



Zambia Medicines Regulatory Authority

**GUIDELINES ON APPLICATION FOR GRANT OF MARKETING  
AUTHORISATION OF IN-VITRO DIAGNOSTIC MEDICAL DEVICES FOR  
HUMAN USE**

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|             | Name                          | Designation                       | Signature | Date       |
|-------------|-------------------------------|-----------------------------------|-----------|------------|
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| Approver    | Hon. Prof. Roman Chilengi, MP | Minster of Health                 |           | 06.10.26   |



**TABLE OF CONTENTS**

|                                                                                        |    |
|----------------------------------------------------------------------------------------|----|
| ABBREVIATIONS AND ACRONYMS .....                                                       | 4  |
| INTERPRETATION.....                                                                    | 5  |
| INTRODUCTION .....                                                                     | 8  |
| OBJECTIVE .....                                                                        | 8  |
| SCOPE .....                                                                            | 8  |
| 1. GENERAL REQUIREMENTS .....                                                          | 9  |
| a) Applicant .....                                                                     | 9  |
| b) Product application.....                                                            | 9  |
| c) Requirements for an application.....                                                | 9  |
| d) Documentation .....                                                                 | 10 |
| e) Payment of Application fees .....                                                   | 10 |
| f) Processing of received applications .....                                           | 11 |
| h) Evaluation of applications for grant of Marketing Authorisation .....               | 11 |
| i) Quality analysis.....                                                               | 11 |
| k) Site Audit for Compliance to ISO 13485 QMS of The Manufacturing Facility .....      | 11 |
| l) Grant of Marketing Authorisation .....                                              | 12 |
| m) Appeals.....                                                                        | 12 |
| n) Application for Change(s) to Marketing Authorisation for an IVD Medical Device..... | 12 |
| o) Retention fees.....                                                                 | 13 |
| p) Vigilance .....                                                                     | 13 |
| q) Renewal of a Marketing Authorisation .....                                          | 13 |
| 2.0 PRODUCT INFORMATION.....                                                           | 13 |
| a) Name(s) .....                                                                       | 13 |
| b) Intended Use/User .....                                                             | 13 |
| c) Instructions for Use (IFU) and User Manual .....                                    | 14 |
| d) Description .....                                                                   | 14 |
| e) Labelling.....                                                                      | 14 |
| f) Claimed shelf-life.....                                                             | 14 |
| g) Storage conditions .....                                                            | 14 |



|                                                                                                  |    |
|--------------------------------------------------------------------------------------------------|----|
| 3.0 CLASSIFICATION .....                                                                         | 14 |
| 4.0 TECHNICAL INFORMATION.....                                                                   | 15 |
| a) Requirements .....                                                                            | 15 |
| b) GROUPING MEDICAL DEVICES AS AN IVD CLUSTER .....                                              | 15 |
| c) Accessories accompanying IVDs.....                                                            | 16 |
| ANNEXES.....                                                                                     | 17 |
| ANNEX I. Application Form.....                                                                   | 17 |
| ANNEX II: Product Dossier Checklist .....                                                        | 21 |
| Annex III: In-Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD<br>ToC) ..... | 23 |
| Annex III Product Dossier requirements for a Class A IVD Medical Device.....                     | 30 |
| Annex IV Cluster Examples .....                                                                  | 32 |

**i. ABBREVIATIONS AND ACRONYMS**

|       |                                                |
|-------|------------------------------------------------|
| GMDN  | Global Medical Device Nomenclature             |
| GMP   | Good Manufacturing Practice                    |
| IFU   | Instructions for Use                           |
| IMDRF | International Medical Devices Regulators Forum |
| IRB   | Institutional Review Board                     |
| ISO   | International Organisation for Standardisation |
| IVD   | <i>In-Vitro</i> Diagnostics                    |
| MAH   | Marketing Authorisation Holder                 |
| NDQCL | National Drug Quality Control Laboratory       |
| QMS   | Quality Management System                      |
| SADC  | Southern Africa Development Community          |
| UDI   | Unique Device Identifier                       |
| WHO   | World Health Organisation                      |
| ZAMRA | Zambia Medicines Regulatory Authority          |



## INTERPRETATION

In these guidelines, unless the context otherwise requires -

“**accessory**” means an article which, is intended specifically by its manufacturer to:

- (i) be used together with a medical device to enable that device to be used in accordance with its intended use as a medical device.
- (ii) augment or extend the capabilities of that device in fulfilment of its intended use as a medical device;

“**Act**” means the Medicines and Allied Substances Act, No. 3 of 2013;

“**applicant**” means a person or entity that submits an application for marketing authorisation of an *In-Vitro* Diagnostic Medical Device (IVD);

“**Authority**” means the Zambia Medicines Regulatory Authority;

“**expedited evaluation**” means the express evaluation of a product application within a 90 – day period;

“**instructions for use**” means information provided by the manufacturer to inform the device user of the medical device’s intended purpose and proper use and handling of the device;

“***In vitro* diagnostic medical device**” means a medical device, whether used alone or in combination with one or more accessories, 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 and includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles as may be determined or classified or identified as such by the Authority excluding *in-vitro* diagnostics for veterinary use;

“**label**” means written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices;



“**labelling**” means the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents;

“**local responsible person**” means a natural or legal person, resident in Zambia, appointed by a foreign-based Marketing Authorisation Holder to be responsible for all regulatory matters in respect of products granted marketing authorisation with a valid Power of Attorney;

“**manufacture**” means operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, repackaging or labelling of medical devices;

“**manufacturer**” means any person and/or institution with the responsibility to design and/or manufacture medical devices with the intention of making the medical device available for use, under their name;

“**marketing authorisation**” means the authorisation granted under section *thirty-nine* of the Medicines and Allied Substances Act, No. 3 of 2013 for the placement of a medicine or allied substance on the Zambian market;

“**medical device**” means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- I. diagnosis, prevention, monitoring, treatment or alleviation of disease,
- II. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- III. investigation, replacement, modification, or support of the anatomy or of a physiological process,
- IV. supporting or sustaining life,
- V. control of conception,
- VI. disinfection of medical devices,



VII. providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means;

**“notified body”** means a third-party independent certification organisation which a competent authority designates to carry out certain tasks in respect of the conformity assessment procedures;

**“product dossier”** means a file that contains detailed information on the device description, manufacturing, quality control and biomedical studies that demonstrates quality, safety and performance of the finished medical device;

**“recognised standards”** means national or international standards accepted to offer conformity to specific essential principles of safety and performance;

**“risk”** means a combination of the probability of occurrence of harm and the severity of that harm;

**“shelf life”** Means the period of time during which a medical device, if handled and stored correctly, is expected to comply with the specification as determined by the Essential Principles of Quality, Safety and Performance;

**“site audit”** Means an inspection conducted at a device manufacturing facility or site in order to determine compliance of that facility to ISO 13485 requirements; and

**“user”** Means the person(s) who uses a medical device.



## **1. INTRODUCTION**

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established pursuant to the Medicines and Allied Substances Act, No.3 of 2013 of the Laws of Zambia (“the Act”). The Authority is responsible for the regulation and control of medicines and allied substances including regulating and controlling the manufacture, importation, exportation, distribution and sale of medicines and allied substances; establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines and allied substances; serve and protect the public interest in all matters relating to the sale of medicines and allied substances among other things.

These Guidelines for Grant of Marketing Authorisation for *In-Vitro* Diagnostic Medical Devices (IVDs) are issued by the Authority pursuant to Section 68 of the Act and will provide information to be incorporated in the applications for grant of marketing authorisation by an applicant who intends to place on the Zambian market *in-vitro* medical devices in accordance with Section 39 of the Act. The Authority may amend any part of these Guidelines from time to time.

