Republic of the Philippines
Department of Health

OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. _____

SUBJECT: **Rules and Regulations Governing the Issuance of an Authorization for an In Vitro Diagnostic Medical Device (IVD)**

I. RATIONALE / BACKGROUND

Republic Act (RA) No. 9711 otherwise known as the "Food and Drug Administration (FDA) Act of 2009" and its Implementing Rules and Regulations declare that it is the policy of the state to insure the safety, efficacy and quality of health products including IVDs in the country so as to protect the health of the Filipino people.

The signing of the ASEAN Medical Device Directive (AMDD) in 2014 mandated the Philippines to implement the following provisions to a) require the person responsible for placing the IVD in that Member State or the authorized representative to register the IVD with the regulatory authority of that Member State; b) undertake all necessary measures to ensure that only IVD which conform to the AMDD may be placed on markets of that Member State; and c) put in place an appropriate system for the registration of IVD with the Regulatory Authority of that Member State.

The Department of Health through the FDA – Center for Device Regulation, Radiation Health and Research (CDRRHR) hereby adopts, issues and implement the AMDD guidelines on the issuance registration of IVDs and to provide the regulatory requirements and registration process for these products.

II. OBJECTIVE

This Administrative Order (AO) aims to specify the rules, guidelines, procedures and requirements of the FDA-CDRRHR relative to the registration of IVDs.

III. SCOPE

This AO shall cover all IVDs and shall apply to all manufacturers, traders and distributors (e.g. importers, exporters and wholesalers) of IVD in the Philippines.

IV. DEFINITION OF TERMS

The terms used in this AO are defined in Annex A.

V. GENERAL GUIDELINES

A. All establishments that intend to place IVDs in the Philippine market are required to secure a License to Operate (LTO) as medical device distributor/importer, distributor/exporter, distributor/wholesaler, manufacturer, or trader (whichever is applicable) prior to securing a Certificate of IVD Registration (CIVDR). Research institutions; educational institutions; and donors, organizations or persons involved in donations, medical missions and other humanitarian activities are exempted from LTO requirements.

B. **IVD for Commercial Distribution**

1. The establishment shall apply for CIVDR for the following classifications of IVDs:

Class	Level
A	Low Individual Risk and Low Public Health Risk
B	Moderate Individual Risk and/or Low Public Health Risk
C	High Individual Risk and/or Moderate Public Health Risk
D	High Individual Risk and High Public Health Risk

2. Compliance with FDA legal and technical requirements shall be required for approval of CIVDR applications. Favorable performance validation/technical review results shall also be required for the issuance of a CIVDR if the IVD involved in the CIVDR application is required to undergo performance validation or technical review by the FDA-Common Services Laboratory (CSL), National Reference Laboratory (NRL) or any FDA-accredited /recognized labortory.

   The performance validation or technical review to be conducted on Class B, C and D IVDs shall be based on the updated list of IVDs that require performance validation or technical review issued by the FDA.

3. The CIVDR shall be issued by the FDA through the FDA-CDRRHR if the application is found to be meritorious; otherwise, the application shall be considered disapproved.

4. The registration number shall be issued to the IVD with approved CIVDR.

5. For registered IVD whose marketing authorization holder (MAH) has post approval commitment/s (PAC), the PAC shall be indicated at the back of the CIVDR.

6. The applicant shall classify the IVD based on the risk classification rules for IVD in Annex 3 of the AMDD. The FDA-CDRRHR shall verify the classification made by the applicant and shall reclassify the device as deemed appropriate or when the level of risk is changed by a certain incident in the manufacture, distribution or use of the IVD upon proper consultation with the advisory committee set forth by the Philippine FDA and/or the ASEAN.

7. Application for CIVDR for Class B, C or D IVD shall be endorsed to FDA-CSL, NRL or other FDA-accredited/recognized laboratory for performance validation or technical review if the IVD involved is required to undergo performance validation or technical review, regardless of any deficiency found during the review of the documents. Guidelines on the endorsement of application and the responsibilities of the applicant and of the NRL regarding the performance validation or technical review of IVDs shall be covered by a separate FDA Circular.

8. NRL shall inform and update FDA regarding its capability to conduct performance validation or technical review of IVD. FDA shall issue updated list of IVDs that need to undergo performance validation or technical review prior to registration.

9. The CIVDR shall be valid for five (5) years and may be renewed every five (5) years after initial approval.

10. The CIVDR shall remain valid as long as there is no change in the composition, labeling, intended use, process, components, procedure and platform of the IVD.

11. The validity of the CIVDR is independent of the validity of the result of performance validation or technical review set by the concerned NRL. The validity of the result of the performance validation or technical review shall be reflected at the back of the CIVDR.

C. **Government Internationally Procured IVDs**

Government internationally procured IVDs shall be registered with the FDA. The documentary requirements are specified in Annex G.

D. **Donated Brand New IVD**

Donated brand new IVD shall be registered with the FDA. The documentary requirements are specified in Annex H.

E. **Research Use Only (RUO) IVD**

Importers of RUO IVD shall secure a Certificate of IVD Listing (CIVDL) from the FDA prior to importation of the product. The documentary requirements are specified in Annex I.

F. **IVDs that are Not Intended for Commercial Distribution**

CIVDL shall be secured from the FDA for the following IVDs that are not intended for commercial distribution within the Philippines:

1. IVD for research or clinical performance study
2. IVD for educational use
3. IVD for exhibit
4. Samples for performance validation or technical review

The documentary requirements are specified in Annex J. For imported IVD, the filing of application for the CIVDL shall be made prior to the importation of the product by

the concerned entity (donor, sponsor, research institution, company, individual, government agency, etc.).

G. **Imported IVD for Personal Use**

Importation of IVD for personal use shall follow the relevant provisions of the Department of Health – Food and Drug Administration – Bureau of Customs Joint Circular No. 1 entitled "Importation of FDA-DOH Regulated Products for Personal Use" or its subsequent amendment/s.

H. All IVDs shall follow the existing labelling requirements of the FDA on medical devices.

I. Reagents, reagent products, calibrators, control materials, kits, instruments, apparatuses, equipment, systems, or software which are manufactured, sold or represented by manufacturers as not for use in in-vitro diagnostic application and general laboratory use purposes shall not be classified as IVD.

