MEDICAL LABORATORY
SCIENCE COUNCIL OF NIGERIA
PULIC HEALTH IN-VITRO DIAGNOSTICS CONTROL LABORATORY
YABA, LAGOS

QUALITY MANUAL
QM-03

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12	TP-5.03	Accommodation and environmental condition
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14	TP-5.06	Measurement traceability
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1.0 HISTORY

The Public Health In-Vitro Diagnostics control Laboratory (IVDs) is a governmental laboratory that was established in the year 2013 to provide world class services in Verification and Validation processes of all In-Vitro diagnostics

Product manufactured locally or imported into Nigeria. This will include Pre-market and Post – market Surveillance of IVD products in Nigeria amongst other activities.

1.1 Health Regulatory Structure

The Federal Ministry of Health is the supervisory ministry of the Federal Government of Nigeria in charge of all health related activities in the country.

Medical Laboratory Science Council of Nigeria (MLSCN) is one of the regulatory agencies under the Federal Ministry of Health that is working with Federal, State, Local Governments and Private Health Institutions to ensure accreditation of laboratory services, regulation of training institutions and professional practice of Medical Laboratory Science in Nigeria.

The Public Health In-Vitro Diagnostics control Laboratory (IVDs) is one of the Departments that is under the Management of MLSCN.

1.2 Laboratory profile

The Public Health In-Vitro Diagnostics Control Laboratory (IVDs) is a laboratory that performs four key functions which are:

-Listing of IVDs manufacturers, importers and marketers in Nigeria;

-Registration of IVD Products;

-Pre-Market Evaluation and Post-Market Surveillance of IVDs such as kits, reagents, laboratory consumables and chemicals;

-Diagnostic equipment evaluation via the use of reagents.

1.3 Legal Situation of the Laboratory

The Public Health In-Vitro Diagnostics Control Laboratory (IVDs) is legally responsible for its own test services which are established under the authority of the MLSCN (Registrar/CEO) and Laboratory Manager. The laboratory is part of the Medical Laboratory Science Council of Nigeria established by Act 11 of 2003.

1.4 Contact information

Address

Public Health In-Vitro Diagnostics Control Laboratory (IVDs)
8, Harvey Road, Yaba, Lagos. Nigeria.

Tel: (Lab.) +234 9021765416-18
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Fax:

Lab. Email: ivds@mlscn.gov.ng
Abuja Head office: info@mlscn.gov.ng

Laboratory Manager: poffutalu@mlscn.gov.ng
Quality Assurance Manager: sfasogbon@mlscn.gov.ng

Lab's website: www.mlscn.gov.ng.

2.1 Policy

The Public Health In-Vitro Diagnostics Control Laboratory is set up to provide services that will always meet customer satisfaction. We are committed to provide an excellent service and have implemented a full quality assurance system. The laboratory's management will continually improve the effectiveness of the quality system within the confines of the international standard ISO/IEC 17025:2005. The laboratory staff are fully competent in using quality system to ensure consistent testing results. Our commitment is ensured and demonstrated as follows:

- Laboratory management is committed to practice its testing works in a good and professional manner using appropriate resources and competent personnel to achieve the quality of its testing.
- Laboratory will strive to provide their customers with "Just in Time (JIT) Quality Service".
- Laboratory will continually cooperate with and involve all personnel concerned with testing and calibration activities in the laboratory, to implement the policies and procedures in their work.
- Laboratory Management ensures their commitment to comply with ISO/IEC 17025:2005 International Standard and will continually improve the effectiveness of its management system.

This policy has been issued under the authority of the Lab. Manager, which reflects its commitment to quality performance.

Mr. Offutalu Paulinus N. **……..**
Lab. Manager Signature

2.2 Quality objectives

S.No	Objective	Measure	Time frame	Responsible
1	Provide sufficient training for staff and evaluate the efficiency of the training of the employee under scope.	• Evaluation of training • Evaluation of employees	6 months	Lab. Manager.
2	Implementation of the QMS of ISO 17025:2005	• Quality and Technical records	9 months	Quality Assurance Manager.
3	Assuring the quality of calibration results and intermediate checks with respect to ISO 17025 requirements.	• Calibration plan • Intermediate check records	6 months	Lab. Manager.
4	Maintain biosafety level in personnel, equipment surroundings through a good environmental control	• Environmental control for lab • Sanitation plan	6 months	Lab. manager And Bio - safety officer.
5	Maintain the test results with confidentiality and impartiality	• Confidentiality records • Customer feedback	6 months	Quality Assurance Manager, MLS and Admin.
6	Continual improvement	• Corrective and preventive action records • Internal audit follow up and management review	Whole year	Lab. Manager and Quality Assurance Manager.

These objectives will need to have a plan of action defining the details of the work.

3. SCOPE

SN	Laboratory section	Materials &products tested	Name of tests	Standard method/	Equipment
1.	**Medical Microbiology / Parasitology lab .**	Lab. Reagents relating to Microbiology and Parasitology. E.g: Gram stains, Culture Media, universal bottles, etc	-Microbial Culture at 37^0C	CLSI:EP-12	-incubator -autoclave - digital balance -media dispenser -PH meter -Anaerobic jar -Microscope
			1. Sterility testing/ culture	CLSI:EP-12	- incubator - autoclave - digital balance - oven - PH meter -Anaerobic jar -Microscope
		Consumables E.g: Universal containers, Swabs stick, etc	1. Sterility testing/ culture	CLSI:EP-12	- incubator - autoclave - digital balance - oven - PH meter
		Equipment. E.g: Incubators, autoclave, Hot air oven, Microscope, Bio-safety cabinet etc	1. Verification / Validation methods 2. Dossier review	CLSI:EP-12	Validated Equipment e.g: Incubators, autoclave, Hot air oven, Microscope,

SN	Laboratory section	Materials &products tested	Name of tests	Standard method/	equipment
1.	**Histopathology/ Cytopathology.**		-Microbial Culture at 37^0C	CLSI:EP-12	-incubator -autoclave - digital balance -media dispenser -PH meter -Anaerobic jar -Microscope
		Lab. Reagents relating to Histopathology and Cytopathology. E.g:Reagents; Formaldehyde, Ether, DPX, Xylene, alcohol, etc.	1. Gross Examination of the fixed tissue	CLSI:EP-12	-Surgical Blade -Knife -Tissue container -Trough
		Stains: Haematoxylin, Eosin, picric acid, etc	1. Staining and comparison with standard slides and atlas	CLSI:EP-12	Automatic tissue processor, -Microtome -Embedding machine, Cryostat
		Consumables E.g: Tissue cassettes, etc	1.	CLSI:EP-12	- incubator - autoclave - digital balance - oven - PH meter
		Equipment. E.g: Tissue processor, Incubators, Hot air oven, Microscope, etc	2. Verification / Validation methods 3. Dossier review	CLSI:EP-12	Validated Equipment e.g: Tissue processor, Incubators, Hot air oven, Microscope,

S.No	Laboratory section	Materials &products tested	Name of tests	Standard method/	Equipment
3.	Chemical Pathology lab	All Chemical pathology Reagents e.g Glucose, Cholesterol and Albumin	1.Quantitative Assays	CLSI:EP-12	-Spectrophotometer-Chemistry analyzer -water bath -Automatic pipettes
		Rapid Diagnostic Test Kits (RDTs) E.g: Uristix and Multistix, and POCs	Comparative Analysis using known panels (Qualitative and Semi-Quantative Assays)	CLSI:EP-12	-Centrifuge -Automatic pipettes -water bath
		Hormones and Enzymes. E.g: Luitenizing Hormone, FSH, Testosterones etc.	Enzyme linked immunoassay method (ELISA)	CLSI:EP-12	-Elisa Reader -Elisa Washer -Automatic pipettes
		Electrolytes: Sodium ion, Calcium	ION selective electrode method (ISE)	CLSI:EP-12	- Flame photometer - ISE -Automatic Pipettes
		Equipment: e.g; Spectrophotometer, Ion Selective Electrode Analyzer, Full Auto analyzers and Semi-autoanalyzer, etc	1.Quantitative analysis	CLSI:EP-12	Validated Equipment: Spectrophotometer, Autochemistry analyzers, etc

S/No	Laboratory section	Materials &products tested	Name of tests	Standard method/	Equipment
4.	Haematology / Blood Group Serology	Romanowsky stains (Leishman stain, Giemsa stains) and Supravital stains (Methylene Blue)	1. Microscopic Examination of stains with comparison with standard slides / atlas.	CLSI:EP-12	-Microscope-Cytofixative (Slide stainer) -stop watch
		Rapid Diagnostic Test Kits (RDTs) E.g: HIV, HCV	1. Qualitative Testing	CLSI:EP-12	-Centrifuge -Automatic pipettes
		Antisera E.g: Anti-A, Anti-B, etc.	1. Slide testing 2. Tube testing	CLSI:EP-12	-Slide/ Tiles -Pasteur pipettes -Water bath/ incubator
		Blood Bags	1. Sterility testing E.g Culture 2. Anticoagulant Concentration testing	CLSI:EP-12	- Culture media -Autoclave -Weighing balance -Spectrophotometer-Automatic Pipettes
		Equipment E.g: Haematology Auto-analyzer, Cytofixative or slide stainer	1.Validation/Verification of Equipment 2. Dossier Review	CLSI:EP-12	-Haematology Analyzer

		Sample Containers E.g: EDTA, Sodium citrate bottles, etc	1. Macro and Microscopic examination of blood	CLSI:EP-12	-Microscope -Slides -Pasteur pipettes

4.1: Organization

4.1.1: The IVDs is an organization that is held legally responsible for its own test services which are established under the authority of the Medical Laboratory Science Council of Nigeria, a parastatal under the Federal Ministry of Health. The legal status is explained in section 1 of this manual. The IVDs is headed by the Laboratory Manager, as described in the organization chart fig (1) in section 1 of this document.

