



**LIBERIA MEDICINES & HEALTH**



**PRODUCTS REGULATORY**

**AUTHORITY (LMHRA)**

VP Road, Old Road  
Monrovia, Liberia

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

***Version No 002***

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## Table of Contents

ACKNOWLEDGEMENTS .....	3
ACRONYMS .....	4
GLOSSARY .....	¡ERROR! MARCADOR NO DEFINIDO.
<b>1. INTRODUCTION</b> .....	<b>5</b>
<b>2. GENERAL REQUIREMENTS</b> .....	<b>6</b>
2.1. COVER LETTER .....	6
2.2. APPLICANT .....	6
2.3. LOCAL REPRESENTATIVE .....	6
2.4. IVDD CLASSIFICATION .....	6
2.4.1. <i>Accessories</i> .....	7
2.4.2. <i>Software</i> .....	7
2.5. FIRST TIME APPLICATION .....	8
2.6. APPLICATION FOR RENEWAL REGISTRATION .....	¡ERROR! MARCADOR NO DEFINIDO.
2.7. VARIATION TO REGISTERED MEDICAL DEVICE APPLICATION .....	8
2.8. APPLICATIONS FOR RENEWAL OF REGISTRATION .....	8
2.9. DOCUMENTATION .....	9
2.10. APPLICATIONS FEES PAYMENT, SCREENING AND PROCESSING .....	9
2.10.1. <i>Fees payment</i> .....	9
2.10.2. PROCESSING OF APPLICATIONS .....	10
2.10.3. PERFORMANCE EVALUATION.....	10
2.11. REGISTRATION OF THE DEVICE.....	10
2.11.1. <i>Registration validity</i> .....	10
2.11.2. <i>Termination of registration</i> .....	11
2.12. DOSSIER COMPILATION .....	11
2.13. APPEALS.....	11
2.14. QUALITY MANAGEMENT SYSTEM COMPLIANCE EVIDENCE .....	¡ERROR! MARCADOR NO DEFINIDO.
<b>3. REQUIREMENTS FOR SUBMISSION</b> .....	<b>12</b>
3.1. CLASS A IVDDs SUBMISSION REQUIREMENTS FOR .....	12
3.2. CLASS B, C AND D IVDS SUBMISSION REQUIREMENTS .....	12
<b>4. SUMMARY TECHNICAL DOCUMENTATION</b> .....	<b>14</b>
4.1. DEVICE FEATURES AND DESCRIPTION .....	14
4.2. ESSENTIAL PRINCIPLES CONFORMITY EVIDENCE ..	¡ERROR! MARCADOR NO DEFINIDO.
4.3. RISK ANALYSIS .....	14
4.4. IVD DESIGN AND MANUFACTURING INFORMATION .....	14
4.4.1. <i>Product design</i> .....	14
4.4.2. <i>IVD formulation and composition</i> .....	15
4.4.3. <i>Manufacturing processes</i> .....	15
4.5. SPECIFICATIONS OF IVD .....	16
4.6. CHARACTERISTICS OF ANALYTICAL PERFORMANCE .....	16
4.6.1. <i>Accuracy of measurement</i> .....	16
4.6.1.3. <i>Analytical sensitivity</i> .....	17
4.7. STABILITY (EXCLUDING SPECIMEN STABILITY).....	17
4.7.1. <i>In use stability</i> .....	17
4.7.2. <i>Claimed shelf life</i> .....	17
4.7.3. <i>Shipping stability</i> .....	18
4.7.4. <i>Robustness studies</i> .....	18
4.8. CLINICAL PERFORMANCE.....	18

Registration of In-Vitro Diagnostics

**ANNEX I.....21**  
**ANNEX II .....23**  
**ANNEX III..... ¡ERROR! MARCADOR NO DEFINIDO.**

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## ACRONYMS

<b>AHWP</b>	- Asian Harmonization Working Party
<b>CSF</b>	- Cerebrospinal Fluid
<b>DoC</b>	- Declaration of Conformity
<b>EPSP</b>	- Essential Principles of Safety and Performance
<b>FOB</b>	- Free on Board
<b>GMDN</b>	- Global Medical Devices Nomenclature
<b>IMDRF</b>	- International Medical Devices Regulator's Forum
<b>ISO</b>	- International Organization for Standardization
<b>IVD(s)</b>	- In-Vitro Diagnostic(s)
<b>LMHRA</b>	- Liberia Medicines and Health Products Regulatory Authority
<b>LSL</b>	- Liberia Standard Laboratory
<b>MoH</b>	- Ministry of Health
<b>PoE</b>	- Ports of Entry
<b>QCL</b>	- Quality Control Laboratory
<b>QMS</b>	- Quality Management System
<b>WHO</b>	- World Health Organization

## INTRODUCTION

Registration of IVDs is an authorized requirement pursuant to Part 4 of the Act that established the Liberia Medicines and Health Products Regulatory Authority (LMHRA), 2010. The registration process enhances easy assessment of data in order to ensure the quality, safety and performance of this class of health products. In hospital settings and many health facilities in Liberia, IVDs are used for diagnosing diseases and other conditions, as well as determining health status, in order to treat, mitigate, cure, or prevent diseases.

This Guideline on the Registration of IVDs has been developed by the LMHRA in order to assist all applicants during submission of their dossiers for assessment and registration of IVDs. It has three (3) main segments which include general requirements, submission requirements and summary technical documents. The technical requirements that allow applicants to compile and submit all registration documents for assessment by the LMHRA are highlighted in these sections.

These details will enable the LMHRA decide whether or not to grant IVDs marketing authorization in Liberia. Therefore, it is the responsibility of the applicant to conduct investigations, studies and tests, and hence to provide sufficient data which allow the timely registration of their IVDs candidate for registration at LMHRA. Hereafter, it is significantly essential that applicants read and understand all requirements as provided in these guidelines to fast-track the approval process and intensify access to IVDs in Liberia.

Since some tests are performed in laboratories or other healthcare provision settings, while others are utilized by consumers at home, the availability of IVDs that are of acceptable quality and safety will significantly improve public health.

To validate compliance to LMHRA requirements and ISO standards, the LMHRA will conduct quality audits of all manufacturers of IVDs which is a part of the registration process. The LMHRA will not register IVDs manufactured at facilities that are noncompliant to audit requirements.

Reference to related international standards is considered during the evaluation of applications in order to ensure that IVDs are safe, of good quality and performing satisfactorily before issuance of authorization for marketing in Liberia.

To avoid duplications and fast-track the registration of IVDs previously prequalified by WHO, a shortened evaluation procedure might be adopted. This will also be applicable to products which are genuinely marked CE, or which have been granted marketing authorization from stringent regulatory bodies such as U.S. FDA, EMA, etc.

It should also be noted that all applicants will be required to carry out post-marketing surveillance (PMS) of all IVDs in order to obtain adequate information on their quality, safety and performance to confirm whether or not they still meet post approval registration requirements. Preparation and submission of such information must be done biannually (after every two years) as specified in these guidelines and pursuant to the Liberia Medicines and Health Products Regulatory Authority Act of 2010.

