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 No. 9711 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 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 Food and Drug Administration (FDA) – Center for Device Regulation, Radiation Health and Research (CDRRHR) hereby adopts, issues and implement the AMDD guidelines on the issuance of an authorization for IVD and to provide the regulatory requirements and authorization process.

II. OBJECTIVE

This Administrative Order aims to specify the rules, guidelines, procedures and requirements of the FDA-CDRRHR relative to the issuance of an authorization for IVD.

III. SCOPE

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

IV. DEFINITION OF TERMS

For purposes of this Administrative Order, the following terms shall be defined as follows:

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

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

3. **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.

4. **Calibrator** - refer to any substance, material or article intended by its product owner to be used in the calibration of a measuring instrument or measuring system.

5. **Certificate of IVD Listing (CIVDL)** - refers to the authorization issued to all IVD intended for clinical evidence study, clinical research, educational purposes, samples for performance evaluation, donation, exhibit, personal use and that is not intended for sale.

6. **Certificate of IVD Notification (CIVDN)** - refers to the authorization issued to all class A IVD that complies with all the requirements for notification.

7. **Certificate of IVD Registration (CIVDR)** - refers to the authorization issued to all class B, C and D IVD that complies with all the requirements for registration.

8. **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.

9. **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.

10. **Establishments** - 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.

11. **Instruction for use** – refers to the all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale 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.

12. **Instrument** - refers to any equipment or apparatus intended by the product owner to be used as IVD.

13. **Intended use** - this 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.

14. **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:

    a. concerning a physiological or pathological state;
    b. concerning a congenital abnormality;
    c. to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients; or
    d. 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.

15. **Label –** 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.

16. **Labelling** - 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.

17. **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.

18. **Listing** - refers to the process of informing the FDA that such IVD are being manufactured and imported solely for clinical evidence study, clinical research, educational purposes, samples for performance evaluation, donation, exhibit, personal use and that is not intended for sale.

19. **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.

20. **Marketing Authorization Holder (MAH)** - refers to the medical device company, corporate or legal entity in whose name the CIVDR or CIVDN 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 CIVDR or CIVDN. The MAH may be a manufacturer, trader, or distributor (exporter, importer or wholesaler) of IVDs.

21. **National Reference Laboratory (NRL)** - refers to agency/laboratories in the Philippines mandated to conduct performance evaluation of the IVD. Please see Annex G - List of host hospitals and testing laboratories with their designated National Reference Laboratories based on technical expertise. The NRLs and their corresponding technical capabilities may be added which will be indicated in a separate Department Order.

22. **Notification** - means the process of approval of an application to notify class A IVDs 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 class A IVDs.

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

24. **Person** - refers to any individual, partnership, corporation, association and/or organization.

25. **Product owner** - refers to any person who:

    a. 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
    b. 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.

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

    a. Department of Trade and Industry - Bureau of Philippine Standards (Philippine National Standard)
    b. International Standardization Organization (ISO)
    c. International Electrochemical Commission (IEC)
    d. Other International Standard Body or any person standards which may be accepted by FDA for the purpose of authorization.

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

28. **Registration** - means the process of approval of an application to register class B, C and D 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 class B, C, and D IVD.

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

30. **Self-testing** – testing/monitoring performed by lay persons.

31. **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.

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

V. POLICIES AND GUIDELINES

A. General Guidelines

1. All establishments that intend to place IVDs in the Philippine market are required to secure an LTO as Medical Device Importer/ Distributor/ Manufacturer/ Trader (whichever is applicable) prior to securing a CIVDN and/or CIVDR. Donors, organizations or person involved in donations, medical missions and other humanitarian activities are exempted from LTO requirements.

2. The establishment shall apply for CIVDN or CIVDR based on the following classification of IVD. The establishment shall apply for CIVDN for Class A IVD and/or CIVDR for Class B, C or D IVD.

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

3. Approval of application for CIVDR shall be based on compliance with the FDA legal and technical requirements and results of performance evaluation for those IVDs that require performance evaluation by NRLs.

4. The certificate of IVD notification or registration shall be issued by the FDA through the CDRRHR if the application is found to be meritorious; otherwise, the application shall be considered disapproved.

5. The Notification Number or Registration Number shall be issued to the IVD with approved CIVDN or CIVDR.

6. Reagents, reagent product, calibrator, control material, kit, instruments, apparatus, equipment or systems or software manufactured, sold or represented by manufacturers not for use in in-vitro diagnostic application and general laboratory use purposes are not classified as IVD.

7. The applicant shall classify the IVD based on the risk classification rules for IVD medical devices in Annex 3 of the AMDD. The 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.

8. IVD strictly for research, clinical trial, exhibit and/or donated brand new IVD equipment except for the reagents are exempted from notification and registration. However, the researcher, institution and/or user of such devices shall apply for a CIVDL. All applicants seeking for CIVDL shall submit the necessary documentary requirements specified in Annex F.