4.1.2: Sections 2 of this document state the policies adopted by the laboratory to meet the requirements of the international standard ISO/IEC17025:2005 to satisfy the needs of the customers and the accreditation body.

4.1.3: The laboratory management system covers the work carried out at Public Health In-Vitro Diagnostics Control Laboratory, 8, Harvey Road, Yaba, Lagos only.

4.1.4: The line of authority for the laboratory management are shown in the organizational charts Fig (1) at the end of this chapter. The Laboratory Manager and Quality Assurance Manager have the responsibilities with no conflicting interests that may adversely influence the laboratory's compliance with the requirements of the international standards. This is explained in the Job description cards and in item 4.1.7 of this manual.

4.1.5: The Laboratory is capable of carrying out the following items:

4.1.5 a) The laboratory has administrative staff (Lab. Manager, Quality Assurance Manager) and technical staff with the authority and resources to execute their duties as reflected in the prepared job descriptions. This authority includes the implementation, maintenance, and improvement of the management system and to identify any departure from the ISO/IEC: 17025:2005 Standard.

4.1.5 b) Laboratory has arrangements to ensure that its management team and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work through:

- Staff respects the legal regulations of employment and civil services; therefore, they do not attempt to have an extra work which may cause deviation to their job behavior from the proper and good work conduction.
- Awareness for employees of these regulations through meetings that is held bi-annually.
- The Laboratory Manager ensures that the employees are not using public office for private gain, and they act impartially and do not have any work relations with private labs or organizations, refer to personnel and training procedure TP-5.02
- Provide its (laboratory) personnel with satisfactory payment, incentives, and allowances, according to the country civil services law so that they do not feel in need to look for another financial support.
- Confidentiality and impartiality agreement is signed by all staff. Form QF 5.02-7
- For more details refer to personnel and training procedure TP-5.02.

4.1.5 c) Laboratory have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the storage and transmission of results (refer to the customers services procedure MP-4.07) through:

- Customer's information is encoded with regard to a laboratory private serial number (code) to exclude the customer name and information, refer to TP-5.0.8 and MP-4.04.
- Laboratory Manager is committed to protect the storage and transmissions of results to the customers, refer to MP-4.13.
- Confidentiality and impartiality agreement is signed by all staff. (Form no QF 5.02-07.)

4.1.5 d) The Laboratory has a policy to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity. This is done through not being involved in any production activity with its customers. Form QF 5.02-7

4.1.5 e) The management system defines the organization and management structure of the laboratory and the relationships between quality management, technical operations and support services as described in the organization chart at the end of this section and in the job description and item 4.1.7.

4.1.5 f) Job responsibilities for laboratory employees are documented in the management system see items 4.1.7.1 to 4.1.7.9 of this manual and also the separate job description.

4.1.5 g) The management system provides adequate supervision of testing staff, including training through the Laboratory manager on the methods and procedures, purpose of each test, and with the assessment of the test results.

4.1.5 h) The Laboratory Manager is responsible for the technical operations of laboratory and the provision of the resources needed to ensure the required quality of laboratory operations. Refer to 4.1.7.

4.1.5 i) The Quality Assurance manager is responsible for the management system implementation and has direct access to the Director who is responsible for the decisions concerning policies, refer to 4.1.7.

4.1.5 j) The Laboratory Manager assigns the deputies of the Quality Assurance Manager and Safety Officer in case of their absence as follows:

Safety officer takes up the job of the Quality Assurance Manager when absent. The Quality Assurance Manager takes up the job of the Laboratory Manager when absent, according to the list authorized by the Registrar/CEO.

4.1.5 k) The Laboratory Manager ensures that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system. This is ensured by the monthly meetings for discussion of the matters related to the management system.

4.1.6: The Laboratory Manager ensures the communication processes are established within the laboratory, and that communication takes place regarding the effectiveness of the management system through,

- Monthly meetings conducted by the Laboratory Manager in the lab every month to discuss the quality objectives, improving work and quality management system implementation. Also it is used to explain the roles of the technical staff. It is also used to explain the regulations for the

impartiality and confidentiality to the staff. Also to explain the importance of meeting customer requirements.

- This communication meeting is conducted and recorded according to form (QF-4.1.6-01) appendix 2.
- Internal communication with laboratory personnel using white board for information exchange and exchange of memos to inform staff of important activities.
- Using adequate internet network which is available in all laboratory units.

4.1.7.1 Job title: Registrar/ Chief Executive officer

Responsible for: All MLSCN activities including all lab activities & staff

Responsibilities: with respect to laboratory:

- Take administration decisions for the Lab policy.
- Provide the laboratory with the required human and financial resources that are required by the Laboratory Manager to carry out the laboratory processes.
- Responsible for the provision of laboratory's human and financial resources that are adequate for the laboratory processes.

4.1.7.2 Job Title: Laboratory Manager

Reporting to: **Registrar / CEO**

Responsible for: Administrations of all lab activities & staff

Responsibilities:

- Take decisions with respect to implementation of laboratory policy and utilization of resources.
- Approve the quality manual.
- Requests the resources needed to participate in the proficiency testing schemes.
- Take decisions to participate in the proficiency testing schemes in the field of his administration.
- Undertake the management reviews of management system.
- Ensure the appropriate communication to check the effectiveness of the management system.
- Recommends Appointment of Quality Assurance Manager and Safety Officer for confirmation by the Registrar/CEO.
- Appoint their deputies when absent.
- Maintain the management system and ensure that it's implemented inside the laboratory.
- Evaluate the quality management system, its maintenance and improvement.
- Ensure that the human and financial resources are adequate for the laboratory processes.
- Approve the management and technical procedures.
- Ensure that the training for key persons is implemented according to the training plan.
- Approve the laboratory developed methods.
- Management representative to ensure the Quality Management System is established, implemented and maintained in the laboratory.

- Follow up the implementation of the accreditation bodies requirements.
- Support and assist staff to solve all issues related to technical affairs.
- Maintain the management system and ensure that it's implemented inside the laboratory section.
- Evaluate the Lab staff in the Lab.
- Approve the training requirements and ensure that the staff is competent for the technical tasks.
- Ensure the quality policy of the management is implemented.
- Introduce the technical advice and consultations for the unit's heads.
- Participate in preparing the quality manual.
- Authorize all the test reports.
- Ensure the awareness of the laboratory staff for the ISO 17025:2005 standard requirements.
- Implement appropriate periodical checks on the laboratory personnel.
- Explain to the laboratory staff the extent and limitation of their responsibilities.
- Plan training programs for the new staff and supervise their work. Select and determine the Medical Laboratory Scientist for each sample.

Qualification:

- A Bachelor's degree of Medical Laboratory Science / Associate of Medical Laboratory Science Council of Nigeria.
- At least 12 years of cognate experience in In-vitro diagnostics and Medical Laboratory Science Practice.
- High managerial skills.
- Communications skills for negotiations with customers.
- Strong analytical capabilities and the ability to give recommendations and increase work efficiency.
- Training courses in IVDs testing and in management activities.
- Training course in ISO 17025 standard requirements.

4.1.7.4: Job title : Quality Assurance Manager

Reporting to: Laboratory Manager

Responsible for: Quality Assurance.

