



LIBERIA MEDICINES & HEALTH



PRODUCTS REGULATORY

AUTHORITY (LMHRA)

VP Road, Old Road
Monrovia, Liberia

***GUIDELINES FOR IMPORTATION OF IN-
VITRO DIAGNOSTICS***

DRAFT

Version No 002

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The project IGORCADIA, which commenced in December 2017, seeks to develop the capacity of LMHRA to regulate, register and license the importation, storage, and use of diagnostics alongside supervision and inspection of use of diagnostics in research. IGORCADIA has a Technical Working Group comprised of LMHRA staff including the Project Local Coordinator and Leader of IVD Regulatory Development, Mr. Alexander E. George, Pharm. Henry K. Gbormoi, Sr. and Pharm. Diana M. Jeator, as well as Prof. Ezekiel Hallie, Dean of the School of Pharmacy. All these persons, along with the Legal Officer of LMHRA, Cllr. Bohley Comehn are herein acknowledged as resource persons involved in the drafting of guidelines for the regulation of in-vitro diagnostics by LMHRA. Special gratitude is also owed to the Managing Director of LMHRA, Hon. David Sumo who provided the overall supervision of this project, as well the former Local Project Coordinator, Hon. Joseph N. Somwarbi of the National Legislature of Liberia, formerly of LMHRA.

Finally, we also acknowledged all stakeholders including the dealers of IVDs who have been organized into a Diagnostic Steering Committee (DSC) for their useful comments and inputs.

The LMHRA will welcome comments for improvement of the guidelines during implementation.

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LIST OF ABBREVIATIONS

LMHRA	Liberia Medicines & Health Products Regulatory Authority
IVD(s)	In-Vitro Diagnostic(s)
PoE	Ports of Entry
FOB	Free on Board
WHO	World Health Organization
LRA	Liberia Revenue Authority
QC	Quality Control
CE	Not an acronym; just a mark of conformity with international requirements

GLOSSARY

For the purpose of these guidelines the following terms shall be defined as follows:

Authority = Liberia Medicines & Health Products Regulatory Authority, or its acronym “LMHRA”.

Consignment = a quantity of goods that are sent to a person or place to be sold.

Donation = an act or instance of presenting in-vitro diagnostics to recipients in emergency or as a part of development aid in non-emergency situations.

Donor = a governmental or non-governmental organization or individual who voluntarily donates IVDs as a donation.

In-Vitro Diagnostic = A device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Importer = a person or institution licensed and/or authorized to import IVDs into the country.

Import permit = a permit issued to importer by the Authority, authorizing him to import IVDs into the country.

Label = any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any IVD.

Labeling = information supplied by the manufacturer written, printed or graphic matter affixed to an IVD or any of its containers or wrappers, or, accompanying an IVD, related to identification, technical description, and use of the IVD, but excluding shipping documents.

Manufacturer = a person who sells IVDs under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing,

manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the IVD, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Neutral Labeling = use of figures, charts, symbols, etc. to label.

Permit = certificate of approval to import IVDs.

Recipient = a governmental, non-governmental or private health Institution that voluntarily receives IVDs as a donation.

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INTRODUCTION

These guidelines have been developed to provide guidance for importers of in vitro diagnostics (IVDs) pursuant to legal requirements prescribed under Part V, Section 2 of the 2010 Act of the National Legislature which established the LMHRA. The document applies to any person, institution and organization that intend to import for the purpose of selling, clinical use, research or donation of IVDs in Liberia. This is the first edition of the guidelines for importation of IVD.

The IVD guidelines apply when a manufacturer or importer wishes to place an IVD on the Liberian market or to put the IVD into service. In this context, putting into service would encompass any use of an IVD for diagnostic purposes involving human samples. Placing on the market is herein defined as “making available in return for payment or free of charge a new or rebranded IVD other than that intended for clinical investigation, with a view to distribution, use, or both, on the Liberian market”. The IVD does not need to be supplied on commercial terms; the supply of free product constitutes placing on the market. The term “making available” incorporates any transfer of a product, whether that involves transfer of legal ownership or the physical handover of product, to a Liberian distributor. It also includes passing the product to a final customer or user, either as part of a commercial transaction or free of charge. In either case the product must comply fully with the requirements of the IVD before any transfer.