## CHAPTER 1 GENERAL REQUIREMENTS

### 1.1. Cover letter

All applications for registration of a IVDs shall be submitted with a completed Application form (Annex II) and a cover letter addressed to:

**The Managing Director  
Liberia Medicines and Health Products Regulatory Authority  
(LMHRA)  
P. O. Box 1994  
VP Road, Old Road, Sinkor  
Monrovia, Liberia**

Additionally, registration may be done online via the LMHRA website.

### 1.2. Applicant

- a. An applicant is a manufacturer or a researcher that submits an application for registration of an IVD or a person ordering the IVD for research purpose. manufactured of an IVD
- b. The applicant shall be held liable for the IVDs and all nonconformities concerning the product, including any information supplied and accompanying the application for registration and all variations as well.
- c. A nonresident applicant in Liberia shall designate a Local Representative. A Local Representative shall submit a certified copy of the power of attorney, official agreement or any other legitimate authorization, shown as an official confirmation of recommendation.

### 1.3. Local Representative

The Local Representative shall:

- a. Always be responsible to monitor the IVDs circulating the commerce of Liberia and immediately inform the Authority after discovering any problematic issue concerning a registered IVD including serious manufacturing deficiencies that may adversely threaten public health.
- b. Expedite and facilitate all communication amongst the Applicant and the Authority on matters concerning the device.
- c. In the case of deficiencies, be responsible for implementation of device recalls.
- d. Be responsible to provide technical support and other services of the registered IVD(s) to consumers. This can be done through the superintendent pharmacist assigned to that health facility.

### 1.4. IVD Classification

- a. IVD classification follows the following principles:
  - i. The indications for use as the manufacturer indicates (specific condition, illness, or risk factor for which the test is anticipated).
  - ii. The scientific/technical/medical expertise of the anticipated user (i.e., professional or nonprofessional individual).

## Registration of In-Vitro Diagnostics

- iii. How influential is the result (true or false) to public health and/or to the individual?
  - iv. Significance of the information to the diagnosis, considering the usual history of the illness or disorder including presenting signs and symptoms that could significantly guide a physician.
- b. The classification of IVD should be considered as one of the four (4) classes of devices A, B, C or D as indicated below:

<b>CLASS</b>	<b>RISK LEVEL</b>	<b>EXAMPLES</b>
A	Low Public Health and Individual Risks	Identification kits for culturing the microorganisms, specimen containers, differential/selective microbiological media, instruments, wash solutions and plain urine cup.
B	Low Public Health and/or Moderate Individual Risks	Urine Test Strips, Pregnancy Self-Testing, and Anti-Nuclear Antibody.
C	Moderate Public Health and/or High Individual Risks	Rubella Antibodies Test, Blood Glucose Test, Prostate Specific Antigen (PSA) Screening, Human Leukocyte Antigen (HLA) Test.
D	High Individual and High Public Health Risks	HIV Diagnostic Test, HIV Blood Donor Screening, etc.

- c. The classification of IVD must be made in accordance to the cataloging rules attached as Annex I in these guidelines.
- d. The highest risk classification resulting from the rules shall be applicable to the candidate IVDs, if the rule applicable to the IVDs exceeds one classification. Nevertheless, the Authority reserves the right on the decision of the IVDs class.

### 1.4.1. Regulations for IVD Kits and Stand-Alone IVDs

A stand-alone IVD is an IVD which does not contain accessories (buffers and other reagents, pipettes, software, etc.). Each batch of a stand-alone IVD shall be considered separately for dossier evaluation. An IVD kit contains accessories such as buffers and other reagents, pipettes, software, etc. There shall be separate dossier evaluation for each component of the IVD kit. However, if the manufacturer uses a single batch number for the IVD along with its accessories, then it shall be considered as a single unit during dossier evaluation.

### 1.4.2. Accessories

The following considerations would apply where appropriate:

- a. IVD reagent must be placed in the same class along with calibrators envisioned to be used with an IVD reagent.
- b. IVD reagent(s) and stand-alone control materials with no given values intended for use with multiple or single analyte(s) must not be placed in the same category.
- c. The IVD reagent(s) and stand-alone control materials having qualitative or quantitative given values envisioned for multiple analyte(s) or a specific analyte must be placed in the same category.

## 1.5. Software

Most softwares are integrated into the IVDs itself, but some are not.



IVDs must be classified as follows provided such stand-alone software falls within the scope of the definition for the device:

- a. Where it is incorporated to influence or control the envisioned output of a separate IVD, it will be in the same class like the device itself.
- b. Where it is not incorporated in an IVD, the software shall be classified on its own using the classification rules.

### **1.6. First time application**

- a. New application must be submitted for any IVD that is intended for circulation in the in Liberia, whether for research purpose or for public healthcare provision. .
- b. There shall be a separate application for each IVD, whether it is a part of a group or it is a single IVD.
- c. Only pdf-formatted electronic copies of product dossiers shall be admitted for each batch of IVD that is submitted for registration.
- d. Every application must be submitted along with a non-refundable evaluation fee for registration as well as charges as per the Fees Schedule provided by the Authority.
- e. Every application must be submitted along with two (2) commercial pack samples of the IVD batch.
- f. **NOTE:** Processing fee for an application is due at the time of submitting an application. .

### **1.7. Registered In-vitro Diagnostics Variation Application**

- a. The LMHRA must be informed appropriately regarding any expected significant change(s) that would adversely affect the safety and efficiency of an IVD.
- b. Application for variation to a registered product must be completed according to all applicable requirements indicated in this Guidance document.
- c. Variation of such may comprise, but not limited to, any of the following:
  - i. Design of the IVD, along with its specifications of materials, principles of operation and energy source (if applicable), performance characteristics, software or accessories (if applicable);
  - ii. Manufacturing facility, equipment and process;
  - iii. Manufacturing quality control procedures such as test methods, sterility and purity of the materials used to manufacture; and
  - iv. The IVD intended indication, mentioning any addition or removal of a contraindication for the device, any new or extended use, and changes in period of use to establish the expiry date.
- d. LMHRA approval is required before implementation of all variation/changes to an IVD.
- e. In order to reflect a variation, IVD whose registration has not expired needs an application for re-registration of any variation approved by the LMHRA before any importation.
- f. Variation applications for all registered device requires the submission of a filled in form attached as Annex III.
- g. The requisite fee for the variation per the Fees Schedule of LMHRA shall be paid at the time of application.

**NOTE:** Processing fee for an application is due at the time of submitting an application.

### **1.8. Applications for Renewal of Registration**

For renewal of registration, applications shall be completed not less than 3 months prior to

the expiration of an existing registration by submitting the following:

- i. Fully filled application form for renewal registration attached as Annex IV.
- ii. Product samples according to the LMHRA samples schedule.
- iii. A non-refundable application fees required for any renewal registration must be paid per the Fees Schedule of LMHRA and shall be paid at the time of the application.