## **2. OBJECTIVE**

These guidelines are intended to be the reference document for use by an applicant in the preparation of product dossiers for marketing authorisation of IVDs by providing general guidance on the application requirements.

## **3. SCOPE**

These guidelines apply to IVDs for human use and shall be used by local responsible persons, marketing authorization holders, distributors, manufacturers, wholesalers, retailers and the public. The guidelines provide for a stepwise procedure to be followed when compiling a product dossier for submission when applying for grant of marketing authorisation of IVDs for human use.



#### 4. GENERAL REQUIREMENTS

##### a) Applicant

A person who intends to place on the Zambian market an *in-vitro* diagnostic medical device for human use shall apply to the authority as provided in these guidelines.

An applicant who is not resident in Zambia shall appoint a local responsible person with power of attorney who shall be responsible for compliance to regulatory requirements with respect to IVDs.

An applicant shall be responsible for the product information in support of the application for Marketing Authorisation and variations thereof.

##### b) Product application

An applicant shall submit an application as provided in these guidelines that shall be accompanied by a product dossier that is presented in an electronic text selectable/editable PDF, submitted via the Authority's online portal.

Where an application has product variants such as size, design, dimensions or capacity, the variants shall be considered as different products and shall require separate applications as determined by the Authority.

Class A or B IVD reagents from the same manufacturer and are of a common test methodology shall be submitted as grouped applications (refer to annex V). Products submitted under grouped applications (cluster) shall bare the same Marketing Authorisation number upon approval.

Any component of IVD CLUSTER to be sold separately as a single medical device shall be registered separately

##### c) Requirements for an application

An Application shall comprise the following:

- (i) Cover letter from the applicant;
- (ii) A duly completed and signed application form as set out in Annex I;
- (iii) Proof of payment of the prescribed application fee;



- (iv) At least two samples of the IVD packaged in the smallest commercial pack size, and labelled in English; IVDs for which submission of samples may not be practical, pictorial and video representations may be acceptable;
- (v) A duly completed checklist as set out in Annex II indicating the sections of the application that have been completed and the pages thereof; and
- (vi) Product dossier.

An incomplete application for grant of marketing authorisation for an IVD shall not be accepted where one of the documents listed above is not part of the application.

#### **d) Documentation**

To facilitate the review of information submitted, an applicant shall take into consideration the following when submitting the application:

##### **(i) Language**

Applications and supporting documents shall be in English.

##### **(ii) Text formatting and layout**

Information shall be presented in legible letters of 12 font size in Times New Roman or Arial font type of 1.5 line spacing and standard margin.

Each page shall be numbered sequentially. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced.

#### **e) Payment of Application fees**

An application for grant of Marketing Authorisation for an *in-vitro* diagnostic medical device shall be accompanied by proof of payment of the fee set out in the Medicines and Allied Substance (Fees) Regulations, 2016.

Bank charges in relation to the application shall be borne by the applicant who shall ensure that proof of payment is submitted to the Authority. Marketing Authorisation fees for IVD shall cover the costs of evaluating the initial submission only and exclude laboratory testing and site audit fees which shall be charged separately.

**f) Processing of received applications**

- (i) Where deficiencies are identified during screening of an application, a request for additional information shall be made to the applicant.
- (ii) Subject to (i), an applicant shall be required to submit all the requested additional information within the period specified by the Authority but not exceeding 60 days from the date of receipt of the request.
- (iii) Where an applicant does not respond to the Authority's request for additional information within the period stated in (ii), the application shall be rejected.
- (iv) Where an applicant fails to provide all the requested information, or the submitted information is incomplete, deficient or immaterial, the application shall be rejected.
- (v) Where the application has been rejected in line with clauses (iii) and (iv), an applicant shall be informed in writing.

**h) Evaluation of applications for grant of Marketing Authorisation**

An application shall be evaluated on a first come first serve basis unless expedited evaluation has been authorised by the Authority.

**i) Quality analysis**

Where necessary, samples of the IVD may be analyzed by the National Drug Quality Control Laboratory (NDQCL) or any other accredited laboratory as recommended by the Authority, against the claimed manufacturer's specifications in accordance with the current available local Standards or other quality specifications such as those prescribed by International Organisation for Standardisation (ISO) and any other internationally recognised standards.

**k) Site Audit for Compliance to ISO 13485 QMS of The Manufacturing Facility**

- (i) An applicant shall be required to facilitate for site audits of their manufacturing site in order to demonstrate compliance to ISO 13485. The GMP inspection fees set out in the Medicines and Allied Substances (Fees) Regulations, 2016 shall apply in relation to a site audit.
- (ii) The Authority may in determining whether to conduct a site audit of a manufacturing site referred to in (i) consider:
  - (a) previous satisfactory site audit outcomes conducted by WHO listed level 3 or 4 National Regulatory Authorities or regional regulatory agencies; and



- (b) that the audit in (ii) was conducted within 24 months preceding receipt of the application.
- (iii) In instances as determined by the Authority, the option to undertake a desk review by the Authority in lieu of a site audit may occur in the following:
- (a) Where the applicant shows proof of compliance to successful previous site audits conducted by WHO listed level 3 or 4 National Regulatory Authorities or regional regulatory agencies; and
  - (b) The past satisfactory record of the safety, quality and performance of the product on the global and regional market.

Notwithstanding the above, the Authority in carrying out an audit may request for any other relevant information.

#### **I) Grant of Marketing Authorisation**

The Authority shall grant Marketing Authorisation where the product meets the requirements of quality, safety and performance and any other requirements as set out in the Regulations and these Guidelines. The Marketing Authorisation once granted shall be valid for a period of five (5) years.

#### **m) Appeals**

An applicant who may be aggrieved by a decision made by the Authority in relation to their application for the grant of marketing authorisation may seek redress in accordance with the provisions of the Act.

#### **n) Application for Change(s) to Marketing Authorisation for an IVD Medical Device**

A Marketing Authorisation Holder (MAH) who intends to effect any change(s) to the device shall inform the Authority of such intended change(s) by means of an application for change(s), which shall be accompanied by relevant supporting documentation and proof of payment of the fee set out in the Medicines and Allied Substance (Fees) Regulations, 2016.

Any such change(s) shall be implemented in line with the guideline for Application for Change(S) To Approved Medical Devices Including Medical Gloves and Condoms for Human Use.

**o) Retention fees**

A Marketing Authorisation Holder (MAH) shall pay the prescribed annual product retention fee for the following year by 31<sup>st</sup> December of each year.

Where the MAH fails to pay the annual retention fee by 31st December:

- (a) the Authority shall not authorise the importation of the IVD;
- (b) in case of a locally manufactured IVD, the Authority shall not authorise the continued manufacture of the product;
- (c) the Marketing Authorisation issued shall be suspended; and
- (d) the Marketing Authorisation may be revoked by the Authority.

**p) Vigilance**

A MAH shall put in place a vigilance system to monitor the quality, safety and performance of an IVD placed on the Zambian market. The MAH shall ensure that modalities to provide routine reports to the Authority on any findings regarding the product are in place in accordance with the Authority's requirements on vigilance.

**q) Renewal of a Marketing Authorisation**

A MAH who intends to renew a Marketing Authorisation shall apply to the Authority on payment of the fee set out in the Medicines and Allied Substance (Fees) Regulations, 2016 at least one hundred and eighty (180) days before the expiry date of the Marketing Authorisation.

**2.0 PRODUCT INFORMATION**

An applicant shall provide product information which shall include but not limited to the following:

**a) Name(s)**

- (i) The brand name of the IVD.
- (ii) The generic name of the IVD.

**b) Intended Use/User**

Provide details specifying the intended use and user of the device.