J. This AO shall be reviewed by the FDA within five (5) years from this AO's effectivity.

VI. SPECIFIC GUIDELINES

A. The applicant shall follow the latest FDA policy/guidelines on the submission of application.

B. Receiving, processing and evaluation of application for initial and renewal of CIVDR shall be covered by a separate FDA Circular.

C. The applicant shall submit the following requirements specified in the following Annexes:
   1. Annex B - Legal Requirements for Application for the Registration of All Classifications of IVDs for Commercial Distribution
   2. Annex C - Technical Requirements for Application for the Registration of Class A IVD for Commercial Distribution
   3. Annex D - Technical Requirements for the Initial Registration of Class B, C, and D IVD for Commercial Distribution
   4. Annex F - Requirements for the Renewal of Registration of All Classifications of IVDs for Commercial Distribution
   5. Annex G - Requirements for Application for the Registration of Government Internationally Procured IVDs
   6. Annex H - Requirements for Application for the Registration of Donated Brand New IVD
   7. Annex I - Requirements for Application for CIVDL for Research Use Only IVD
   8. Annex J – Requirements for Application for CIVDL for IVDs that are Not Intended for Commercial Distribution

   The summary list of legal and technical requirements for the initial registration of Class B, C and D IVD can be found in Annex E.

D. An application for CIVDR shall be filed separately per specific IVD. The FDA-CDRRHR reserves the right to ask for additional documents not indicated in this AO in case the need for such additional documents or clarification/s arises. All documents shall be submitted in English language. Documents submitted in any other language or dialect and are not accompanied by an English translation shall be disapproved.

E. **Renewal of CIVDR**

1. The establishment may apply for renewal six (6) months before the expiration date of the CIVDR.
2. There shall be automatic renewal of CIVDR when the following conditions are satisfied:
    a. The application is filed before the expiration date of registration or notification;
    b. The prescribed renewal fee is paid upon filing of the application
    c. A sworn statement indicating no change or variation whatsoever in the product is attached to the application; and
    d. The following documents are submitted together with the application:
        i. Copy of Letter of Authorization. For imported IVD, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
        ii. A government - issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported IVD, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
        iii. Clear and complete colored pictures of actual commercial label from all sides of the packaging.

3. CIVDR with the following conditions shall be subjected to regular renewal process:
    a. CIVDR with variation approval
    b. CIVDR with post approval commitment/s (PAC) (e.g. submission of real time ageing stability study during renewal)
    c. CIVDR with expired validity of performance validation or technical review result
    d. CIVDR with late filing of renewal within one hundred twenty (120) days after its expiration

4. Late Filing for Renewal of CIVDR
    a. Applications for renewal of CIVDR filed after the validity date shall be fined with the corresponding penalty in accordance with the existing rules and regulations on fees and charges.
    b. An application for renewal of CIVDR filed after one hundred twenty (120) calendar days after its expiration shall not be accepted and shall be considered an initial application. The distribution and sale of that IVD shall automatically stop until such time that the CIVDR has been approved. The applicant can opt, however, to request the retention of the product registration number.

F. **Variation of CIVDR**

For registered IVD that will undergo administrative or tehcnical modification, the MAH shall apply for variation of the issued CIVDR. Guidelines for variation of CIVDR shall be covered by a separate FDA Circular.

VII. FEES AND CHARGES

Payment of initial and renewal application fees and other charges (surcharges, penalties, legal research fund fees, etc.) shall be collected as may be allowed subject to the existing rules and regulations of the FDA on fees and charges such as Department of Health Administrative Order No. 50 s. 2001 entitled "Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs", FDA Circular No. 2011-003 or the "Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further amended by PD 1856" and/or their subsequent amendments.

Fee for the performance validation of IVDs to be conducted by the FDA-CSL shall be paid together with the registration fee at the FDA; whereas fee for the performance validation or technical review of IVDs to be conducted by the NRL shall be paid directly to the NRL.

VIII. GROUNDS FOR DISAPPROVAL OF APPLICATION, CANCELLATION, REVOCATION AND/OR NON-RENEWAL OF CIVDR

In addition to the provisions of R.A. 9711 and its Implementing Rules and Regulations, the following are the grounds for disapproval of application, cancellation, revocation and/or non-renewal of CIVDR:

A. Failure to pass/meet the performance validation or technical review conducted by the FDA-CSL, NRL or FDA-accredited/recognized laboratory for Classes B, C and D IVDs;

B. Non - coordination with the FDA-CSL, NRL or FDA-accredited/recognized laboratory for Classes B, C and D IVDs six (6) months after endorsement for product performance validation/technical review. Evidence of non-coordination shall include non-compliance of the applicant with any of the following requirements of the NRL after receipt of the letter from the CDRRHR:
   1. submission of technical requirements;
   2. submission of samples for performance validation/technical review; and
   3. payment of fees

   Evidence of non-coordination shall also include list of applicants that did not coordinate with the testing laboratory submitted by the NRL to FDA-CDRRHR.

C. The manufacture, distribution, sale, offering for sale or transfer of IVD that does not meet all the requirements of safety, quality and effectiveness;

D. Misrepresentation or concealment of significant data or information about the product sought to be registered;

E. Alteration, mutilation, destruction, obliteration or removal of any part of the IVD and labeling;

F. IVD that has a biological, chemical or physical property that may cause an unacceptable health risk;

G. Submission of falsified document(s); and/or

H. Alteration or falsification of issued CIVDR.

IX. PENALTY CLAUSE

Any violation of this AO consistent with RA No. 3720 and RA No. 9711 and its Implementing Rules and Regulations shall be a ground for filing appropriate administrative charges and/or imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation or revocation of any license, permit or registration issued by FDA.

X. REPEALING CLAUSE

Section B of FDA Memorandum Circular No. 2014-005 entitled "Updated List of Medical Devices required to be registered prior to sale, distribution and use"; FDA Memorandum No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19"; and Sections III Items B, C, and the first paragraph of Item D of FDA Memorandum No. 2021-009 entitled "Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection" are hereby repealed. Administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provisions of this Order are hereby repealed or modified accordingly.