**NOTE:** Processing fee for an application is due at the time of submitting an application. Any product which registration is not renewed within 3 months as stated above shall be considered for confiscation by the authority. A notification for renewal of registration shall be sent to the applicant/importer.

### 1.9. Documentation

#### 1.9.1. Language

All applications and supporting documents for registration shall be done in English and must be legibly printed but not handwritten. Applications submitted in languages other than English will automatically be rejected.

When all accompanying documents of an IVD are not originally in English, a copy of the original language should be submitted along with a copy of the full translation into English. The applicant is accountable for the accuracy of the translation.

#### 1.9.2. Class A IVDs - Requirements

- a. There are two (2) categories of class A IVDs:
  - those IVDs in Class A supplied in sterile, active with measuring function,
  - and those IVDs in Class A supplied in non-sterile state, non-active with non-measuring function.
- b. Section 2.1 of this Guideline specifies each category of Class A IVDs submission requirements.

#### 1.9.3. Class B, C and D IVDDs requirements

Section 2.2 of this Guideline specifies Class B, C and D IVDs categories submission requirements.

### 1.10. Applications Fees Payment, Screening and Processing

#### 1.10.1. Fees payment

- a. All application should be accompanied by the appropriate fees as specified in the Fees and Charges Schedule of the Authority at the time of various application. All fees are payable at the time of submitting an application. The fees may be paid directly to the LMHRA or by bank transfer to:

**The Liberia Medicines and Health Products Regulatory Authority(LMHRA),  
Account Name: The Liberia Medicines and Health Products Regulatory  
Authority General Account  
Account No. 0011134721054401  
Currency: United States Dollars  
Swift Code: ECOCLRLM  
Name of bank: ECOBANK Liberia Ltd.  
11<sup>th</sup> Street, Tubman Boulevard, Sinlor  
P. O. Box 71625  
Monrovia, Liberia**

**The Liberia Medicines and Health Products Regulatory Authority (LMHRA)**  
**AccountName: LMHRA Project**  
**Account No.: 207700196210**  
**Name of Bank: Guaranty Trust Bank (Lib) Limited**  
**Currency: United States Dollars**  
**Swift Code: GTBILRLM**  
**13<sup>th</sup> Street Sinkor, Tubman Boulevard**  
**Monrovia, Liberia**

OR, by banker's draft.

- b. If payment is through bank transfer, the applicant will bear all bank charges who must ensure that LMHRA receives an advice note, giving payment details of the applicant, the sum of fees paid and the candidate IVDs been paid for.
- c. Once paid to the LMHRA, all fees are non-refundable.
- d. An annual retention fees for individually registered device must be paid on or before the end of January of each year, even if registered at the end of previous year. During the time of payment, the registration number of the device must be mentioned.
- e. At the time of application, the required sum of retention fee shall be paid per the Fees Schedule of LMHRA at the time of application.

#### **1.10.2. Processing of applications**

- a. An application will be processed once an application has been accepted and the evaluation fees paid.
- b. The evaluation process will involve assessment of applications, clarification of some issues and request for additional data or samples, where appropriate.
- c. When a request or query has been raised, the evaluation process shall be halted pending receipt of a response to the query. An application shall be rejected if the applicant does not respond to the request or query within six months.
- d. All applications shall be processed within six months (fast track) and nine months (regular), commencing the day all required documents have been submitted. Such submissions shall include justifications for payments made.

#### **1.10.3. Performance evaluation**

During the assessment of the submitted technical documentation (dossier), the LMHRA shall conduct performance evaluation and laboratory investigation of the individual In-Vitro Diagnostic to ensure there are no issues with quality.

### **1.11. Registration of the Device**

- a. Applicant shall be informed if an IVD is in compliance with all standard registration requirements within 6 month (fast track) or 9 months (regular).
- b. The LMHRA shall issue a registration certificate/marketing license after an IVD meets all standard requirements.

#### **1.11.1. Registration validity**

All IVD registration certificates shall be valid for five (5) years except when the Authority must have suspended or revoked or terminated the certificates.

All registration validity shall be subject to:

- a. Annual retention fees payment as prescribed in the LMHRA Fees and Charges

- schedule.
- b. Biennial post-marketing surveillance (PMS) report(s) submission.

**1.11.2. Termination of registration**

- a. With substantial reasons given in writing, the LMHRA might suspend or revoke the registration of an IVD, or amend its registration conditions.
- b. The applicant may, within 60 days submits a written notice indicating reasons to the LMHRA, terminate the registration of an IVD.

**1.12. Dossier Compilation**

- (1) It is required that all application dossiers are appropriately arranged in the format stated below:
  - i. The application form (Annex II).
  - ii. Details of the IVD.
  - iii. Technical documents summary (Section 4 of the guidelines)
  - iv. Labeling information as per the Guideline for Labeling and Packaging
  - v. Checklist for Crucial requirements

- (2) Application will be rejected if the application dossier is not arranged appropriately.

**1.13. Appeals**

- 1.13.1. Any applicant that is aggrieved due to a decision made by the LMHRA regarding any IVD application for registration may make formal representations in writing to the LMHRA. Said representation/appeal should be made to the following address:  
**The Managing Director**  
**Liberia Medicines and Health Products Regulatory Authority**  
**(LMHRA) P. O. Box 1994, VP Road, Old Road, Oldest Congo**  
**Town, Monrovia, Liberia**
- 1.13.2. If the Authority is satisfied and considers the representations, it may approve the registration of the IVD,
- 1.13.3. If the Authority is not satisfied, the application shall be rejected.
- 1.13.4. If the applicant is not pleased with the LMHRA's decision, it may appeal to the Court of Competent Jurisdiction in Liberia.

## CHAPTER 2 REQUIREMENTS FOR SUBMISSION

### 2.1 Class A IVDs Submission Requirements

- 2.1.1 Class A IVDs supplied in non-active, non-sterile state and non-measuring function state are subject to registration at the LMHRA.
- 2.1.2 It is required that Class A IVDs that are supplied in active, sterile and having measuring function to be registered by the LMHRA. It shall be required that applicants submit the following:
- i. A filled in application form (Annex II).
  - ii. Copies of the labels (in English and in original color) on the IVDs and its packaging in primary and secondary packaging. Labels must be made available for all components of the IVD system, IVD family members and accessories and subsequently submitted for registration. Provided the variable fields on the artwork are annotated and the range of values for the variable fields are indicated, a representative label may be alternatively submitted for the variants. All labels shall be done according to the Guideline for Labeling & Packaging.
  - iii. Brochures and catalogues presented as promotional material.
  - iv. The patient information leaflet.
  - v. The instructions for use.
  - vi. The sterilization validation report for sterile IVDs.
  - vii. The certification on IVDs metrology or equivalent for an IVD with measuring function.
  - viii. The certification to electrical safety standards for active IVD. e.g. IEC 60601, if applicable.
  - ix. In addition to the information mentioned above, the following information must be submitted for an IVD that contains materials of human, animal, microbial and/or recombinant origin:
    - (i) A list of all materials of human, animal, microbial and/or recombinant origin used in the IVDs and in the manufacturing process of the IVDs. This includes, but not limited to human or animal cells, tissues and/or derivatives, and cells, tissues and/or derivatives of microbial or recombinant origin; and
    - (ii) Immediate identity of sources of the above mentioned.