The main objective of these guidelines is to provide importers of IVDs with the necessary information to enable them comply with the law and regulations governing importation of IVDs into the country. Other objectives include control of unwanted IVDs as well as minimizing the accumulation of nonfunctional IVDs and to alleviate problems associated with donation by promoting good IVD donation practice.

The document has been organized into three main sections. The first section provides for the importation of IVDs for commercial purpose, for personal use and for investigational purpose. It also focuses on requirements for inspection of imported consignment of IVDs. The second section outlines the requirements and procedures for the importation of donated IVDs. The third section describes sanctions for dealing with non-compliant consignments, rectifying non-compliance, and unauthorized importation. Formats of application forms and certificates have been appended for easy referencing.

The Authority would like to emphasize that the requirements in these guidelines have been provided to ensure that only safe, effective IVDs and spare parts of acceptable quality are imported into the country. All applicants are therefore encouraged to familiarize themselves with the guidelines and follow them strictly when preparing and submitting applications. It is therefore expected that all concerned parties will adhere to the specified requirements in these guidelines to ensure that all relevant information and documentations are submitted, thus avoiding unnecessary delays in approval process and hence expedite provision of quality services to clients.

CHAPTER ONE

IMPORTATION OF IN-VITRO DIAGNOSTICS

1.1 Classification of in-vitro diagnostics

In-vitro diagnostics shall be classified on the basis of risk to patients, user or to public health.

Class A - no public health risk or low personal risk

Class B - low public health risk or moderate personal risk

Class C - moderate public health risk or high personal risk

Class D - high public health risk

1.2 Categories of importers

Importers of in-vitro diagnostics shall fall under the following categories:

- (a) Authorized Government and Non- Governmental institutions
- (b) In-Vitro Diagnostics wholesalers
- (c) Clinical Trial, Clinical Research and Biomedical Investigators
- (d) Recipients of donations or institutions aiming to donate IVD to Liberian organizations
- (e) Persons importing medical devices for medical purposes
- (f) Exhibitors

1.3 Requirements for importers

- 1.3.1 All IVDs to be imported must be registered by the LMHRA unless given special approval by the Authority. Special approval shall be given **ONLY** for IVDs required in emergency situations and for unregistered IVDs in experimental stage required for research conducted in Liberia by a Liberian governmental and/or non-governmental research institution.
- 1.3.2 All importations of IVDs must be done by importers whose premises are duly registered by LMHRA. An exception will be donated IVDs
- 1.3.3 All importers must import IVDs through the authorized ports of entry (POE).
- 1.3.4 In case of donations please refer to chapter two of these guidelines.

1.4 Procedure for application for importation

- 1.4.1 Authorized importers intending to import IVDs shall apply to the Managing Director of LMHRA by filling in the application form as prescribed in **Annex I** of these guidelines.
- 1.4.2 All applications may be submitted to LMHRA head offices or the nearest county offices by would be importer.
- 1.4.3 For IVDs intended for clinical trials, clinical research and/or biomedical research, written application must be filed to any of the legally recognized Ethics Board in Liberia and approval given.
- 1.4.4 The application form shall be accompanied by one original proforma invoice and two (2) copies of original from the marketing authorization holder of the product(s) or authorized supplier(s), subject to provision of the original proforma at the time of importation. Duly signed pdf versions are accepted.
- 1.4.5 The proforma invoice shall state for each IVD type to be imported, the following:
 - (a) Proforma Invoice number and date;
 - (b) Name and address of the supplier;
 - (c) Name and address of the importer;
 - (d) Name and address of the manufacturer;
 - (e) Country of origin;

- (f) Clear description of items including brand and common names as declared in the information of IVD submitted to LMHRA;
 - (g) The quantity, pack size, unit value, total value in convertible currency;
 - (h) Batch or Lot number;
 - (i) Manufacturing and expiring date;
 - (j) Mode of shipment (sea, air, road);
 - (k) Port of entry;
 - (l) Signature and stamp of the supplier and/or manufacturer.
- 1.4.6 Application form shall be stamped and signed by the importer before submission to LMHRA.
- 1.4.7 Once the authorization has expired or has been cancelled, no further importation and supply of IVD at any quantity shall be permitted.