Responsibilities:

- Writing the quality manual with respect to the ISO 17025 standards & taking director's approval.
- Update management on all matters relating to quality activities.
- Ensure on day-to-day bases that the operations of management system are in compliance with the quality manual and accreditation body requirements.
- Organize the quality internal audit programs and ensure that the auditors are appropriately trained.
- Ensure that the corrective actions arising from audits are carried out within an agreed time scale.
- Keeps records of registry and evaluation of suppliers.
- Update the standard test methods/protocols& management on all matters relating to technical activities.
- Review the management, technical procedures and the work instructions
- Prepare the specification for the purchased supplies and services which affect the quality.
- Initiate and establish new work instructions where appropriate.
- Initiate all the test reports, and take the responsibility for their technical contents.
- Supervise the internal quality control programs for the laboratory test results.
- Supervise the intermediate calibration check programs for the laboratory equipment.
- Check the calculations, data and results before reporting.
- Maintain the management system and ensure that it's implemented inside the laboratory.
- Ensure the records of the laboratory environmental conditions are maintained.
- Ensure the construction of quality control charts according to laboratory program.
- Implement maintenance & calibration programs.
- Organize the management reviews of the management system.
- Analyze the customer service feedback.
- Assist in solving the customer complaints and receive records.
- Ensure that the laboratory staff is communicated about the policies and the objectives of the quality management system.
- Make and maintain the backup copies from the management system documents.

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Qualification:

- Appropriate Bachelor's degree (BMLS / AMLSCN)
- At least 7 years of experience in QMS field.
- Training courses in IVDs and Medical laboratory Science Practice according to national and international standards.
- Training courses in relevant quality and technical field.
- Training course in ISO 17025 standard requirements.

4.1.7.5: Job title : Auditor (Internal).

Reporting to : Quality Assurance Manager

Responsible For : Internal Auditing Process

Responsibilities :

- Carrying out planned audit programs.
- Carrying out the additional audits.
- Advice the laboratory personnel in the management system related matters.
- Assist the Quality Assurance Manager in his/her responsibilities.
- Monitor the laboratory personnel in the administrative and technical works during the audits.
- Follow up the implementation of the corrective actions arising from audits.

Qualification:

- Appropriate Bachelor's degree (BMLS or AMLSCN).
  - Training courses in test activities.
  - Training course in ISO 17025 standard requirements..
  - At least 2 years of experience in relevant fields.
  - Training courses in auditing according to ISO 17025.
  - Training in QMS

4.1.7.6: Job title : Quality Assurance Officer

Reporting to: Quality Assurance manager

Responsible for: Implementation of QMS; Reporting / documentation / recording activities…

Responsibilities:

- Assist in writing up the most important activities, work achievements, initiatives reports.

- Writing and documentation of records required by ISO/IEC 17025.
- Write and edit reports, concept notes, official letters, and proposals in coordination with the concerned members /departments.
- Identify important reports and documentation needed for the implemented tests and activities.
- Assist technical staff in writing, editing, and translating different materials.
- Assist in laboratory reports including: quality records, problems, technical records and encourages the good quality work.
- Advice the laboratory personnel in the management system related to documentation and reporting matters.
- Assist the Quality Assurance Manager in her/his responsibilities.
- Evaluate the laboratory personnel periodically and during the internal audits.
- Maintain needed repots and records.
- Ensure the software back-up copies are kept, as appropriate.
- Performs the internal quality control tests to ensure compliance with test methods.

Qualification:

- Appropriate degree in the relevant field.
- Training courses in test activities.
- Training course in ISO 17025 standard requirements.
- At least 2 years of experience in relevant fields.
- Training in QMS

4.1.7.7: Job title: Medical Lab. Scientist

Reporting to: Lab. manager

Responsibilities:

- Perform the daily work, ensuring that it is running according to the standards and quality management system.
- Ensure that the laboratory is following the quality manual and procedures, as per instructed.
- Coordinate with other departments in case of any deviation from the standards, as appropriate.
- Responsible for issuing test reports.
- Maintain the management system and ensure that it's implemented inside the laboratory.

- Ensure the compliance with local/international standards.
- Overall responsibility for the sample performed tests.
- Monitor and record the environmental conditions during the test.
- Monitor the implementation of the housekeeping program.
- Technical responsibility for tests performed.
- Ensure that Medical Lab Technician(s) are competent for the tasks they undertake by means of appropriate guidance.
- Maintain the confidentiality and impartiality.

Qualification:

- Appropriate Bachelor's degree (BMLS or AMLSCN).
- Training courses in relevant activities.
- Training course in ISO 17025 standard requirements.

4.1.7.8: Job title: **Medical Lab technician.**

Reporting to : Med. Lab Scientist and Quality Assurance Manager

Responsibilities :

- Perform the daily work through the guidance of Medical Lab Scientist, ensuring that it is running according to the standards and Quality management system.
- Ensure that the laboratory is following the quality manual and procedures, as per instructed.
- Coordinate with other units in case of any deviation from the standards, as appropriate.
- Maintain the management system and ensure that it's implemented inside the laboratory.
- Ensure the compliance with local/international standards.
- Overall responsibility for the samples test under supervision of a Medical Lab Scientist.
- Monitor and record the environmental conditions of the Laboratory.
- Monitor the implementation of the housekeeping program.

Qualification:

- Appropriate MLT qualification with registration with MLSCN.
- Training courses in relevant activities.
- Training course in ISO 17025 standard awareness.

4.1.7.9: Job title: **Safety officer**

Reporting to : Quality Assurance Manager and Laboratory Manager

Responsibilities :

- Perform the daily work through the guidance of Medical Lab Scientist concerning biosafety matters ensuring that it is running according to the biosafety standards and quality management system.
- Follow the quality manual and procedures, as per instructed.
- Coordinate with other departments in case of any deviation from the biosafety standards, as appropriate, under the supervision of Laboratory Manager.
- Ensure the compliance with local/international standards.
- Monitor and record the environmental conditions before /after and during the test.
- Monitor the implementation of the housekeeping program.
- Technical responsibility for tests performed with precautions of biosafety and biosecurity.
- Maintain the awareness and training of Medical Lab. Technicians and housekeepers about matters related to biosafety and biosecurity.

Qualification:

- Appropriate training in biosafety & biosecurity fields.
- Training courses in relevant activities.
- Training course in ISO 17025 standard awareness.

4.1.8.0: Job title: **Biomedical Engineer**

Reporting to : Laboratory Manager and Quality Assurance Manager

Responsibilities :

- Perform the daily recordings, fueling of generators and monitoring of the power operations under the directive of the Lab Manager.
- Responsible for the upkeep, maintenance of equipment, matters related to information technology, periodic calibration of Lab equipment under the supervision of Quality Assurance Manager and Lab Manager.
- Assist the Quality Assurance manager in making and maintaining Backup copies of technical documents.

4.1.8.1: Job title: **Legal Officer**

Reporting to : Laboratory Manager

Responsibilities :

- Responsible for matters related to Legal Unit
- Maintain the confidentiality and impartiality.

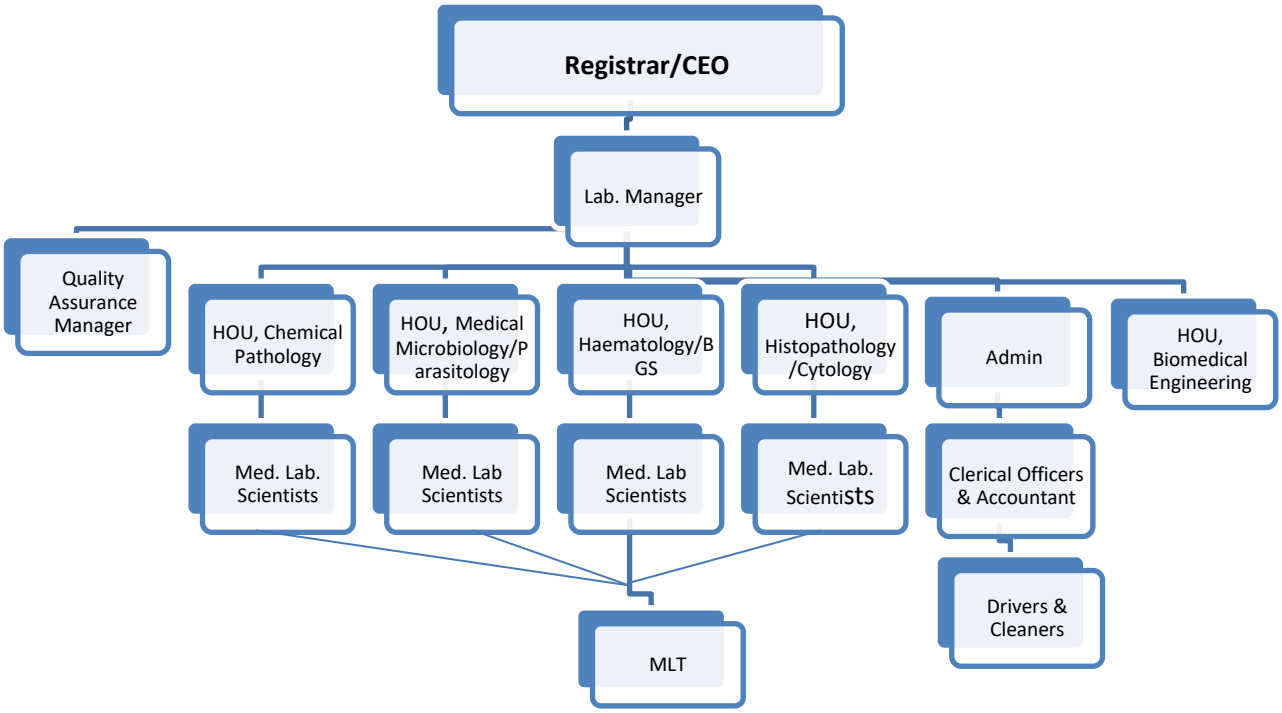

Fig (1): Laboratory Organogram of Public Health In-Vitro Diagnostic Control Lab., Lagos.

