



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-001





# MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA



**If your lab  
diagnostics  
equipment,  
reagents, and  
consumables  
does not have  
MLSCN reg.  
Number,  
it is fake**

**Are your  
IVD products  
listed and  
evaluated  
by MLSCN?**

**Is the  
company  
you patronize  
for your lab  
equipment,  
reagents and  
consumables  
registered  
with MLSCN?**

**Before you  
patronize any  
IVDs vendor  
contact and  
confirm from  
MLSCN today!**

**Are you an IVD  
Manufacturer,  
Importer or  
Marketer...  
and you are not  
registered  
with MLSCN?**

**Do you  
know if their  
IVDs product  
are listed  
and approved  
by MLSCN?**

**Get registered before  
the law catches up  
with you**

## **MLSCN IVDs LABORATORY:**

**8, Harvey Road,  
Yaba, Lagos  
[www.mlscn.gov.ng](http://www.mlscn.gov.ng)  
[ivds@mlscn.gov.ng](mailto:ivds@mlscn.gov.ng)  
Tel: 07062118574**

**MLSCN, strengthening health systems in Nigeria**

# SCOPE

**T**his Laboratory Handbook is intended to provide an overview of the scope of work, services and policies of the MLSCN 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 the basic information they may require for their effective interaction with the Laboratory.





# PREFACE

**M**edical Laboratory Science is the bedrock of the 21<sup>st</sup> 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 5<sup>th</sup> September, 2013, the MLSCN IVDs laboratory was commissioned by the President of Nigeria. The MLSCN IVDs laboratory 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 National Guidelines for In-VitroDiagnostics (IVDs) Regulation in Nigeria to ensure that only In – Vitro Diagnostics Products that meet the set standards are produced in or imported into Nigeria. This Guideline implementation is coordinated by the Public Health In-vitro Diagnostics Control Laboratory, Yaba, Lagos (Established and managed by MLSCN).

Furthermore, this 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.



**Erhabor, Tosan**  
Acting Registrar/CEO  
MLSCN





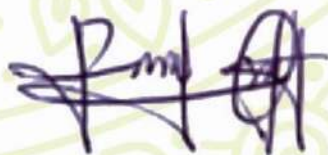
# ACKNOWLEDGEMENT

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

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

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

We sincerely thank all other stakeholders for their inputs to this document especially the WHO for their training support received as a National Regulatory Body in Tanzania and South-Africa in October and November 2016 amongst others. We remain grateful to all.



**Offutalu, Paulinus N.**  
Laboratory Manager,  
Public Health In-vitro Diagnostics Control Laboratory, Lagos,  
MLSCN.





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## **1. INTRODUCTION**

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 5<sup>th</sup> September 2013, the MLSCN Public Health IVDs Control Laboratory was commissioned by the President of Nigeria. The MLSCN Public Health IVDs Control Laboratory 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.

This handbook aims to provide information and a guide to our laboratory users. 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 numbers or email address:

Tel (Lab): +2349021765416 – 18

Mobile: +2347062118574

Email: [ivds@mlscn.gov.ng](mailto:ivds@mlscn.gov.ng) or [info@mlscn.gov.ng](mailto:info@mlscn.gov.ng)

## **2. OUR CORE VALUES, VISION AND MISSION**

### **2a. Core Values**

We believe strongly in Quality, integrity, innovation and team work.

### **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 regulations and accreditation

## **3. HOURS OF OPERATION**

The IVDs Laboratory is opened **8am to 4pm Monday to Friday** but closed to customers on Saturday, Sunday and public holidays. IVDs product collection is done within the facility between 8am to 4pm, Monday to Friday.





#### **4. UNITS AVAILABLE IN THE IVDs 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 (NOT YET DEVELOPED)

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

#### **5. IVDs TEST REQUEST FORM**

The IVDs test request form can be obtained from the reception desk. The requesting importer, marketer or manufacturer should endeavor to provide the required information shown below:

- i. Name of company
- ii. MLSCN company ID number
- iii. Date
- iv. Description of product
- v. Product brand name
- vi. Product serial number
- vii. HS code
- viii. Quantity of Product
- ix. IVDs class
- x. Batch/Lot number
- xi. Manufacture date
- xii. Expiry date
- xiii. Result/Certificate collection method (Note: Letter of delegation should be given to the company representative coming to the IVDs Laboratory for collection of result/certificate of product).

