



MEDICAL LABORATORY SCIENCE COUNCIL OF NIGERIA
PUBLIC HEALTH IN-VITRO
DIAGNOSTICS CONTROL
LABORATORY (IVDS)
8 HARVEY ROAD YABA-LAGOS



LABORATORY

HANDBOOK

Draft copy

PREFACE

FOREWORD

ACKNOWLEDGEMENT

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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 5th 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 is a team effort put together 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 service, please contact us through the following telephone numbers or email address:

Tel (Lab): +2349021765416 – 18

Mobile: +2347062118574

Email: ivds@mlscn.gov.ng

2. OUR CORE VALUES

We believe strongly in professionalism, integrity, excellence, commitment, efficiency and team work.

3. HOURS OF OPERATION

The IVDs Laboratory is opened **8am to 4pm Monday to Friday** but closed to customers on Saturdays, 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/SITOPATHOLOGY

- IMMOUNOLOGY /IMMOUNOLO CHEMISTRY
- MOLECULAR BIOLOGY/DIAGNOSTIC UNITY

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
- 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 for hand 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 COMPANY REGISTRATION

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

- Application for company listing
- Download, fill and submit IVDs company registration form (MLSCN/IVD/100) from www.mlscn.gov.ng (click on IVDs regulation submenu) with relevant documents attached as stated on the website;
- Submit photocopy of Corporate Affairs Commission (CAC) registration certificate;
- Pay the importers/manufacturers/marketer company registration fee of N50,000 only and present the teller to the IVDs Laboratory Administration Desk;
- Company registration certificate will be duly issued by the IVDs Laboratory.

9. REQUIREMENTS FOR PRODUCT LISTING

The following are required for IVDs product listing:

- Evidence of company registration from the IVDs Laboratory (as in A above);
- Application for provisional import permit (if required);
- Submission of IVDs products for evaluation with company listing file document (refer to www.mlscn.gov.ng submenu IVDs regulation, submenu product listing file).

10. REQUIREMENT FOR EQUIPMENT REGISTRATION

The following are required for equipment registration:

- Equipment presentation, installation and trail run by the distribution/manufacture'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.

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.

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 registration | Within 3 Month |

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 turn around 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

Client 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. OUR CONTACT ADDRESS

Public Health In-Vitro Diagnostics Control Laboratory

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