### 2.2 Class B, C and D IVDs Submission Requirements

- 2.2.1 All applicants are required to provide the following information during submission:
- a. A dully filled application form (Annex II).
  - b. Details of the device as defined below:
    - i. Name(s) - IVD brand and generic names.
    - ii. Description – The IVD general information on characteristics, design, performance and packaging.
    - iii. Category - The IVD class and applicable classification rule attached as Annex I of the guidelines.
    - iv. Intended Use/Indication - The IVD intended use and/or state the general description of the illness or condition the device will diagnose, prevent, treat, or mitigate.
    - v. Instructions of Use - provide a concise summary information for safe

- use of the IVD including methods, procedures, quantity, frequency, duration, and preparation to be followed.
- vi. Contraindications – Mention the conditions for which the IVD ought not to be used. i.e., limitation of an assay using specimens from patients who have received preparations of mouse monoclonal antibodies for therapy when tested with assay kits, which employed mouse monoclonal antibodies. Such may show either depressed or false elevated values.
  - vii. Precautions - Briefly mention precautionary measures to be taken including any special care necessary to ensure that the IVD is used safely and effectively.
  - viii. Warnings - Provide the specific hazardous alert information that a user needs to know prior to using the IVD. E.g. for products containing radioactive material, biological material, explosive material and any other hazardous material. Applicants must also include safety warnings.
  - ix. Adverse Effects - Depict all side and adverse effects associated with the IVD use under standard conditions.  
Storage conditions - State the IVD storage conditions.
  - x. IVD use under standard conditions.
  - xi. Alternative use – Mention any alternative procedures or practices that can be used for diagnosing, treating, or mitigating the condition or disease for which the IVD is intended.
  - xii. Recommended shelf-life (where applicable) - The recommended shelf-life of the IVD should be stated.

## CHAPTER 3 SUMMARY TECHNICAL DOCUMENT

### 3.1 Device Features and Description

Applicants should provide detailed description of the candidate IVD attributes explaining how its functions; including:

- i. IVD intended use.
- ii. If IVD is automatic or not;
- iii. The function (e.g. monitoring, screening, diagnosis);
- iv. State whether the test is quantitative or qualitative;
- v. What has been identified;
- vi. Condition, risk factor or disorder of interest that are specific, and envisioned for detecting, defining or differentiating;
- vii. Mention the required type of specimen (e.g. whole blood, plasma, serum, urine, sputum, cerebrospinal fluid (CSF));
- viii. Population targeted to test (e.g. adults, antenatal women, neonates, etc.);
- ix. The environmental condition compatibility during operation (attitude and temperature range).
- x. The targeted user (laboratory professional and/or nonprofessional).
- xi. Describe general principle of the assay method or IVD operation.
- xii. Describe the assay components (e.g. calibrators, reagents and assay controls), and where applicable, components of the active ingredients description (e.g. antibodies and antigens).
- xiii. Describe any software to be used with the IVD, when appropriate.
- xiv. Provide complete list or explanation of the several variants/configurations that will be available for the IVD. Example, diagnostics for infectious diseases.
- xv. Describe the accessories, and other non-IVD products that are targeted use in combination with the diagnostic, if applicable.
- xvi. Mention the risk class and the applicable classification rule for the IVD as stated in these guidelines.

### 2.3 Risk analysis

Summary of the risks identified during the risk analysis process should be provided and how these risks have been mitigated to a satisfactory level. Rather, the risk analysis should be established on recognized standards and be part of the risk management plan of the manufacturer. Possible hazards to the IVD should be addressed by the summary. For example, the risk from false negative or false positive results, indirect risks that could lead to inaccurate results, or from user-related hazards, like reagents containing infectious agents. A conclusion should be provided by the risk analysis results showing evidence that the remaining risks when compared to the benefits, are satisfactory. In other words, the cumulative benefits must surpass the cumulative risks. If sensitivity/specificity ratio exceeds specificity/sensitivity ratio, the benefits are high. Conversely, the risks are high.

### 2.4 IVD Design and Manufacturing Information

#### 2.4.1 Product design

Provide general and understandable information regarding the design applied to the IVD. The information should describe the critical ingredients of an assay like antigens, antibodies, and enzymes provided or recommended to be used with the IVD:

- a. Except for stand-alone instruments, major subsystems, analytical technology (i.e. control mechanisms, operating principles, etc. MUST be described.

- b. For instruments and software, a summary of the entire system, including an Architecture Design Chart (a typical flowchart of the relationships among the major functional units in the software as well as relationships to hardware and to data flows or networking) must be provided.
- c. In case of stand-alone software, the data interpretation methodology (i.e. algorithms) must be described.
- d. For self-testing devices, the design aspects making it suitable for use by all persons must be described.
- e. A controlling site should be indicated if the design takes place at multiple sites.

#### **2.4.2 IVD formulation and composition**

The formulation/composition for each ingredient should be provided as follow:

##### **2.4.2.1 Materials**

Complete details of the material specifications and raw materials should be provided as follow:

- a. Provide list of all components of the IVD and they should be characterized biologically and chemically, plus antigens, antibodies, and substrates used to identify antigen-antibody complexes, assay controls, and test reagents. Applicable references must be cited to substantiate your information.
- b. The source should be specified and production details provided, if the components are of biological or recombinant origin.
- c. The peptide sequence must be provided when synthetic peptides are used.
- d. Provide the process validation results to validate that all procedures for manufacturing are set to decrease biological risks, such as viruses and other transmissible agents. The production of reagents and inactivation of communicable organisms in reagents must be included.
- e. Information on irradiating components, nonionizing or ionizing (e.g. Iodide- 131 in the Radioimmunoassay kit) should be provided.
- f. When appropriate, information on poison or controlled substance (e.g. Buprenorphine in drug assay kit) should be provided

##### **2.4.2.2 Biological safety**

All biological components such as bacterial, viral, parasitic, animal, or human origin or their derivatives materials used in the IVD must be listed. Specify the name of the biological component, details of use in the IVD and describe steps that are taken to minimize infection or transmission risk.

#### **2.4.3 Manufacturing processes**

##### **2.4.3.1 Manufacturing process overview**

Presented as a process flow chart, information on the manufacturing process should be provided, displaying an overview of the production, considering the assembly, packaging of the finished IVD and the technologies used. Details of any in-process and final product testing (e.g. QC release program of the manufacturer) should be provided.