4.2.1: Laboratory Management System:

The laboratory has a management system appropriate to its scope and activities. The management system contains all documents, data and instructions to ensure that the work is in accordance with the requirements of ISO/IEC 17025:2005 and accreditation bodies' criteria. The Lab Manager ensures that system's documentation communicated to, understood by, available to, and implemented by the appropriate personnel. The documentation of this system is defined by:

- The international and local laws and regulations.
- The quality manual and quality policy.

- Management procedures (*Covered the requirements of item 4 of ISO 17025:2005 Standard)*. Listed in section 6 - Appendix 1 in this manual.
- Technical procedures (*Covered the requirements of item 5 of ISO 17025:2005 Standard)*. Listed in section 6 - Appendix 1 in this manual.
- Work Instructions, listed in the section 6 - Appendix 2 in this manual.
- Standards/specifications, listed in section 6 - Appendix 3 in this manual.
- Forms.

4.2.1.1: Quality Manual

The quality manual (which is this document) describes the general principles and the policies of operations as well as arrangements made to ensure the quality of the process, equipment and associated services supplied to the customer in accordance with *ISO/IEC 17025:2005 and* the accreditation bodies' requirements, stated policy and objective for an efficient quality assurance system.

4.2.1.1 a) Structure of Quality Manual

The structure of the quality manual is in accordance with the management and technical requirements of the ISO/IEC 17025:2005 enforce by the signature of the Lab manager, this manual is regarded as a part of the quality management system of the Lab. The manual is divided to chapters related to the requirements of the ISO/IEC 17025:2005, if necessary, required amendments can be done.

4.2.1.1 b) Quality Manual Distribution.

The quality manual is controlled by the Quality Assurance Manager; all quality manual copies are distributed by the Quality Assurance Manager according to the distribution list; two types of copies are distinguished:

- Controlled copies subject to regular amendment, these copies are distributed according to the distribution list (See appendix 8 of this manual). For control purpose all copies are numbered.
- Uncontrolled copies (Information copies) not subject to regular amendment, these manuals are valid at the moment of their issue and they aren't numbered.

4.2.1.2: Management Procedures.

Management procedures describe the interrelated management processes and activities required to implement the quality management system (***Refer to Appendix 1***) to comply with the management requirements of ISO/IEC 17025:2005.

4.2.1.3: Technical Procedures.

Management technical procedures describe the interrelated technical processes and activities required to implement the quality management system (***Refer to Appendix 1***) to comply with the technical requirements of ISO/IEC 17025:2005.

4.2.1.4: Work instructions.

The work instructions are describing the technical requirements for the daily work in the laboratory (***Refer to Appendix 2***).

4.2.1.5: Records and Forms.

The management, technical procedures and work instructions include a set of forms, which are used by the laboratory staff in the daily work for different purposes such as applications , recording , orders, data sheets, certificates, reports , etc . Only the listed forms used should be signed by the appropriate authorized personnel.

4.2.2: Quality System Policy.

The laboratory are committed to provide tests that meet the needs of the customers and the requirements of ISO/IEC 17025:2005. The quality policy is described in details in section 2 of this manual.

4.2.3 All management levels provide an evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness, see organization chart at the end of chapter 4.1 of this Manual.

4.2.4 The quality control and quality assurance ensure to communicate to the laboratory staff the importance of meeting customer's requirements as well as statutory and regulatory requirements. See item 4.1.6 of this manual.

4.2.5 The quality manual includes a reference to the supporting procedures and work instruction (refer to appendices No. 1 and 2 of this manual). It outlines the structure of the documentation of the management system.

4.2.6: Roles and Responsibilities

The responsibilities and authorities of Registrar/CEO, Laboratory Manager and Quality Assurance Manager are in compliance with the international standard ISO/IEC 17025:2005 (See item 4.1.7 of this manual.)

4.2.7 All management levels ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented according to the following:

- Assigning deputies for the key functions in the Lab.

- Explaining all functions and processes in the Lab in the procedures and work instructions which are controlled according to the Document Control Procedure MP-4.03.
- Having the new Managers work with the old ones before taking charge of their new positions.

4.3 Document Control

4.3.1: General

Quality Assurance Manager /Officers responsibility is to ensure that the essential operations for the management system are working effectively, and that the management system is carried out with appropriate and updated documents, all laboratory activities are controlled according to documented procedures which guaranteed their verification, distribution and revisions in accordance with document control procedure MP-4.03.

The following documents represent the back bone of the laboratory quality system:

a. Laboratory Quality Manual.
b. Management procedures.
c. Technical procedures.
d. Work Instructions.
e. Standard Test Methods.
f. Equipment manuals.
g. Computer software.
h. The national and international standards.

NOTE 1: In this context "document" could be policy statements, procedures, specifications charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic.

4.3.2: Document Approval and Issue

4.3.2.1. a): Documents issued in the laboratory (as a part of the management system) are reviewed and approved for use in accordance with Document Control Procedure MP-4.03.

4.3.2.1. b): With respect to items mentioned in the item 4.3.1 the control and review mechanism has been designed to ensure that the document under control is updated and available to the concerned personnel and protected against any random changes. The procedure MP-4.03 gives the details of this mechanism.

4.3.2.1. c): The Quality Assurance Manager and officers are responsible for the process of modification, amending and issuing of the above mentioned documents .

4.3.2.2: The Document Procedure Content

The Quality Assurance Manager/Officers through the Document Control Procedure provides the following:

a) The authorized editions of the appropriate documents are available at all locations as indicated from the distribution list attached for each document.

b) Documents are reviewed according to a schedule and revised to ensure continuing suitability and conformance with the management system and ISO 17025:2005 requirements.

c) The invalid or obsolete documents are promptly withdrawn from all points of use.

d) The obsolete documents retained for either legal or knowledge purposes are marked with the obsolete copy red stamp and are kept in the Quality Assurance Manager's office.

4.3.2.3: Document Identification

The identification and control of the management system documents is detailed in the document control procedure MP-4.03.

4.3.3: Document Changes

4.3.3.1: The procedure MP-4.03 explains the control of changes which are introduced to the management system documents.

4.3.3.3: Computerized Systems:

The document control procedure MP-4.03 explains the control method of electronic management system documents.

4.4 Review of requests

4.4.1: General

The request for sample testing comes from the manufacturers, importers and marketers by hand or electronic means and the required test methods are included in the test request. The Laboratory Manager or her/his representative reviews the request(s) to ensure the following, before Medical Laboratory Scientist accepts the samples:

a) The requirement including the method to be used is adequately defined, documented and understood.

b) The laboratory have the capability and resources to meet the requirements of the customers.
c) The appropriate test method is selected and capable of meeting the customer's requirements
d) Each request should be conducted in practical and efficient manner and the financial, legal and time schedule should be acceptable for both the customers and the laboratory.
e) Provision of the customer with the best testing services.

4.4.2: Records of Review

Records of review including any significant changes are maintained in the testing laboratory according to procedure MP-4.04. Records of modifications with a customer are maintained on the request itself.

4.4.3: Requests Deviations

The customers are informed of any deviations from the request.

4.4.4: Amendments to requests

No amendments are allowed after accepting the sample test request.

4.5 Subcontracting of tests

The Lab's policy is not to subcontract its accredited scope tests.

4.6 Purchasing service and supplies

4.6.1: General

The laboratory management system follows policies, rules and procedures for selection, purchasing and evaluation of services and supplies. Refer to the purchasing services and suppliers procedure MP-4.06.

4.6.2: Inspection and Verification

The Lab Manager ensure that the purchased equipment and services that affect the quality of test are not to be used until being inspected or otherwise verified as complying with standard specifications or requirements defined in the method for test concerned. Refer to the purchasing file for inspection and verification rules.

4.6.3: Purchasing Documents

Purchasing documents for equipment and services that affect the quality of tests include the data that describe the services and supplies ordered. These purchasing documents includes type, class, grade, precise, identification, specification, inspection, work instructions and other technical data are reviewed and approved for technical content prior to release.

4.6.4: Records and Registry of evaluation

The Laboratory Manager evaluate and select the suppliers on the basis to meet the requirement of ISO/IEC 17025:2005. The Lab. Manager keeps and maintains records of all approved suppliers. These records are kept in the purchasing file under control of the Lab. Manager.

