.5	List of Approved Referral Labs	BG/REC/GEN/040
4.5	Send Out Sample Form for Referral Lab.	BG/REC/SAMP/002
4.5	Referral Lab. Register	BG/REC/GEN/041
4.5	Selection form for Referral Lab	BG/REC/GEN/042
4.5	Evaluation Form for Referral Lab.	BG/REC/GEN/043

4.6. EXTERNAL SERVICES AND SUPPLIES

BIOGENIX Laboratory has established a document procedure and uncompromising criteria for selecting and purchasing of external services, equipment, reagents and consumable supplies to ensure fulfilling the quality requirements and conforming to relevant rules and regulations.

BIOGENIX Laboratory has defined and documented its policies and procedures for the selection and use of purchased external services (equipment, reagents, consumables, waste management, security, and referral labs) in accordance with the laboratory's requirements; however, it is necessary to collaborate with other departments to fulfil this requirement. Criteria for selection has been established.

A list of selected and approved suppliers of equipment, reagents and consumables are maintained thru. Purchasing information describes the requirement for the product or service to be purchased.

The laboratory monitors the performance of suppliers FORM to ensure that purchased services or items consistently meet the stated criteria.

SUPPORTING DOCUMENTSRECORDS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.6	Procedure For External Services and supplies	BG/PP/GEN/004
4.6	Checklist for Criteria for selection of Equipment and Equipment Suppliers	BG/REC/BME/002
4.6	Checklist for Criteria for selection of Reagent and consumable suppliers	BG/REC/GEN/044
4.6	Checklist for contractor/ vendor evaluation	BG/REC/GEN/045
4.6	Checklist for Service Supplier evaluation	BG/REC/GEN/046
4.6	List of Selected And Approved Suppliers	BG/REC/GEN/048
4.6	Checklist for service & calibration Supplier evaluation	BG/REC/GEN/047

4.7. ADVISORY SERVICES

The Medical Laboratory services offered at BIOGENIX Laboratory include appropriate interpretation and advisory services designed to meet the needs of patients and all clinical personnel responsible for patient care.

BIOGENIX Laboratory has established arrangements for communicating with users on the following:

- advising on choice of examinations and use of the services, including required type of sample, clinical indications and limitations of examination procedures and the frequency of requesting the examination;
- advising on individual clinical cases;
- professional judgments on the interpretation of the results of examinations;
- promoting the effective utilization of laboratory services;
- consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.7.	Scope Of Service	BG/PP/GEN/006
4.7.	Advisory Service File	_

4.8. RESOLUTION OF COMPLAINTS

BIOGENIX Laboratory undertakes to receive suggestions, feedback and complaints from all its customers and resolve them within a time frame and whenever deemed necessary.

BIOGENIX has policies & procedures for the resolution of complaints or other feedback received from clinicians, patients or other parties BIOGENIX Laboratory also maintains records of complaints and follow-up investigations and corrective actions taken as required by ISO15189: 2012.

Based on the criticality of the complaints / suggestions and the sections of BIOGENIX Laboratory to which the complaints pertain, they are segregated and analyzed for root cause by the Laboratory Director in consultation with Quality Manager and suitable Corrective and Preventive Action is initiated and recorded

It is also ensured that concerned personnel of BIOGENIX Laboratory are made aware of the client's complaint or suggestion and the planned Corrective Action initiated by BIOGENIX Laboratory.

Corrective Action taken on the complaints/feedback and suggestions received from clients is communicated to the clients if means of communication are available and the details of communicating to the clients are recorded. The results of the Corrective Action taken for the complaint are submitted for BIOGENIX Management Review during Quality meeting.

The effectiveness of the Corrective Action taken against complaints and suggestions is reviewed in the Management Review Meeting.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.8.	Policy Procedure For Complaint Management	BG/PP/GEN/005
4.8	Complaint Form Verbal.	BG/REC/GEN/050
4.8	Complaint Form Written.	BG/REC/GEN/049

4.9. IDENTIFICATION OF NON CONFORMITIES

To improve the quality of our procedures and processes, all errors or non-conformities are identified and control. The annual audit plan is developed which assists to identify problems. The process to track and investigate potential non-conformances in all areas of Laboratory Quality Management System is already in the developed audit plan. There is written and retrievable documentation of actions taken and follow-up monitoring to determine that corrective and preventive actions have been implemented and documented. The principles designed to effectively manage nonconforming examinations or activities are described in: **Policy Procedure for Identification and Control 0f Non Conformities (BG/PP/GEN/007)**

Any non-conformity that has been raised from audits, staff actions, meetings or errors in the Laboratory is recorded. Capturing this information supports improvements to service delivery by increasing efficiencies and to provide quality assurance to all stakeholders by ensuring the expectations of the service users are met. Incidents are reported by all levels of staff. All incidents with an investigation are risk assessed, categorized, severity assessed and the root cause can be conducted where required. All investigations are approved and closed by the laboratory director.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.9	Policy Procedure for Identification And Control of Non Conformities	BG/PP/GEN/007
4.9	Non Conformance Form	BG/REC/GEN/051

4.10. CORRECTIVE ACTION

The corrective action includes an investigative procedure to determine the underlying cause or causes of the problem, which leads to preventive actions where appropriate. Corrective actions are decided as appropriate to the magnitude of the problem and commensurate with the risks encountered. The corrective action is initiated based on the non-conformances raised in the internal audits with respect to compliance to the documented procedures and documentation adequacy, external audits, customer complaints, management review meetings, feedback from clients & staff, KPI and process weaknesses.

Types of corrective/ Preventive actions include:

i. Meeting actions
ii. Individual Staff actions
iii. Performance Development Review (Appraisal) actions
iv. Equipment error logs and issues requiring investigation / engineer support
v. Improvement suggestions
vi. Staff Trainings

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.10	Policy Procedure for Corrective Action	BG/PP/GEN/008

4.10	Corrective And Preventive Action Report Form	BG/REC/GEN/052
4.10	Action Plan	BG/REC/GEN/053

4.11. PREVENTIVE ACTION:

Improvement and potential sources of nonconformities either technical or concerning the quality system is identified by the Laboratory Director/Quality Manager along with technical staff. Preventive action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities

The preventive actions are process for identifying opportunities for the improvement in two ways:

i. Once problem is identified and corrective/preventive action taken so problem is not recurring. This is reaction to the identification of the problem;
ii. The other, potential problem identified to eliminate the causes of non-conformities, so problem doesn't occur. This is proactive approach.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.11	Procedure for Preventive Action	BG/PP/GEN/009
4.10/4.11	Corrective and Preventive Action Report Form	BG/REC/GEN/052
4.9	Nonconformance form	BG/REC/GEN/051

4.12. CONTINUAL IMPROVEMENT:

The laboratory is committed to meeting the needs of users and therefore uses a total 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 of instruments
v. Corrective/ Preventive action
vi. Review of progress with objectives
vii. Quality management meetings
viii. Audit for simple improvements
ix. More complex issues may require an investigation, root cause analysis (RCA), risk assessment, an action plan. These are feedback to staff via staff meetings.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.12	Procedure for Continuous Quality Improvement	BG/PP/GEN/010
4.10/4.11	Corrective And Preventive Action Report Form	BG/REC/GEN/052
4.9	Nonconformance form	BG/REC/GEN/051