##### **2.4.3.2 Manufacturing sites**

The following information should be provided:

- a. Name of the site,
- b. the physical address of site,
- c. Description of the manufacturing process performed at the site,



- d. A simple sight plan that highlights the production areas and number of employees at the site,
- e. The occurrence of any other manufacturing at the site should be stated. All critical manufacturing sites involved in the manufacture of the IVD (i.e. including the design, quality control stages or procedures of manufacture and warehousing)

#### **2.4.3.3 Key suppliers**

Key suppliers, as well the costs of ingredients/products/services for manufacturing the IVD should be listed, as well as the;

- a. Supplier's name,
- b. Physical address of supplier's manufacturing site,
- c. Ingredient/product/service supplied description,
- d. Proof of purchasing and authentication procedures for the ingredients/products/services sourced from these suppliers.

## **2.5 Specifications of IVD**

- a. List of dimensions, performance and features characteristics of the IVD and its variants and accessories should be made available within the dossier and to the end user.
- b. Description of IVD's functional characteristics and technical performance specifications such as relevance, accuracy, sensitivity, specificity of measuring and other specifications including biological, chemical, electrical, mechanical and physical.

## **2.6 Characteristics of Analytical Performance**

### **2.6.1 Accuracy of measurement**

Make studies information available, describing both precision and trueness.

#### **2.6.1.1 Trueness of measurement**

Provision of information regarding the trueness of measurement procedure and summary of data used to establish both qualitative and quantitative assays trueness measures.

#### **2.6.1.2 Precision of measurement**

Provide studies information on repeatability and reproducibility.

##### **a. Repeatability**

Show details information on repeatability estimation and studies used to estimate within-run variability. Appropriate assay should be used to obtain repeatability data for instruments. Use of the IVD at the point-of-care where the analysis is performed by non-laboratory trained personnel (e.g., clinic nurses), repeatability must be established in two steps:

- Step 1: A professional laboratory personnel must establish the IVD optimal repeatability under controlled laboratory conditions.
- Step 2: A consumer field evaluation for determining the performance of the IVD when used by unassisted, non-laboratory trained personnel, following provision of instructions must be conducted

##### **b. Reproducibility**

Provision of information on reproducibility estimates and studies used for estimation, as applicable, variability between sites, runs, days, lots,

instruments and operators. Variability of such is identified as “Intermediate Precision”. Use of the IVDs at point-of-care where the analysis is performed by non- laboratory trained personnel (e.g., clinic nurses), reproducibility must be established in two steps:

- Step 1: A professional laboratory personnel must establish the IVD optimal reproducibility under controlled laboratory conditions.
- Step 2: A second consumer field evaluation for determining the performance of the IVD, when used by unassisted, non-laboratory trained personnel, following provision of instructions, must be conducted.

### 2.6.1.3 Analytical Sensitivity

Information on the study design and results should be provided with a comprehensive explanation of the type and preparation of specimen. Include analyte (measured) levels, matrix, and the way levels were established. The quantity of replicates tested for every concentration and the calculation used to establish assay sensitivity must be made available and also describe. For example:

- i. Amount of standard deviations above the mean value of the sample without analyte, generally implied as ‘Limit of Blank’ (LoB).
- ii. Based on the measurements of samples that contain analyte, the lowest distinguishable concentration is from zero, generally implied to as ‘Limit of Detection (LoD).
- iii. The lowest concentration at which the trueness and/or precisions are within specified criteria is generally implied as ‘Limit of Quantitation’ (LoQ).

## 2.7 Stability (Excluding Specimen Stability)

Description of claimed shelf life, in use stability and shipping studies:

### 2.7.1 In use stability

In order to reflect the actual routine use of an IVD (actual or replicated), in use stability studies information must be provided for one lot, including automated instruments and/or open vial stability and board stability.

If calibration stability has been claimed for automated instruments, sufficient supporting data must be included to describe the study protocol (i.e. protocol, testing intervals and acceptance criteria), claimed in use stability and conclusions.

### 2.7.2 Claimed shelf life

- i. Stability testing studies information provision to support the claimed shelf life that has been conducted on at least three different lots manufactured at conditions that are basically equivalent to regular production conditions. The summary should contain: The study report that include the protocol, testing intervals, acceptance criteria and quantity of lots.
- ii. Identification of method used for the accelerated studies, where accelerated studies have been completed in expectation of real time studies.
- iii. Conclusion and claimed shelf life.

Note: The lot with the longest real time stability data can be utilized to determine the shelf life if only the extrapolated or accelerated data are comparable from three lots.

### 2.7.3 Shipping stability

Shipping stability studies information for one lot should be provided to assess the IVD tolerance to the expected shipping situations, describing the method used for simulated conditions, study report (i.e. protocol, acceptance criteria), conclusion and recommended shipping conditions. Shipping studies can be performed under real and/or replicated conditions and must contain variable shipping conditions like extreme heat and cold.

### 2.7.4 Robustness studies

Applicant must provide information to prove that an IVD design is robust; for example, insensitive to environmental and usage variation. Robustness studies are usually designed to challenge the system under stress conditions to recognize potential IVD deficiencies, such as failures, and product robustness determination. Multiple skill levels of users, potential instrument and reagent problems must be considered by manufacturer. In performing robustness studies, consider the following factors:

1. Human factors or operator error, which include but not limited to;
  - a. Use of incorrect specimen type,
  - b. Incorrect volume and placement of the specimen to the IVD,
  - c. Improper ordering of reagent application,
  - d. Inappropriate handling of reagents which include those in self-contained unitized test IVDs, incorrect placement of IVD (e.g., unlevelled surface),
  - e. Use of incorrect reagents (e.g., unspecified reagents for the particular IVD or lot or generic reagents),
  - f. Use of incorrect amount of reagent,
  - g. Inappropriate placement of reagents, and this include test strips, or other components containing reagent,
  - h. Improper timing of procedures (e.g., specimen application, running the test, or results reading),
  - i. Improper reading of test results, incorrect reading due to color blindness, etc.
2. Specimen integrity and handling which include specimen collection errors, clotted specimens, inappropriate anticoagulant usage, specimen handling errors, inappropriate specimen transport and storage, presence of interfering substances, presence of bubbles in specimen, etc.,
3. Reagent viability (Reagent integrity) including usage of inappropriately stored reagents, use of expired reagents, improperly mixed reagents, contaminated reagents, etc.,
4. Integrity of the hardware, software, and electronics also including power fluctuation, power failure, incorrect voltage, repeated device plugging and unplugging, hardware and software, electronic failures, physical shock to unit, etc.,
5. Calibration and internal controls stability including factors that affect calibration stability and calibrator, factors that may interfere with calibration,
6. Environmental factors such as impact of key environmental factors (heat, humidity, barometric pressure changes, sunlight, surface angle, device movement, changes in pH or temperature, etc.) on specimens, reagents, and test results.