**c) Instructions for Use (IFU) and User Manual**

An applicant shall provide the device Instructions for Use which shall contain clear information, including intended use/user, contraindications, storage conditions, warnings and precautions.

Where applicable, an applicant shall provide a copy of the user manual for a respective medical device.

**d) Description**

An applicant shall provide a general description on design, size and dimensions of the IVD Medical Device. The description shall also include the following:

- (i) material of construction of the device;
- (ii) accessories where available;
- (iii) packaging material;
- (iv) model Numbers;
- (v) Global Medical Device Nomenclature (GMDN) Code; and
- (vi) Pack size.

**e) Labelling**

Labelling information shall be as per ZAMRA Guidelines for Label and Instructions for Use for Medical Devices.

**f) Claimed shelf-life**

The claimed shelf-life of an IVD shall be stated. The manufacturer shall determine the shelf-life of a product based on stability studies conducted.

**g) Storage conditions**

An applicant shall state the storage conditions in accordance with the manufacturer's recommendations.

**3.0 CLASSIFICATION**

An IVD shall be classified as per ZAMRA Guidelines on the Principles of Medical Devices Classification



#### 4.0 TECHNICAL INFORMATION

##### a) Requirements

For class B, C and D IVD medical devices, an applicant shall be required to compile a product dossier containing technical information in the format as set out in Annex III.

For Class A IVD Medical Devices, an applicant is required to compile a product dossier in the format as set out in Annex IV.

##### b) GROUPING MEDICAL DEVICES AS AN IVD CLUSTER

Class A or B IVD reagents from the same manufacturer which are of a common test methodology shall be submitted as grouped applications.

##### 1. IVD Clustering Requirements

An IVD Cluster comprises a number of *in vitro* diagnostic reagents that are:

- i. from the same manufacturer;
- ii. of the same risk classification (Class A or B only);
- iii. of a common test methodology (based on IFU); and
- iv. of the same cluster category.

The IVD Cluster may include analysers that are designed for use with the reagents in the IVD Cluster.

##### Types of IVD Clusters

| IVD Clusters                                                                                                                                                               | How to Register                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>Individual (Single) reagents or articles.</li><li>Test kits.</li><li>Family of reagents or articles within an IVD Cluster.</li></ul> | <p>Register separately</p> <p><b>Note:</b> The different device brand names, and common intended purpose would be key considerations for the separate listings.</p> |



| IVD Clusters                                                                                                                                  | How to Register                                                                                                                                                                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• IVD Clusters which include IVD analyser.</li><li>• IVD Test Kit which include IVD analyser.</li></ul> | <p>Select one of the following options:</p> <ul style="list-style-type: none"><li>• Register together as an IVD system.</li><li>• Register the IVD analyser separately from the IVD test kit as a separate product.</li></ul> |

### Grouping limitations

The IVD Cluster grouping is only used for marketing authorisation and will not apply as a grouping criterion for the addition of models through a change.

All devices and articles that are listed as part of a Cluster can be supplied separately but solely for the registered intended purpose.

A reagent or article that is intended for multiple usage categories, such that it can be grouped in more than one IVD Cluster, can be grouped as part of any IVD Cluster. Information to support all the intended purposes of the reagent or article shall be submitted as part of the medical device marketing authorisation.

### List of IVD Cluster Categories

This list of IVD Cluster categories only applies to Class A or B IVD medical devices. The label of each reagent or article should state clearly whether it is intended to be used alone or in combination, for the same category.

#### e) Accessories accompanying IVDs

Accessories shall be classified in their own right as a medical device and do not necessarily take the classification of the device with which they are intended to be used.

A product qualifies to be an accessory to a medical device if there is an established intended use in conjunction with a medical device. If a medical device can fulfil its original intended purpose without the supplementary use of a product, that product would not qualify as an accessory to a medical device.



An Accessory that augments or extends the capabilities of that device in fulfilment of its intended use as a medical device shall also be considered as an independent medical device and will be classified under the class of the parent device and shall fulfil the requirements under these Guidelines.

For examples of cluster categories, see Annex V

## ANNEXES

### ANNEX I. Application Form



**The Medicines and Allied Substances Act, 2013(Act No.3 of 2013)**

**The Medicines and Allied Substances (Marketing Authorisation of *In-vitro* Diagnostic  
Medical Devices for Human Use) Guidelines, 2024**

#### **APPLICATION FOR GRANT OF MARKETING AUTHORISATION OF *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES FOR HUMAN USE IN ZAMBIA**

*For Official Use*

Date

Application number

#### **PART I: PARTICULARS OF THE APPLICANT**

|                                       |                                     |
|---------------------------------------|-------------------------------------|
| <b>Applicant name and<br/>address</b> | <b>Name:</b>                        |
|                                       | <b>Physical and Postal Address:</b> |
|                                       | <b>Phone:</b>                       |
|                                       | <b>Fax:</b>                         |
|                                       | <b>Email:</b>                       |



|                                                                                             |                                                   |
|---------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Details of Contact Person<sup>1</sup></b>                                                | Name:<br>Designation:<br>Phone:<br>Fax:<br>Email: |
| <b>Details of Local Responsible Person<sup>2</sup></b><br><i>(Attach Power of Attorney)</i> | Name:<br>Designation:<br>Phone:<br>Fax:<br>Email: |

**PART II: PARTICULARS OF THE MEDICAL DEVICE**

|                                                                            |                                                                                                                                         |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacturers name (s), site address (s) and Scope</b>                  | Name:<br>Physical and Postal Address:<br>Phone:<br>Fax:<br>Email:<br>GPS Coordinates:<br>Scope of activities in relation to the device: |
| <b>Number of samples of the medical devices submitted</b>                  |                                                                                                                                         |
| <b>Generic name of the medical device <i>(Where applicable)</i></b>        |                                                                                                                                         |
| <b>Brand name of the medical device</b>                                    |                                                                                                                                         |
| <b>Model/Series/System of the medical device <i>(Where applicable)</i></b> |                                                                                                                                         |

1 1 Contact person will be responsible for communicating with the Authority and a letter of Authorisation to communicate on behalf of the applicant should be submitted.

2 2 Should be a person, resident in Zambia, appointed by a foreign-based applicant to be responsible for all regulatory matters in respect of products granted marketing authorisation with Power of Attorney or a letter of acting as an agent.



|                                                                    |                                                                                                                                                                                                                        |
|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Type of Application (Single, Kit, System, Cluster)                 |                                                                                                                                                                                                                        |
| GMDN description of the medical device                             |                                                                                                                                                                                                                        |
| Short description of the GMDN descriptions as appropriate          |                                                                                                                                                                                                                        |
| GMDN code of the medical device (if known)                         |                                                                                                                                                                                                                        |
| Intended use of the medical device                                 |                                                                                                                                                                                                                        |
| Sample of Instructions for use                                     |                                                                                                                                                                                                                        |
| Sample of User's Manual (where applicable)                         |                                                                                                                                                                                                                        |
| Sample (s) of accessory (s) accompanying the medical device if any |                                                                                                                                                                                                                        |
| Medical device Classification                                      | <input type="checkbox"/> Class A<br><input type="checkbox"/> Class B<br><input type="checkbox"/> Class C<br><input type="checkbox"/> Class D                                                                           |
| Rule(s) of product classification used                             |                                                                                                                                                                                                                        |
| Have there been any of the following:                              | <input type="checkbox"/> Previous recalls<br><input type="checkbox"/> Reportable adverse incidents<br><input type="checkbox"/> Banning in other countries<br><input type="checkbox"/> Post-market surveillance studies |



|                                                                                                                                        |  |
|----------------------------------------------------------------------------------------------------------------------------------------|--|
| Please provide details on each item you have ticked (attach any relevant documentation)                                                |  |
|                                                                                                                                        |  |
|                                                                                                                                        |  |
|                                                                                                                                        |  |
|                                                                                                                                        |  |
|                                                                                                                                        |  |
|                                                                                                                                        |  |
|                                                                                                                                        |  |
|                                                                                                                                        |  |
|                                                                                                                                        |  |
| International or national standards with which the device complies (enclose a copy of valid certificates)                              |  |
| List the SADC states where the medical device has obtained marketing approval (Attach documentation)                                   |  |
| Is the device WHO prequalified, US FDA approved, CE Marked or approved in any IMDRF member state?<br>If so, attach valid documentation |  |

**PART III: DECLARATION AND SIGNATURE**

I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief.