9. Application for registration of IVD for class B, C and D shall be endorsed to the FDA Common Services Laboratory, NRL or other FDA accredited/recognized laboratory for performance evaluation, regardless if deficiencies were found during the document and technical review. Guidelines on the endorsement of application, responsibilities of the applicant and of the NRL regarding the performance evaluation of IVDs shall be covered by a separate FDA Circular.

10. Validity of CIVDR

    a. The validity of CIVDN shall be as specified in Section VII (1) of this Order.

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

    c. The CIVDN or CIVDR shall remain valid as long as there is no change in the composition, packaging, intended use, process and components of the IVD.

    d. The validity of the CIVDR is independent of the validity of the performance evaluation set by the concerned NRL.

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

12. This Order shall be reviewed by the FDA within five (5) years of implementation.

B. Specific Guidelines

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

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

3. All applicants shall submit the following requirements specified in the following Annexes:

    a. Annex A - Legal Requirements for Application for the Notification of IVD under Class A and Registration of IVD under Class B, C and D

b. Annex B - Technical Requirements for Application for the Notification of IVD under Class A

c. Annex C - Technical Requirements for the Initial Registration of Class B, C, and D IVD
   The summary list of requirements for the initial registration of Class B, C and D IVD can be found in Annex D.
d. Annex E - Requirements for the Renewal of Notification/Registration of IVD for All Classifications
e. Annex F - Requirements for Application for the Certificate of IVD Listing

4. An application shall be filed separately per specific IVD whether for CIVDN or CIVDR. The CDRRHR reserves the right to ask for additional documents not indicated in this Order that may arise based on the submitted compliance documents. All documents shall be submitted in English language. Documents submitted in any other foreign language not accompanied with English translation shall be disapproved.

5. IVDs that passed the World Health Organization (WHO) pre-qualification shall not undergo performance evaluation but will undergo document review by the FDA. However, the IVD shall conform to the standard criteria on parameters set by the NRL.

6. Renewal of CIVDR/CIVDN

   a. There shall be automatic renewal of CMDR or CMDN when the following conditions are satisfied:
      i. The application is filed before the expiration date of registration or notification;
      ii. The prescribed renewal fee is paid upon filing of the application; and
      iii. A sworn statement indicating no change or variation whatsoever in the product is attached to the application

   b. Selected IVDs that require post approval commitments to ensure their quality, safety and performance shall not be qualified for automatic renewal. Post approval commitments are indicated in the issued CIVDR or CIVDN. These PAC shall be submitted to FDA during application for renewal of CIVDR or CIVDN in addition to the regular requirements specified in Annex E.

7. IVD Listings

   The filing of application for IVD Listing shall be made prior to the importation of the IVD by the concerned entity (donor, sponsor, research institution, company, individual, etc.)

VI. 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.

Performance evaluation fee is separately collected and paid to NRL.

VII. PHASES OF IMPLEMENTATION

This Administrative Order shall be implemented in phases as specified below:

1. Phase 1: Registration of IVDs based on the latest FDA list of registrable IVDs, Notification of all Class A IVDs, notification of Class B, C and D IVDs that are not included in the latest FDA list of registrable IVDs, and IVD listing.

   The legal and technical requirements for the notification of Class B, C and D under this Phase shall be the same as in Annex A and Annex C, respectively, of this Order.

   The validity of CIVDN for Class A IVDs shall be five (5) years and shall be renewed every five (5) years after initial approval.

   The CIVDN for Class B, C and D IVDs issued under Phase 1 shall be valid for two (2) years after which the MAH shall apply for registration certificate for these IVDs.

2. Phase 2: Registration of all Class B, C and D IVDs (Notification of Class B, C and D IVDs shall cease during this phase)

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

1. Failure to pass/meet the performance evaluation conducted by NRL for Class B, C and D IVDs;
2. Non - coordination with the NRL after product endorsement;
3. The manufacture, sale, offering for sale or transfer of IVD that does not meet all the requirements of safety, quality and efficacy;
4. Misrepresentation or concealment of significant data or information about the product sought to be registered;
5. Alteration, mutilation, destruction, obliteration or removal of any part of the IVD and labeling;
6. IVD that has a biological, chemical or physical property that may cause an unacceptable health risk;
7. Submission of falsified document(s); and/or
8. Alteration or falsification of issued CIVDN or CIVDR.

IX. PENALTY CLAUSE

Any violation of this Administrative Order consistent with Republic Act No. 3720 and Republic Act 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.

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. 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", relevant provisions of FDA Memorandum No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19" and FDA Memorandum No. 2021-009 entitled "Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection", administrative orders, rules and regulations and administrative issuances or parts thereof inconsistent with the provisions of this Order are hereby repealed or modified accordingly.

X. TRANSITORY PROVISIONS

Phase 1 shall be implemented six (6) months after the effectivity of this Order. The schedule of implementation of phase 2 shall be issued in a separate FDA Circular.

NRL shall inform and update FDA regarding its capability to conduct performance evaluation of IVD. FDA shall issue updated list of IVDs that need to undergo performance testing/verification of NRLs prior to registration.