#### **6. IVDs PRODUCT COLLECTION**

The Medical Laboratory Scientist (MLS)/Sample Receiving Committee should review the request and ensure that the product(s) meet the acceptance criteria. Once the product is accepted, it will be given a laboratory code number and sent for evaluation.

Where a product does not meet the acceptance criteria of the IVDs Laboratory, the client shall be contacted by the Laboratory Manager





via telephone or email and informed of the reason for the product rejection. The client will be asked to rectify or meet up with the deficiency.

## **7. PRODUCT TRANSPORTATION/STORAGE**

IVDs products that are already well packaged in individual packets should be brought to the IVDs Laboratory in that packet. Further advise on product transportation and storage for other products can be obtained from the IVDs Laboratory. Instructions on packaging products can be obtained from the IVDs Laboratory. IVDs products should be brought as soon as possible after manufacture/importation to the IVDs Laboratory for evaluation.

## **8. REQUIREMENTS FOR REGISTERING AS IVD PROVIDER (COMPANY REGISTRATION)**

The following are the steps for company registration with the IVDs Laboratory:

- A. Application for company registration;
- B. Download, fill and submit IVDs company registration form (MLSCN/IVD/181) from [www.mlscn.gov.ng](http://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) registration certificate;
- D. Submit a photocopy of your Trade Mark Registration Certificate as applicable;
- E. Submit a photocopy of a Memorandum of Understanding (MOU) or Letter of Authorization as a Distributor as applicable;
- F. Submit Letter of Intent with correct physical address of facility.
- G. Pay the importers/manufacturers/marketer company registration fee as applicable (N50,000 or N30,000) only to the MLSCN TSA account via Remita platform and present the evidence of payment to the IVDs Laboratory Administration Desk;
- H. Company registration certificate will be duly issued by the IVDs Laboratory in line with our turnaround time (TAT).

## **9. REGISTERING AN IVD PRODUCT (REAGENTS, RDTS,**





## **CONSUMMABLES): (REQUIREMENTS FOR PRODUCT LISTING)**

The following are required for IVDs Product Listing:

- Evidence of company registration from the IVDs Laboratory;
- Application for Product Listing;
- Submit a photocopy of your Trade Mark Registration Certificate as applicable;
- Submit a photocopy of a Memorandum of Understanding (MOU) or Letter of Authorization as a Distributor as applicable;
- Application for provisional import permit (if required);
- Submission of the required quantity of IVDs products for evaluation with company listing file document (refer to [www.mlscn.gov.ng](http://www.mlscn.gov.ng) submenu IVDs regulation, submenu product listing file).
- Submit evidence of payment for Product Listing to MLSCN TSA account via Remita platform.

## **10. REQUIREMENT/PROCESS FOR EQUIPMENT LISTING WITH IVDS LAB.**

The following are required for Equipment Listing:

- Equipment presentation, installation and trial runs by the Distributor/Manufacturer's Field Service Engineer;
- Presentation of payment evidence of N250,000 for product evaluation and listing;
- Equipment evaluation;
- Equipment collection from IVDs Laboratory by the distributor/manufacturer;
- Issuance of product listing certificate by IVDs Lab.

## **11. PRICE LIST**

- a) Company registration - N50,000
- b) Product listing:
  - i. Equipment - N250,000
  - ii. Reagent and consumables- N50,000 per product.
- c) Annual renewal of company registration - N5,000
- d) Re-evaluation of already evaluated product - N25,000

## **12. CONDITIONS FOR IVDS PRODUCT REJECTION**

- The time of product receipt is not within the IVDs





- Laboratory's hours of operation;
- Documentation is incomplete or the information documented on the product label and test request forms do not match;
- The product or product volume is inappropriate or insufficient for the evaluation required;
- If the integrity of the product, according to the manufacturer's specification has been compromised or contaminated in any way;
- If the product has or is about to expire;
- Non-payment of appropriate fees.

### 13. TURN AROUND TIME

S/N	ITEM	TURN AROUND TIME
1	Company registration	1 month
2	Annual renewal of company registration	1 week
3	Product Evaluation and Product listing	Within 3 months
4	Equipment Listing	Within 3 Months

Concerted efforts are made by the IVDs Laboratory to ensure that services and evaluation of products are performed, and certificates and results are ready for collection within the turnaround time indicated in the table above. Notification concerning delays due to equipment breakdown or other unforeseen circumstances are communicated through the client's contact address, phone number or email.