**Particulars of the authorised person signing on behalf of the applicant**

a) Name: .....

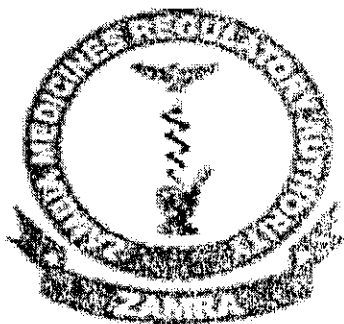
b) Designation: .....

c) Signature: ..... d) Date: .../.../..... (dd/mm/yyyy)

d) Company seal or official stamp



## ANNEX II: Product Dossier Checklist



The Medicines and Allied Substances Act, 2013(Act No.3 of 2013)

The Medicines and Allied Substances (Marketing Authorisation of *In-vitro* Diagnostic  
Devices for Human Use) Guidelines, 2024APPLICATION FOR GRANT OF MARKETING AUTHORISATION OF *IN-VITRO*  
DIAGNOSTIC DEVICES FOR HUMAN USE IN ZAMBIA

(An Applicant is required to complete the checklist with the necessary information)

A completed copy of the checklist should be included in the dossier.

## 1. Supporting documents

| Supporting documents                                                   | Yes (Y)/<br>No (N)/<br>Not applicable<br>(N/A) | Comment | For ZAMRA<br>Use Only |
|------------------------------------------------------------------------|------------------------------------------------|---------|-----------------------|
| Duly signed cover Letter<br>from applicant                             |                                                |         |                       |
| Proof of payment                                                       |                                                |         |                       |
| Samples (2) of device                                                  |                                                |         |                       |
| Where product is WHO<br>prequalified, applicant to<br>provide a letter |                                                |         |                       |
| Instructions for Use<br>(IFU)                                          |                                                |         |                       |
| Mock-up Label                                                          |                                                |         |                       |

## 2. Product Dossier

| Description | Dossier sections | Yes (Y)<br>No (N) | Comment | For ZAMRA<br>Use Only |
|-------------|------------------|-------------------|---------|-----------------------|
|-------------|------------------|-------------------|---------|-----------------------|



|                                               |                                                                                                                                |  |  |  |  |
|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|
| Administrative information                    | Completed and signed application form                                                                                          |  |  |  |  |
| Certificates                                  | Notarized Free Sale Certificate                                                                                                |  |  |  |  |
|                                               | Notarized Manufacturing Licence                                                                                                |  |  |  |  |
|                                               | Notarized Registration Certificates                                                                                            |  |  |  |  |
|                                               | ISO 13485 certificate                                                                                                          |  |  |  |  |
| Technical Information                         | Information provided as per Annex III for Class B to D and as per Annex IV for Class A Devices; provided for in the guideline. |  |  |  |  |
| Any other relevant documents (please specify) |                                                                                                                                |  |  |  |  |
|                                               |                                                                                                                                |  |  |  |  |
|                                               |                                                                                                                                |  |  |  |  |
|                                               |                                                                                                                                |  |  |  |  |
|                                               |                                                                                                                                |  |  |  |  |
|                                               |                                                                                                                                |  |  |  |  |

**Annex III: In-Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD ToC)**

| <b>CHAPTER 1 – REGIONAL ADMINISTRATIVE</b> |                                                                                 |
|--------------------------------------------|---------------------------------------------------------------------------------|
| 1.01                                       | Cover Letter                                                                    |
| 1.02                                       | Submission Table of Contents                                                    |
| 1.03                                       | List of Terms/Acronyms                                                          |
| 1.04                                       | Application Form/Administrative Information                                     |
| 1.05                                       | Listing of Device(s)                                                            |
| 1.06                                       | Quality Management System, Full Quality System or other Regulatory Certificates |
| 1.07                                       | Free Sale Certificate/ Certificate of Marketing authorization                   |
| 1.08                                       | Expedited Review Documentation                                                  |
| 1.09                                       | User Fees                                                                       |
| 1.10                                       | Pre-Submission Correspondence and Previous Regulator Interactions               |
| 1.11                                       | Acceptance for Review Checklist                                                 |
| 1.12                                       | Statements/Certifications/Declarations of Conformity                            |
| 1.12.01                                    | Performance and Voluntary Standard                                              |
| 1.12.02                                    | Environmental Assessment                                                        |
| 1.12.03                                    | Clinical Trial Certifications                                                   |
| 1.12.04                                    | Indications for Use Statement with Rx and/or OTC designation<br>Enclosure       |
| 1.12.05                                    | Truthful and Accurate Statement                                                 |
| 1.12.06                                    | Declaration of Conformity                                                       |
| 1.13                                       | Letters of Reference for Master Files                                           |
| 1.14                                       | Letter of Authorization                                                         |
| 1.15                                       | Other Regional Administrative Information                                       |
| <b>CHAPTER 2 – SUBMISSION CONTEXT</b>      |                                                                                 |
| 2.01                                       | Chapter Table of Contents                                                       |
| 2.02                                       | General Summary of Submission                                                   |
| 2.03                                       | Summary and Certifications for Premarket Submissions                            |
| 2.04                                       | Device Description                                                              |
| 2.04.01                                    | Comprehensive Device Description and Principle of Operation                     |
| 2.04.02                                    | Material Specifications                                                         |
| 2.04.03                                    | Description of Device Packaging                                                 |
| 2.04.04                                    | History of Development                                                          |
| 2.04.05                                    | Reference and Comparison to Similar and/or Previous Generations of the Device   |
| 2.04.06                                    | Substantial Equivalence Discussion                                              |
| 2.05                                       | Indications for Use and/or Intended Use                                         |
| 2.05.01                                    | Intended Use; Intended Purpose; Intended User; Indications for Use              |
| 2.05.02                                    | Intended Environment/Setting for use                                            |



|                                                              |                                                                               |
|--------------------------------------------------------------|-------------------------------------------------------------------------------|
| 2.05.03                                                      | Paediatric Use                                                                |
| 2.05.04                                                      | Contraindications for Use                                                     |
| 2.06                                                         | Global Market History                                                         |
| 2.06.01                                                      | Global Market History                                                         |
| 2.06.02                                                      | Global Incident Reports and Recalls                                           |
| 2.06.03                                                      | Sales*(number of units sold), Incident and Recall Rates                       |
| 2.06.04                                                      | Evaluation/Inspection Reports                                                 |
| 2.07                                                         | Other Submission Context Information                                          |
| <b>CHAPTER 3 – ANALYTICAL PERFORMANCE AND OTHER EVIDENCE</b> |                                                                               |
| 3.01                                                         | Chapter Table of Contents                                                     |
| 3.02                                                         | Risk Management                                                               |
| 3.03                                                         | Essential Principles (EP) Checklist                                           |
| 3.04                                                         | Standards                                                                     |
| 3.04.01                                                      | List of Standards                                                             |
| 3.04.02                                                      | Declaration and/or Certification of Conformity                                |
| 3.05                                                         | Analytical Performance                                                        |
| 3.05.01                                                      | Stability of Sample(s)                                                        |
| 3.05.01.01                                                   | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.01.01.01                                                | Summary                                                                       |
| 3.05.01.01.02                                                | Full Report                                                                   |
| 3.05.01.01.03                                                | Statistical Data                                                              |
| 3.05.02                                                      | Validation of Specimens                                                       |
| 3.05.02.01                                                   | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.02.01.01                                                | Summary                                                                       |
| 3.05.02.01.02                                                | Full Report                                                                   |
| 3.05.02.01.03                                                | Statistical Data                                                              |
| 3.05.03                                                      | Metrological traceability of calibrator and control material values           |
| 3.05.03.01                                                   | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.03.01.01                                                | Summary                                                                       |
| 3.05.03.01.02                                                | Full Report                                                                   |
| 3.05.03.01.03                                                | Statistical Data                                                              |
| 3.05.04                                                      | Accuracy of Measurement                                                       |
| 3.05.04.01                                                   | Trueness                                                                      |
| 3.05.04.01.01                                                | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.04.01.01.01                                             | Summary                                                                       |