4.13. CONTROLS OF RECORDS:

BIOGENIX has established and implemented procedures for the identification, collection, indexing, access, storage and safe disposal of quality and technical records. BIOGENIX laboratory creates records in order to maintain the quality of work. All records are legible and stored in such a way that they are readily retrievable. At BIOGENIX laboratory we have following type of records which are identified by its name and reference number.

i. Work instruction
ii. Flow Process
iii. Forms
iv. Calibration records / Maintenance record
v. Chart, posters, notice
vi. Quality Control Record
vii. Incident Record
viii. Risk Management Record
ix. Customer compliant and action taken
x. Agenda and Meeting Minutes
xi. Attendance sheet for minutes and training;
xii. Record of Internal External Audits
xiii. Inter Laboratory Comparison Examination
xiv. Record of management Review
xv. Corrective and preventive action plans
xvi. Staff qualification, training and competency records
xvii. Request for examination – results and reports
xviii. Records of receipt of samples in lab
xix. Lab work books and work sheets
xx. Information on reagent used for examination, lot documentation, certificate of supplier etc.
xxi. Equipment records: maintenance records, supplier information, reagents information for that equipment, calibration records, print out from the instruments.

The records which are confidential are kept confidential, secure in an optimal storage environment to prevent deterioration and unauthorized access. Storage and release of documents

is controlled and recorded. The laboratory has a procedure that defines the length of time various records pertaining to the quality management system and examination results are to be retained.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.3/4.13	Policy Procedure for Control of Records	BG/PP/GEN/011
4.3/4.13	Document Change Form	BG/REC/GEN/037

4.14. EVALUATION AND AUDITS

4.14.1. General

The laboratory plans and implements the evaluation and internal audit processes needed to:

a) demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users;

b) ensure conformity to the quality management system;

c) Continually improve the effectiveness of the quality management system.

The results of evaluation and improvement activities will be included in the input to the management review.

4.14.2. PERIODIC REVIEW OF REQUESTS, AND SUITABILITY OF PROCEDURES AND SAMPLE REQUIREMENTS

Authorized personnel periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received.

The laboratory periodically reviews its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected, and the sample is properly collected to preserve the measured analyte.

4.14.3. ASSESSMENT OF USER FEEDBACK

The laboratory seeks information relating to user perception as to whether the service has met the needs and requirements of users. The methods for obtaining and using this information includes cooperation with users or their representatives in monitoring the laboratory's performance. Laboratory ensures

the confidentiality to other users. Records are kept of information collected and actions taken.

4.14.4. STAFF SUGGESTIONS

G42 Laboratory encourages staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions are evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management are maintained.

4.14.5. INTERNAL AUDIT

Internal audits are conducted to comply with the requirements of the ISO 15189: 2012 Quality Management System, Internal Audit of all elements of the system, both managerial and technical is conducted (at least) once in a year as per the audit schedule prepared by the Quality Manager. The Internal Audit focuses on all elements and emphasizes areas critically important to patient care. Quality Manager ensures that personnel at BIOGENIX Laboratory does not audit their own activities / department at the time of Internal Quality Audit. Internal audits are conducted to determine whether all activities in the quality management system including pre-examination, examination, and post examination:

4.14.5.1. Conform to the requirements of ISO 15189:2012 and to the requirements established by BIOGENIX Laboratory, and

4.14.5.2. Are implemented, effective, and maintained BIOGENIX laboratory conducts internal audits to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination conform to the requirements of the International Standard ISO15189:2012 and to the requirements established by the laboratory, and are implemented, effective, and maintained.

Audits are planned, organized and carried out by the Laboratory director and Laboratory Quality Managers. When deficiencies or opportunities for improvement are noted, the laboratory undertakes actions, which are documented and carried out within agreed upon time. The main elements of the Quality Management System are subjected to Internal Audit (at least) once every year.

Audits are conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system. The audit program takes into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined and documented.

The results of the internal audits are submitted to management for review and it forms part of the Management Review Meeting

4.14.6. RISK MANAGEMENT

The laboratory evaluates the impact of work processes and potential failures on examination results as they affect patient safety and modifies processes to reduce or eliminate the identified risks and document decisions and actions taken.

4.14.7. QUALITY INDICATORS

The laboratory establishes quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

The process of monitoring quality indicators is planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement. Quality indicator data are collected at the end of each month and submitted to the Laboratory quality department. The data are analyzed, validated and presented in the monthly quality council meeting. The indicators are reviewed by the entire Laboratory management team to ensure their continued appropriateness. Any deviation is discussed with the Laboratory Director and corrective action are suggested and implemented.

The laboratory, in consultation with the users, establishes turnaround times for each of its examinations that reflect clinical needs. The laboratory periodically evaluates whether or not it is meeting the established turnaround times.

4.14.8. REVIEWS BY EXTERNAL ORGANIZATIONS

When reviews by external organizations (DOH, EHSMS, JCI and CAP) indicate the laboratory has nonconformities or potential nonconformities, the laboratory takes appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.14	Policy Procedure for Evaluation and Audit	BG/PP/GEN/012
4.14	Internal Audit Checklist	BG/REC/GEN/054
4.14	Internal Audit Plan	BG/REC/GEN/055
4.14.6	Risk Management Policy Procedure	BG/PP/GEN/013
4.14.6	Risk Assessment Work Sheet	BG/REC/GEN/056

4.14.6	Risk Registry	BG/REC/GEN/057
4.14.7.	Ongoing Monitoring of Laboratory Procedures	BG/PP/GEN/021
4.14.7	Template for KPI Reports	BG/REC/GEN/058

4.15. MANAGEMENT REVIEW

4.15.1. General

BIOGENIX Laboratory reviews the quality management system annually to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

4.15.2. REVIEW INPUT

In order to ensure continuing suitability and effectiveness in support of patient care and to introduce any necessary changes or improvements, BIOGENIX Laboratory reviews the laboratory's Quality Management System and all of its medical services, including examination and advisory activities, the results of the review are incorporated into a plan that includes goals, objectives and action plans. Management review meeting are held once every year after the Internal Audit Report submitted to the management to ensure continuing suitability and effectiveness in support of patient care and to introduce necessary changes.

The input to management review includes information from the results of evaluations of the following:

4.15.2.1. the periodic review of requests, and suitability of procedures and sample requirements (see 4.14.2);

4.15.2.2. assessment of user feedback (see 4.14.3);

4.15.2.3. staff suggestions (see4.14.5);

4.15.2.4. internal audits (see 4.14.6);

4.15.2.5. risk management (see 4.14.6);

4.15.2.6. use of quality indicators (see 4.14.7);

4.15.2.7. reviews by external organizations (see 4.14.8);

4.15.2.8. results of participation in inter laboratory comparison programs (PT/EQA) (see 5.6.3);

4.15.2.9. monitoring and resolution of complaints (see 4.8);

4.15.2.10. performance of suppliers (see 4.6);

4.15.2.11. identification and control of nonconformities (see 4.9);

4.15.2.12. results of continual improvement (see 4.12) including current

status of corrective actions (see 4.10) and preventive actions (see 4.11);

4.15.2.13. follow up actions from previous management reviews;

4.15.2.14. changes in the volume and scope of work, personnel, and premises that could affect the quality management system;

4.15.2.15. recommendations for improvement, including technical requirements.