1.5 Processing of applications

- 1.5.1 Upon receiving the application as specified above, LMHRA will scrutinize to verify whether the requirements have been fulfilled.
- 1.5.2 If the application meets the prescribed requirements, the applicant will be required to pay import Free-on-Board (FoB) fees as stipulated in the existing regulations for fees, and the Authority will issue an **Import Permit** as set out in *Annex II* of this guideline.
- 1.5.3 An application will be rejected if it does not meet any of the importation requirements. An applicant will be given a **Importation Rejection Form (Annex III)** stating clearly reason(s) for rejection.
- 1.5.4 All applications will be processed after forty-eight (48) working hours with the exception of special requests which may take a shorter or longer period depending on the nature of the request.
- 1.5.5 All importers will be required to hold a valid importation permit issued by the Authority prior to shipment of the consignment.
- 1.5.6 Once issued, Importation Permit shall be valid for ninety (90) days and shall not be transferable and will be issued to cover only one shipment. From the point of application to the point of issuance of the permit, the duration shall be no more than 14 working days.
- 1.5.7 Once the authorization has expired or has been cancelled, no further importation and supply of IVD at any quantity shall be permitted.

1.6 Special Importation Requirements

The same application requirements and procedures as prescribed under sections 1.3 and 1.4, respectively shall apply. However, in some special circumstances, the following will be applicable:

1.6.1 **Importation of unregistered IVD**

An application for importation of unregistered IVD should be accompanied by a letter stating reasons for importation. Exception shall be granted for IVDs approved for procurement by the WHO/GLOBAL Fund Expert Review Panel. An import permit will be issued if the following criteria are met:

- (a) IVD type is on the LMHRA notification list;
- (b) IVD type has been prequalified by WHO;
- (c) IVD type is listed in the WHO Model List of Essential In Vitro Diagnostics
- (d) There is evidence that the IVD is in circulation in the manufacturer's country of origin (Free Sales Certificate);
- (e) There exists a Declaration of Conformity;
- (f) There exists a CE Certificate except for IVD of "class A";
- (g) The IVD is not Class D.

Failure to submit any of the above shall render the application invalid and shall be rejected.

1.6.2 Importation of IVD for personal use

- (a) Applications for importation of class B, C and D IVD for personal or animal use, should be accompanied by a written recommendation from a registered medical practitioner, dentist, veterinary surgeon or any other authorized practitioner.
- (b) Applications for importation of IVD for personal use should also be submitted along with a letter giving reasons for importation from applicant or qualified medical practitioner, dentist, veterinary surgeon or any other authorized practitioner.
- (c) Unregistered IVD for personal use can be imported provided they are approved by a stringent regulatory authority and/or a WHO-prequalified only. It can also be accepted for importation if it on the WHO model list of essential IVD list.

1.6.3 Importation of investigational IVD

Applications for importation of investigational IVD should be made by a clinical trial, clinical research or biomedical research sponsor or Principal Investigator for a study approved by a legally recognized Ethics Review Board in Liberia and that is to be conducted in Liberia. Such applications should be accompanied by ethics approval letter and, in the case of clinical trials, please follow this link: <https://www.lmhra.org/clinical-trial-applications>.

1.7 Inspection of Imported Consignments at Ports of Entry

- (a) On arrival at the ports of entry, the IVD will be inspected by an LMHRA Inspector
- (b) The Inspector shall inspect import permit to ensure that it is within the 90-day period, an original proforma invoice, a corresponding certificate of analysis for each batch and airway bill or bill of landing.
- (c) Other government agencies may also conduct inspection activities as the rules and regulations apply. Such agencies may include the Liberia Revenue Authority (LRA) or other authorized agents.
- (d) At the time of importation, the IVD must have a valid shelf life not less than 60% of the original shelf life. In the case of an IVD (reagent or diagnostics) which require cold chain, the product shall be immediately released for storage with a written declaration signed by the importer, of the location of product storage that the product will remain available for the next 15 days to allow inspection.