## 2.8 Clinical Performance

Sufficient evidence on data assessment and analysis generated from the clinical use of

## Registration of In-Vitro Diagnostics

the IVD to validate the clinical safety. Also, claims for diagnostic/clinical sensitivity and specificity should be included. Every claim must be substantiated and supported by well-designed performance evaluations which should comprise of:

- i. A comprehensive written plan and protocol of the evaluation study
- ii. The study performance dates and at which site
- iii. A written report on the outcome of the study; all inconsistent results must be explained and justified. The report outline should comprise,
  - a) The technology on which the IVD is based, the intended use of the device as well as any claims concerning the clinical performance or safety of the IVD.
  - b) The nature and extent of the clinical data that has been evaluated; and
  - c) How the referenced or documented standards and/or clinical data information demonstrate the clinical performance and safety of the IVD.
- iv. Specifics of the IVD lots/batches used for the evaluation, considering the lot number date of expiry, and storage conditions of the IVD prior to and during the study.
- v. The evaluator(s) must sign and date the clinical evaluation report and report must be accompanied by manufacturer's justification of the choice of evaluator.

This Guideline on Registration of In-Vitro Diagnostics is endorsed by:

\_\_\_\_\_, Managing Director of LMHRA on this  
\_\_\_\_\_ day of of \_\_\_\_\_ in the year of our Lord, AD \_\_\_\_\_ at  
\_\_\_\_\_ (location).

Signed and Sealed: \_\_\_\_\_





**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



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**IN VITRO DIAGNOSTICS (IVDs) CLASSIFICATION RULES**

**Rule 1**

IVDs that are intended to be used for the following purposes are classified as Class D:

- a. IVDs intended to be used for detecting the presence of, or exposure to, a communicable agent in blood, blood components, blood derivatives, cells, tissue, or organs for the purpose of assessing their suitability for transplantation or transfusion, or
- b. IVDs anticipated for use in detecting the presence of, or exposure to, a communicable agent that causes or have the potential to cause a life-threatening, often incurable, disease with a proliferation of high risk

**Rationale:**

As defined above, application of this rule should be in accordance with the rationale that follows: IVDs in Class D are anticipated to be used for ensuring the safety of blood and blood components for transfusion, organs, tissues and cells used for transplantation. In most instances, result of the test is the key determinant to know whether or not the product/donation will be utilized. Examples: Tests to detect infection caused by HTLV, HCV, HIV, HBV. This Rule applies to first-line assays, supplemental assays and assays confirmation.

**Rule 2**

IVDs that are anticipated for use in tissue typing or blood grouping in order to confirm the immunological compatibility of blood, blood components, cells, tissue or organs that are anticipated for transfusion or transplantation, are categorized as Class C, except for determining ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kell (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] which are categorized as Class D.

**Rationale:**

As outlined above, the application of this rule must be according to the rationale intended for this rule which is as follows: An IVD is placed into Class D where an erroneous result would put the patient in an imminent life-threatening situation with a high individual risk. Depending on the nature of the blood group antigen the IVD is intended to detect, the rule divides blood grouping devices into two subsets, Class C or D, and its significance in a transfusion setting. Examples: HLA, Duffy system (other Duffy systems excluding those itemized in the rule as Class D are in Class C).

**Rule 3**

IVDs can be classified as Class C when they are anticipated for use:

- i. in cerebrospinal fluid presence detection or blood of an infectious agent with a risk of limited spread. Examples: Cryptococcus neoformans or Neisseria meningitidis.
- ii. in detecting the exposure to, or presence of, a sexually transmitted agent. Examples: Neisseria gonorrhoeae, Chlamydia trachomatis, etc.
- iii. in detecting the presence of an infectious agent where there is a substantial risk that an erroneous result would cause severe disability or death to the individual or fetus being tested. Examples: diagnostic assay for Chlamydia pneumoniae, CMV, Methycillin Resistant Staphylococcus aureus.

## Registration of In-Vitro Diagnostics

- iv. in the determination of women immune status towards transmissible agents via pre-natal screening. Examples: Immune status tests for Toxoplasmosis or Rubella.
- v. in determining the status of infectious disease and where a risk of erroneous resulting to a patient management decision leading to an imminent life-threatening condition for the patient. Examples: HSV, CMV and Enteroviruses in transplant patients.
- vi. in assessing patients for selective therapy and management, or for disease presentation, or the diagnosis of cancer. Example: personalized medicine.

NOTE: IVDs used where further investigation is done before therapy decision is generally taken and those used for monitoring would fall into class B under rule 6.

- vii. in gene testing of human. Examples: Cystic Fibrosis, Huntington's disease.
- viii. in monitoring the levels of substances, biological components, or medicines, if an erroneous risk result could result to a patient management decision which result in instant life-threatening state for a patient. Examples: Cyclosporin, Prothrombin time testing, Cardiac markers.
- ix. In managing patients that are suffering due to a life-threatening infectious disease. Examples: HCV genoand sub-typing, HCV viral load, HIV Viral Load and HIV.
- x. to screen congenital disorders in fetus. Examples: Down Syndrome or Spina Bifida.

### **Rationale:**

Applying this rule as defined above must be per the rationale for this rule as follows: a moderate public health risks are presented by IVDs in this Class, or a high individual risk, where an erroneous result may put the patient in an imminent life-threatening condition, or may have a key negative effect on outcome. The IVDs provide critical, or sole, determinant for the appropriate diagnosis. These IVDs might also have high individual risk since the information and the nature of possible follow-up measures could result to stress and anxiety.

### **Rule 4**

All IVDs anticipated for self-testing are categorized as Class C, excluding those IVDs that do not give result to determine a medically life-threatening status, or is initial and requires follow-up with applicable laboratory testing where in this instance they are Class B. IVDs that are anticipated for blood gases and blood glucose determinations for near-patient testing can be Class C. But other IVDs that anticipated for near-patient should be classified using the right classification rules.

### **Rationale:**

As indicated above, this rule is applicable in accordance with the rationale for this rule, which is as follow: generally, these IVDs can be used by nontechnical expertise individuals and therefore the user instructions and labelling are essential to the appropriate outcome of the test.

Example for self-testing class C: Blood glucose monitoring, addition data required

Example for self-testing class B: Urine test strips, Fertility testing, Pregnancy self-testing.

### **Rule 5**

The below IVDs are classified as Class A:

- i. Reagents that possess specific features, which the manufacturer anticipates to make them suitable for in-vitro diagnostic procedures linked to a specific examination.
- ii. Instruments that the manufacturer specifically anticipated to be used for in vitro diagnostic procedures.

### **Specimen receptacles**

Note: Any product for general laboratory use which are not manufactured, sold or exemplified for use in a specified in-vitro diagnostic applications are not considered to be IVDs as defined in these guidelines. Nevertheless, certain authorities' products are considered to be IVDs for general laboratory use.

## Registration of In-Vitro Diagnostics

### **Rationale:**

As stated above, this rule must be applied in accordance with the rationale for this rule which is as follows: These IVDs presenting low individual risk and with absence of or minimal public health risk. Examples: Differential/selective microbiological media (excluding the dehydrated powders considered as unfinished IVD), wash solutions, identification kits for cultured microorganisms, plain urine cup and instruments.

