MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA

PUBLIC HEALTH IN-VITRO DIAGNOSTICS CONTROL LABORATORY (IVDs)

8 HARVEY ROAD YABA, LAGOS

LABORATORY HANDBOOK

MLSCN/IVD/HB/196
V-002

SCOPE

This Laboratory Handbook is intended to provide an overview of the scope of work, services and policies of the Public Health In-vitro Diagnostic Control Laboratory (IVDs Lab), Yaba, Lagos State, Nigeria for the benefit of clients, users, inspection and accreditation bodies as well as MLSCN-IVD Laboratory Management and staff.

Furthermore, this Laboratory handbook provides the users of this laboratory and other IVD stakeholders of the basic information they may require for their effective interaction with the Laboratory.

PREFACE

Medical Laboratory Science is the bedrock of the 21st Century evidence-based medicine. This means accurate reproducible results are invaluable to providing quality health care services. There are several elements of quality in medical laboratory practice; this includes qualified and skilled personnel, regular supply and use of appropriate equipment, reagents and consumables, use of appropriate procedure and a preventive maintenance schedule.

Before now, there has been no regulation or coordination on the types of equipment, reagents and consumables imported, distributed, marketed and used in the country by people with limited knowledge about these products dealing in such products. This has resulted in substandard, non-appropriate equipment, reagents and consumables being imported and used in the country which ultimately affects the quality of reports emanating from the laboratories.

In 2003, the MLSCN Act was passed which empowers MLSCN to, *inter alia*, regulate the production, importation, sales and stocking of diagnostic laboratory reagents and chemicals (in-vitro diagnostics - IVDs). Subsequently on 5th September 2013, the MLSCN IVD laboratory was commissioned by the President of Nigeria. The MLSCN IVD laboratory's mandate is to ensure that only quality IVDs enters the Nigerian market and stamp out all fake and adulterated IVDs in line with the international standard and the vision of the MLSCN to be a world acclaimed regulatory agency driving the culture of quality and efficient health laboratory care to the public.

Therefore, as part of efforts to contribute to improving the quality of health care services in the country and its regulatory function over the profession and practice of medical laboratory

science, the Medical Laboratory Science Council of Nigeria developed the In-Vitro Diagnostics (IVDs) Regulation in Nigeria to ensure that only in–vitro diagnostic products that meet the set standards are produced in or imported into Nigeria. The implementation of this regulation is coordinated by the Public Health In-vitro Diagnostics Control Laboratory, Yaba, Lagos State (established and managed by MLSCN).

Furthermore, this revised Laboratory handbook provides the users of this laboratory and other IVD stakeholders the basic information they may require for their effective interaction with the Laboratory.

Dr. Tosan Erhabor, FMLSN, FWAPCMLS
Registrar/CEO
MLSCN

ACKNOWLEDGEMENT

It is my privilege to sincerely thank all who contributed to the successful development and review of this document.

Worthy of mention is the unflinching motivation from the Registrar\CEO and the Top Management of MLSCN and their tremendous support to the IVD Laboratory.

Furthermore, sincere thanks to the hardworking IVD Team for their efforts to review this document and the other documents used in the operation of the Laboratory.

We sincerely thank all other stakeholders for their input to this document especially for the WHO for their training support as a National Regulatory Body in Tanzania and South-Africa in 2016, Geneva, Switzerland in 2019 and JHPIEGO in 2022.

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1. INTRODUCTION

In 2003, the MLSCN Act was passed which empowers MLSCN to, among other things, regulate the production, importation, sales and stocking of diagnostic laboratory reagents and chemicals (in-vitro diagnostics - IVDs). Subsequently on 5th September 2013, the MLSCN Public Health In-Vitro Diagnostics Control Laboratory (hereafter referred to as IVD Laboratory) was commissioned by the President of Nigeria. The MLSCN IVD Laboratory's mandate is to ensure that only quality IVDs enters the Nigerian market and stamp out all fake and adulterated IVDs in line with international standard and the vision of the Council to be a world acclaimed regulatory agency driving the culture of quality and efficient health laboratory care to the public.

In furtherance of the mandate and vision of Council, the IVD Laboratory applied for and was accredited by the Nigeria National Accreditation System (NiNAS) on the ISO 17025:2017 standard in January 2021. This means that the processes of the IVD Laboratory used in validating IVDs kits and equipment meets with international standard. This accreditation means that clients can be assured that only the best international practice will be used by the IVD Laboratory in dealing with its client and the products they submit for validation.