4.15.3. REVIEW ACTIVITIES

The review analyses the input information for causes of nonconformities, trends and patterns that indicate process problems. This review includes assessing these opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The quality and appropriateness of the laboratory's contribution to patient care are, to the extent possible, also objectively evaluated.

4.15.4. REVIEW OUTPUT

The output from the management review is incorporated into a record that documents any decisions made and actions taken during management review related to:

a) improvement of the effectiveness of the quality management system and its processes;

b) improvement of services to users;

c) Resource needs.

d) Laboratory staff are informed of these findings and the decisions made as a result of the review. Quality Manager ensures

e) that all actions planned out of management review are discharged within the agreed upon time.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
4.15	Policy Procedure for Management Review	BG/PP/GEN/015

5. TECHNICAL REQUIREMENTS

5.1. PERSONNEL

5.1.1. General

The laboratory has a documented procedure for personnel management and maintains records for all personnel to indicate compliance with requirements.

5.1.2. PERSONAL QUALIFICATIONS

BIOGENIX Laboratory is committed to use qualified and competent professionals in its processes fulfilling the requirements of ISO15189:2012, and DOH standards and assigning specific responsibilities and authority to all its personnel.

BIOGENIX management has an organizational plan, personnel policies and job descriptions that define qualifications and duties for all personnel. BIOGENIX Laboratory ensures that the authorized signatories have the necessary qualification in the concerned specialty as per the requirement of Clause 5.1.1.3 and demonstrate knowledge and competence in the concerned specialty. The personnel making judgments with reference to examinations will have the applicable theoretical and practical background and experience.

Laboratory Director of BIOGENIX Laboratory has the necessary qualification, responsibility and authority as per the requirement of ISO 15189 and DOH requirements.

Technical staffs of BIOGENIX Laboratory have the necessary qualifications as per the requirement of DOH.

5.1.3. JOB DESCRIPTIONS

BIOGENIX Laboratory has adequate staff resources to undertake the work required and to carry out other functions of the Quality Management System. BIOGENIX Laboratory has job descriptions that describe responsibilities, authorities and tasks for all personnel.

5.1.4. PERSONNEL INTRODUCTION TO THE ORGANIZATIONAL ENVIRONMENT

BIOGENIX has a program to introduce new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services.

5.1.5. TRAINING

G42Laboratory provides training for all personnel which includes the following areas:

a) the quality management system;
b) assigned work processes and procedures;
c) the applicable laboratory information system;
d) health and safety, including the prevention or containment of the effects of adverse incidents;
e) ethics;

f) Confidentiality of patient information.

Personnel that are undergoing training are supervised at all times. The effectiveness of the training program is reviewed periodically.

5.1.6. COMPETENCE ASSESSMENT

Following appropriate training, BIOGENIX Laboratory assesses the competence of each person to perform assigned managerial or technical tasks according to established criteria.

Reassessment takes place at regular intervals. Retraining occurs when necessary.

Competence of laboratory staff are assessed by using any combination or all of the following approaches under the same conditions as the general working environment:

a) direct observation of routine work processes and procedures, including all applicable safety practices;

b) direct observation of equipment maintenance and function checks;

c) monitoring the recording and reporting of examination results;

d) review of work records;

e) assessment of problem-solving skills;

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
5.1.	Procedure for Personnel Management	BG/PP/GEN/016
5.1.3	Technical Staff Assignment	BG/PP/HR/001
5.1.3.	Lab Director Job Description	BG/JD/HR/005
5.1.3.	Job Description For Biomedical Engineer	BG/JD/HR/001
5.1.3.	Job Description For Safety Manager	BG/JD/HR/002
5.1.3.	Job Description For Lab. Coordinator	BG/JD/HR/003
	Job Description For Deputy Director	BG/JD/HR/004
5.1.3.	Job Description For Quality Manager	BG/JD/HR/006
5.1.3.	Job Description For Facility manager	BG/JD/HR/007

5.1.3.	Job Description For MLT Collection Department	BG/JD/HR/008
5.1.3.	Job Description For MLT Extraction Department	BG/JD/HR/009
5.1.3.	Job Description of MLT Reagent Department	BG/JD/HR/010
5.1.3	Job Description For MLT QPCR Department	BG/JD/HR/011
5.1.3	Job Description For MLT Core Lab	BG/JD/HR/014
5.1.3	Job Description For Inventory Manager	BG/JD/HR/012
5.1.3	Job Description For Quality Officer	BG/JD/HR/013
5.1.5.	New Staff General Orientation Checklist	BG/REC/GEN/012
5.1.5.	New Staff Training Checklist	BG/REC/GEN/063
5.1.5.	Attendance Sheet	BG/REC/GEN/001
5.1.6.	Competency Assessment Form.(Core Lab)	BG/REC/GEN/009-A
5.1.6.	Competency Assessment Form for Molecular Lab- Sample Collection	BG/REC/GEN/009-B
5.1.6	Competency Assessment Form for Molecular Lab- Reagent preparation	BG/REC/GEN/009-C
5.1.6	Competency Assessment Form for Molecular Lab- Extraction	BG/REC/GEN/009-D
5.1.6	Competency Assessment Form for Molecular Lab- Q-PCR	BG/REC/GEN/009-E
5.1.7.	Staff Annual Appraisal Form	BG/REC/GEN/070
5.1.5.	Training Plan	BG/REC/GEN/013
5.1.	Staff Summary Monitoring List	BG/REC/GEN/065
5.1.6.	Trainee Assessment Sheet	BG/REC/GEN/014
5.1.6.	Trainer Assessment	BG/REC/GEN/015

5.1.6.	Competency Of Quality Manager	BG/REC/GEN/066
5.16	Competency of Pathologist	BG/REC/GEN/071

5.2. ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

5.2.1. General

BIOGENIX Laboratory has enough space allocated so that the work is performed without compromising the quality of work, quality control procedures, and safety of personnel and patients. For effective operation, the laboratory has allocated space considered as adequate by the Laboratory Director

5.2.2. LABORATORY AND OFFICE FACILITIES

BIOGENIX Laboratory provides an environment suitable for the tasks to be undertaken, to ensure the following conditions are met:

5.2.2.1. Access to all BIOGENIX Laboratory work areas affecting the quality of examinations is controlled. Access control ensures entry for laboratory staff only considering safety, confidentiality, quality and prevailing practices.

5.2.2.2. Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access.

5.2.2.3. Facilities for examination are taken care for correct performance of examinations including, energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions.

5.2.2.4. Communication systems are provided within the laboratory, which are appropriate to the size and complexity of our facility to ensure the efficient transfer of information.

5.2.2.5. Safety facilities and devices are provided and their functioning regularly verified.

5.2.3. STORAGE FACILITIES

Storage space and temperature are provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results.

Clinical samples and materials used in examination processes are stored in a manner to prevent cross contamination.

BIOGENIX Laboratory segregates, stores and disposes dangerous materials

as per DOH and Abu Dhabi, OHSHAD regulations.