1.7.1 Inspection During Sampling of Imported IVD

During inspection of the consignment the following actions may be taken:

- (a) An approval for release will be granted;
- (b) A query may arise whereby the consignment may be held at customs warehouse or owner's premises;
- (c) An outright rejection of the consignment pending re-exportation or destruction at owner's expenses.
- (d) The restriction mentioned in 1.7.2 (b) shall not apply to IVDs requiring cold chain or those used for outbreak/emergency situations.

1.7.2 Authorized Ports of Entry (POE)

Class B, C and D IVD imported into Liberia would be allowed to enter through the following official POEs:

- (a) Freeport of Monrovia
- (b) Roberts International Airport
- (c) James Sprigg Payne Airport

- (d) Port of Buchanan
- (e) Port of Greenville
- (f) Port of Harper

The Authority reserves the right to restrict importation of IVD through any one or more of the POEs indicated above or not mentioned above.

1.7.3 Conditions for Release of a consignment

- (a) All approved consignments will be released by LMHRA Inspector once satisfied that all importation conditions have been fulfilled.
- (b) An inspector will stamp all the supporting documents with an official stamp marked 'APPROVED FOR RELEASE'
- (c) Approval for release shall not be granted for partial shipment..

1.7.4 Conditions for not Releasing the consignment

- (a) Consignments which do not meet importation requirements will be rejected by LMHRA and the accompanied documents shall be stamped with an official stamp marked "STOP RELEASE".
- (b) IVD rejected for quality reasons will be CONDEMNED;
- (c) If an IVD is rejected by the Authority, it may be re-exported to a third country on special request and with special clearance from the Regulatory Authority of the country where the consignment is being exported to.
- (d) A re-export exercise should be preceded by re-inspection of the rejected consignment to confirm that it is still intact before re-export permit is issued by LMHRA.
- (e) Re-loading for re-export should be witnessed by Customs officials and Inspector(s) from LMHRA.
- (f) Copies of re-export documents stamped at the exit port shall be submitted to LMHRA as evidence of completion of re-exportation exercise.
- (g) Destruction/incineration of rejected IVD will be done as per the Customs requirements and LMHRA will provide technical advice on mode of destruction according to the guidelines for disposal of unfit medical devices.
- (h) LMHRA will issue a Destruction Certificate after completion of the destruction exercise.
- (i) Where the consignment is rejected/quarantined, an inspector will issue a *Rejection/Quarantine Form of the IVD consignment(s)* as specified under *Annex IV of this guideline*.
- (j) The consignee shall incur all expenses for re-exportation and incineration.

1.8 Noncompliant IVDs

n IVD is said to be non-compliant if it:

1. does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means
2. is not CE marked (in the case of Class B, C and D IVD) to indicate its conformity with internationally acceptable regulatory requirements
3. has no valid import authorization from LMHRA

CHAPTER TWO

IMPORTATION OF DONATED IN-VITRO DIAGNOSTICS

2.1 Scope of Application

The procedures outlined below will be applicable to all donated IVDs.

- 2.1.1 All donations will be in accordance with the recipient's need and should comply with the existing government health policies, laws, guidelines and administrative arrangements.
- 2.1.2 Donation should comply with applicable standards and there will not be double standards regarding quality of donated items.
- 2.1.3 IVDs rejected in the donor country shall not be accepted. If the IVD is undergoing dossier review, but it is WHO-prequalified or it has come from a country with stringent regulatory bodies, it shall be accepted.;