|                      |                                                                               |
|----------------------|-------------------------------------------------------------------------------|
| 3.05.04.01.01<br>.02 | Full Report                                                                   |
| 3.05.04.01.01<br>.03 | Statistical Data                                                              |
| 3.05.04.02           | Precision (Repeatability and Reproducibility)                                 |
| 3.05.04.02.01        | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.04.02.01<br>.01 | Summary                                                                       |
| 3.05.04.02.01<br>.02 | Full Report                                                                   |
| 3.05.04.02.01<br>.03 | Statistical Data                                                              |
| 3.05.05              | Analytical Sensitivity                                                        |
| 3.05.05.01           | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.05.01.01        | Summary                                                                       |
| 3.05.05.01.02        | Full Report                                                                   |
| 3.05.05.01.03        | Statistical Data                                                              |
| 3.05.06              | Analytic Specificity                                                          |
| 3.05.06.01           | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.06.01.01        | Summary                                                                       |
| 3.05.06.01.02        | Full Report                                                                   |
| 3.05.06.01.03        | Statistical Data                                                              |
| 3.05.07              | High Dose Hook Effect                                                         |
| 3.05.07.01           | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.07.01.01        | Summary                                                                       |
| 3.05.07.01.02        | Full Report                                                                   |
| 3.05.07.01.03        | Statistical Data                                                              |
| 3.05.08              | Measuring Range of the Assay                                                  |
| 3.05.08.01           | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.08.01.01        | Summary                                                                       |
| 3.05.08.01.02        | Full Report                                                                   |
| 3.05.08.01.03        | Statistical Data                                                              |
| 3.05.09              | Validation of Assay Cut-off                                                   |
| 3.05.09.01           | [Study description, study identifier, date of initiation, date of completion] |
| 3.05.09.01.01        | Summary                                                                       |
| 3.05.09.01.02        | Full Report                                                                   |



|                  |                                                                                                        |
|------------------|--------------------------------------------------------------------------------------------------------|
| 3.05.09.01.03    | Statistical Data                                                                                       |
| 3.05.10          | Validation of the Assay Procedure                                                                      |
| 3.05.10.01       | [Study description, study identifier, date of initiation, date of completion]                          |
| 3.05.10.01.01    | Summary                                                                                                |
| 3.05.10.01.02    | Full Report                                                                                            |
| 3.05.10.01.03    | Statistical Data                                                                                       |
| 3.06             | Other Studies                                                                                          |
| 3.06.01          | Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility |
| 3.06.01.01       | [Study description, study identifier, date of initiation, date of completion]                          |
| 3.06.01.01.01    | Summary                                                                                                |
| 3.06.01.01.02    | Full Report                                                                                            |
| 3.06.01.01.03    | Statistical Data                                                                                       |
| 3.06.02          | Software/Firmware                                                                                      |
| 3.06.02.01       | Software/Firmware Description                                                                          |
| 3.06.02.02       | Hazard Analysis                                                                                        |
| 3.06.02.03       | Software Requirement Specification                                                                     |
| 3.06.02.04       | Architecture Design Chart                                                                              |
| 3.06.02.05       | Software Design Specification                                                                          |
| 3.06.02.06       | Traceability Analysis                                                                                  |
| 3.06.02.07       | Software Life Cycle Process Description                                                                |
| 3.06.02.08       | Software Verification and Validation                                                                   |
| 3.06.02.08.01    | [Study description, study identifier, date of initiation]                                              |
| 3.06.02.08.01.01 | Summary                                                                                                |
| 3.06.02.08.01.02 | Full Report                                                                                            |
| 3.06.02.08.01.03 | Statistical Data                                                                                       |
| 3.06.02.09       | Revision Level History                                                                                 |
| 3.06.02.10       | Unresolved Anomalies (Bugs or Defects)                                                                 |
| 3.06.02.11       | Cybersecurity                                                                                          |
| 3.06.02.12       | Interoperability                                                                                       |
| 3.06.03          | Cleaning and Disinfection Validation                                                                   |
| 3.06.3.01        | [Study description, study identifier, date of initiation, date of completion]                          |
| 3.06.3.01.01     | Summary                                                                                                |
| 3.06.3.01.02     | Full Report                                                                                            |
| 3.06.3.01.03     | Statistical Data                                                                                       |
| 3.06.04          | Usability/Human Factors                                                                                |
| 3.06.04.01       | [Study description, study identifier, date of initiation, date of completion]                          |
| 3.06.04.01.01    | Summary                                                                                                |



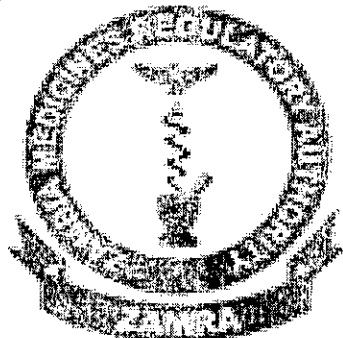
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|--------------------------------------|-------------------------------------------------------------------------------|
| 3.06.04.01.02                        | Full Report                                                                   |
| 3.06.04.01.03                        | Statistical Data                                                              |
| 3.06.05                              | Stability of the IVD                                                          |
| 3.06.05.01                           | Claimed Shelf-life                                                            |
| 3.06.05.01.01                        | [Study description, study identifier, date of initiation, date of completion] |
| 3.06.05.01.01.01                     | Summary                                                                       |
| 3.06.05.01.01.02                     | Full Report                                                                   |
| 3.06.05.01.01.03                     | Statistical Data                                                              |
| 3.06.05.02                           | In Use Stability                                                              |
| 3.06.05.02.01                        | [Study description, study identifier, date of initiation, date of completion] |
| 3.06.05.02.01.01                     | Summary                                                                       |
| 3.06.05.02.01.02                     | Full Report                                                                   |
| 3.06.05.02.01.03                     | Statistical Data                                                              |
| 3.06.05.03                           | Shipping Stability                                                            |
| 3.06.05.3.01                         | [Study description, study identifier, date of initiation, date of completion] |
| 3.06.05.3.01.01                      | Summary                                                                       |
| 3.06.05.3.01.02                      | Full Report                                                                   |
| 3.06.05.3.01.03                      | Statistical Data                                                              |
| 3.07                                 | Analytical Performance and Other Evidence Bibliography                        |
| 3.08                                 | Other Evidence                                                                |
| 3.08.01                              | [Study description, study identifier, date of initiation, date of completion] |
| 3.08.01.01                           | Summary                                                                       |
| 3.08.01.02                           | Full Report                                                                   |
| 3.08.01.03                           | Statistical Data                                                              |
| <b>CHAPTER 4 – CLINICAL EVIDENCE</b> |                                                                               |
| 4.01                                 | Chapter Table of Contents                                                     |
| 4.02                                 | Overall Clinical Evidence Summary                                             |
| 4.02.01                              | Expected Values/Reference Ranges                                              |
| 4.02.02                              | Clinical Evidence Evaluation Report                                           |