XI. SEPARABILITY CLAUSE

In the event that any provision or portion of this Order is declared unauthorized or rendered invalid by any court of law, those provisions not affected by such declaration shall remain valid and effective.

XII. TRANSITORY PROVISIONS

A. Upon effectivity of this AO, IVDs that are included in FDA Memorandum Circular No. 2014-005, COVID-19 test kits and monkeypox test kits shall be registered with the FDA in accordance with this AO.

B. Class A IVDs other than blood collection tube and those that are not included in FDA Memorandum Circular No. 2014-005 shall be allowed to be manufactured, imported, exported, distributed, transferred, sold or offered for sale within two (2) years without CIVDR from the effectivity of this AO. The LTO of the medical device establishment shall be provided at the point of entry and/or part of bidding requirements.

During the transition period (within 2 years after the effectivity of this AO), companies may apply for voluntary registration of such Class A IVDs.

C. Class B, C and D IVDs other than COVID-19 test kits and those that are not included FDA Memorandum Circular No. 2014-005 shall be allowed to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without CIVDR within three (3) years after the effectivity of this AO. The LTO of the medical device establishment shall be provided at the point of entry and/or part of bidding requirements.

During the transition period (within 3 years after the effectivity of this AO), companies may apply for voluntary registration of such Class B, C and D IVDs.

D. Certificate of Product Registration (CPR) issued to collection tubes and IVDs that are included in FDA Memorandum Circular No. 2014-005 prior to the effecticvity of this AO shall remain valid until its expiry. Six (6) months prior to the expiration of the CPR, the MAH may apply for the renewal of the CPR based on the requirements specified under Annex F. In addition to the requirements in Annex F, the MAH shall submit the requirement/s below for the following IVDs when applying for the renewal of the CPR:

1. Collection tube : Declaration of Conformity (self declaration by the manufacturer) with product standards, if applicable
2. Moneypox test kits and other IVDs that are included in FDA Memorandum Circular No. 2014-005
   a. Executive Summary (Refer to Item A of Annex D for the details)
   b. Essential Principle Checklist (Refer to Item B of Annex D for the details)
   c. Declaration of Conformity (self declaration by the manufacturer) with product standards, if applicable

While the CIVDR is on process, the MAH may continue to manufacture, import, export, distribute and/or sell the product. The issued CPR and proof application for CIVDR shall be provided at the point of entry and/or part of bidding requirements.

E. Special Certification for COVID-19 test kits issued prior to the effectivity of this AO shall remain valid until its expiry. Six (6) months prior to the expiration of the Special Certification, the company may apply for a CIVDR based on the requirements specified in Annex B and Annex D of this AO. While the CIVDR is on process, the MAH may continue to manufacture, import, export, distribute and/or sell the product. The issued Special Certification and proof of application for CIVDR shall be provided at the point of entry and/or part of bidding requirements.

F. COVID-19 test kits with pending application for Special Certification prior to the effectivity of this AO shall continue to the processed by the FDA-CDRRHR based on the requirements in FDA Memorandum Circular No. 2020-006 and FDA Circular No. 2021-009. Six (6) months prior to the expiration of the issued Special Certification, the company may apply for a CIVDR based on the requirements specified in Annex B and Annex D of this AO. While the CIVDR is on process, the MAH may continue to manufacture, import, export, distribute and/or sell the product. The issued Special Certification and proof of application for CIVDR shall be provided at the point of entry and/or part of bidding requirements.

G. IVDs with pending application for registration prior to the effectivity of this AO shall continue to be processed by the FDA-CDRRHR based on the previous requirements. Renewal of the the issued CPR shall follow the requirements provided in Section XII (D) of this Order.

XIII. EFFECTIVITY

This Order shall take effect fifteen (15) days from the date of its publication in the Official Gazette or in any national newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register.

MARIA ROSARIO S. VERGEIRE, MD, MPH, CESO II
Officer-in-Charge
Department of Health

ANNEX A

Definition of Terms

A. **Applicant** - refers to any individual, partnership, corporation, association, and/or organization either a manufacturer, trader, distributor, importer, exporter applying for an authorization.

B. **ASEAN Medical Device Directive (AMDD)** - refers to the agreement of ASEAN Member States harmonizing the regulation of medical device.

C. **Authorization** - means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution transfer, and/or where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption or any similar document.

D. **Certificate of IVD Registration (CIVDR)** - refers to the authorization issued to an IVD that comply with all the requirements for registration.

E. **Clinical performance of an IVD** – refers to the ability of an IVD to yield results that are correlated with a particular condition/physiological state in accordance with target population and intended user

F. **Clinical performance study** – refers to study undertaken to establish or confirm the clinical performance of an IVD.

G. **Detailed information** - refers to the complete study protocol, method of analysis, study report, and study conclusion

H. **Distributor/importer/exporter** - means any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets.

I. **Distributor/wholesaler** - means any establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on a wholesale basis.

J. **Establishment** - means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of IVD including the facilities and installation needed for its activities.

K. **Instruction for use** (IFU)– refers to all the necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for safe use of the IVD, instructions needed to use the IVD in a safe manner shall, to the extent possible, be included on the IVD itself and/or its packaging by other formats/forms. This is the detailed instruction for use

for the users of the medical device. The instruction should be clear enough to guide its users.

L. **Intended use** - refers to the use for which the IVD is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the IVD.

M. **In-Vitro Diagnostic Medical Device (IVD)** - refers to any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donation, derived from the human body, solely or principally for the purpose of providing information:

1. concerning a physiological or pathological state;
2. concerning a congenital abnormality;
3. to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients; or
4. to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its product owner to be used for in vitro diagnostic examination.

N. **IVDs for Commercial Distribution –** refers to IVDs that are intended for sale to clinical laboratories, hospitals, pharmacies and/or medical device retailers to be used for or by patients for in vitro diagnostic purposes.

O. **Label –** refers to a written, printed or graphic information provided upon the IVD itself. It includes information provided on the packaging of each unit or on the packaging of multiple medical devices.

P. **Labelling** – refers to the label**,** instructions for use, and/or any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.