5.2.4. STAFF FACILITIES

BIOGENIX Laboratory ensures adequate access to washrooms, supply of drinking water and to facilities for storage of personal protective equipment and clothing for all its staff.

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5.2.5. FACILITY MAINTENANCE AND ENVIRONMENTAL CONDITIONS

BIOGENIX Laboratory ensures that the work areas are clean and well maintained. BIOGENIX Laboratory ensures good housekeeping practices and trains its personnel to achieve the same.

BIOGENIX Laboratory monitors, controls and records environmental conditions, as required by local regulations or where they may influence the quality of the sample, results, and/or the health of staff. Attention is paid to factors such as light, sterility, dust, noxious or hazardous fumes, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics, as appropriate to its activities concerned so that these factors do not invalidate the results or adversely affect the required quality of any examination.

There are effective separations between adjacent laboratory sections where incompatible activities take place. Measures are taken to prevent cross contamination.

The laboratory provides a quiet and uninterrupted work environment where it is needed.

SUPPORTING DOCUMENTS

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
5.2.	Policy Procedure for Accommodation and Environment	BG/PP/GEN/030
5.2	Standard precaution	BG/PP/INF/001
5.2.	Infection Control Plan	BG/PP/INF/002
5.2.	Personal Protective Equipment	BG/PP/INF/003
5.2.	Occupational Exposure Management	BG/PP/INF/004
5.2	Biohazard Spillage Management	BG/PP/INF/005

5.2	Biohazard Spill Kit Checklist	BG/REC/INF/004
5.2	Chemical Spill Kit Checklist	BG/REC/OSH/007
5.2	First Aid Box Checklist	BG/REC/OSH/008
5.2	Eyewash and Shower Checklist	BG/REC/OSH/003
5.2	Exposure Control Plan	BG/PP/INF/006
5.2.	Laboratory Waste management	BG/PP/INF/007
5.2.	Laboratory Cleaning and Disinfection	BG/PP/INF/008
5.2.	Formulating Disinfectants	BG/PP/INF/009
5.2.	Communication of Infectious Diseases	BG/PP/INF/010
5.2.	Operation & Maintenance of Medibios	BG/PP/INF/011
5.2.	Operation & Maintenance of Autoclave	BG/PP/INF/012
5.2.	Infection Control Staff Compliance Checklist	BG/REC/INF/001
5.2.	Daily Laboratory Cleaning & Disinfection	BG/REC/INF/002
5.2.	Fumigation Checklist	BG/REC/INF/003
5.2	Laboratory Waste Management	BG/POS/INF/001
5.2	How to Hand Rub	BG/POS/INF/002
5.2	How to Hand Wash	BG/POS/INF/003
5.2	Donning of PPE Illustration Posters – Molecular Laboratory.	BG/POS/INF/004
5.2	Doffing of PPE Illustration Posters – Molecular Laboratory.	BG/POS/INF/005
5.2	Room Temperature and Humidity	BG/REC/GEN/005

5.3. LABORATORY EQUIPMENT, REAGENTS AND CONSUMABLES

5.3.1. EQUIPMENT

5.3.1.1. General

BIOGENIX Laboratory has a documented procedure for selection, purchasing and management of equipment. The laboratory is well furnished with all the equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage). Whenever BIOGENIX Laboratory uses equipment that is outside its permanent control, the laboratory management ensures that the requirements of ISO 15189:2012 standards are met.

5.3.1.2. EQUIPMENT ACCEPTANCE TESTING

BIOGENIX Laboratory ensures [upon installation and before use] that the equipment it uses is capable of achieving the performance required and complies with specifications relevant to the examinations concerned.

Each item of equipment in the laboratory is uniquely labelled with an asset ID by the biomedical engineering department. The label mentions the date of last PPM performed and when the next PPM due. BIOGENIX Laboratory staff ensures all reagents, consumables and kits are labeled and stored as per the requirement. The label clearly indicates content and quantity, concentration or titer, date received/prepared, date of opening, storage requirements and expiry dates, as applicable.

5.3.1.3. EQUIPMENT INSTRUCTIONS FOR USE

The equipment in the BIOGENIX Laboratory are operated at all times by trained and authorized personnel.

BIOGENIX Laboratory ensures that up to date instructions on the use and maintenance of equipment including any relevant manuals and directions for use provided by the manufacturer of the equipment are readily available to the laboratory personnel.

BIOGENIX has procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.

5.3.1.4. EQUIPMENT CALIBRATION AND METROLOGICAL TRACEABILITY

All the analyzers used in the laboratory are calibrated by the vendor's engineer as per the established schedule.

This procedure includes the following:

5.3.1.4.1. BIOGENIX Laboratory follows the conditions of use and the manufacturer's instructions;

5.3.1.4.2. BIOGENIX Laboratory ensures the metrological

traceability of the calibration standard and the traceable calibration of the item of equipment;

5.3.1.4.3. BIOGENIX Laboratory verifies the required measurement accuracy and the functioning of the measuring system at defined intervals;

5.3.1.4.4. BIOGENIX Laboratory keeps records provided by the vendor's engineer for the calibration status and date of recalibration;

5.3.1.4.5. BIOGENIX Laboratory ensures that prior correction factors are correctly updated, whenever calibrations give rise to a set of correction factors.

5.3.1.4.6. BIOGENIX Laboratory safeguards equipment, including hardware, software, reference materials, consumables, reagents and analytical systems from adjustments or tampering that might invalidate examination results.

Metrological traceability is to a reference material or reference procedure of the higher metrological order available.

Documentation of calibration traceability to a higher order reference material or reference procedure are provided by our examination system manufacturer. The manufacturer's examination system and calibration procedures are used without modification in BIOGENIX Laboratory.

5.3.1.5. EQUIPMENT MAINTENANCE AND REPAIR

BIOGENIX management has established and implemented a program that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. BIOGENIX management also has a documented and recorded program of preventive maintenance and calibration which at a minimum follows manufacturer's recommendation.

BIOGENIX Laboratory has a procedure addressing monitoring the calibration status of equipment, reagent and analytical systems. This is supported by calibration plan and equipment history record.

BIOGENIX Laboratory also has a procedure explaining preventive maintenance practices followed in the laboratory.

BIOGENIX Laboratory has a documented program of preventive maintenance as per the manufacturer's instructions.