|                                                          |                                                                               |
|----------------------------------------------------------|-------------------------------------------------------------------------------|
| 4.02.03                                                  | Device Specific Clinical Studies                                              |
| 4.02.03.01                                               | [Study description, protocol #, date of initiation, date of completion]       |
| 4.02.03.01.01                                            | Clinical Study Summary                                                        |
| 4.02.03.01.02                                            | Clinical Study Report                                                         |
| 4.02.02.01.03                                            | Clinical Study Data                                                           |
| 4.02.04                                                  | Clinical Literature Review and Other Reasonable Known Information             |
| 4.03                                                     | IRB Approved Informed Consent Forms                                           |
| 4.04                                                     | Investigators Sites and IRB contact information                               |
| 4.05                                                     | Other Clinical Evidence                                                       |
| 4.05.01                                                  | [Study description, study identifier, date of initiation, date of completion] |
| 4.05.01.01                                               | Summary                                                                       |
| 4.05.01.02                                               | Full Report                                                                   |
| 4.05.01.03                                               | Statistical Data                                                              |
| <b>CHAPTER 5 – LABELLING AND PROMOTIONAL MATERIAL</b>    |                                                                               |
| 5.01                                                     | Chapter Table of Contents                                                     |
| 5.02                                                     | Product/Package Labels                                                        |
| 5.03                                                     | Package Insert/Instructions for Use                                           |
| 5.04                                                     | e-labelling                                                                   |
| 5.05                                                     | Patient Labelling                                                             |
| 5.06                                                     | Technical/Operators Manual                                                    |
| 5.07                                                     | Other Labelling                                                               |
| <b>CHAPTER 6A – QUALITY MANAGEMENT SYSTEM PROCEDURES</b> |                                                                               |
| 6A.01                                                    | Cover Letter                                                                  |
| 6A.02                                                    | Chapter Table of Contents                                                     |
| 6A.03                                                    | Administrative                                                                |
| 6A.03.01                                                 | Product Descriptive Information                                               |
| 6A.03.02                                                 | General Manufacturing Information                                             |
| 6A.03.03                                                 | Required Forms                                                                |
| 6A.04                                                    | Quality management system procedures                                          |
| 6A.05                                                    | Management responsibilities procedures                                        |
| 6A.06                                                    | Resource management procedures                                                |
| 6A.07                                                    | Product realization procedures                                                |
| 6A.08                                                    | Design and development procedures                                             |
| 6A.09                                                    | Purchasing procedures                                                         |
| 6A.10                                                    | Production and service controls procedures                                    |
| 6A.11                                                    | Control of monitoring and measuring devices procedures                        |



|                                                                           |                                                             |
|---------------------------------------------------------------------------|-------------------------------------------------------------|
| 6A.12                                                                     | QMS measurement, analysis and improvement procedures        |
| 6A.13                                                                     | Other Quality System Procedures Information                 |
| <b>CHAPTER 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION</b> |                                                             |
| 6B.01                                                                     | Chapter Table of Contents                                   |
| 6B.02                                                                     | Quality management system information                       |
| 6B.03                                                                     | Management responsibilities information                     |
| 6B.04                                                                     | Resource management information                             |
| 6B.05                                                                     | Device Specific Quality Plan                                |
| 6B.06                                                                     | Product realization information                             |
| 6B.07                                                                     | Design and development information                          |
| 6B.08                                                                     | Purchasing information                                      |
| 6B.09                                                                     | Production and service controls information                 |
| 6B.10                                                                     | Control of monitoring and measuring devices information     |
| 6B.11                                                                     | QMS measurement, analysis and improvement information       |
| 6B.12                                                                     | Other Device Specific Quality Management System Information |

**Annex III Product Dossier requirements for a Class A IVD Medical Device**

**The Medicines and Allied Substances Act, 2013(Act No.3 of 2013)**

**The Medicines and Allied Substances (Marketing Authorisation of In-vitro Diagnostic  
Medical Devices for Human Use) Guidelines, 20...**

**GRANT OF MARKETING AUTHORISATION OF A CLASS A IN-VITRO  
DIAGNOSTIC MEDICAL DEVICE FOR HUMAN USE IN ZAMBIA**

**Requirements for a Class A IVD Medical Device**

(An Applicant is required to complete this document with the necessary information and  
attach the required supporting documentation where necessary)

| No. | DEVICE INFORMATION                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.  | Brand name of Device                                                                                                                                                                                                                                                                                                                                                                                                                       |
|     |                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2.  | Generic name of Device                                                                                                                                                                                                                                                                                                                                                                                                                     |
|     |                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.  | <b>Device Description</b><br><i>Provide a general description on design/size of the Device. The description should also include the following:</i> <ul style="list-style-type: none"><li>a) <i>material of construction for:</i><ul style="list-style-type: none"><li>(i) the device</li><li>(ii) packaging material where applicable</li></ul></li><li>b) <i>device dimensions</i></li><li>c) <i>GMDN Code, Lot No. and UDI</i></li></ul> |
|     |                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 4.  | Device model/series                                                                                                                                                                                                                                                                                                                                                                                                                        |



|     |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.  | <b>Certificates</b><br><i>Provide:</i> <ul style="list-style-type: none"><li>a) <i>Notarised copy of the Free Sale Certificate specifically addressed to Zambia</i></li><li>b) <i>Manufacturing Licence of the device manufacturer</i></li><li>c) <i>Valid ISO 13485 certificate</i></li><li>d) <i>Documentary proof of registration for the product in other countries especially those in the SADC region, if applicable</i></li></ul> |
| 6.  | <b>State the intended use of the device</b>                                                                                                                                                                                                                                                                                                                                                                                              |
| 7.  | <b>Intended User</b>                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 8.  | <b>Device Shelf-life (in months)</b>                                                                                                                                                                                                                                                                                                                                                                                                     |
| 9.  | <b>Sample Instructions for Use</b>                                                                                                                                                                                                                                                                                                                                                                                                       |
| 10. | <b>Sample label (mock -up)</b>                                                                                                                                                                                                                                                                                                                                                                                                           |
| 11. | <b>Storage conditions</b>                                                                                                                                                                                                                                                                                                                                                                                                                |
| 12. | <b>Name and address of Applicant</b>                                                                                                                                                                                                                                                                                                                                                                                                     |
| 14. | <b>Name, contact details and address of appointed local responsible person</b><br><i>(include valid letter of appointment)</i>                                                                                                                                                                                                                                                                                                           |
| 15. | <b>Complete name(s), address(es) and the scope of the manufacturing site(s) of the Device</b>                                                                                                                                                                                                                                                                                                                                            |
| 16. | <b>Contract of manufacture (where applicable)</b>                                                                                                                                                                                                                                                                                                                                                                                        |
| 17. | <b>Summary of manufacturing process</b><br><i>(provide narrative and flow diagram)</i>                                                                                                                                                                                                                                                                                                                                                   |



|     |                                                                             |
|-----|-----------------------------------------------------------------------------|
|     |                                                                             |
| 18. | Provide information of notified body (if device is “CE” marked for example) |
|     |                                                                             |
| 19. | Signed and dated device quality release specifications                      |
|     |                                                                             |
| 20. | Provide at least two (2) certificates of analysis                           |
|     |                                                                             |
| 21. | Two (2) samples of the product in the smallest commercial pack size         |