Q. **Legal manufacturer** – refers to the product owner or any foreign medical device establishment with responsibility for the design, manufacture, packaging and labeling of a medical device before it is placed in the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

R. **License to Operate (LTO)** - refers to the authorization issued by the FDA to a person or establishment to operate as a manufacturer, trader, distributor/ importer/ exporter/ wholesaler of IVD.

S. **Manufacturer** - means an establishment engaged in any and all operations involved in the production of IVD including preparation, processing, compounding, formulating, filling, packing, re-packing, altering, ornamenting, finishing, and labeling with the end view of its storage, sale or distribution.

T. **Marketing Authorization Holder (MAH)** - refers to the medical device company, corporate or legal entity in whose name the CPR/CIVDR for an IVD has been granted. The MAH is responsible for all aspects of the product, including quality and

compliance with the conditions of the issued CPR/CIVDR. The MAH may be a manufacturer, trader, or distributor (exporter, importer or wholesaler) of IVDs.

U. **National Reference Laboratory (NRL)** - refers to the agency/laboratory in the Philippines mandated to conduct performance validation of the IVD. The list of the host hospitals and testing laboratories with their designated NRLs is found in Annex J.

V. **Physical manufacturer -** in relation to a medical device, means any person who performs the activity of manufacture.

W. **Post Approval Commitment** – refers to the commitment/s or obligation/s of the MAH specified in the issued CIVDR that shall be submitted to FDA during renewal application.

X. **Performance validation** - refers to the tests being done by the appropriate NRL on the IVD to verify compliance with the set test criteria or the data submitted by the applicant for the purpose of FDA registration.

Y. **Research Use Only (RUO) IVD** - refers to IVD/s that is/are sold to institutions/laboratories to be subject to studies intended for collation of data only. The product is not intendedfor any medical purpose or objective.

Z. **Technical review** – refers to the documentary review of the technical requirements conducted by the NRL to verify compliance of the IVD with the NRL set of requirements.

AA. **Person** – refers to a natural person or a legal entity including a corporation, a partnership or association duly established pursuant to the prevailing laws and regulations of the Philippines.

BB. **Product owner -** refers to any person who supplies the IVD under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the IVD, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

CC. **Product standard** - refers to in-vitro standard set, formulated, and or/established by the following:

1. Department of Trade and Industry - Bureau of Philippine Standards (Philippine National Standard)
2. International Standardization Organization (ISO)
3. International Electrochemical Commission (IEC)
4. Other International Standard Body or any foreign standards which may be accepted by FDA for the purpose of authorization.

DD. **Reagent** - refers to any chemical, biological or immunological components, solutions or preparations intended by the product owner to be used as IVD.

EE. **Registration** - means the process of approval of an application to register an IVD prior to engaging in the manufacture, importation, exportation, sale, offer for sale,

distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of an IVD.

FF. **Safety** - means that the product will not impose any danger, injury, damage or undesirable effect to a person.

GG. **Self-testing** – refers to testing performed by lay persons.

HH. **Summary information** - refers to the brief description of the study protocols, results with acceptance/ standard criteria used and conclusion

II. **Trader** - means any establishment which is registered owner of a health product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.

JJ. **Warning** – refers to the specific hazard alert information that a user needs to know before using the IVD.

ANNEX B

Legal Requirements for Application for the Registration of All Classifications of IVD for Commercial Distribution

A. Notarized Application Form
- Shall be completely filled-out
- Model / reference number / sizes / codes must be properly identified
- Refrain from indicating the brand name (if applicable) on the name of the product and vice versa
- For kits/sets, identify the complete contents/inclusions on the space provided for IVD name
- For multiple models / reference number / size / codes, an annex page may be attached
- For multiple models / reference number / size / codes; a Word copy must be submitted
- Shall be signed by the proper authority as indicated on the form
- Re-used/Altered forms is not acceptable since this is a legal document

B. Payment

C. Copy of Letter of Authorization. For imported IVD, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
- Shall be valid
- The product being applied shall be indicated.
- For imported IVD but the agreements are signed by both the principal and importer in the Philippines, it shall be notarized locally, with passport and record of arrival and departure of the principal to and from the Philippines.
- For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a re-issued agreement/authorization shall be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect.
- For locally manufactured IVD with exclusive distributors, the agreement shall be duly notarized. For locally manufactured IVD with toll manufacturer, agreement between the trader and the manufacturer shall be duly notarized.

D. A government issued certificate attesting to the status of the manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported IVD, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.

E. For imported IVD, the CIVDR or any equivalent document attesting to the safety, quality and effectiveness of the IVD issued by the National Regulatory Agency or accredited notified body in the country of origin. The copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
- Shall be valid
- For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from.
- The product being applied shall be indicated in the scope.

F. Colored picture of the device from all sides. However, the FDA-CDRRHR can require a representative sample or commercial presentation for verification purposes.

ANNEX C

Technical Requirements for Application for the Registration of Class A IVD for Commercial Distribution

A. Device description consisting of the following:
   1. Intended use
   2. Instruction for use
   3. List of all raw materials
   4. Technical specification of the finished product
   5. List of references codes, sizes, colors, models and variance, whichever is applicable.

B. Certificate of Conformity (issued by government agency dealing with metrology) on the aspect of manufacture relating to metrology for devices with measuring functions, if applicable

C. Declaration of Conformity (self declaration by the manufacturer) with product standards, if applicable

D. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging

E. Declaration of shelf life

ANNEX D

Technical Requirements for the Registration of CLASS B, C, and D IVD for Commercial Distribution

A. EXECUTIVE SUMMARY

1. Overview
   a. Introductory descriptive information on the medical device, the intended use and indications for use of the device.
   b. Information on the use of the device, if any, such as targeted patient population, user profile (e.g. specific trained users), specific disease status or clinical condition (e.g. monitoring of a disease), assay principle (e.g. immunoassay) etc.
   c. If the medical device has any unique or novel feature or characteristic (e.g. nanotechnology), a description must be provided.
   d. Any high-level background information or details that the product owner wishes to highlight in relation to the device, its history or relation to other approved devices (e.g. predicate devices) or previous submissions (provides context to submission).
   e. Risk classification of the device and the rule it is based on as listed in Annex 3 of the AMDD
2. Commercial Marketing History
   a. List of countries where the medical device is marketed.
   b. Date and country where the device was first introduced for commercial distribution, globally.
3. List of Regulatory Approval
   a. Registration status (i.e. submitted, not submitted, pending approval, rejected or withdrawn), registration certificate number and approved intended use and indications of the medical device, in a tabular format. If device is withdrawn/ rejected by any reference agencies, reason for rejection or withdrawal shall be provided.
4. Important Safety and Performance Related Information
   a. To include a summary of reportable adverse events (AEs) and field safety corrective actions (FSCAs) for the medical device since its first introduction on the global market, in a tabular format.