2.2 Requirements for Donation

2.2.1 General Requirements

1. Any person, institution and organization intending to donate IVDs will be required to apply for import permit at LMHRA by filling in the application form in Annex I of this guideline, PRIOR TO SHIPMENT of the donated consignment.
2. Application form should be accompanied by the following documents:
 - (a) A support letter from the relevant authority which supports such donation (where applicable).
 - (b) A support letter from the importer
 - (c) Donation certificate
 - (d) One original proforma invoice and two copies of the original
3. The Authority will assess if the IVD is compatible with the recipient.
4. IVDs intended to be donated must be collected as much as possible from known sources for ease of traceability.
5. Donated IVDs should have a shelf life of not less than twelve months (where applicable).
6. If the IVD is used, it must be reconditioned, tested and all essential parts, accessories and working materials included before shipment together with the relevant supporting documents to indicate that the IVD is in good order and must not be in use for more than five years.
7. Donated IVDs shall:
 - (a) be robust and fully operational as a full system or as a separate subsystem;
 - (b) meet or exceed existing safety and performance specifications provided by the manufacturer, international or appropriate national standards;
 - (c) include all essential parts, accessories and working materials;
 - (d) have its label, packaging, user manual and other documents (i.e maintenance, calibration manuals) written in English;
 - (e) be packed suitable for road, air or sea transport under tropical conditions.
8. For software operated IVDs, the software shall be either preloaded and/or accompanied by the software package.
9. For electrical equipment, the electrical needs of the equipment shall be set to the standard voltage of 220V/50Hz to 240V/50Hz
10. Damaged, outmoded, and redundant IVDs for which spare parts and consumables are no longer available and/or equipment which is no longer supported by the manufacturer shall not be accepted.
11. The LMHRA will issue Donation Import Permit when satisfied that all conditions of application have been fulfilled; otherwise the application will be rejected in writing, stating the reason for rejection.

12. The permit issued for importation of donated IVDs will be valid for 90 days from the point of issuance.

2.2.2 *Requirements at the Port of Entry*

Donated IVDs shall have port clearance from the Authority and shall be accompanied by the following documentary evidences:

- (a) valid import permit;
- (b) packing list;
- (c) proforma invoice;
- (d) airway bill or bill of landing;
- (e) certificate of refurbishment for used IVDs (issued by manufacturer of certified company);
- (f) certificate of analysis for sterile IVDs;
- (g) In case the IVD emits radiation, a permit or certificate from a recognized Atomic Energy Agency shall be required.
- (h) The certificate of refurbishment mentioned under (e) must state the following:
 - i. tested, labeled and packed; and
 - ii. replaced or repaired and the repair service that were performed on the IVD
 - iii. the source of the repair parts with provision of an acceptance report for these parts;
 - iv. calibrated - it shall state and verify the operation of the IVD.
- (i) performance standard used to calibrate
- (j) disinfected or decontaminated

2.2.3 **Label of the donated IVD**

- (a) Depending on its nature and type, the label of donated IVD should have the following minimum information:
 - i. The label 'IVD and name of the particular IVD
 - ii. model number or serial number
 - iii. manufacturing and expiry date;(where applicable)
 - iv. life span or expectancy
 - v. name and address of the manufacturer;
 - vi. handling and storage requirement (s);
 - vii. technical direction for use;
 - viii. an indication, if applicable, what the IVD is intended to be used for
 - ix. The words “used only for clinical or performance investigations” before being supplied;
 - x. for a sterile IVD, the word “Sterile” and where appropriate, description of methods of re-sterilization;
 - xi. if the IVD is refurbished, an indication of the device as refurbished device;.
 - xii. if the IVD is intended for presentation or demonstration purposes only, it must be labeled as “for presentation or demonstration purposes only, not for use on humans”;
 - xiii. if the IVD emits radiation for medical purpose, details of its nature, type and where appropriate, the intensity and distribution of this radiation
 - xiv. if the IVD is to be installed with or connected to another IVD or medical device or equipment, or with dedicated software, in order to operate as required for its intended use, sufficient details of its characteristics to identify the correct device or equipment to use in order to obtain a safe combination;
 - xv. the intended purpose of the IVD, the intended user of the IVD, and the kind of patient on whom the IVD is intended to be used (if this information is not obvious).
 - xvi. Any number, letter or symbol, and any letter or number in a symbol, used in the label shall be legible.