This handbook aims to provide relevant information and serves as a guide to IVD Laboratory clients. The handbook will be reviewed from time to time in the future. In case of suggestions or corrections on how to improve the usefulness of the handbook or other aspects of our services, please contact us through the following telephone number or email address:
Mobile: +2347062118574
Email: ivds@mlscn.gov.ng or info@mlscn.gov.ng

2. OUR CORE VALUES, VISION AND MISSION

2a. Core Values

We believe strongly in quality, integrity, innovation and team work and below are what these values represent for us:

Quality: We strive to produce excellent and outstanding results to our

clients by conforming to international standards. We are committed to improving quality healthcare service delivery in Nigeria.

Integrity: We maintain confidentiality and impartiality in handling all information which is given to us by clients or third parties. We are consistently open and transparent; we do what we say we will do and strive to do the right thing.

Innovation: We are committed to introducing new ideas to improve what we do and recognize that our continuous improvement is everyone's responsibility.

Teamwork: We share knowledge, support and learn from each other, collaborate and appreciate the efforts of other people and celebrate successes.

2b. VISION

To be a world acclaimed national IVD regulatory reference laboratory driving the culture of quality and efficient health laboratory care to the public and ensuring high IVD standards in Nigeria.

2c. MISSION

Strengthening health laboratory systems and professional practice for quality services through strategic IVD regulation and accreditation.

3. CONFIDENTIALITY AND IMPARTIALITY IN CONDUCTING ALL OUR SERVICES

The staff of the IVD Laboratory are trained to carry out their duties to the client with utmost confidentiality and impartiality. The requirement of confidentiality means that all information given by the client to the IVD Laboratory is kept confidential and not disclosed to a third party without the consent of the client. In conducting their duties impartially, the staff of the IVD Laboratory will not grant undue favour to any client for any reason. Clients are therefore not allowed to offer any inducements (whether in cash or kind) to any staff of the IVD Laboratory to try to gain undue advantage or expedite action on the validation of the IVD products submitted for validation.

4. HOURS OF OPERATION

The IVD Laboratory hours of operation is from 8am to 4pm Monday to Friday. The IVD Laboratory is closed on Saturdays, Sundays and public holidays. IVDs product collection is done within the facility between 8am to 4pm on Monday to Friday.

5. UNITS AVAILABLE IN THE IVD LABORATORY

- Chemical Pathology
- Heamatology and Blood Group Serology
- Microbiology and Parasitology
- Histopathology/Histochemistry Unit
- Immunology /Immuno-Chemistry Unit
- Molecular Biology/Diagnostic Unit
- Nano-Medicine Unit

The IVD Laboratory receives all IVDs products related to the listed units above.

6. PRODUCTS/SAMPLE RECEPTION CHECKLIST

When the client brings samples of IVD product to the IVD Laboratory for validation, the Medical Laboratory Scientist (MLS)/Sample Receiving Committee will use the product/sample reception checklist to verify that all the information required for the product is available before the product is received/accepted for validation. Below is the information contained in the checklist:

I. Name of company;
II. MLSCN Company ID number;
III. IVD Number;
iv. Date;
v. Description of product;
vi. Product brand name;
vii. Language of product insert;
viii. Product serial number;
ix. HS code;
x. Quantity of product;
xi. IVDs class;
xii. Batch/Lot number;
xiii. Manufacture date;
xiv. Expiry date;

xv. Remita receipt indicating payment of the service fee charged;
xvi. Result/ License collection method (Note: Letter of delegation should be given to the company representative coming to the IVDs Laboratory for collection of result/license);
xvii. Temperature of storage;
xviii. Manufacturer's name;
xix. Country of origin.

7. IVDs PRODUCT COLLECTION

The Medical Laboratory Scientist (MLS)/Sample Receiving Committee will review the request and ensure that the product(s) meets the acceptance criteria listed in the product/sample reception checklist. Once the product is accepted, it will be given a laboratory code number and validated.

Where a product does not meet the acceptance criteria of the IVD Laboratory, the client shall be contacted by either the Laboratory Manager or any designated staff via telephone or email and informed of the reason for the product rejection. The client will be asked to rectify the deficiency before the product will be accepted for validation.