B. ESSENTIAL PRINCIPLES CHECKLIST

1. Include in the dossier an Essential Principles checklist in the form of a table that lists:
   a. The Essential Principles of Safety and Performance of Medical Devices applicable to IVDs (See Annex 1 of ASEAN Medical Device Directive).
   b. Whether each Essential Principle applies to the IVD and if not, provide a justification as to why not.
   c. The method used to demonstrate conformity with each Essential Principle that applies, as well as the reference for the method used.
   d. A reference for the manufacturer's actual technical documentation that provides evidence of conformity with each method used.
   e. Where that technical documentation is located, both within the full technical documentation held by the manufacturer (e.g., the names of documents) and within the dossier (when such documentation is specifically required for inclusion in the dossier as outlined in this instructions).

C. DEVICE DESCRIPTION

1. The intended use of the diagnostic.
    a. What the product detects.
    b. The function of the product (e.g., screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease).
    c. The specific disorder, condition or risk factor of interest that the product is intended to detect, define or differentiate.
    d. Whether the product is automated or manually operated.
    e. Whether the test is qualitative or quantitative.
    f. The type of specimen(s) required (e.g. serum, plasma, whole blood, sputum, urine, etc.).
2. The intended testing population (e.g. neonates, antenatal women, symptomatic individuals, etc.).
3. The intended user (laboratory professional and/or health care worker at point-of-care).
4. The intended setting of use (laboratory, point-of-care).
5. A general description of the principle of the assay method or instrument principles of operation.
6. A description of the components of the assay (e.g., reagents, assay controls and calibrators), and, where appropriate, a description of the reactive ingredients of relevant components (e.g., antibodies, antigens, nucleic acid primers).
7. A description of the specimen collection and transport materials are provided with the product or descriptions of specifications recommended for use.
8. For instruments of automated assays: a description of the appropriate assay characteristics or dedicated assays.
9. For automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation.
10. If applicable, a description of any software to be used with the product.
11. If applicable, a description or complete list of the various configurations/variants of product that will be made available.
12. If applicable, a description of the accessories, and other products that are intended to be used in combination with the diagnostic.
13. Where safety and effectiveness data of similar or previous generation devices are used in the current submission, the following information is to be provided:
    a. A list of such devices and specific information on the registration status of these devices are to be included (e.g. Registration number).
    b. A comparison, preferably in a table, of the design, specifications and intended use/indications for use between the subject device in the current submission and the comparator devices (similar and/or previous generation). To include labelled pictorial representation (diagrams, photos, drawings) where necessary
14. Materials
    a. For each of the ingredients, provide formulation/composition information. For example, include information such as nucleic acid sequences for primers, ingredient lists for buffers, amino acid sequence details for recombinant proteins, etc.
    b. Identify the sources of the materials from which the IVD components are constructed.
    c. Provide a table or list of all biological components included in the product under assessment. This should include material of bacterial, viral, parasitic, animal, or

human origin, such as plasma, cells, tissues, or their derivatives. The table or list should include:
   i. the name of the biological component
   ii. details of the use of the biological component in the product
   iii. a description of steps taken for the reduction of transmission or infection risk
15. Declaration from the legal manufacturer and/or importer and/or distributor for the following:
   a. Storage conditions
   b. Shelf life
   c. Packaging material
   d. Commercial presentation (i.e. kit contents, No. of tests/package)
   e. Suggested retail price

D. SUMMARY OF DESIGN VERIFICATION AND VALIDATION DOCUMENTS

For each study to be submitted, the following must be provided:

1. Study description, study identifier, product identifier (for example, lot numbers), IFU version used, the date of initiation and the date of completion
2. A summary of the study findings including a conclusion that clarifies how the study objectives have been met
3. The study protocol and full report, which incorporates at a minimum, the following information:
   a. study objectives, study design, the methodology used and data collected
   b. the site where the study was performed (for example, Manufacturers R&D laboratory, hospital laboratory, health care clinic)
   c. operator of the assay
   d. the reference standard, if applicable
   e. specimen acceptance criteria, specimen characterization
   f. specimen type (serum, plasma, finger stick whole blood, venous whole blood) and numbers of each type
   g. actual test result summaries with their acceptance criteria and not just pass/fail statements
   h. all data is clearly labeled, and clearly linked to the study report
   i. details of statistical methods, estimations and calculations applied
   j. the study conclusion
   k. when performed by a party other than the manufacturer, details of this party and the relationship to the manufacturer
4. If using other brand name
   a. Analytical studies
      i. Specimen type
         (1) Detailed information for each matrix and anticoagulant, when applicable
         (2) Provide studies and information supporting the use of each specimen type (and where applicable, anticoagulant).
         (3) Provide studies and information in support of stability claims, storage claims and, where applicable, claims for transport conditions for each applicable specimen type, including:
            (a) Duration
            (b) Temperatures
            (c) Number of allowable freeze/thaw cycles
            (d) Specimen stability claims

ii. Analytical performance characteristics
(1) Accuracy of measurement
(a) Trueness of measurement
(b) Precision of measurement
(i) Repeatability
For products to be used at point-of-care, where the testing may be undertaken by non-laboratory trained personnel (for example, clinic nurses), repeatability should be established in two steps, first, with professional laboratory personnel to establish the optimal repeatability of the IVD under controlled laboratory conditions then followed by a consumer field evaluation to determine the product's performance when used by non-laboratory trained personnel, unassisted, following instructions provided with the product.
(ii) Reproducibility
For products to be used at point-of-care, where the testing may be undertaken by non-laboratory trained personnel (for example, clinic nurses), repeatability should be established in two steps, first, with professional laboratory personnel to establish the optimal repeatability of the IVD under controlled laboratory conditions then followed by a consumer field evaluation to determine the product's performance when used by non-laboratory trained personnel, unassisted, following instructions provided with the product.
(2) Analytical sensitivity
(a) For a quantitative assay, identify the following parameters and provide details on how they were derived:
(i) Limit of blank (LoB)
(ii) Limit of detection (LoD)
(iii) Limit of quantitation (LoQ)
(3) Analytical specificity
(a) Interference studies
(b) Cross reactivity studies
(4) Traceability of calibrators and control material values
(5) Measuring range of the assay
(6) Validation of assay cut-off
(7) Validation of assay procedure – reading time