4.7 Service to the customer

4.7.2 General

The laboratory cooperate with the customer (or his representatives) in clarifying his request and allowing him to monitor his samples. That is done in the condition that the laboratory ensure confidentiality to other customers. This attendance is organized by the Laboratory Manager in his/her presence in coordination with the Quality Assurance Manager or Medical Lab Scientist. Refer to procedure MP-4.07 for more details.

Such cooperation may include:

- Giving the customer or customer's representative a reasonable access to relevant areas of the laboratory for the witnessing of tests performed for the customer.
- Preparation, packaging, and dispatch of test samples needed by the customer for verification purposes.

4.7.2 The customer feedback

The laboratory seek feedback, both positive and negative, from its customers. The feedback is used and analyzed to improve the management system, testing activities and customer service. The laboratory has the "**Customers services feedback**" form QF4.07-02, which is edited by the customers and reviewed by the Quality Assurance Manager, The feedback is analyzed to improve the management system, testing activities and customer service, refer to procedure MP-4.07 for more details about the handling of **"Customers service feedback".**

4.8 Complaints

4.8.1. Policy

The laboratory has a system for resolution of complaints in suitable time. Complaints identified as nonconformities are processed according to MP-4.08 complaint procedure.

4.8.2. Procedure

The laboratory has a complaint procedure describing the process for the receipt, register and dealing with complaints received from the customers. Refer to the procedure MP-4.08 for more detail about the complaint procedures.

4.8.3. Records

Any complaints are recorded, dated and kept in the complaint and customer service feedback file. The Laboratory Quality Assurance Manager/ officer with the cooperation of the Medical Laboratory Scientist to solve complaints and keep all relevant documents in the complaints file.

4.8.4. Corrective action

When the complaints show a deviation of the laboratory activities from the procedures, the Quality Assurance Manager takes corrective action for the complaint cause. The Quality Assurance Manager/ officer is responsible for implementation of the corrective action.

4.9 Control of nonconforming testing work

4.9.1 : The laboratory has a policy and procedure for control of non-conforming testing work .It is implemented when any aspect of testing work, or the results of this work, does not conform to requirements of the management system, test methods, or the requests of the customer. For more details for the policy of nonconforming testing work refer to procedure MP-4.09.

The Quality Assurance Manager through this procedure addresses the following elements:

- The responsibilities and authorities for the management of non-conforming work and actions taken such as stopping work and withholding of test reports by Medical Laboratory Scientist/technician and inform the Lab. Manager immediately.
- Application of criteria to evaluate the significance of non-conforming work.
- Correction taken, together with any decision about the acceptability of the non-conforming work.
- If necessary notification of the customer, and recall of work.
- The responsibility for authorizing the resumption of work is entrusted to the concerned Lab Manager.

NOTE: Identification of nonconforming work or problems with the management system or with testing activities can occur at various places within the management system and technical operations. For such identification the following areas are checked:

Customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate check management reviews and internal or external audits.

4.9.2 : In case of the evaluation during the internal audits indicate that the nonconforming work could reoccur or that there is doubt in the compliance of the testing operations with its policies and procedures , the corrective/preventive action procedure MP-4.11 is followed promptly.

4.10 Improvement

The Registrar/CEO, Lab Manager and other Laboratory staff are committed to improve the effectiveness of the Laboratory management system continually through:

4.10.1 The review of the quality policy, the use of the quality objectives and the audit results, corrective and preventive actions and management review.

4.10.2 All operational procedures are systematically reviewed by laboratory staff at regular intervals as defined in the document control procedure MP-4.03, in order to identify any potential sources of non-conformance or other opportunities for improvement in the quality management system.

4.10.3 The results of the review are submitted to laboratory management for review and implementation of any needed changes to the quality management system.

4.10.4 This is also done through the analysis of test data and quality control. This data may be like accuracy and precision of the test results and quality control charts for systematically monitoring and evaluation of the test results.

4.10.5 Any actions taken for improving the management system may be done through the Preventive Actions procedure MP-4.11 and recorded in the appropriate formats.

4.11 Corrective action

4.11.1: General

The laboratory have a corrective /preventive action procedure MP-4.11**,** it establishes a policy to designate appropriate authorities in implementing corrective/preventive action; after reviewing it with the Quality Assurance Manager when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified such as:

- Departures from the policies, procedures and required technical operations.
- Staff performance and staff observations
- Reporting results.
- The agreed requirements of the customers.
- Internal/external audits, management reviews.
- Feedback from customers.

4.11.2: Root cause analysis

The procedure for corrective/preventive action MP-4.11 includes investigating and determining the root cause of the non-conformance. The Medical Lab. Scientist is responsible to manage the cause of that departure.

4.11.3: Selection and implementation of corrective actions

The corrective action is selected for the findings of the following reasons: internal audits, test performance, customers' requirements, complaints and management review. Where the corrective action is needed, the laboratory area responsible identifies:

- The action most likely to eliminate the problem and to prevent recurrence.
- Corrective action appropriate to the magnitude of the non-conformance and the risk attributed to it.
- Corrective actions that are implemented, and any changes resulted from the corrective action investigation are documented by the Quality Assurance Manager.

4.11.4: Monitoring of Corrective Actions

The corrective action procedure addresses the monitoring for the effectiveness of corrective actions performed. The Quality Assurance Manager is responsible for monitoring and confirms the effectiveness of the corrective actions which are taken by the technical officers in the laboratory.

4.11.5: Additional Audits

Where the identification of non-conformances or departures casts doubts on the laboratory conformance with management system policies and procedures or conformance with ISO/IEC 17025:2005, it's the decision of the Lab Manager to request the Quality Assurance Manager to carry out additional audits, when it is noticed that a serious nonconformance occurs.

Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit is necessary only when a serious issue or risk to the business is identified.

4.12 Preventive actions

4.12.1 : General

The Lab Manager realizes that preventive actions are adopted within the various activities in the laboratory, as they are one of the main factors which improve and stabilize the quality of the management and technical work. Preventive actions are also needed to reduce the likelihood of the occurrence of non-conformities. The preventive actions follow the same procedure as the corrective actions according to procedure (corrective/preventive action procedure MP-4.11)

4.12.2 : Procedure

The laboratory establish a procedure (corrective/preventive action procedure MP-4.11) to activate the preventive action mechanism. It includes the initiation of action. The management review process monitors the effectiveness of such actions in providing improvement to the quality system.

4.12.3 : Preventive plans.

The majority of the preventive actions adopted by the laboratory are embedded within the activities themselves, such practices includes but not limited to:

- **Regular calibrations** of laboratory equipment are preventive actions against drifts
- **Internal audits** are preventive actions against departure which occur in either management system or technical operations.
- **Continuous training** is preventive action against the deterioration of personnel capabilities occur by time passing.
- **Continuous checking and backup of the operating software** are considered preventive actions against random interferences.
- **Check performance of the personnel plan** is a preventive action against any deviation of the technical level for performance of the personnel.
- **Analysis of proficiency testing results**
- **Review of operational procedures.**
- **Intermediate calibration checks for laboratory equipment**.

4.13 Records Control

4.13.1: General

4.13.1.1: Procedure

The laboratory established procedure MP-4.13 for identification, collection, indexing, filing, storage, maintenance and disposal of quality and technical records .Quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions.

4.13.1.2: Legibility, Storage, and Retention

All records are legible, stored properly, retained and readily retraceable in suitable environment to prevent damage or deterioration and to prevent loss. Retention periods of records are mentioned in procedure MP-4.13.

4.13.1.3: Security and Confidentially

The access to the quality or technical records is controlled by the authorized personnel. Medical lab. Scientist and quality officers or other personnel assigned by them are allowed to access the records through the document controller. Records are stored in secured areas, and kept confidential before release. Records may be hard copy or electronic media.

4.13.1.4: Electronic Records

The laboratory have a procedure describing the protection and back-up of electronic records. The procedure also describes the safeguards in place to prevent unauthorized access to or amendment of electronic records.

4.13.2: Technical Record

4.13.2.1: Retained records, Audit trail, and Identification

The laboratory retain records of original observations, derived data and sufficient information to establish an effective audit performance, the staff hand writing observations and a copy of each test report issued for a defined period.

The record for each test contain sufficient information to facilitate, if possible, identification factors affecting the uncertainty and to enable the test results to be repeated under conditions as close as possible to the original.

The records include the identification of personnel responsible for the performance of the test and checking of results. The records contain sufficient information to establish an audit trail.

4.13.2.2: Recording and Identification

Observations, data, and calculations are recorded at the time they are made and identifiable to the activity performed. Method number is used to provide traceability of records to activities.

4.13.2.3: Corrections

When mistakes occur in records, each mistake is lined out and not erased, made illegible or deleted, and the correct values entered a long side. All alterations to records are signed or initialed by the person making the correction. In the case records are stored electronically, measures governed by Quality Assurance Manager are taken to avoid loss or change of the original data.