Clients who have been given a reason for the rejection of the IVD samples submitted for validation are to rectify the deficiency and submit accurate samples within the period advertised for the particular batch of validation. Failure to submit within the advertised time means the client will wait for the next batch of validation for the inclusion of the products in the next validation cycle.

Submission of IVD products for validation is now done in response to the advertisement of Council calling for the submission of IVD test kits in the national dailies. From the date in which submission of kits is advertised, IVD manufacturers/Importers have eight weeks within which to submit IVD kits for validation. Validation of the IVDs products will begin after that period.

8. PRODUCT TRANSPORTATION/STORAGE

IVDs products that are already well packaged in individual packets should be brought to the IVD Laboratory in that packet. Further advise on product transportation and storage for other products can be obtained from the IVD Laboratory. Instructions on packaging products

can be obtained from the IVD Laboratory. IVDs products should be brought as soon as possible after manufacture/importation to the IVD Laboratory for validation.

9. REQUIREMENTS FOR REGISTERING AS AN IVD PROVIDER (COMPANY REGISTRATION)

The following are the steps to take to register your company with the IVD Laboratory as a registered IVD Provider:

A. Written application for company registration from the client on their letter head addressed to the Registrar/CEO;

B. Download, fill and submit IVDs company registration form (MLSCN/IVD/181) from www.mlscn.gov.ng (click on IVDs regulation submenu) with relevant documents attached as stated on the website;

C. Submit photocopy of Corporate Affairs Commission (CAC) incorporation certificate or business name registration certificate (whichever is applicable);

D. Submit a photocopy of Trade Mark Registration Certificate if applicable;

E. Submit a photocopy of Memorandum of Understanding (MOU) or Letter of Authorization as a Distributor if applicable;

F. Pay the importers/manufacturers/marketers company registration fee as applicable to the MLSCN TSA account via Remita platform and present the Remita receipt as evidence of payment to the IVD Laboratory Administration Desk;

G. A provisional registration letter will be duly issued by the IVD Laboratory in line with our turnaround time (TAT). Company registration certificate will be issued after an inspection of the facility has been carried out.

10. ANNUAL RENEWAL OF COMPANY REGISTRATION

After registering with the IVD Laboratory as an IVD Provider, the client is required to renew the registration annually. The annual renewal must be done before 31st March of each year. A notice reminding the

company of the annual renewal of the company registration will be sent by the Administration Team of the IVD Laboratory at the beginning of each year.

Clients are advised to renew their annual registration before 31st March as the IVD Laboratory will not render any service to the clients who fail to renew their registration.

11. REQUIREMENTS FOR PRODUCT LISTING (REGISTERING AN IVD PRODUCT: REAGENTS, RDTS, CONSUMABLES)

The following are required for IVDs Product Listing:

a. Evidence of company registration with the IVD Laboratory;

b. Application for product listing;

c. Submit a photocopy of trade mark registration certificate if applicable;

d. Submit a photocopy of memorandum of understanding (MOU) or letter of authorization as a distributor if applicable;

e. Application for provisional import permit (if required) to bring in samples of the IVD product required for validation;

f. Submission of the required quantity of IVDs products for validation with dossier document (refer to www.mlscn.gov.ng submenu IVDs, submenu registering an IVD product, check the product listing file/dossier document submission requirement link);

g. Submit evidence of payment of the service fee (Remita receipt) for Product Listing.

Once the above requirements are met, the IVD Lab will conduct validation on the IVD product(s). If the product(s) passes the validation, it will be listed on the Council website and the appropriate license issued to the client.

12. REQUIREMENT/PROCESS FOR EQUIPMENT LISTING

The following are required for equipment listing:

a. Equipment presentation, installation and trial runs by the

distributor/manufacturer's Field Service Engineer;

b. Presentation of evidence of payment of service fee (Remita receipt) for product validation and listing;

c. Equipment validation;

d. Equipment collection from IVDs Laboratory by the distributor/manufacturer;

e. The appropriate license will be issued to the client once the equipment passes validation.