Note 1: for certain authorities, there could be variances as to whether an IVD categorized in this rule is considered an IVD.

Note 2: The software performance or instrument particularly required to perform a specific test will be assessed along with the test kit.

Note 3: The test methodology and the interdependence of the IVD prevents it from being separately assessed, yet the IVD itself is still classified as Class A.

### **Rule 6**

IVDs that are not covered in Rules 1 through 5 are classified as Class B.

### **Rationale:**

As defined above, application of this rule must be in accordance with the rationale for this rule which is as follows: These IVDs give a moderate individual risk since they are unlikely to indicate an erroneous result that might cause severe disability or death, have a key negative effect on patient outcome or put the individual in instant jeopardy. The IVDs give results that are generally one of several determinants. Other information is available such as presenting signs and symptoms if the analysis result is the only determinant or other clinical information that may serve as guidance to a physician, such that the classification into Class B might be justified. Other applicable controls could likewise be in place to authenticate the results. Also, this Class comprises those IVDs that present a low public health risk since they identify infectious agents not simply transmitted in a population.

Examples: Blood gases, H. pylori and physiological markers such as enzymes, hormones, vitamins, metabolic markers, celiac disease markers and specific IgE assays.

### **Rule 7**

IVDs that are controls without a qualitative or quantitative allocated value will be classified as Class B.

### **Rationale:**

The qualitative or quantitative values for such controls are not assigned by the manufacturer but the user.





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APPLICATION FORM FOR REGISTRATION OF IN-VITRO DIAGNOSTICS (IVDs)

<b><u>Please carefully read and understand this section before filling the form</u></b>			
➤ Please check the corresponding boxes in the “Encl.” column if any document is enclosed and indicate the respective indexes in the submission folder			
➤ If applicable, please tick the corresponding boxes			
<b>No.</b>	<b>Part I: Details of Applicant</b>		
<b>1</b>	Name of applicant:		
	Country:	Postal code:	
	Contact person:	Fax:	
	Telephone:	E-mail:	
	Website:		
<b>2</b>	<b>Part II: Details of the Manufacturing site</b>		
	Name:		
	Site address:		
	Country:	Postal code:	
	Contact person:	Fax:	
	Telephone:	E-mail:	
	Website:		
<b>3</b>	<u>Quality Management System Established by the Manufacturer</u>		
	Standards with which the system complies:		
	ISO 9001 (current version)		
	ISO13485 (current version)		
	Manufacturing site Quality Audit		
	Others _____ (please specify)		
	System certified by _____, and a certified		

## Registration of In-Vitro Diagnostics

	<p>copy of the certificate is enclosed.</p> <p>Indicate areas covered by Quality Management System</p> <p>Device design,</p> <p>Production</p> <p>Post-production processes</p> <p>Others (please specify)</p> <p>_____</p> <p>_____</p>	
<b>Part III: Details of Local Agent</b>		
<b>4</b>	Name of Local Agent:	
	Registered business address:	
	Contact person:	Fax:
	Telephone:	E-mail:
	Contact person:	Telephone:
<b>5</b>	Certified copy of business registration certificate with business registration number: _____ is enclosed	
<b>6</b>	Certified copy of power of attorney attached (if applicable).	
<b>Details of IVD</b>		
<b>7</b>	<p>Generic name: _____</p> <p>Brand name: _____</p> <p>Model/Serial No. (If applicable): _____</p> <p>Family (If applicable): _____</p> <p>Commercial presentation: _____</p> <p>Country of origin: _____</p>	
<b>8</b>	Any special storage condition (if applicable):	
<b>9</b>	<p>IVD anticipated use: _____</p> <p>_____</p> <p>_____</p>	
<b>10</b>	Description of the IVD:	
<b>11</b>	<p>Class of the IVD device:</p> <p>Class A</p> <p>Class B</p> <p>Class C</p> <p>Class D</p>	

<b>12</b>	Basis for classifying the IVD as A, B, C or D: _____ _____ _____																	
<b>13</b>	Details of manufacturing procedure and documentation a. Give a brief summary of the manufacturing process: _____ _____ _____  b. Please attach copy of the analytical control procedures performed during the manufacturing process.  c. Please attach all relevant Certificates confirming the quality of the finished IVDs (i.e., sensitivity, specificity, sterility, pyrogen test, etc).  d. Please attach the final analytical report with signatures of individuals authorizing the release of the finished IVDs.  <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 25%;">Department/section</th> <th style="width: 25%;">Authorized person</th> <th style="width: 25%;">Qualification</th> <th style="width: 25%;">Address</th> </tr> </thead> <tbody> <tr> <td>Quality control</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Products packaging</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Products release</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> e. IVD estimated shelf-life: _____ f. Provide the stability data along with justification for the predicted shelf-life. g. Provide the source of the active ingredient/starting material and classification of the antigen that was used in the manufacturing the test strip of the IVD.  Note: Please attach four(4) copies of labels (text of labels and written material must be indelible and conform to the existing labeling guidelines), package inserts and packaging materials proposed for marketing the product in Liberia.	Department/section	Authorized person	Qualification	Address	Quality control				Products packaging				Products release				
Department/section	Authorized person	Qualification	Address															
Quality control																		
Products packaging																		
Products release																		
<b>14</b>	a. Has there been an application for the registration of the IVD in any other country? YES <input type="checkbox"/> NO <input type="checkbox"/>  If YES, list the countries: _____ _____ _____  b. Is the device registered in country of origin? YES <input type="checkbox"/> NO <input type="checkbox"/>  If YES, attach a certified copy of certificates of registration for the IVD issued by the relevant authority established for the registration of IVDs in the country. _____ _____ _____  c. Is the registration of the IVD been refused, rejected, deferred or cancelled in any country? YES <input type="checkbox"/> NO <input type="checkbox"/>																	





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**APPLICATION FORM FOR VARIATION OF A REGISTERED  
 IN-VITRO DIAGNOSTIC (IVD)**

1.	IVD Brand name:	
2.	IVD classification	
3.	Anticipated use	
4.	Model/series/system (if applicable)	
5.	Indicate the type of variation/change(s)	
6.	Scope (Kindly stipulate scope of the change)	
7.	Applicant must provide a background for the change and justification for change(s). Also, applicant must provide a short background explanation for the suggested change(s).	
8.	Existing (Please specify accurate current wording or specification)	9. Proposed (Please specify accurate proposed wording or specification)
NOTE: The Applicant must continuously enclose working model which will clearly differentiate between the existing and proposed version.		
10.	Details of the Applicant (must be the one holding the registration certificate or marketing authorization)	
	Name: _____	
	Business Address: _____	
	Postal Address: _____	
	Country: _____	
	Phone: _____ Fax: _____ Email: _____	
	Signature: _____ Date: _____	
	Stamp: _____	



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**APPLICATION FORM FOR RENEWAL OF A REGISTERED  
 IN-VITRO DIAGNOSTIC (IVD)**