4.14 Internal Audits

4.14.1: Purpose:

4.14.1.1 General

Internal audits are conducted according to a schedule included in the laboratory's audit procedure MP-4.14.

- Internal audits are conducted for activities to verify that operations continue to conform to the requirements of the management system and ISO/IEC 17025:2005.
- A continuous program of internal auditing is conducted to ensure that quality policy described in this manual is correctly and effectively implemented as defined by the laboratory procedures.
- The internal audit program addresses all elements of the management system, including testing activities. The laboratory Quality Assurance Manager is responsible for the coordination of internal audits as listed in the schedule and requested by the Management.
- Trained and qualified personnel are responsible for conducting internal audits. Audits are performed by personnel other than those who perform the work being audited. The list of management system Audit officer is described in appendix 7 in the quality manual.

4.14.1.2 Audit Plan:

- An annual plan is established by Quality Assurance Manager/officers and approved by Lab Manager to check the conformance with the processes and procedures which may affect the quality of the laboratory works.
- The plan ensures that each item of the management system is examined at least once a year.

4.14.1.3 Responsibility:

The Quality Assurance Manager/officer is responsible for:

- Organizing and conducting the audits.
- Choosing auditors who are independent of the specific activities being audited.
- Extended to verify that all corrective actions required by audits have been completed.

4.14.2 Corrective Action

When audit finding cast doubt on the effectiveness of the operations or on correctness or validity of the laboratory's test results, corrective action is undertaken.

The customer is notified in writing if investigations show that non-conformances affected the tests results

4.14.3 Audit Records

The area of activity audited, the audit findings, and corrective action(s) that arise from them are recorded according to internal audits procedure MP-4.14.

4.14.4 Follow-up Audit Activities

Follow-up audit activities are conducted to verify and record the implementation and effectiveness of the corrective action taken. This follow-up of the audit results is included as part of the management review process.

4.15 Management Reviews

4.15.1General

In accordance with a predetermined schedule and procedure, the Lab Manager periodically conduct a review of the laboratory's management system and testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. This is conducted once a year to ensure that the system complies with the accreditation requirements on continual bases according to the management review procedure MP-4.15.

The laboratory management review procedure MP-4.15 includes the schedule for conducting annual management reviews.

4.15.2: Management review elements

The Quality Assurance Manager prepares for the management review. The management review addresses the elements of the management system and includes, but not limited to:

- Suitability of policies and procedures.
- Laboratory objectives
- Reports from managerial and supervisory personnel.
- Outcome of recent internal audits.
- Corrective and preventive actions.
- Assessments by external bodies.
- Results of inter laboratory comparisons, proficiency test, and quality control.
- Changes in the volume and type of work.

- Customer feedback and Complaints.

4.15.3: Management review actions & recording

The findings and actions that arise from the review are recorded according to the laboratory's management review procedure MP-4.15. Each action includes a target date for resolution; and the Quality Assurance Manager is responsible for ensuring that reviews are recorded including any actions required and verifying that all corrective actions have been completed within the required time scale.

5.1 General

5.1.1 Correctness and reliability factor.

The items following below address the factors affecting the correctness and reliability of the tests performed by any laboratory in the system scope. These factors include contributions from:

- Personnel
- Accommodation and environmental conditions
- Test methods and method selection and validation
- Equipment selection and test
- Measurement of uncertainty and traceability
- Handling of test samples

The procedures listed in each section address these factors.

5.1.2 Contribution to total uncertainty of measurement

These factors (5.1.1) are considered in determining total measurement of uncertainty and in developing uncertainty budgets. Additionally, these factors are considered by the laboratory when developing test procedures, in the training and qualification of personnel, and in the selection of the equipment utilized.

5.2 Personnel

5.2.1 Personnel competence

The laboratory ensure that personnel have the knowledge, skills, and abilities to perform their duties. Competence is based on education, experience, demonstrated skills, and training. Staff records contain the documentation of personnel education, experience, skills, and training for the position held. Trainees undergo a training program in accordance with the laboratory training procedure. For in-house training,

the Laboratory Manager and/or Quality Assurance Manager serves as the trainers. Trainees perform procedures when training is completed and competency has been demonstrated, (refer to T.P/5.02, personnel procedure).

5.2.2 Goals for Education, Training and Skills

The individual and management are jointly responsible for the setting, the pursuit, and achievement of educational goals for professional advancement. The annual performance evaluation process can be used by the individual to discuss career advancement and training possibilities.

By using this process, individuals have the opportunity to identify areas of study and request training oriented towards the attainment of their goals.

Training needs are identified by the Laboratory Manager with cooperation of the authorized Legal affair & Administration Officer; through the human resources development unit. In-house training is conducted according to laboratory personnel procedure for more details refer to T.P/5.02.

Skills of personnel are based upon demonstration of competence. This demonstration is to be completed successfully before Medical Lab Scientists generate data independently. The effectiveness of personnel training is documented in but not limited to management reviews, internal audits, external assessments, proficiency testing, and performance evaluations, refer to T.P/5.02 personnel procedure for more details.

The laboratory have a procedure for evaluation of the training programs, the measurement of their effectiveness. For details refer to T.P/5.02 personnel procedure.

5.2.3 Employees and Contracted Personnel

The laboratory utilizes the skills and talent of both the employees. The requirements of the management system are applied. Supervision, training, and competence are documented for all technical and key support personnel. The Medical Lab Scientists ensure that such personnel are supervised and competent to the work they carry out within the management system, refer to T.P/5.02 personnel procedure for more details.

5.2.4 Job description

The laboratory maintains active job descriptions (duties, responsibilities, qualifications and training) for managerial, technical, or key support personnel involved in testing. Job descriptions are established in details in the management item 4.01 (Organization) in this manual.

5.2.5 Management Authorization

The authorized Medical Lab. Scientist & Quality Assurance Manager under supervision of Lab Manager authorizes to identify personnel to:

- Perform tests,
- Issue test reports ,
- Give opinions and interpretations (If any),
- Operate particular types of equipment.

The laboratory maintain records of the relevant authorization, competence educational, professional qualification, skills and experience of all technical personnel. This information readily available and including the date of authorization and competence. The list of key persons and authorized staff persons are listed in appendices 5 and 6 in this manual.

5.3 Accommodation and Environmental Conditions

5.3.1 :Facilities and Environmental Conditions

The laboratory environmental conditions facilitate the correct performance of the tests. The methods used by the laboratory include instructions addressing applicable environmental conditions.

The laboratory unit of concern monitors the critical environmental conditions to ensure that results and the quality of the measurements are not adversely affected or invalidated.

The laboratory are complying with environmental requirements of ISO/IEC 17025:2005 as well local laws, and regulations. For more details refer to the procedure TP-5.03 (Facilities and Environmental conditions).

5.3.2: Monitoring:

Environmental conditions monitoring include, but not limited to the room's temperature and humidity, where more environmental controls are needed, the environmental conditions are recorded. The environmental conditions for the accredited test is described in TP-5.03 (Facilities and environmental conditions)

The Medical Lab. Scientist is responsible for collecting and arranging those records for each test. The environmental conditions records are kept in environmental conditions file.

5.3.3: Cross –Contamination

The laboratory's activities are physically separated according to the requirements of ISO/IEC 17025:2005 to avoid cross -contamination and to be environmentally suitable for the tests.

5.3.4: Access

The access to the laboratory area is controlled by the Lab Manager and laboratory staff, any circulation within the laboratory is limited and under supervision.

Lists of authorized personnel who have access to the various areas of the laboratory are kept in the personnel file.

5.3.5: Housekeeping

Laboratory areas are maintained clean and orderly to prevent contamination of equipment and to facilitate the efficiency of laboratory operation.

- The laboratory is accommodated with places for keeping chemicals, glassware, reference standard, reference material and documents used by personnel.
- Key staff are responsible for maintaining good housekeeping throughout the laboratory
- The laboratory have special security regulations; the laboratory staff are responsible to execute it.

5.4 Test methods and method validation

5.4.1: Policy and scope

The laboratory use appropriate methods and procedures for the tests within their scopes. These include handling, transport, and storage of sample to be tested.

In addition the laboratory estimate the uncertainty as well as statistical techniques for the test data. Refer to the work instruction W.I/5.04/01.

5.4.2: Selection of Methods

The laboratory use test methods which meet the national standards and which are appropriate for the test undertake refer to the list of standards in appendix 3 in this manual.

The laboratory inform the customers of the test method and confirm that it can properly operate standard method before submitting any offer for test services.

5.4.3: The Laboratory Developed Methods:

In case of use of developed methods, the laboratory design their test methods according to the national and international standards. The developed methods are validated and prepared by laboratory Quality Assurance Manager, reviewed and approved by Laboratory Manager.