**Annex IV Cluster Examples**

| Methodology        | Cluster Category (Closed list) | Examples of analytes                                                                                                                                                                                       |
|--------------------|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Clinical chemistry | Enzymes                        | <ul style="list-style-type: none"><li>• Acid Phosphatase</li><li>• Alpha-Amylase</li><li>• Creatine Kinase</li><li>• Gamma-Glutamyl Transferase</li><li>• Lactate Dehydrogenase</li><li>• Lipase</li></ul> |
| Clinical chemistry | Substrates                     | <ul style="list-style-type: none"><li>• Albumin</li><li>• Bilirubin</li><li>• Urea/blood urea nitrogen</li><li>• Cholesterol</li><li>• Creatinine</li><li>• Glucose</li></ul>                              |
| Clinical chemistry | Electrolytes<br>Reagents       | <ul style="list-style-type: none"><li>• Ammonia</li><li>• Bicarbonate</li><li>• Calcium</li><li>• Chloride</li></ul>                                                                                       |



| Methodology        | Cluster Category (Closed list)  | Examples of analytes                                                                                                                                                                                                                            |
|--------------------|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    |                                 | <ul style="list-style-type: none"><li>• Magnesium</li><li>• Phosphate inorganic/phosphorus</li></ul>                                                                                                                                            |
| Clinical chemistry | Electrolyte Electrodes          | <ul style="list-style-type: none"><li>• Ammonia electrodes</li><li>• Carbon dioxide (bicarbonate) electrodes</li><li>• Calcium electrodes</li><li>• Chloride electrodes</li><li>• Magnesium electrodes</li><li>• Potassium electrodes</li></ul> |
| Clinical chemistry | Substrate electrodes/biosensors | <ul style="list-style-type: none"><li>• Creatinine Electrodes</li><li>• Glucose Electrodes</li><li>• Glycated Hemoglobin Electrodes</li><li>• Lactate Electrodes</li><li>• Urea Electrodes</li><li>• Bilirubin Electrodes</li></ul>             |
| Immunochemistry    | Immunoglobulins (without IgE)   | <ul style="list-style-type: none"><li>• Immunoglobulin A</li><li>• Immunoglobulin D</li><li>• Immunoglobulin G</li><li>• Immunoglobulin M</li><li>• Immunofixation kits</li></ul>                                                               |
| Immunochemistry    | Complement components           | <ul style="list-style-type: none"><li>• Complement component C1q</li><li>• Complement component C1 inactivator</li><li>• Complement component C3/C3c</li></ul>                                                                                  |



| Methodology     | Cluster Category (Closed list) | Examples of analytes                                                                                                                                                                          |
|-----------------|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                 |                                | <ul style="list-style-type: none"><li>• Complement component Bb</li><li>• Complement component C4</li><li>• Complement component C5a</li></ul>                                                |
| Immunochemistry | Transport proteins             | <ul style="list-style-type: none"><li>• Albumin</li><li>• Ceruloplasmin</li><li>• Haptoglobin</li><li>• Hemopixin</li><li>• Lactoferrin</li><li>• Pre-albumin/Transthyretin</li></ul>         |
| Immunochemistry | Lipoproteins                   | <ul style="list-style-type: none"><li>• Apolipoprotein A I</li><li>• Apolipoprotein A II</li><li>• Apolipoprotein B</li><li>• Apolipoprotein E Sub-typing</li><li>• Lipoprotein (a)</li></ul> |
| Immunochemistry | Other Specific Proteins        | <ul style="list-style-type: none"><li>• a1-Acid Glycoprotein</li><li>• a1-Antitrypsin</li><li>• a1- Microglobulin</li><li>• Fribonectin</li><li>• Immuno Reactive Trypsin</li></ul>           |
| Immunochemistry | Allergy                        | <ul style="list-style-type: none"><li>• Immunoglobuin E - Total</li><li>• Immunoglobulin E - Screen</li></ul>                                                                                 |



| Methodology     | Cluster Category (Closed list)         | Examples of analytes                                                                                                                                                                                           |
|-----------------|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                 |                                        | <ul style="list-style-type: none"><li>• Immunoglobulin E - Specific, monotest/monoresult</li><li>• Allergen specific IgA</li><li>• Allergen specific IgG</li></ul>                                             |
| Immunochemistry | Cancer markers                         | <ul style="list-style-type: none"><li>• G1- marker CA242</li><li>• p53</li></ul>                                                                                                                               |
| Immunochemistry | Thyroid function markers               | <ul style="list-style-type: none"><li>• Free triiodothyronine</li><li>• Free thyroxine</li><li>• Thyroid stimulating hormone</li><li>• T-uptake</li><li>• Thyroglobulin</li><li>• Neonatal thyroxine</li></ul> |
| Immunochemistry | Fertility/Pregnancy Hormones/ Proteins | <ul style="list-style-type: none"><li>• Androstenedione</li><li>• Estradiol</li><li>• Prolactin</li><li>• Human Placental Lactogen</li><li>• Estriol</li></ul>                                                 |
| Immunochemistry | Diabetes assays (hormones)             | <ul style="list-style-type: none"><li>• C-peptide</li><li>• Glucagon</li><li>• Insulin</li><li>• Glycosylated/glycated haemoglobin</li><li>• Islet Cell Ab</li><li>• Proinsulin</li></ul>                      |
| Immunochemistry | Renal metabolism assays                | <ul style="list-style-type: none"><li>• Aldosterone</li></ul>                                                                                                                                                  |



| Methodology     | Cluster Category (Closed list)     | Examples of analytes                                                                                                                                                                                                                                               |
|-----------------|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                 |                                    | <ul style="list-style-type: none"><li>• Angiotensin I/II</li><li>• Angiotensin converting enzyme</li><li>• Cortisol</li><li>• Renine</li></ul>                                                                                                                     |
| Immunochemistry | Bone and mineral metabolism assays | <ul style="list-style-type: none"><li>• Bone alkaline phosphatase</li><li>• Calcitonin</li><li>• Cross-linked C-Telopeptides</li><li>• Cross-linked N-Telopeptides</li><li>• Cyclic adenosin monophosphate</li><li>• Hydroxyproline</li></ul>                      |
| Immunochemistry | Endocrine hormones and peptides    | <ul style="list-style-type: none"><li>• Adrenocorticotrophic Hormone</li><li>• Human Growth Hormone</li><li>• Insulin-like Growth Factor I</li><li>• Insulin-like Growth Factor Binding Protein 1</li><li>• Vasointestinal Peptide</li><li>• Vasopressin</li></ul> |
| Immunochemistry | Neuroendocrine Function Assays     | <ul style="list-style-type: none"><li>• Bombesin</li><li>• 17-Hydroxy-Ketosterone</li><li>• <math>\beta</math>-Endorphin</li><li>• Neurotensin</li></ul>                                                                                                           |



| Methodology     | Cluster Category (Closed list)          | Examples of analytes                                                                                                                                                                                              |
|-----------------|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                 |                                         | <ul style="list-style-type: none"><li>• Somatostatin</li><li>• Substance P</li></ul>                                                                                                                              |
| Immunochemistry | Other individual and specified hormones | <ul style="list-style-type: none"><li>• Gastrin</li><li>• Gonadotropin-releasing hormone</li><li>• Melatonin</li><li>• Pepsinogen</li><li>• Adrenalin</li><li>• Dopamine</li></ul>                                |
| Immunochemistry | Anaemia                                 | <ul style="list-style-type: none"><li>• Erythropoietin</li><li>• Ferritin</li><li>• Folate</li><li>• Iron</li><li>• Iron binding capacity</li><li>• Soluble transferrin receptor</li></ul>                        |
| Immunochemistry | Vitamins                                | <ul style="list-style-type: none"><li>• Vitamin B1</li><li>• Vitamin B2</li><li>• Vitamin B6</li><li>• Vitamin B12</li><li>• Vitamin D (cholecalciferol)</li><li>• Intrinsic factor (blocking antibody)</li></ul> |
| Immunochemistry | Drug monitoring                         | <ul style="list-style-type: none"><li>• Caffeine</li><li>• Benzodiazepines</li><li>• Penicillins</li><li>• Tetracyclines</li></ul>                                                                                |