SUPPORTIVE DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
5.3	Policy Procedure For Selection, Purchasing And Management Of Equipment	BG/PP/GEN/017
5.3	Policy Procedure of Selection, verification, validation of Examination Instruments	BG/PP/GEN/027
5.3	Policy Procedure for Equipment calibration and Metrological Traceability	BG/PP/GEN/018
5.3	Policy Procedure For Planned Preventive Maintenance Of Equipment	BG/PP/BME/001
5.3	Policy Procedure For Corrective Maintenance Of Equipment	BG/PP/BME/002
5.3	Procedure For Reception, Storage, Acceptance Testing And Inventory Management	BG/PP/GEN/019
5.3	Policy Procedure For Verification of new lots & shipments prior to use.	BG/PP/GEN/033
5.3	Checklist for Criteria for selection of Equipment and Equipment Supplier	BG/REC/BME/012
5.3	Checklist for IQ	BG/REC/BME/003
5.3	Checklist for OQ	BG/REC/BME/004
5.3	Checklist for HA	BG/REC/BME/005
5.3	Authorization List to use Lab. Equipment	BG/REC/GEN/011
5.3	Instrument Summary monitoring List	BG/REC/BME/011
5.3	Maintenance of Freezer	BG/REC/GEN/031
5.3	Maintenance of Refrigerator	BG/REC/GEN/032
5.3	Maintenance of Hot Air Oven	BG/REC/GEN/033
5.3	Maintenance of BIOER line 96610 (QPCR machine)	BG/REC/MOL/001

5.3	Big Centrifuge (CENC)	BG/REC/GEN/059
5.3	Maintenance for Alinity	BG/REC/GEN/060
5.3	Roller Mixer Maintenance Sheets	BG/REC/GEN/061
5.3	Daily Maintenance Sheet Uranus Elisa machine	BG/REC/GEN/062
5.3	Weekly Maintenance Sheet Uranus Elisa machine	BG/REC/GEN/063
5.3	Maintenance of Plate Vortex	BG/REC/GEN/024
5.3	Biosafety Cabinet Maintenance Sheet	BG/REC/GEN/021
5.3.	Maintenance of Plate Centrifuge	BG/REC/GEN/022
5.3.	Maintenance of Eppendorf Centrifuge	BG/REC/GEN/023
5.3.	CELL DYN EMERALD 22 maintenance sheet	BG/REC/HEM/001
5.3.	Maintenance Procedure of Cell Dyn Emerald	BG/PP/HEM/001
5.3.	SOP for Cell Dyn Emerald	BG/SOP/HEM/001
5.3.	SOP for Abbott Alinity	BG/SOP/SERO/002
5.3.	SOP for Uranus (ELISA Analyzer)	BG/SOP/SERO/004
5.3.	Policy Procedure for Plate Centrifuge	BG/PP/GEN/027
5.3.	Policy Procedure for Eppendorf Centrifuge	BG/PP/GEN/028
5.3.	Policy Procedure for Big Centrifuge	BG/PP/GEN/029
5.3.	Refrigerator Temperature log	BG/REC/GEN/006
5.3.	Freezer Temperature Log	BG/REC/GEN/007
5.3.	Controls & Calibrator Reconstitution Records	BG/REC/GEN/004
5.3.	Vendor Evaluation Form	BG/REC/BME/010
5.3.	Third Party Calibration company evaluation	BG/REC/BME/013

5.3	Third Party Calibration company Selection	BG/REC/BME/014
5.3	Policy Procedure for Extraction room process	BG/PP/MOL/003
5.3	Policy Procedure for QPCR room Process	BG/PP/MOL/004
5.3	Maintenance of MGI960	BG/REC/MOL/002
5.3	Endorsement sheet for reagent Room	BG/REC/MOL/014
5.3	Request and transfer of Reagent Preparation for extraction log sheet	BG/REC/MOL/015
5.3	RT PCR kit internal Quality Control Vials transfer Log Sheet	BG/REC/MOL/016
5.3	Internal Quality Control Transfer and storage slip	BG/REC/MOL/017

5.4. PRE-EXAMINATION PROCEDURE

5.4.1. General

BIOGENIX Laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.

5.4.2. INFORMATION FOR PATIENTS AND USERS

BIOGENIX Laboratory has information available for patients and users of the laboratory services. The information includes as appropriate:

a) the location of the laboratory;
b) types of clinical services offered by the laboratory;
c) opening hours of the laboratory;
d) the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time;
e) instruction for preparation of the patient;
f) instructions for patient-collected samples;
g) instructions for transportation of samples, including any special handling needs;
h) any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed);
i) the laboratory's criteria for accepting and rejecting samples;
j) a list of factors known to significantly affect the performance of the examination or the interpretation of the results;

k) availability of clinical advice on ordering of examinations and on interpretation of examination results;
l) the laboratory's policy on protection of personal information;
m) the laboratory's complaint procedure.

5.4.3. Request form information

BIOGENIX Laboratory has a test request form, which contains the information to identify the patient and the authorized requester, as well as pertinent clinical data as required by DOH and ISO 15189:2012 Test request form of BIOGENIX Laboratory provide for gathering relevant patient information.

The test request of BIOGENIX Laboratory has the following details:

a) patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier;
b) name of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details;
c) type of primary sample;
d) examinations requested;
e) clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;
f) date and, where relevant, time of primary sample collection;
g) date and time of sample receipt.

The format of the request form (e.g. electronic or paper) and the manner in which requests are communicated to the laboratory are determined in discussion with the users of laboratory services.

BIOGENIX Laboratory has a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time.

BIOGENIX Laboratory cooperates with users or their representatives in clarifying the user's request.

5.4.4. PRIMARY SAMPLE COLLECTION AND HANDLING

5.4.4.1. General

BIOGENIX Laboratory has well-defined instructions documented and implemented for primary sample collection and handling. These instructions are contained in a Collection Manual.

The documented procedures are available to those responsible for primary sample collection whether or not the collectors are laboratory

staff.

Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, need a more detailed explanation and, in some cases, written consent.

In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.

5.4.4.2. INSTRUCTIONS FOR PRE-COLLECTION ACTIVITIES

BIOGENIX Laboratory's sample collection policy procedures include the following:

5.4.4.2.1. Completion of request form or electronic request,
5.4.4.2.2. Preparation of the patient
5.4.4.2.3. Type and amount of primary sample to be collected with descriptions of the primary sample containers and any necessary additives;
5.4.4.2.4. Special timing of collection, if required,
5.4.4.2.5. Clinical information relevant to or affecting sample collection, examination performance or result interpretation

5.4.4.3. INSTRUCTIONS FOR COLLECTION ACTIVITIES

BIOGENIX Laboratory has instructions for collection activities that include the following:

5.4.4.3.1. Positive identification, in detail, of the patient from whom a primary sample is collected,
5.4.4.3.2. Verification that the patient meets pre-examination requirements [e.g. medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.],
5.4.4.3.3. Primary sample collection instructions for Nasopharyngeal swabs, with descriptions of the primary sample containers and any necessary additives
5.4.4.3.4. In situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any processing and sample transport conditions are determined and communicated to the appropriate clinical staff,
5.4.4.3.5. Labelling of primary samples in a manner that provides

an unequivocal link with the patients from whom they are collected,

5.4.4.3.6. Recording the identity of the person collecting the primary sample and collection date, and, when needed, recording of the collection time,

5.4.4.3.7. Instructions for proper storage conditions before collected samples are delivered to the laboratory,

5.4.4.3.8. Safe disposal of materials used in the collection.

5.4.4.3.9. Primary samples are traceable, normally by request, to an identified individual.

5.4.5. SAMPLE TRANSPORTATION

BIOGENIX Laboratory monitors the transportation of samples to the laboratory such that they are transported:

5.4.5.1. within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned,

5.4.5.2. within a temperature interval specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples, and

5.4.5.3. In a manner that ensures safety for the carrier, the general public and the receiving laboratory, in compliance with DOH and OSHAD regulations.