5.4.4: Non-standard methods:

In case of the laboratory use of methods not covered by standard methods, the laboratory edit agreement with the customer which include a clear specification of the customer requirement and purpose of the test. The non-standard methods are validated and prepared by Medical Laboratory Scientist and reviewed by Laboratory Quality Assurance Manager and approved by the Laboratory Manager. This will only be done outside the accredited scope.

5.4.5: Validation of the methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular specifications for an intended use are fulfilled. This will only be done outside the accredited scope.

5.4.5.2 Methods Requiring Validation

When the laboratory validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods, then it is validated to confirm that the methods are fit for the intended use. The validation are extensive as is necessary to meet the needs of the given application or field of application. When needed the laboratory validates and verifies its methods and records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use. This will only be done outside the accredited scope.

- Validation may include procedures for sampling, handling and transportation when is applicable.
- The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:
    1. Calibration by using reference materials;
    2. Comparison of results achieved with other methods;
    3. Inter-laboratory comparisons;
    4. Systematic assessment of the factors influencing the result;
    5. Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.
- When some changes are made in the validated non-standard methods, the influence of such changes is documented and, if appropriate, a new validation will be carried out.

5.4.5.3 Process

The laboratory ensure that the obtainable values from the usable method such as the accuracy, precision, uncertainty of the results, limit of repeatability, reproducibility limit, limit of detection, limit of quantification/reporting, as assessed for the intended use, shall be relevant to the customers' needs. This will only be done outside the accredited scope.

5.4.6: Estimation of uncertainty of measurements

5.4.6.1 Procedure for test activities

The laboratory apply the work instruction (WI-5.04.01), Estimation of measurement uncertainty to estimate the uncertainty of measurement for testing activities according to the requirements mentioned in the ISO/IEC17025:2005 and when it is applicable.

5.4.6.2: The laboratory have and apply procedures for estimating measurement uncertainty, when the nature of the test method may preclude rigorous metrological and statistically valid calculation of uncertainty of measurement. In these cases the laboratory will attempt to identify all components of uncertainty whose have affected values on the final result and make a reasonable estimation, and will ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation will be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data. The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

1. The requirements of the test method;
2. The requirements of the customer;
3. The existence of narrow limits on which decisions on conformity to a specification are based.

5.4.6.3: Uncertainty Components

When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation will be taken into account using appropriate methods of analysis as addressed in the work instruction (WI-5.04.01), the requirements mentioned are covered by the test procedures which is performed by laboratory staff. Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

5.4.7 Control of Data

5.4.7.1 Data Transfers

Calculations and data transfers are subject to appropriate checks in a systematic manner before being reported by the Laboratory Manager as described in his responsibility. All changes are identified and verified whenever they occur. Checking of the calculations and data transfer is performed to its nature (Hard and Electronics copies).

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory will ensure that:

a) Computer software developed by the Laboratory staff is documented in sufficient detail and is suitably validated;
b) The laboratory established and implemented a procedures for protecting the data; such as but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
c) Computers and automated equipment are maintained to ensure proper functioning with the environmental and operating conditions necessary to maintain the integrity of test data.

5.5 Equipment

5.5.1: Laboratory Equipment

The laboratory is furnished with sufficient equipment required for the correct performance of the tests (including sampling, preparation of test items, processing and analysis of test data).

5.5.2: Equipment Capability

Equipment and their software used for testing are capable of achieving the accuracy required and comply with specifications relevant to the test concerned. Calibration programs established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment will be calibrated and checked to ensure that it meets the laboratory's specification requirements and complies with the relevant standard specifications.

5.5.3: Authorized Operation

Personnel are authorized to operate equipment according to the clause 5.2.5 of ISO/IEC 17025 and management authorization in this manual, see appendix 6. Authorization is based on work assignment, training, experience and demonstrated proficiency. Equipment manuals and maintenance procedures are maintained and supplied to laboratory personnel.

5.5.4: Equipment Identification

Each equipment used for testing and significant to the result shall be uniquely identified.

5.5.5: Equipment Records:-

Equipment records shall be maintained for each equipment significant to the tests performed.

5.5.6: Management of Equipment

The laboratory has work instruction WI-5.05.1 to describe the method of handling, transport, storage, planned maintenance and calibration of the equipment to ensure proper functioning and to prevent contamination.

5.5.7: Defective Equipment

Any equipment that has been subjected to overloading or un proper handling, gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service. It is isolated and clearly labeled or marked as being "**Out of service"** which indicate that the equipment is out of the service to prevent its use until it has been repaired.

Laboratory examines the effect of the defect or departure from specified limits on previous tests

5.5.8: Calibration Status

Equipment under the control of the laboratory is coded to indicate the calibration status, including the date of the last calibration and the due date for recalibration. Alternatively, equipment calibration status may be identified in an associated record to indicate the status of calibration.

5.5.9: Equipment leaving the Laboratory

When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory checks the function and shown to be satisfactory before the equipment used.

5.5.10 Calibration Confirmation

Intermediate confirmation checks are performed to maintain confidence in the calibration status of the equipment. These checks are conducted according to the work instruction (WI-5.06.1).

5.5.11 Correction Factors

Where the calibration results give rise to a set of correction factors, these factors are communicated to equipment users to take it in his calculations.

5.5.12 Safeguards

The test equipment is safeguarded from any unauthorized personnel and adjustments that would invalidate the test results. Safeguards are provided using access control to the laboratory.

5.6 Measurement traceability

5.6.1: General

The laboratory equipment including equipment for subsidiary measurements (e.g. for environmental conditions) that having a significant effect on the accuracy are calibrated before being placed into service according to annual plan, Refer to TP-5.06, measurement traceability procedure and TP-5.05 equipment management procedure.

5.6.2: Specific requirement:

5.6.2.1 Calibration.

This is a testing Lab so this clause is not applicable.

5.6.2.2 Testing

5.6.2.2.1 Measurement Traceability

The program for calibration of laboratory equipment requires that measurements made by specific calibration laboratory shall be traceable to the international system of units (SI). Refer toTP-5.06 Measurement traceability procedure

These requirements are included in the laboratory calibration programs for equipment that has a significant contribution from its calibration to the total measurement uncertainty. In this case the laboratory will ensure that the equipment used can provide the uncertainty of measurement needed. The uncertainty of measurement is determined and recorded according to the work instructionWI-5.04/01

5.6.2.2.2. No direct traceability to SI units

When the calibrations of laboratory equipment cannot be strictly related to SI units, in these cases the laboratory provides confidence in the measurements by establishing traceability to appropriate measurement standards as:

- The use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material. It has to be traceable to SI units.

- The use of specified methods and standards that are clearly described and agreed to by all parties concerned.
- The laboratory participates in suitable program of inter-laboratory comparisons and proficiency testing.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Certified Reference Standards

The laboratory uses its reference standards (if founded) for in house intermediate calibration checks according to calibration plan; details are included in the Measurement traceability procedure

The reference standards are not used for testing of the samples but are used for calibration of other equipment and the intermediate calibration checks for the equipment.

5.6.3.2: Reference materials

The laboratory reference materials are traceable to SI units of measurement, or to certified reference materials. The laboratory checks the internal reference materials according to the procedure.

5.6.3.3: Intermediate Confirmation of Calibration Status (**Intermediate checks)**

Metrological confirmation for reference standards and certified reference material and reference materials used in the intermediate calibration checks programs are conducted according to a schedule addressed in the measurement traceability procedure

5.6.3.4: Transport and Storage.

The laboratory have a work instruction to describe the safe handling, transport, storage and use of reference standards and reference materials. These activities are established in order to prevent contamination, deterioration, and to protect the integrity of reference standards and reference materials.

5.7 Sampling

5.7.1: Sampling Methods

The laboratory receive IVDs Product/ sample (Reagents, Rapid diagnostic test kits, consumables, Laboratory chemicals and Laboratory Equipment). The laboratory has a sample management procedure TP-5.08 for describing the reception, distributing, storing, handling and disposal of the tested samples being received from manufacturer/importers/marketers.

5.7.2: Customer deviations

According to the clause (5.7.1) the customers are responsible to provide the number of products/sample for the evaluation of the services required.

5.7.3: Sampling Records

According to the clause (5.7.1) the laboratory maintain records for reception, samples chain of custody, storing and disposal of products/sample received according to TP-5.08.

5.8 Handling of test samples

5.8.1 Protection of Samples

The laboratory have samples management procedure TP 5.08, which describes the receipt, processing, and storage of samples. This procedure addresses the laboratory activities conducted to protect sample integrity.

5.8.2 Identification of Samples

The laboratory depend on the uniquely identifying of samples by inspection section or branches, in addition then will be coded as described in the procedure TP-5.08.