| Methodology     | Cluster Category (Closed list)            | Examples of analytes                                                                                                                                                                                                                                               |
|-----------------|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Immunochemistry | Toxicology                                | <ul style="list-style-type: none"><li>• Amphetamines</li><li>• Cocaine</li><li>• Morphine</li><li>• Phencyclidine</li><li>• Acetaminophen</li><li>• Catecholamines</li><li>• Ethanol</li><li>• Salicylate</li></ul>                                                |
| Immunochemistry | Auto-immune diseases                      | <ul style="list-style-type: none"><li>• Anti-nuclear antibodies (ANAs)</li><li>• Anti-topoisomerase</li><li>• Organ-specific autoantibodies</li><li>• Circulating Immuno-complex</li><li>• TSH Receptor antibodies</li><li>• Anti-Cardiolipin antibodies</li></ul> |
| Immunochemistry | Rheumatoid- Inflammatory diseases markers | <ul style="list-style-type: none"><li>• Anti-Streptococcal Hyaluronidase</li><li>• Anti-Streptokinase</li><li>• Anti-Streptolysin O</li><li>• C-Reactive Protein</li><li>• Anti-Staphylolysin</li><li>• Anti-Streptococcal Screening</li></ul>                     |
| Immunochemistry | Liver function                            | <ul style="list-style-type: none"><li>• MEGX</li><li>• Carbohydrate Deficient Transferrin</li></ul>                                                                                                                                                                |



| Methodology                                                            | Cluster Category (Closed list)   | Examples of analytes                                                                                                                                                                                                         |
|------------------------------------------------------------------------|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Immunochemistry                                                        | Cardiac markers                  | <ul style="list-style-type: none"><li>• Homocysteine</li><li>• ST2</li><li>• Galectin-3</li><li>• Myeloperoxidase (MPO)</li></ul>                                                                                            |
| Immunochemistry                                                        | Bacterial Infection - Immunology | <ul style="list-style-type: none"><li>• <i>Bacillus subtilis</i></li><li>• <i>Pseudomonas Aeruginosa</i></li><li>• <i>Helicobacter Pylori</i></li><li>• <i>Lactobacillus casei</i></li></ul>                                 |
| Immunochemistry                                                        | Viral infection - Immunology     | <ul style="list-style-type: none"><li>• Norovirus</li><li>• Rotavirus</li><li>• Hantavirus</li></ul>                                                                                                                         |
| Immunochemistry                                                        | Parasitic Infection - Immunology | <ul style="list-style-type: none"><li>• <i>Leishmania</i></li></ul>                                                                                                                                                          |
| Immunochemistry                                                        | Fungal Infection - Immunology    | <ul style="list-style-type: none"><li>• <i>Candida albicans</i></li><li>• <i>Aspergillus</i></li></ul>                                                                                                                       |
| Haematology/histology/cytology (blood tests for transfusions excluded) | Haemoglobin testing              | <ul style="list-style-type: none"><li>• Hemoglobin determinations (Total Hb)</li><li>• Fractional oxyhemoglobin (FO2Hb)</li><li>• Fractional carboxyhemoglobin (FCOHb)</li><li>• Fractional methemoglobin (FMetHb)</li></ul> |



| Methodology                                                            | Cluster Category (Closed list)           | Examples of analytes                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                        |                                          | <ul style="list-style-type: none"><li>• Fractional deoxyhemoglobin (FHHb)</li></ul>                                                                                                                                                                  |
| Haematology/histology/cytology (blood tests for transfusions excluded) | General coagulation tests                | <ul style="list-style-type: none"><li>• Prothrombin Time</li><li>• Thrombin Time</li><li>• Activated Clotting Time</li><li>• Activated Partial Thromboplastin Time</li></ul>                                                                         |
| Haematology/histology/cytology (blood tests for transfusions excluded) | Haemostasis (coagulation)                | <ul style="list-style-type: none"><li>• Fibrinogen</li><li>• Protein C and Protein S reagents</li><li>• C1-inhibitors</li><li>• Alpha-Antiplasmin</li><li>• Fibrin</li><li>• Factor XIII</li><li>• Platelet Factor 4</li><li>• Plasminogen</li></ul> |
| Haematology/histology/cytology (blood tests for transfusions excluded) | Other hematology tests                   | <ul style="list-style-type: none"><li>• Complete blood count</li><li>• Hematocrit</li><li>• Erythrocyte sedimentation rate</li></ul>                                                                                                                 |
| Haematology/histology/cytology (blood tests for transfusions excluded) | Cytokines (lymphokines)/immunomodulators | <ul style="list-style-type: none"><li>• Interferons</li><li>• Soluble antigens/receptors</li><li>• Tumor necrosis factors</li><li>• Colony stimulating factors</li><li>• Tumor necrosis factors receptors</li></ul>                                  |



| Methodology                                                            | Cluster Category (Closed list)                                                         | Examples of analytes                                                                                                                                                                                                                   |
|------------------------------------------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Haematology/histology/cytology (blood tests for transfusions excluded) | Histology/cytology reagents                                                            | <ul style="list-style-type: none"><li>• Cytochemical staining</li><li>• Embedding, fixing, mounting media</li><li>• Stain solutions</li><li>• Immunohistology kits</li></ul>                                                           |
| Microbiology culture                                                   | Culture media                                                                          | <ul style="list-style-type: none"><li>• Dehydrated culture media (DCM)</li><li>• Additives for DCM</li><li>• Prepared media (tubes, bottles, plates)</li><li>• Cells, media, serum for viral culture</li></ul>                         |
| Microbiology culture                                                   | Susceptibility testing (Testing the susceptibility of bacteria to certain antibiotics) | <ul style="list-style-type: none"><li>• Erythromycin susceptibility test for <i>Staphylococcus aureus</i></li><li>• Tobramycin susceptibility test for <i>Pseudomonas aeruginosa</i></li><li>• Fungal susceptibility testing</li></ul> |
| Microbiology culture                                                   | Biochemical culture Identification (ID)                                                | <ul style="list-style-type: none"><li>• Gram negative manual ID</li><li>• Gram positive manual ID</li><li>• Other ID kits manual - anaerobes, fastidious</li></ul>                                                                     |
| Microbiology culture                                                   | Immunological culture Identification (ID)                                              | <ul style="list-style-type: none"><li>• Streptococci grouping slide tests</li><li>• Serotyping (Shigella etc.)</li></ul>                                                                                                               |



| Methodology          | Cluster Category (Closed list)                      | Examples of analytes                                                                                                 |
|----------------------|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| Microbiology culture | Nucleic Acid (NA) based culture identification (ID) | <ul style="list-style-type: none"><li>• Streptococci</li><li>• Shigella</li></ul>                                    |
| Microbiology culture | Serological identification (ID)                     | For Parasitology and Mycology (Fungi and Yeast)                                                                      |
| Microbiology culture | Bacterial Infections (detection by NA reagents)     | <ul style="list-style-type: none"><li>• Streptococci</li><li>• Shigella</li></ul>                                    |
| Microbiology culture | Viral infections (detection by NA reagents)         | Para-influenza NA reagents                                                                                           |
| Microbiology culture | Fungal infections                                   | <ul style="list-style-type: none"><li>• Fungi NA reagents</li><li>• Candida albicans</li><li>• Aspergillus</li></ul> |