1.	IVD Brand name:	
2.	Generic Name:	
3.	IVD classification/Reis class:	
4.	Anticipated use:	
5.	GMDN code:	
6.	GMDN category:	
7.	Model/series/system (if applicable):	
8.	Pack size:	
9.	IVD description(Additional detailed information should be attached):	
10.	Name and address of Applicant (must be the one holding the registration certificate or marketing authorization):	
11.	Manufacturers' name and address:	
12.	Manufacturing sites' name and address:	
13.	Name and address of Local Agent (who must be resident in Liberia and, if a company, be incorporated in Liberia)	
14.	Variation application in parallel with this renewal application must be utilized if there are major changes to the IVD and manufacturing process:	
<p><b>Applicant's declaration</b>                  I hereby submit a renewal application for the above IVD and therefore declare that all information provided on this application form are correct and that there are no other changes other than those identified in this application(except for those that may be addressed in the variations application submitted in parallel; such parallel variations must be indicated under different application).</p> <p>Name: _____</p> <p>Qualification: _____</p>		

Registration of In-Vitro Diagnostics

Position: \_\_\_\_\_

Email: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Stamp:

## Glossary

In the context of these guidelines, the following terms shall be defined as follows:

### **Accessory**

An item intended explicitly by its manufacturer to be used in combination with apparent device to facilitate usage of that device according to its intended use as an IVD or to enhance or prolong the competences of the parent device in accomplishing its projected use as an IVD.

### **Act**

The Liberia Medicines and Health Products Regulatory Authority Act of 2010

### **Analytical performance**

The capacity of an IVD to detect or measure a particular analyte

### **Applicant**

Any individual or institution or company applying officially to obtain market authorization for In-Vitro Diagnostic Devices in Liberia

### **Assay**

Is an investigative (analytic) procedure performed in laboratory for quantitative measurement or qualitative assessment of the amount, presence or functional activity of a target analyte.

### **Authentication**

Means confirmation by analysis and providing objective evidence that the requirements for a specific anticipated IVD use have been fulfilled

### **Authority**

The Liberia Medicines and Health Products Regulatory Authority or the acronym “LMHRA” established under Part 1 section 1 and 2 of the Act of 2010.

### **Calibrator**

An object, substance or material envisioned by its manufacturer/owner to be utilized in calibration a measuring system or measuring instrument.

### **Certified Copy**

The genuine copy of an original document certified by a person registered to practice law in the manufacturer’s country of origin and sanctioned with the official stamp and signature of the legal practitioner.

### **Clinical Performance**

The capability of an IVDD yielding results that are linked with a particular clinical condition or physiological state according to intended use and target population.

### **Confirmation**

Means validation by examination and provision of objective evidence that the specified requirements have been fulfilled

### **Conformity Assessment**

Is a methodical examination of evidence generated and procedures assumed by the manufacturer, under the Authority’s established requirements, for the purpose of determining that an IVD is safe and performs as anticipated by the manufacturer hence, conforms to the Essential Principles of Safety and



## Registration of In-Vitro Diagnostics

Performance of IVDs.

### **High Dose Hook Effect**

Wrong or low measurement of analyte(s) present in the specimen in a very high concentration

### **In-Vitro Diagnostic or its acronym IVD**

- ✓ A device whether used in combination or alone, anticipated by the manufacturer for the in-vitro analysis of specimens originated from the human body and animals mainly aimed at information provision for diagnostic, monitoring or compatibility purposes. IVD comprise calibrators, reagents, specimen receptacles, control materials, software, and related instruments or apparatus and are used as example for the following analysis purposes: aid to diagnosis, diagnosis, prognosis, monitoring, screening, predisposition, prediction and determination of physiological status Label.
- ✓ Any written, printed or graphic demonstration that appears on or is attached to the IVD or active ingredient or any part of its packaging, and comprises any informational sheet or leaflet that accompanies the in-vitro diagnostics or active constituent while it is being supplied.

### **Nonprofessional Person**

- ✓ Any individual who does not have formal training in a relevant field or discipline

### **Local Agent**

- ✓ A local agent is a natural person residing in Liberia or cooperate body registered in Liberia who has received a mandate from the applicant to act on his behalf with regard to matters relating to registration of devices in Liberia.

### **Manufacture**

- ✓ To produce, make, process or fabricate an IVD and comprises:
  - Any process conducted in the course of so producing, making, processing or fabricating the in-vitro diagnostic; and
  - Packaging and labeling of an IVD prior to its supplied.

### **Manufacturer**

- ✓ Any person or a company that is engaged in the manufacture of IVD

### **Medical Device(s)**

- ✓ Any implant, in-vitro reagent or calibrator, software, material or other similar or related article which:
  - a. is intended by manufacturer to be used, alone or in combination for human or other animals for one or more of the following specific purpose(s):
    - i. diagnosis, prevention, monitoring, treatment or alleviation of diseases or compensation for an injury;
    - ii. supporting or sustaining life;
    - iii. investigation, replacement, modification or support or the anatomy or of a physiological process;
    - iv. medical devices disinfection;
    - v. controlling conception;
    - vi. providing information for diagnostic or medical purposes through in-vitro analysis or specimens that are derived from human or other animal; and
  - b. cannot achieve its principal anticipated action in or on the human body via pharmacological, metabolic or immunological means, but which might be supported in its anticipated function.

### **Near Patient Testing**

- ✓ Any testing performed outside the laboratory environment by qualified personnel, commonly near to or at the side of the patient, also known as Point-of-Care Testing.

### **Performance Evaluation**

- ✓ Evaluation and analysis of data to establish or authenticate the performance (i.e., analytical

## Registration of In-Vitro Diagnostics

performance and where appropriate, clinical performance) of an IVD

### **Process Validation**

- ✓ Confirmation by objective evidence that a process consistently produces a result or IVD meeting its pre-determined requirements

### **Quality Audit**

- ✓ The process of systematic examination of a quality system of IVDs manufacturing facilities carried out by the Authority to demonstrate conformity for regulatory purposes.

### **Quality Management System**

- ✓ Collection of business processes aim to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system

### **Reagent**

- ✓ Any chemical, biological or immunological component, solution or preparation intended by the manufacturer to be used as IVD

### **Recall**

- ✓ Any action taken by its manufacturer, importer, supplier or applicant to remove the IVD from the market or to retrieve the IVD from any person to whom it has been supplied, because the IVD may:
  - fail to conform to any claim made by its manufacturer or importer relating to its quality, safety or performance;
  - be dangerous to health.

### **Recognized Standards**

- ✓ National or international standards deemed to offer the presumption of conformity to specific Essential Principles of Safety and Performance.

### **Applicant**

- ✓ The person who applied for and obtained the registration of the IVD

### **Risk**

- ✓ Combination of the probability of occurrence of harm and the severity of that harm

### **Self-testing**

- ✓ Means testing performed by oneself

### **Technical Documentation**

- ✓ Means documented evidence, normally an output of the Quality Management System that demonstrates compliance with the Essential Principles of Safety and Performance of IVD