The identification shall be retained throughout the life of the samples, from receipt up to delivery of results to customers. The identification system is designed and operated to ensure that tested samples are not confused physically, or when referred to in records or other documents. The identification system provides traceability between the sample and the data. The identification system also provides traceability during transfer of samples within the laboratory; this is described in the sample management procedure TP-5.08. The identification of sample is in a code of letters and numbers is done by Quality Assurance Manager/QC staff designated. This help in preventing operator bias, conflict of interest and any pressure on the laboratory operations by sample owner.

5.8.3 Departures, Additions or Exclusions

Upon receipt of the sample, abnormalities or departures from normal or specified conditions, as described in the methods are recorded according to the samples management procedureTP-5.08, in this case the sample shall be rejected and returned to the customer.

5.8.4 Protection of samples during processing and storage

The sample management procedure TP-5.08 provides details for protecting samples from deterioration, loss or damage during storage and testing. The laboratory have arrangements for storage and security that protect the condition and integrity of samples. Sample security arrangements apply inside and

outside the laboratory. Handling instruction provided with the tested sample is followed, as well as procedure TP-5.08

5.9 Assuring of the quality of test results

5.9.1 Quality Control Procedures

5.9.1.1 The laboratory have the procedure to assure the quality of the results as in the procedures TP-5.09 to validate the results of test undertaken according to the ISO/IEC 17025:2005.

5.9.1.2 The monitoring data is recorded in such a way that trends may be detected, for example, statistical process control charts (Accuracy & precision charts), the laboratory construct the mean chart to monitor the trend of the accuracy of the quality control sample results. Also construct the RPD and range charts are for monitoring the trend of the precision of the quality control sample results refer to the work instruction WI-5.09/01 for more details.

5.9.1.3 The laboratory monitoring activities are planned and evaluated; monitoring techniques may include, but are not limited to, the followings:

1) Regular use of certified reference material and internal quality control using secondary reference material.

2) Participation in inter-laboratory comparison or proficiency-testing programs as described in assuring the quality of test results procedure TP-5.09.

3) Replicate the test by using the same methods;

4) Retesting the standard equipment and retained test sample.

5.9.2 Quality Control results corrections:

The laboratory has defined the criteria for quality control data and performs analysis by such means as control charts. When data is found to be outside the established criteria, action is taken in accordance with the laboratory's control of non-conforming work procedure.

5.10 Reporting the results

5.10.1 General

The results of each test, carried out by the laboratory staff are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods.

The results will be reported, usually in a test report and includes all the information required by the customer, the accreditation bodies and information necessary for the interpretation of the result and all information required by the method used. These information are normally those required by (5.10.2, and 5.10.3).

5.10.2 Reporting Results

Data entered onto the worksheets (Data Presentation) includes all the information specified by the laboratory, the test report including at least the following information:

- A Title of "Test Report"
- The name and address of the laboratory.
- Unique identification of the test report on each page, this in order to ensure that the page is recognized as a part of the test report and a clear identification of the end of the report.
- The name and address of the customers.
- The unique identification of the test report.
- Description, the condition and unambiguous identification of the test sample.
- The date of receipt of the sample.
- Test results and measurement units.
- The function and signature (s) equivalent identification of person (s) authorizing test report.
- The test report includes the page number and the total number of pages.
- The test report includes a statement specifying that the test report must not be reproduced without a written approval of the laboratory section.

5.10.3 Test report

5.10.3.1 Specific Requirements

The following information is included in test reports for the interpretation of the test results:

- Deviations from, additions to, or exclusions from the test method, and information on test conditions, such as environmental conditions;
- A statement of the estimated uncertainty of measurement.
- Additional information that may be requested by methods, customers or groups of customers.
- Environmental conditions under which the tests were made.

5.10.3.2 Sampling Results

In addition to the instructions listed in Sections (5.10.2, and 5.10.3.1), sampling information and conditions are posted to the laboratory.

5.10.4 Calibration certificate

(Not applicable)

5.10.5 Opinions and Interpretations

The technical responsible is the unique person that can express any opinion and interpretation of the compliance or non-compliance of the results in the test report.

5.10.6 Electronic Transmission of Results

Unless otherwise approved by management, the management system does not allow transmission of test results by telephone, faxes, electronic mail or other electronic means.

5.10.7 Format of Worksheets

The format for test report is written in according with the policy and requirement of customers, the accreditation body's requirements are kept in order to minimize the possibility of misunderstanding or misuse. (See Appendix 4) in sample management procedure.

5.10.8 Amendments to Worksheet

The laboratory do not issue any amendment to the test reports, when there is an error, the report is withdrawn, and a new one with the same identification code is issued.

In some cases when the results of the sample are released in different stages, they are reported in supplement reports with the same identification code.

Appendix 1

Index of management & technical procedures

S. No	ISO 17025 Clause	Procedure code	Procedure Title
1	4.03	MP-4.03	Document control
2	4.04	MP-4.04	Review of requests, tenders and contracts
3	4.06	MP-4.06	Purchasing services and suppliers
4	4.07	MP-4.07	Customers services
5	4.08	MP-4.08	Customers complaints
6	4.09	MP-4.09	Control of nonconforming testing works
7	4.11	MP-4.11	Corrective actions
8	4.13	MP-4.13	Records control
9	4.14	MP-4.14	Internal Audits
10	4.15	MP-4.15	Management reviews
11	5.02	TP-5.02	Personnel and training
12	5.03	TP-5.03	Facilities and environmental conditions
13	5.05	TP-5.05	Equipment
14	5.06	TP-5.06	Measurement traceability
15	5.08	TP-5.08	Samples Management

16	5.09	TP-5.09	Assuring the quality of the test results

Appendix 2
Index of Work Instructions

S.NO	Instruction code	Instruction Title
1		
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S.NO	Instruction code	Instruction Title
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Appendix 3
List of standard specifications

#	Standard Number	Standard Title	Edition	Issuing Date	Remark
General Standard					
1					
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Appendix 5

Laboratory Authorized Key Persons

#	Name	Job Description	Signature
1	Mr. Tosan Erhabor	Registrar/CEO	
2	Mr. Offutalu, Paulinus N.	Laboratory Manager	
3	Mr. Fasogbon, Samuel A.	Deputy Quality Assurance Manager	
4	Mr. Akinola Timothy O.	Chief Medical Lab. Scientist	
5	Mr. Ogbonna Kelechi	Biomedical Engineer / Equipment officer	
6	Mrs. Rotoye	Principal Legal Officer	
7	Mrs. Lawretta Okonji	Administration Officer	
8	Mrs. Adetoro Basirat	Administration Officer II	
9	……..	Quality officer	
10	……..	Quality officer	
11	.....	Quality officer	
12			
13			

Laboratory Manager: ……..

Appendix 6

List of staff authorized carrying out tests.

#	Name	Job Description	Signature
1	Mr. Offutalu, Paulinus N.	Haematology/Blood Transfusion Service	
2	Mr. Oparanozie, Jude A.	Microbiology/Parasitology	
3	Mr. Fasogbon, Samuel A.	Histopathology/Cytology	
4	Mr. Akinola T. O.	Chemical Pathology	
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List of staff authorized carrying out tests.

Calibration Administration

#	Name	Job Description	Signature
1	Mr. Offutalu, Paulinus N.	Haematology/Blood Transfusion Service	
2	Mr. Oparanozie, Jude A.	Microbiology/Parasitology	
3	Mr. Fasogbon, Samuel A.	Histopathology/Cytology	
4	Mr. Akinola T. O.	Chemical Pathology	
5	Mr Essien, Victor	Immunology	
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Appendix 7

Internal Auditor

S.N.	Name
1	Mr. Offutalu, Paulinus N.
012	Mr. Akinola Timothy O.
301	Mr. Fasogbon, Samuel A.
4	
5	

Appendix 8
Distribution lists for quality manual

S.N	Holder	Number of copies
1	Laboratory Manager	1
2	Quality Assurance Manager	1
3	Registrar/CEO	1
4		
5		
6		
7		

Appendix 9

Monthly Meetings Agenda & Minutes

Meeting no. ( )

Date/Time: …… Location: ……

Attendees:

1. ……
2. ……
3. ……
4. ……

S.No	Subject	Remarks
1	**Improvement Recommendations** (Discussing Quality policy, Quality objectives, Audit Results, Customer feedbacks, Complaints, Analysis of data, CARs, Management Review outputs)	
2	**Personnel Awareness against their duties and the requirements of QMS of the Lab** (Showing a quick review for the QMS of the lab and the new changes if present)	
3	**The Effectiveness of the QMS of the lab** (taking a random sample of quality records, Charts, analysis of data … etc)	
4	**Emphasize the Importance of Meeting the Requirements of the customers, QMS, ISO 17025 and the accreditation body**	
5	**Checking the Integrity of the QMS in case of changes**	
6	**Explain the regulations for the impartiality and confidentiality to the staff.**	
7	**Others**	
8	**….**	
9	**...**	
10	**..**	

Laboratory Manager:

Date : / /