5. Stability (excluding specimen stability)
a. Claimed shelf life
i. Testing is done on at least three different lots manufactured under conditions that are equivalent to routine production conditions
ii. Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies. Results derived from testing three different lots is required.
iii. The conclusions must clearly identify claimed shelf life stability.
b. In-use stability
i. Studies should be submitted for each assay component (for example, test cartridge, buffer, conjugate, substrate, acid).
ii. For each component, testing is required on a minimum of one lot.

iii. Open vial stability and/or on-board stability.
iv. If calibration stability is claimed, then supporting data should be included.
v. The conclusions must clearly identify the claimed in-use stability.

c. Shipping stability

d. For IVDs that does not have expiry dates, provide the projected useful life of the device.

6. Robustness Studies

7. Clinical evidence (clinical or diagnostic sensitivity and specificity)
   a. Clinical evaluation – Manufacturer
   b. Clinical evaluation - Independent study
   c. Additional requirements for self-testing and near-patient testing, if applicable

8. Declaration of Conformity to the recognized product standards issued by the legal manufacturer/product owner.

9. Software Verification and Validation
   a. Specify the version of the software to be supplied.
   b. An overview of all verification, validation and testing performed for the software both in-house and in a simulated or actual user environment prior to final release. Where the software has been validated together with the IVD instruments (e.g. IVD analysers), reports of such validation addressing the safety and performance considerations for the software is to be provided.
   c. All unresolved anomalies in the release version of the software should be summarized, along with a justification for acceptability (i.e. the problem, impact on safety and effectiveness, and any plans for correction of the problems).

10. Electrical Safety and Electromagnetic Compatibility
    a. For example, if a device is claimed to meet the requirements of IEC 60601-1 and IEC 60601-1-2, summary test reports and/or certificates are to be submitted for verification of conformance to these standards.

11. Other Evidences
    a. Evidence to support the cybersecurity of connected medical devices such as wireless enabled, internet-connected and network-connected devices. For example, but not limited to:
       i. Cybersecurity vulnerabilities and risks analysis
       ii. Cybersecurity control measures
       iii. On-going plans, processes or mechanisms for surveillance, timely detection and management of the cybersecurity related threats during the useful life of the device, especially when a breach has been detected.
    b. For non-IVD medical device accessories to be registered with the IVD medical device e.g. a lancet that is provided in the package to the user to perform a test, information on preclinical studies necessary to establish the safety and performance of these medical devices shall be provided e.g. biocompatibility and sterilisation validation studies.

E. CLEAR AND COMPLETE COLORED PICTURES OF LABEL IN ALL ANGLES OF THE PACKAGING

1. Photographs of all kit components (packaged and individually).
2. Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable.
3. For any additional product claims on the label, submit studies or tests supporting the claims.

4. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name
5. If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark.
6. Pictures and text of the label should be clear and not be pixelated when the view is increased in size.
7. Lot No., Batch No., Serial No., whichever is applicable, should be reflected.
8. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected.
9. Storage condition, sterilization method should be reflected if applicable.
10. Importer and/or distributor's name and address should be reflected on the label of the product together with the Registration Number.
11. Suggested Retail Price (SRP) in Philippine peso.

F. **RISK ANALYSIS/RISK ASSESSMENT**

1. A summary report of the risks identified during the risk analysis process, including, but not limited to:
    a. Risk to the patient arising from false positive or false negative results
    b. Indirect risks that may result from product-associated hazards, such as instability, which could lead to erroneous results
    c. User-related hazards, such as reagents containing infectious agents
    d. Production-related risks
2. Failure Mode Effect Analysis / Risk Benefit Analysis
3. A description of how these risks have been controlled to an acceptable level.
4. A conclusion with evidence that the remaining risks are acceptable when compared to the benefits. This should be signed by senior management.
5. Identification of specific standards or guidelines (for example, ISO 14791:2007 (E) "Medical devices -- Application of risk management to medical devices").

G. **PHYSICAL MANUFACTURER INFORMATION**

1. Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device.
2. A brief summary of the sterilization method should be included.
3. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation.
4. If the sterilization of the device is contracted out, submit a copy of valid ISO Certificate of the contracted sterilizing company.
5. For non-sterile devices:
    a. Submit Non-sterile declaration from the manufacturer
    b. If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer

ANNEX E

Summary List of Legal and Technical Requirements for the Initial Registration of Class B, C and D IVD for Commercial Distribution

Requirements	CLASS B	CLASS C	CLASS D
Legal Documents			
A. Notarized application form	√	√	√
B. Copy of Letter of Authorization. For imported IVD, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.	√	√	√
C. A government issued certificate attesting to the status of the manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported IVD, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	√	√	√
D. For imported IVD, the CIVDR or any equivalent document attesting to the safety, quality and effectiveness of the IVD issued by the National Regulatory Agency or accredited notified body in the country of origin. The copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	√	√	√
E. Colored picture of the device from all sides. However, the FDA-CDRRHR can require a representative sample or commercial presentation for verification purposes.	√	√	√
Technical Requirements			
F. Executive Summary	√	√	√
G. Essential Principle Checklist	√	√	√
H. Device Description	√	√	√ Detailed information on the material specification would be provided
I. Summary of Design Verification and Validation Documents (whichever is applicable)			
1. Declaration of Conformity to recognized product standards issued by the legal manufacturer/product owner	√	√	√
2. Summary of each study conducted	√	√	√