5.4.6. SAMPLE RECEPTION

BIOGENIX Laboratory's procedure for sample reception ensures that the following conditions are met:

5.4.6.1. Samples are unequivocally traceable, by request and labelling, to an identified patient or site. Patient samples and request are labelled with barcode ID containing demographics and ordered test details making them traceable throughout the processing.

5.4.6.2. BIOGENIX Laboratory has developed and documented criteria for acceptance or rejection of samples and the same is applied to all the samples received in the laboratory.

5.4.6.3. Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report indicates the nature of the problem and, where applicable, that caution is required when interpreting the result.

5.4.6.4. All samples received in the BIOGENIX Laboratory are recorded. The date and time of receipt and/or registration of samples is recorded. The identity

of the person receiving the sample is also being recorded.

5.4.6.5. Sample technologists evaluates received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).

5.4.6.6. All (aliquot) portions of the primary sample are labelled with a minimum of two identifiers to unequivocally trace them to the original primary sample.

5.4.7. PRE-EXAMINATION HANDLING, PREPARATION AND STORAGE

5.4.7.1. BIOGENIX Laboratory has procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.

5.4.7.2. Laboratory procedures includes time limits for requesting additional examinations or further examinations on the same primary sample.

SUPPORTIVE DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
5.4.2.	Policy Procedure On Service Agreement	BG/PP/GEN/025
5.4.2	Test request Form	BG/REC/GEN/039
5.4.2.	Scope Of Service	BG/PP/GEN/006
5.4.	Policy Procedure for Patient Identification	BG/PP/SAMP/001
5.4	Policy Procedure for Sample Labelling	BG/PP/SAMP/002
5.4.4.2.	Policy Procedure for Patient Instruction and Preparation	BG/PP/SAMP/003
5.4	Policy Procedure for Covid19 sample collection, handling and transportation	BG/PP/SAMP/004
5.4.	Phlebotomy adverse Reactions	BG/PP/SAMP/007
5.4.	Blood Sample handling, preparation and Storage	BG/PP/SAMP/008
5.4	Blood Sample Transportation	BG/PP/SAMP/009
5.4	Policy Procedure Sample Rejection	BG/PP/SAMP/010

5.4.4.1	Policy Procedure for Patient Consent	BG/PP/GEN/036
5.4.4.1	General Consent form	BG/REC/GEN/004
5.4.4.1.	Policy Procedure for COVID Sample Reception and Inactivation	BG/PP/MOL/001
5.4.4.1.	Flow Process Molecular Lab.	BG/FP/GEN/001
5.4.3.	Flow Process Core Lab.	BG/FP/GEN/002
5.4.4.1	Policy Procedure for Blood Sample Collection By Venipuncture Using Syringe.	BG/PP/SAMP/006
5.4.6.	Sample Rejection Form	BG/REC/SAMP/003
5.4.2.	Procedure For Complaint Management	BG/PP/GEN/005
5.4.2.	Written Complaint Form	BG/REC/GEN/049
5.4.2.	Verbal Complaint Form	BG/REC/GEN/050
5.4.	Sample Information Verification Record	BG/REC/SAMP/004
5.4.	Matching Serial Number Details	BG/REC/SAMP/005
5.4.	COVID-19 Sample Inactivation Record	BG/REC/MOL/004
5.4	Record of Inactivated Sample Handover to Extraction Room	BG/REC/MOL/005
5.4	Sample inactivation Slip	BG/REC/MOL/006
5.4	Sample storage slip	BG/REC/MOL/007
5.4	sample inactivation processing record	BG/REC/MOL/008
5.4	Shift Summary Report	BG/REC/MOL/009
5.4	Empty Transport Box Dispatch Log Sheet	BG/REC/MOL/010
5.4	Empty Transport Box Dispatch Log Slip	BG/REC/MOL/011
5.4	Sample on Hold	BG/REC/MOL/012

5.4	COVID-19 Sample arrangement work sheet	BG/REC/MOL/024

5.5. EXAMINATION PROCESSES

5.5.1. SELECTION, VERIFICATION AND VALIDATION OF EXAMINATION PROCEDURES

5.5.1.1. GENERAL

BIOGENIX Laboratory uses examination procedures, including those for selecting/taking sample portions, which meets the needs of the users of laboratory services and are appropriate for the examinations. BIOGENIX Laboratory uses only those procedures that have been published in authoritative textbooks, peer – reviewed journals or published by regional, national or international bodies. The identity of persons performing activities in examination processes will be recorded and documented.

It will be made sure that the specified requirements (performance specifications) for each examination procedure will relate to the intended use of that examination.

5.5.1.2. VERIFICATION OF EXAMINATION PROCEDURES

BIOGENIX Laboratory uses only validated procedures for confirming that the examination procedures are suitable for use. The verifications are done as extensively as necessary to meet the needs in the given application. BIOGENIX Laboratory records the results obtained during validation and the procedure used for validation. The methods and procedures selected for use in BIOGENIX Laboratory are evaluated and only if found to give satisfactory results they are used for medical examinations. The Laboratory Director reviews the laboratory procedures initially and then biannually or whenever methodology is changed, and such reviews are documented.

BIOGENIX Laboratory obtains information from the manufacturer/method developer for confirming the performance characteristics of the procedure.

Performance specification claimed for each procedure used in an examination is independently verified and confirmed so that they relate to the intended use of that procedure.

BIOGENIX Laboratory documents the procedure used for the

verification and records the results obtained. The Laboratory Director reviews the verification results and record the review.

5.5.1.3. Measurement uncertainty of measured quantity values

The principles of estimating uncertainty of measurement contribute to ensure that test outputs are fit for their clinical purpose by:

- Defining what an analytical method measures
- Meeting a defined analytical goal
- Indicating the confidence that can be placed in a test result

Contributing to defining, monitoring and indicating where a test procedure may be improved. The measurement uncertainty is established by technical staff as a future reference for the review, and reestablishment of the measurement uncertainty.

There is a laboratory document describing the principles of measurement of uncertainty (MOU)

5.5.1.4. VALIDATION OF EXAMINATION PROCEDURES

BIOGENIX Laboratory validates examination procedures derived from the following sources if they are put into use:

5.5.1.4.1. non-standard methods;
5.5.1.4.2. laboratory designed or developed methods;
5.5.1.4.3. standard methods used outside their intended scope;
5.5.1.4.4. Validated methods subsequently modified.

The validation is as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.

When changes are made to a validated examination procedure, the influence of such changes is documented and, when appropriate, a new validation is carried out.

5.5.2. BIOLOGICAL REFERENCE INTERVALS OR CLINICAL DECISION VALUES

Biological reference range study of the population served is regarded as negative or Not detected.