13. IN-VITRO DIAGNOSTICS APPLICABLE FEES/ PRICE LIST

Below are the applicable fees for services rendered by the IVD Laboratory as approved by the Governing Board of Council:

a.	Annual renewal of company registration	₦30,000.00
b.	Class 1 IVD imported products	₦5,000,000.00
c.	Class 1 IVD product locally produced	₦3,500,000.00
d.	Class 2 IVD imported products	₦11,000,000.00
e.	Class 2 IVD product locally produced	₦8,500,000.00
f.	Class 3 IVD imported products	₦21,000,000.00
g.	Class 3 IVD product locally produced	₦17,000,000.00
h.	Company registration for IVD manufacturers/importers	₦250,000.00
i.	Company registration for IVD marketers	₦150,000.00
j.	List updating imported IVDs	₦1,000,000.00
k.	List updating locally produced IVDs	₦500,000.00
l.	Penalty for manufacturing/importing without registration	₦500,000.00
m.	Penalty for marketing without registration	₦300,000.00
n.	Penalty for marketing of unlisted IVDs (except equipment)	₦5,000,000.00
o.	Penalty for marketing of unlisted equipment	₦5,500,000.00

p. Repackaging/re-labeling penalty fees ₦5,500,000.00
q. Validation of IVD equipment and system imported ₦22,000,000.00
r. Validation of IVD equipment and system locally produced ₦18,500,000.00

14. CONDITIONS FOR IVDS PRODUCT REJECTION

IVD products submitted for validation will be rejected if:

a. The language of product insert is not in English;
b. The product does not conform to the required temperature stated by the manufacturer;
c. The product quantity/volume submitted is insufficient for the required procedure;
d. Incomplete documentation or documented information on the product label and products/sample reception checklist do not match;
e. Expired or nearly expired product;
f. Product integrity, according to the manufacturer's specification has been compromised or contaminated;
g. Non-payment of appropriate service fee;
h. Time when the product is submitted is not within the IVD Laboratory's hours of operation.

15. TURN AROUND TIME

S/N	ITEM	TURN AROUND TIME
1	Company registration	1 month
2	Annual renewal of company registration	1 month
3	Product validation and product listing	Within 4 months
4	Equipment listing	Within 4 months
5	WHO prequalified products (in-country verification)	3 months (90 days)

Concerted efforts will be made by the IVD Laboratory to ensure that services and validation of products are performed and that certificates, licenses and reports are ready for collection within the turnaround time indicated in the table above. Notice of any delays due to equipment breakdown or other unforeseen circumstances will be communicated to the client via email or telephone.

16. COLLECTION AND DISPATCH

Letter of registration, import permit, IVD Marketing License, IVD Manufacture & Marketing License and IVD Import & Marketing License may be collected by the client at the Administration Desk of the IVD Laboratory or may be dispatched by e-mail. Letter of delegation is required for collection of any document from the IVD Laboratory by the client's representative.

17. QUALITY MANAGEMENT SYSTEM (QMS)

The IVD Laboratory employs a standard and comprehensive quality management system to ensure that reliable and reproducible validation results/reports are produced to meet with international standards and thus ensure client satisfaction. We have impressive performance in external quality control assessment such as One World Accuracy. The IVD Laboratory has also been accredited by the Nigeria National Accreditation System (NiNAS) on ISO 17025:2017 standard which also ensures that the quality of work done at the IVD Laboratory meets international standards.

18. COMPLAINTS AND FEEDBACK FROM CUSTOMERS

Clients of the IVD Laboratory are treasured costumers and feedback, criticism and complaints about our services are welcome. Such feedback can be given using the Customer Service Feedback Form. The Customer Service Feedback Form is available at the Administration desk of the IVD Laboratory or on the website of MLSCN. Periodically the IVD Laboratory will conduct customer survey to evaluate our performance. We count on your feedback to improve our service delivery. Please help us serve you better.

19. SAFETY PRECUATION

Clients are encouraged to adhere strictly to the safety precaution

provided by the manufacturer of the IVDs product. Protective coverings such as laboratory coats, hand gloves, eye goggles are worn during collection and handling of IVDs product/sample as applicable. All biological waste is well managed. Autoclaving of infectious waste is carried out in the Laboratory before incineration and disposal to ensure a healthy environment. In addition, all staff are vaccinated accordingly. Post exposure prophylaxis is readily available in case of accidental exposure such as needle prick injury.

20. PUBLICATION

The IVD Laboratory may from time to time publish in peer reviewed journals, academic journals or online articles the results of the validation exercises. The consent of the client will be obtained before information is published.

21. CONTACT ADDRESS

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