- (b) Each donated IVD shall have accompanying user manual having detailed information on handling, installation, operation, maintenance, trouble shooting, precautions and other important information.
- (c) Donated IVDs shall be transported, stored and handled in accordance with acceptable transportation, storage and handling requirements.
- (d) Labeling information of the IVD can be provided on the IVD itself, packaging used for the medical device, on an insert supplied with the medical device or in a printed document or using other appropriate media.
- (e) At the time of importation, medical devices must have a valid shelf life not less than 60 % of the original shelf life.

2.2.4 Reporting

The recipient will be required to report relevant information to the Authority including defects, adverse effects, problems related to quality and safety and other reportable cases related to the donated equipment.

2.2.5 Disposal

If donated IVDs are found to be in violation, the recipient shall dispose or return the product to the country of origin at its own expense.

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CHAPTER THREE

SANCTIONS

3.1 Unauthorized Importation of In-Vitro Diagnostics

- 3.1.1 Where a person or entity imports products without valid authorization by LMHRA, the imported IVDs will be confiscated, the importer fined, and the IVDS may be re-exported or destroyed.
- 3.1.2 The fine imposed shall be proportional to the value of the IVD imported. Such determination shall be made only by LMHRA.
- 3.1.3 The determination to re-export or destroy the IVD shall be made only by LMHRA and the cost shall be borne solely by the importer.
- 3.1.4 LMHRA may also make a determination to prosecute the importer depending on the gravity and frequency of the offense.

3.2 Non-Compliant In-Vitro Diagnostics

- 3.2.1 When a person or entity imports a non-compliant IVD, the imported IVD will be confiscated, the importer fined, and the IVDS may be re-exported or destroyed. Section 3.1 shall apply.
- 3.2.2 LMHRA may permit an importer to bring an imported non-compliant IVD into compliance with law.
- 3.2.3 The IVD will be quarantined and any sorting, processing, labeling/re-labeling or analysis shall be performed or supervised by an LMHRA regulatory officer at the full expense of the importer.
- 3.2.4 Where the non-compliant IVD is unregistered prior to importation, the importer shall be made to submit the IVD for registration and pay the appropriate fees in addition to a penalty to be determined by the Authority.

Document History

Summary of Revision	Rationale for Revision
Rev 01	
New Edition	

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REPUBLIC OF LIBERIA
LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)
 P. O. Box 1994 VP Road, Old Road
 Oldest Congo Town
 1000 Monrovia 10, Liberia



APPLICATION FOR IMPORTATION OF IN-VITRO DIAGNOSTICS

To: The Managing Director
 Liberia Medicines & Health Products
 Regulatory Authority (LMHRA)
 P.O. Box 1994
 Monrovia, Liberia

I/We.....

of (postal address).....undertaking the business of Wholesale/manufacturing/Other
 Specify).....

hereby apply for importation permit for In-Vitro Diagnostics into the Republic of Tanzania.

License Number.....issued on.....

Location of Business.....

Name of the Owner of the business.....

Purpose of importation permit, for: **(Tick whichever is applicable)**

Spare parts for In-Vitro Diagnostics for human/veterinary use;

Finished In-Vitro Diagnostics for human/veterinary use;

Clinical Trial of a specified product (only one product per application)

Donation

Reasons for donation:

Emergency

Development aid program

Others

Checklist for completeness of proforma invoice **(Tick as appropriate)**

Name and address of the supplier

Name and address of the importer

Name and country of the manufacturer

Importation of In-Vitro Diagnostics

General Information

- Invoice number
- Invoice date
- Quantity of each item
- Mode of transport
- Clear description of items including brand names and common names as declared in information of medical devices submitted to TFDA Stamp and/or signature of supplier
- Stamp and/or signature of importer
- Certificate of donation (for donated medical devices)
- FoB and CIF value of the items
- Port of discharge of goods

Attached herewith the Proforma Invoice No..... of (date).....

Declaration:

I certify that the information provided in the application form and proforma invoice is true and correct.