3. Analytical Studies	√	√	√
a. Specimen type	Summary information	Summary information	Detailed information including formatted raw data must be submitted
b. Analytical performance characteristics	√	√	√
i. Accuracy measurement	Summary information	Detailed information	Detailed information
ii. Analytical sensitivity	Summary information	Detailed information	Detailed information
iii. Analytical specificity	Summary information	Detailed information	Detailed information
iv. Traceability of calibrators and control material values	Summary report	Summary report	Detailed report
v. Measuring range of the assay	Summary information	Detailed information	Detailed information
vi. Validation of assay cut-off	Summary information	Detailed information	Detailed information
vii. Validation of assay procedure-reading time	Summary information	Detailed information	Detailed information
4. Stability Studies	√	√	√
a. Claimed shelf life	Summary information	Detailed information	Detailed information
b. In-use stability	Summary information	Detailed information	Detailed information
c. Shipping stability	Summary information	Detailed information	Detailed information
5. Robustness Studies	√ Summary information	√ Summary information	√ Detailed information
6. Clinical Evidence	√ Summary information	√ Summary information	√ Detailed information including formatted raw data must be submitted
7. Software Verification and Validation	√ Summary information	√ Summary information	√ Detailed information
8. Electrical Safety and Electromagnetic Compatibility	√	√	√
9. Other Evidences a. Evidence to support the cybersecurity	√ Summary information	√ Summary information	√ Detailed information
10. Clear and complete colored pictures of labels in all angles of the packaging	√	√	√
11. Risk Analysis/ Risk Assessment	√ Summary information	√ Summary information	√ Detailed information
12. Physical Manufacturer Information	√	√	√

NOTES:

1. Summary information -refers to the brief description of the study protocols, results with acceptance/ standard criteria used and conclusion
2. Detailed information- refers to the complete study protocol, method of analysis, study report, and study conclusion
3. The specific details of each technical requirement are in ANNEX D

ANNEX F

Requirements for the Renewal of Registration of All Classifications of IVD for Commercial Distribution

A. For Automatic Renewal

1. Notarized Application Form
2. A sworn statement indicating no change or variation whatsoever in the product is attached to the application
3. Colored picture of the IVD from all sides. However, the FDA-CDRRHR can require a representative sample or commercial presentation for verification purposes.
4. Copy of Letter of Authorization. For imported IVD, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
5. A government - issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported IVD, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
6. Clear and complete colored pictures of actual commercial label from all sides of the packaging.
7. Payment

B. For Regular Renewal

1. Notarized Application Form
2. Copy of CIVDR. If with variation, include copy/ies of variation approval/s.
3. Copy of Letter of Authorization. For imported IVD, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
4. A government - issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported IVD, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
5. Colored picture of the IVD from all sides. However, the FDA-CDRRHR can require a representative sample or commercial presentation for verification purposes.
6. Clear and complete colored pictures of actual commercial label from all sides of the packaging.
7. Documents to comply the Post Approval Commitments (e.g. Real-time aging stability test data and results which shall include shelf life; in-use stability; shipping stability studies to justify claimed shelf life; and which shall be performed on at least three (3) different product lots manufactured under conditions that are essentially equivalent to routine production conditions.)
8. Payment

ANNEX G

Requirements for Application for the Registration of Government Internationally Procured IVD

A. Notarized Application Form
B. Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health, and Research. The letter should contain the following information:
    1. Complete list of the IVD indicating the quantity, brand and the name of the manufacturer of the product
    2. Declaration that the concerned government agency shall be the sole entity responsible for the IVD and that the FDA-CDRRHR will not be held liable for any safety issue concerning the product.
C. Packing list or any document that will show the quantity of the product
D. Certificate of In-Vitro Diagnostic Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.

ANNEX H

Requirements for Application for the Registration of Donated Brand New IVD

A. Notarized Application Form
B. Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health, and Research. The letter should contain the following information:
    1. Complete list of the IVD indicating the quantity, brand and the name of the manufacturer of the product
    2. Declaration that the concerned organization/office shall be the sole entity responsible for the IVD and that the FDA-CDRRHR will not be held liable for any safety issue concerning the product.
C. Packing list or any document that will show the quantity of the product
D. Copy of SEC or DTI registration, when applicable
E. Certificate of In-Vitro Diagnostic Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.
F. A certified true copy of the duly notarized deed of donation and duly notarized deed of acceptance
G. Payment when applicable

ANNEX I

Requirements for Application for CIVDL for Research Use Only IVD

A. Notarized Application Form
B. Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health, and Research, stating that the IVD will be used solely for research. The letter should contain the following information:
    1. Complete list of the IVD indicating the quantity, brand and the name of the manufacturer of the product
    2. Declaration that the company shall be the sole entity responsible for the IVD and that the FDA-CDRRHR will not be held liable for any safety issue concerning the product.
C. Packing list or any document that will show the quantity of the product
D. Copy of SEC or DTI registration
E. Certificate of In-Vitro Diagnostic Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.
F. Payment

ANNEX J

Requirements for Application for CIVDL for IVDs that are Not Intended for Commercial Distribution

A. Notarized Application Form
B. Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health, and Research, stating that the IVD will be used solely for research, clinical performance study, performance validation or technical review, educational use, exhibit, or analysis. The letter should contain the following information:
    1. Complete list of the IVD indicating the quantity, brand and the name of the manufacturer of the product
    2. Declaration that the company shall be the sole entity responsible for the IVD and that the FDA-CDRRHR will not be held liable for any safety issue concerning the product.
C. For imported products, packing list or any document that will show the quantity of the product
D. Copy of SEC or DTI registration, when applicable
E. Payment
F. Additional requirements for IVDs for research or clinical performance study
    1. IVD for clinical performance study (not intended for sale)
        a. Approval from the ethics committee from the institution that will conduct the clinical performance study
        b. Clinical performance study protocol
        c. Number of subjects
    2. IVD for clinical trial involving drugs (not intended for sale)
        a. CDRR approval for the clinical trial
        b. Clinical trial protocol
        c. Certificate of In-Vitro Diagnostic Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from
        d. Number of subjects
G. Additional requirements for IVD for educational use
    1. For laboratory use by educational institutions
        a. Certificate of In-Vitro Diagnostic Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.
    2. For training purposes
        a. Proof of the activity (e.g. Invitation, program or notice to accept the invitation for the training)
        b. Certificate of In-Vitro Diagnostic Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.
H. Additional requirements for IVD for exhibit
    1. Proof of the activity (e.g. Invitation, program or notice to accept the invitation for the exhibit)
    2. Certificate of In-Vitro Diagnostic Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.
I. Additional requirements for samples for performance validation or technical review
    1. Samples for performance validation or technical review to be conducted by NRL
        a. Proof of FDA endorsement for performance validation or technical review
        b. Letter/email from NRL regarding the required number of samples for performance validation or technical review