5.5.3. DOCUMENTATION OF EXAMINATION PROCEDURES

All procedures and necessary instructions (SOPs) in BIOGENIX Laboratory are documented in English language, which is commonly understood by the

staff in the laboratory and is made available at the working area for relevant staff. The procedures are based on the product insert provided by the manufacturer. Any deviation is reviewed and documented. Additional information required to perform the procedure is also documented. Each new version of examination kits with major changes in reagents or procedure is checked for performance and suitability for intended use. The standard operating procedures (SOPs) are prepared by the section in charges and technologists with review & approval by the Quality Manger. Only approved manuals are issued by the Laboratory Director and used. The documentation includes when applicable, the following:

a) purpose of the examination;
b) principle and method of the procedure used for examinations;
c) performance characteristics (see 5.5.1.2 and 5.5.1.3);
d) type of sample (e.g. plasma, serum, urine);
e) patient preparation;
f) type of container and additives;
g) required equipment and reagents;
h) environmental and safety controls;
i) calibration procedures (metrological traceability);
j) procedural steps;
k) quality control procedures;
l) interferences (e.g. other human corona viruses) and cross reactions;
m) principle of procedure for calculating results including, where relevant, the measurement uncertainty of measured quantity values;
n) biological reference intervals or clinical decision values;
o) reportable interval of examination results;
p) instructions for determining quantitative results when a result is not within the measurement interval;
q) alert/critical values, where appropriate;
r) laboratory clinical interpretation;
s) potential sources of variation;
t) references.

The Laboratory Director and Quality manger are responsible for ensuring that the contents of examination procedures are complete, current and have been thoroughly reviewed. If the BIOGENIX Laboratory intends to change an existing examination procedure such that results or their interpretations could be significantly different, the implications are explained to users of the laboratory services after validating the procedure

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
5.5.1.2/5.5.1.3.	Selection, Verification and Validation of Examination Processes	BG/PP/GEN/027
5.5.1.4.	SOP of Measurement of uncertainty of measured quantity values	BG/SOP/EXAM/001
5.5.1.4.	Worksheet for Measurement of uncertainty	BG/REC/EXAM/001
5.5.3.	Policy Procedure for Sample Collection and Inactivation (Molecular)	BG/PP/MOL/001
5.5.3.	Policy procedure for Reagent Room process (Molecular)	BG/PP/MOL/002
5.5.3.	Policy Procedure for Extraction Room Process (Molecular)	BG/PP/MOL/003
5.5.3.	Policy Procedure for QPCR (Molecular)	BG/SOP/MOL/004
5.5.3.	SOP for Complete Blood Count	BG/ SOP/HEM/001
5.5.3.	SOP for SARS CoV2 IgG qualitative	BG/ SOP/SERO/003
5.5.3	SOP for SARS CoV2 IgG qualitative (ELISA)	BG/SOP/SERO/005
5.5.3	SOP for SARS CoV2 IgM qualitative (ELISA)	BG/SOP/SERO/006
5.5.3	SOP for SARS CoV2 IgG Quantitative	BG/SOP/SERO/010
5.5.3	SOP for SARS CoV2 IgM Quantitative	BG/SOP/SERO/011
5.5.3	SOP for HBs Antibodies	BG/SOP/SERO/001
5.5.3	SOP for HIV Ag /Ab combo	BG/SOP/SERO/007
5.5.3.	SOP for HBsAg	BG/SOP/SERO/008
5.5.3.	SOP for Anti HCV	BG/SOP/SERO/009

5.6. ENSURING THE QUALITY OF THE EXAMINATION RESULTS

5.6.1. GENERAL

BIOGENIX Laboratory ensures the quality of examinations by performing them under defined conditions. Appropriate pre and post-examination processes are implemented. BIOGENIX Laboratory does not fabricate any results.

BIOGENIX Laboratory has designed Internal Quality Control Systems that verify the attainment of the intended quality of results. BIOGENIX Laboratory has control systems, which provide staff members with clear and easily understood information on which technical & medical decisions will be based. Special attention is paid to the elimination of mistakes in the process of handling samples, requests, examinations, reports, etc.

5.6.2. QUALITY CONTROL

5.6.2.1. GENERAL

BIOGENIX Laboratory designs quality control procedures that verify the attainment of the intended quality of results.

5.6.2.2. QUALITY CONTROL MATERIALS

BIOGENIX Laboratory uses quality control materials that react to the examining system in a manner as close as possible to patient samples.

Quality control materials are periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.

BIOGENIX Laboratory uses mostly the internal control materials supplied by the manufacturer of the kit. Use of thirty party provided control material is considered if it is feasible to attain.

5.6.2.3. QUALITY CONTROL DATA

BIOGENIX Laboratory has a procedure to prevent the release of patient results in the event of quality control failure. Patient samples are tested only after ensuring quality control results are within acceptable limits.

When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results are rejected, and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. BIOGENIX Laboratory also evaluates the results from patient samples that are examined after the last successful quality control event (delta check).

Quality control data are reviewed daily by the performing technologists and section in charges to detect trends in examination performance that may indicate problems in the examination system. Monthly quality

control data including SD and CV variations are assessed by the Laboratory Director. When trends are noted, preventive actions are taken and recorded.

5.6.3. INTER LABORATORY COMPARISONS

5.6.3.1. Proficiency Testing Participation

BIOGENIX Laboratory participates in the proficiency testing program provided by College of American Pathologists appropriate to the examination and interpretations of examination results. All the tests in the laboratory activity menu are covered for proficiency testing.

BIOGENIX Laboratory monitor the results of the proficiency testing program and implements corrective actions when predetermined performance criteria are not fulfilled and an unacceptable evaluation result.

BIOGENIX Laboratory has established a documented procedure for inter laboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the proficiency testing program.

Proficiency testing program provided by College of American Pathologists (CAP) provides only clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.

BIOGENIX Laboratory integrates inter laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples.

Inter-laboratory comparison samples are examined by personnel who routinely examines patient samples using the same procedures as those used for patient samples.

BIOGENIX Laboratory does not communicate with other participants in the inter laboratory comparison program about sample data until after the date for submission of the data.

BIOGENIX Laboratory does not refer inter-laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.

5.6.3.2. ALTERNATIVE APPROACHES

Whenever an inter laboratory comparison (proficiency testing program test) is not available, BIOGENIX Laboratory performs an alternative

assessment to provide objective evidence for determining the acceptability of examination results.
Whenever possible, this mechanism utilizes appropriate materials
Analysis of inter laboratory comparison samples

5.6.3.3. EVALUATION OF LABORATORY PERFORMANCE

The performance in inter laboratory comparisons is reviewed and discussed with relevant staff and in the monthly laboratory meetings.
When predetermined CAP proficiency testing performance criteria are not fulfilled (i.e. nonconformities are present), involved staff participates in the implementation and recording of corrective action. The effectiveness of corrective action is monitored. The returned results (CAP evaluations and participant summary) is evaluated for trends that indicate potential nonconformities and preventive action is taken. The CAP issues comprehensive reports which include histograms for each analyte, SDI, mean and comparison of the results with other participating laboratories;

5.6.4. COMPARABILITY OF EXAMINATION RESULTS

BIOGENIX Laboratory has a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these.
Laboratory notifies users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measured and when examination methods are changed.
The laboratory documents, records and, as appropriate, expeditiously acts upon results from the comparisons performed. Problems or deficiencies identified are acted upon and records of actions retained.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
5.6.2.1/5.6.2.2./5.6.2.3.	Ensuring Quality Of Examination Results	BG/PP/GEN/028
5.6.2.1/5.6.2.2./5.6.2.3.	Cell Dyn Emerald Internal Control Review log	BG/REC/QC/007