Date of application

Signature of Applicant.....

Stamp.....

For official use only:

.....

.....

.....

.....

.....

Name of Officer:

Signature.....

Stamp

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REPUBLIC OF LIBERIA
LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)
 P. O. Box 1994 VP Road, Old Road
 Oldest Congo Town
 1000 Monrovia 10, Liberia



PERMISSION TO IMPORT IN-VITRO DIAGNOSTICS

Permit No: LMHRA/...../.../.....

PART A:

Name of registered importer..... Postal address Tel No.....
 Exporting Country..... .Invoice No.....
 Date..... Time.....
 Exporter/Sender..... Postal address
 Arrival expected by ship/air/motor vehicle, via

Port of entry

Application for permission to import the following product (s) in accordance with the above mentioned Act and Regulations made

SN	Product		Batch No.	Registration/Notifi- cation Number	Permit Quantity	Value of the products
	Generic Name	Brand Name				

TOTAL:

Fees _____ Receipt No _____ Dated _____

.....

PART B:

Permission is hereby granted to import the mentioned IVD. The importer has to inform the LMHRA Port Inspector to examine the approved IVDs for fitness of the intended use before being allowed entry into Liberia.

Date

FOR: Managing Director and stamp

.....

PART C:

I _____ being LMHRA inspector at _____ LMHRA port office has examined the above listed IVDs and have found **them fit/unfit** for the intended use. Hence, they are **allowed/not allowed** entry into Liberia.

Date

Signature of LMHRA port officer and stamp

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(The Inspector has to return immediately a completed copy of this permit together with a copy of a release certificate to the Managing Director)

NB: This permit is for *single consignment* only and shall be valid for *3 Months* from the date of approval.



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IMPORT PERMIT REJECTION FORM FOR IN-VITRO DIAGNOSTICS

LMHRA Serial Number _____ of _____

Proforma Invoice Number _____ Dated _____

A. Reasons for rejection (Tick as appropriate)

- Product is not registered/notified
- Importer/Consignee is not registered
- Manufacturer(s) of the product is not indicated
- Number of Proforma Invoice is not shown
- Name and/or identity of items is not clear
- The product (s) is/are not regulated by the Authority
- The Proforma Invoice is not signed and/or stamped by supplier
- The Proforma Invoice is not countersigned and or stamped by Importer
- Certificate of Donation is not attached
- Product(s) registration number is not shown
- Proforma Invoice is not original
- Others

B. Conditions for approval

In case item(s) listed under A above have been fulfilled/submitted, the proforma invoice will be approved.

Name of officer rejecting	Signature	Date
Name of Person collecting	Signature	Date



REPUBLIC OF LIBERIA
LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)
 P. O. Box 1994 VP Road, Old Road
 Oldest Congo Town
 1000 Monrovia 10, Liberia



REJECTION/RETENTION OF IN-VITRO DIAGNOSTICS CONSIGNMENT(S)

Exporter /Consigner

Importer/Consignee.....

The inspected consignment (s) as per Proforma Invoice No.....Airway

Bill No...../Bill of Lading

No...../R.Number.....dated.....and the

single Bill of Entry Number.....dated.....has been

Rejected/Retained for the following reasons: (Tick whichever applicable)

Proforma Invoice is not approved by LMHRA

1% FOB is not paid to LMHRA

The products (s) is/are not registered by LMHRA

Consignee is unauthorized dealer of pharmaceuticals

Manufacturer of product is not indicated

Description of the items is not clear

Manufacturing and/expiring date of products (s) not indicated

The products (s) shelf life is too short/expired

Physical quality of the product is poor

Packaging Insert not included

Certificate of analysis not present

Batch number not indicated

Any Other (Specify)

Comments from the inspector if any.....

.....

Name of Inspector

Signature

Date

.....

Full name of consignee/

Signature

Date

Clearing agent:

.....

DRAFT

Annex V

**SOP FOR SAMPLING OF IVD
(TO BE INCLUDED IN FINAL DRAFT)**

DRAFT