### 14. COLLECTION AND DISPATCH

Letter of Registration, Import Permit or Product Certificate may be collected by the client at the Administration Desk of the IVDs Laboratory or may be dispatched by e-mail. Letter of delegation is required for collection of any document from the IVDs Laboratory by the client's representative.

### 15. QUALITY MANAGEMENT SYSTEM (QMS)

The IVDs Laboratory employs a standard and comprehensive QMS to ensure that reliable and reproducible evaluation and results are produced to meet our client satisfaction. We have





impressive performance in External Quality Control Assessment such as One World Accuracy.

#### **16. COMPLAINTS AND FEEDBACK FROM CUSTOMERS**

Clients of the IVDs Laboratory are our treasured costumers. They are most welcome to send us feedback, criticism and complaints about the services we render using our Customer Service Feedback Form. The Customer Services Feedback Form is available at the Administration desk of the IVDs Laboratory or on the website of MLSCN. Our customers should feel free to give us their feedback on our services. Periodically the IVDs Laboratory will conduct customers survey to evaluate our performance. We count on your feedback to improve our service delivery. Please help us serve you better.

#### **17. SAFETY PRECUATION**

Clients are encouraged to adhere strictly to the safety precaution as stated by the manufacturer of the IVDs product. Protective coverings such as laboratory coats, hand gloves, eye goggles must be worn during collection and handling of IVDs product/sample. All biological waste should be well managed. Autoclaving of infectious waste is recommended before incineration and disposal to ensure a healthy environment. In addition, staff handling infectious materials should be vaccinated accordingly. Post exposure prophylaxis should be readily available in case of accidental exposure such as needle stick injury.

#### **18. DIGITAL OPERATIONS**

With the completion of our connectivity to Nigerian Customs NICIS and the ongoing portal development and linkage to the Nigerian trade hub, we shall be completing our digital operation migration soon.

#### **19. OUR CONTACT ADDRESS**

Public Health In-Vitro Diagnostics Control Laboratory  
8, Harvey Road, Yaba, Lagos, Nigeria  
Tel (Lab): +2349021765416 – 18  
Mobile: +2347062118574  
Email: [ivds@mlscn.gov.ng](mailto:ivds@mlscn.gov.ng)





Head office (Abuja): [info@mlscn.gov.ng](mailto:info@mlscn.gov.ng)  
 Lab. Manager: [poffutalu@mlscn.gov.ng](mailto:poffutalu@mlscn.gov.ng)  
 Quality Assurance Manager: [sfasogbon@mlscn.gov.ng](mailto:sfasogbon@mlscn.gov.ng)  
 Lab. website: [www.mlscn.gov.ng](http://www.mlscn.gov.ng)

**Abuja office:**

Medical Laboratory Science Council of Nigeria

MLSCN Headquarters,

Plot 1166 Mohammed N. Umar Lane,

Durumi Phase 11 Garki, Abuja.

Website: [www.mlscn.gov.ng](http://www.mlscn.gov.ng) E-mail: [info@mlscn.gov.ng](mailto:info@mlscn.gov.ng)

### LIST OF CONTRIBUTORS

1.	Sir Tosan Erhabor	-	Ag. Registrar/CEO
2.	Dr. Lawrena C. Okoro	-	Director Special Duties
3.	Mr Godwin Aikpitanyi-Iditua	-	Ag. Head, Education Department
4.	Mrs. Stella Udo	-	Ag. Head, Planning, Research & Statistics Department
5.	Dr. Donald Ofili	-	Ag. Head Laboratory Registration & Department
6.	Mr. Gregory Uchuno	-	Ag. Head, Practitioner Regulation & Discipline Department
7.	Mr Ime Idim	-	Director (Finance & Administration)
8.	Mr. Samuel Shiaka	-	DD Administration
9.	Mr. Offutalu Paulinus N.	-	Laboratory Manager
10.	Mrs. Rotoye Martha	-	Principal Legal Officer
11.	Mr. Fasogbon, Samuel.	-	Quality Assurance Manager
12.	Mrs. Lauretta Okonji	-	Admin Officer
13.	Mrs. Basirat Adetoro	-	Admin Officer





# MLSCN



## Laboratory Handbook

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