2. Samples for performance validation to be conducted by FDA-CSL
    a. Email from CDRRHR regarding the required number of samples for performance validation or technical review

ANNEX K

List of Host Hospitals and Testing Laboratories with their Designated National Reference Laboratories Based on Technical Expertise

A. **East Avenue Medical Center**
   1. National Reference Laboratory for Environment and Occupational Health
   2. National Reference Laboratory for Toxicology
   3. National Reference Laboratory for Micronutrient Assay
   4. National Reference Laboratory for Industrial and Chemical Emergencies

B. **Lung Center of the Philippines**
   1. National Reference Laboratory for General Clinical Chemistry
   2. National Reference Laboratory for Anatomic Pathology for Pulmonary and Pleural Diseases

C. **National Kidney and Transplant Institute**
   1. National Reference Laboratory for Hematology
   2. National Reference Laboratory for Immunohematology
   3. National Reference Laboratory for Urinalysis
   4. National Reference Laboratory for Anatomic Pathology for Renal Diseases and other Unassigned Organ Systems
   5. National Reference Laboratory for Cellular-Based Product Testing

D. **Philippine Heart Center**
   1. National Reference Laboratory for Anatomic Pathology for Cardiac Diseases
   2. National Reference Laboratory for Cardiac Makers

E. **Research Institute for Tropical Medicine**
   1. National Reference Laboratory for Antimicrobial Resistance
   2. National Tuberculosis Reference Laboratory
   3. National Reference Laboratory for Transfusion-Transmissible Infections
   4. National Reference Laboratory for Dengue and Other Arboviruses
   5. National Reference Laboratory for Influenza and Other Respiratory Viruses
   6. National Reference Laboratory for Emerging and Re-Emerging Bacterial Diseases
   7. National Reference Laboratory for Leptospirosis
   8. National Reference Laboratory for Special Pathogens
   9. National Reference Laboratory for Mosquito Vectors of Human Diseases
   10. National Reference Laboratory for Malaria and Other Parasites
   11. National Reference Laboratory for Schistosomiasis
   12. National Reference Laboratory for Rabies and Other Lyssaviruses
   13. National Reference Laboratory for Polio and Other Enteroviruses
   14. National Reference Laboratory for Measles and Other Exanthems
   15. National Reference Laboratory for Invasive Bacterial Vaccine Preventable Diseases
   16. National Reference Laboratory for Rotavirus and Other Enteric Viruses
   17. National Reference Laboratory for Bacterial Enteric Diseases
   18. National Reference Laboratory for Mycology

F. **San Lazaro Hospital - STD AIDS Cooperative Central Laboratory (SACCL)**
   1. National Reference Laboratory for HIV/AIDS
   2. National Reference Laboratory for Hepatitis B and Hepatitis C
   3. Reference Laboratory for Syphilis and Other Sexually-Transmitted Infections

G. **Food and Drug Administration – Common Services Laboratory**
   1. Testing Laboratory for Pregnancy Test Kit

ANNEX K

References

Food and Drug Administration Act (FDA) of 2009. Republic Act No. 9711. Retrieved from https://www.fda.gov.ph/wp-content/uploads/2021/04/Republic-Act-No.-9711.pdf

ASEAN Agreement on Medical Device Directive (AMDD). (2014). Retrieved from http://agreement.asean.org/media/download/20141204115621.pdf

Department of Health. (2018). Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements. Administrative Order No. 2018-0002. Retrieved from https://dmas.doh.gov.ph:8083/Rest/GetFile?id=605689

Department of Health. Food and Drug Administration. Citizen's Charter. (2021). (1st Edition). Retrieved from https://www.fda.gov.ph/wp-content/uploads/2021/03/09-Feb-2021-FDA-Citizen_s-Charter-CDRRHR_CPR_02-February-2021.pdf

Department of Health. (2001). Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs. Administrative Order No. 50 s. 2001. Retrieved from https://dmas.doh.gov.ph:8083/Rest/GetFile?id=336397

Department of Health. (2020). Institutionalizing and Strengthening the National Reference Laboratories in the Philippines. Department Order No. 2020-0820.

Global Harmonization Task Force. (2011). Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Medical Devices. GHTF/SG1/N063:2011. Retrieved from http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n063-2011-summary-technical-documentation-ivd-safety-conformity-110317.pdf

World Health Organization. (2014). WHO Instruction for Compilation of a Product Dossier – Prequalification of IVD Programme. PQDx_018 v3. Geneva: WHO. Retrieved from https://www.who.int/diagnostics_laboratory/evaluations/141015_pqdx_018_dossier_instructions_v4.pdf

Health Sciences Authority. (2021). GN-18: Guidance on Preparation of a Product Registration Submission for In-vitro Diagnostic Medical Device using the ASEAN CSDT. Singapore. Retrieved from https://www.hsa.gov.sg/docs/default-source/hprg-mdb/gn-18-r1-1-guidance-on-preparation-of-a-product-registration-submission-for-in-vitro-diagnostic-medical-devices-using-the-asean-csdt-(aug21-pub).pdf

Global Harmonization Task Force. (2012). Clinical Evidence for IVD medical devices – Key Definitions and Concepts. GHTF/SG5/N6:2012. Retrieved from https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n6-2012-clinical-evidence-ivd-medical-devices-121102.pdf