5.6.2.1/5.6.2.2./5.6.2.3.	Alinity Daily QC checklist	BG/REC/QC/005
5.6.2.1/5.6.2.2./5.6.2.3.	Monthly CV monitoring -Hematology	BG/REC/QC/001-A
5.6.2.1/5.6.2.2./5.6.2.3.	Internal control corrective action form (Core Lab)	BG/REC/QC/002-A
5.6.2.1/5.6.2.2./5.6.2.3.	Internal control corrective action form (PCR Lab)	BG/REC/QC/002-B
5.6.3	Investigation form for PT out of limit	BG/REC/QC/003
5.6.3	CAP sample receiving Sheet	BG/REC/QC/004
5.6.2.	Control and calibrator reconstitution record	BG/REC/QC/006
5.6	RT PCR kit internal Quality Control Vials transfer Log Sheet	BG/REC/MOL/016
5.6	Internal Quality Control Transfer and storage slip	BG/REC/MOL/017
5.6	RT-PCR Kit Internal quality Control Vials Receiving Log Sheet	BG/REC/MOL/021
5.6	Quality Control Monitoring Sheet qPCR	BG/REC/MOL/025
5.6	Quality Control Monitoring Sheet- Reagent Preparation-Reagent Preparation on MGI960	BG/REC/MOL/026
5.6	Quality Control Monitoring Sheet- Reagent Preparation-Manual Reagent Preparation	BG/REC/MOL/027
5.6	Quality Control Monitoring Sheet- Reagent -Extraction Room	BG/REC/MOL/028

5.7. POST EXAMINATION PROCESSES

5.7.1. Review of results

BIOGENIX Laboratory has procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results

5.7.2. STORAGE, RETENTION AND DISPOSAL OF CLINICAL SAMPLES

BIOGENIX Laboratory has a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples.

BIOGENIX Laboratory has defined the length of time clinical samples are to be retained. Retention time depends on the nature of the sample, the

examination and any applicable requirements.

i. COVID 19 Positive samples for PCR are retained for 1 year.
ii. COVID 19 Negative samples are discarded after 1 week.
iii. Blood samples are retained for 1 week.

Safe disposal of samples is carried out in accordance with local regulations or recommendations for waste management.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
5.7.	Post Examination Procedures	BG/PP/GEN/030
5.7.	Procedure For Waste Management	BG/PP/INF/007
5.7	COVID-19 Sample storage record	BG/REC/MOL/018
5.7	COVID-19 Sample disposing Record	BG/REC/MOL/019

5.8. REPORTING OF RESULTS

5.8.1. General

BIOGENIX Laboratory reports the results of each examination accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.

BIOGENIX Laboratory has defined the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory.

BIOGENIX Laboratory has a procedure to ensure the correctness of transcription of laboratory results.

Reports released by BIOGENIX Laboratory includes all the information necessary for the interpretation of the examination results.

BIOGENIX Laboratory has a process for notifying the requester when an examination is delayed that could compromise patient care.

5.8.2. REPORT ATTRIBUTES

BIOGENIX Laboratory ensures that the following report attributes effectively communicate laboratory results and meet the users' needs:

a) comments on sample quality that might compromise examination results;
b) comments regarding sample suitability with respect to acceptance/rejection criteria;
c) critical results, where applicable;
d) Interpretive comments on results are provided, where applicable, which includes the verification of the interpretation of automatically selected and reported results in the final report.

5.8.3. REPORT CONTENT

Laboratory reports issued in BIOGENIX Laboratory includes the following:

a) a clear, unambiguous identification of the examination including, where appropriate, the examination procedure;
b) the identification of the laboratory that issued the report;
c) identification of all examinations that have been performed by a referral laboratory;
d) patient identification and patient location on each page;
e) name or other unique identifier of the requester and the requester's contact details;
f) date of primary sample collection (and time, when available and relevant to patient care);
g) type of primary sample;
h) measurement procedure, where appropriate;
i) examination results reported in SI units, units traceable to SI units, or other applicable units;
j) biological reference intervals, clinical decision values, or diagrams/monograms supporting clinical decision values, where applicable;
k) interpretation of results, where appropriate;
l) other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories);
m) identification of examinations undertaken as part of a research or development program and for which no specific claims on measurement performance is available;
n) identification of the person(s) reviewing the results and authorizing the release of the report;
o) date of the report, and time of release;
p) page number to total number of pages.

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
5.8	Procedure For Reporting of Results	BG/PP/GEN/030
5.8	Hematology Critical Value List	BG/REC/HEM/002

5.9. RELEASE OF RESULTS

5.9.1. General

BIOGENIX Laboratory has an established documented procedure for the release of examination results, including details of who may release results and to whom. The procedures ensure that the following conditions are met.

a) When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.

b) When examination results fall within established "alert" or "critical" intervals:

- The requesting facility contact person (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination;
- records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications.

c) Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.

d) When results are transmitted as an interim report, the final report is always forwarded to the requester.

e) There are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients. Results provided orally will be followed by a written report. There shall be a record of all oral results provided.

5.9.2. AUTOMATED SELECTION AND REPORTING OF RESULTS

The lab has not implemented automated selection and reporting of results.

5.9.3. REVISED REPORTS

When an original report is revised by the BIOGENIX Laboratory there are written instructions regarding the revision so that:

a) the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;
b) the user is made aware of the revision;
c) the revised record shows the time and date of the change and the name of the person responsible for the change;
d) the original report entries remain in the record when revisions are made. Results that have been made available for clinical decision making and revised is retained in subsequent cumulative reports and clearly identified as having been revised.
e) When the reporting system cannot capture amendments, changes or alterations, a record of such is kept

SUPPORTING DOCUMENTS:

CLAUSE NO.	DOCUMENT NAME	REFERENCE NUMBER
5.9	Procedure For Releasing of Results	BG/PP/GEN/031
5.9	Hematology Critical Values	BG/REC/HEM/002
5.9	Critical Result Record Sheet	BG/REC/GEN/069

5.10. LABORATORY INFORMATION MANAGEMENT

5.10.1. General

BIOGENIX Laboratory has access to the data and information needed to provide a service which meets the needs and requirements of the user. The laboratory also has a documented procedure to ensure that the confidentiality of patient information is maintained at all times.

5.10.2. AUTHORITIES AND RESPONSIBILITIES

BIOGENIX ensures that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care.

BIOGENIX Laboratory defines the authorities and responsibilities of all personnel who use the system, in particular those who:

a) access patient data and information;
b) enter patient data and examination results;

c) change patient data or examination results;
d) authorize the release of examination results and reports.

5.10.3. INFORMATION SYSTEM MANAGEMENT

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information in the BIOGENIX Laboratory is:

a) validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation;
b) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;
c) protected from unauthorized access;
d) safeguarded against tampering or loss;
e) operated in an environment that complies with supplier specifications or, in the case of non- computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
f) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;
g) in compliance with national or international requirements regarding data protection.

BIOGENIX Laboratory verifies that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, fax machines, e- mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

BIOGENIX Laboratory have documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service.

When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, BIOGENIX management is responsible for ensuring that the provider or operator of the system complies with all applicable requirements of the International Standard (ISO15189:2012).

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