XIII. EFFECTIVITY

This Administrative Order shall take effect fifteen (15) days following its publication in one (1) newspaper of general circulation or upon filing of the same to the Office of the National Administrative Register, University of the Philippines.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

ANNEX A

Legal Requirements for Application for the Notification of IVD under Class A and Registration of IVD under Class B, C and D

1. 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
2. Payment
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.
   - Shall be valid
   - Shall be authenticated/apostilled by the territorial Philippine Consulate
   - 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 medical devices with toll manufacturer, agreement between the trader and the manufacturer shall be duly notarized.
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. For imported IVD, the CIVDN or 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
   - Shall be authenticated/apostilled by the territorial Philippine Consulate
   - 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.
6. Colored picture of the device from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.

ANNEX B

Technical Requirements for Application for the Notification of IVD under Class A

1. Device description consisting of the following:
   1.2 Intended use
   1.3 Instruction for use
   1.4 List of all raw materials
   1.5 Technical specification of the finished product
   1.6 List of references codes, sizes, colors, models and variance, whichever is applicable.
2. 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
3. Declaration of Conformity (self declaration by the manufacturer) with product standards, if applicable
4. Clear and complete colored pictures of label from all sides of the packaging) loose label or artworks of all layers of packaging)
5. Declaration of shelf life

ANNEX C

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

1. EXECUTIVE SUMMARY

1.1. Overview

1.1.1. Introductory descriptive information on the medical device, the intended use and indications for use of the device.

1.1.2. 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.

1.1.3. If the medical device has any unique or novel feature or characteristic (e.g. nanotechnology), a description must be provided.

1.1.4. 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).

1.1.5. Risk classification of the device and the rule it is based on as listed in Annex 3 of the AMDD

1.2. Commercial Marketing History

1.2.1. List of countries where the medical device is marketed.

1.2.2. Date and country where the device was first introduced for commercial distribution, globally.

1.3. List of Regulatory Approval

1.3.1. 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.

1.4. Important Safety and Performance Related Information

1.4.1. 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.

2. ESSENTIAL PRINCIPLES CHECKLIST

2.1. Include in the dossier an Essential Principles checklist in the form of a table that lists:

2.1.1. The Essential Principles of Safety and Performance of Medical Devices applicable to IVDs (See Annex 1 of ASEAN Medical Device Directive).

2.1.2. Whether each Essential Principle applies to the IVD and if not, provide a justification as to why not.

2.1.3. The method used to demonstrate conformity with each Essential Principle that applies, as well as the reference for the method used.

2.1.4. A reference for the manufacturer's actual technical documentation that provides evidence of conformity with each method used.

2.1.5. 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).

3. DEVICE DESCRIPTION

3.1. The intended use of the diagnostic.
    3.1.1. What the product detects.
    3.1.2. The function of the product (e.g., screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease).
    3.1.3. The specific disorder, condition or risk factor of interest that the product is intended to detect, define or differentiate.
    3.1.4. Whether the product is automated or manually operated.
    3.1.5. Whether the test is qualitative or quantitative.
    3.1.6. The type of specimen(s) required (e.g. serum, plasma, whole blood, sputum, urine, etc.).
3.2. The intended testing population (e.g. neonates, antenatal women, symptomatic individuals, etc.).
3.3. The intended user (laboratory professional and/or health care worker at point-of-care).
3.4. The intended setting of use (laboratory, point-of-care).
3.5. A general description of the principle of the assay method or instrument principles of operation.
3.6. 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).
3.7. A description of the specimen collection and transport materials are provided with the product or descriptions of specifications recommended for use.
3.8. For instruments of automated assays: a description of the appropriate assay characteristics or dedicated assays.
3.9. For automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation.
3.10. If applicable, a description of any software to be used with the product.
3.11. If applicable, a description or complete list of the various configurations/variants of product that will be made available.
3.12. If applicable, a description of the accessories, and other products that are intended to be used in combination with the diagnostic.
3.13. Where safety and effectiveness data of similar or previous generation devices are used in the current submission, the following information is to be provided:
    3.13.1. A list of such devices and specific information on the registration status of these devices are to be included (e.g. Registration number).
    3.13.2. 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

3.14. Materials
    3.14.1. 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.
    3.14.2. Identify the sources of the materials from which the IVD components are constructed.
    3.14.3. Provide a table or list of all biological components included in the product under assessment. This should include material of bacterial, viral, parasi

animal, or human origin, such as plasma, cells, tissues, or their derivatives. The table or list should include:

3.14.3.1. the name of the biological component
3.14.3.2. details of the use of the biological component in the product
3.14.3.3. a description of steps taken for the reduction of transmission or infection risk

3.15. Declaration from the legal manufacturer and/or importer and/or distributor for the following:

3.15.1. Storage conditions
3.15.2. Shelf life
3.15.3. Packaging material
3.15.4. Commercial presentation (i.e. kit contents, No. of tests/package)
3.15.5. Suggested retail price

4. SUMMARY OF DESIGN VERIFICATION AND VALIDATION DOCUMENTS

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

4.1 Study description, study identifier, product identifier (for example, lot numbers), IFU version used, the date of initiation and the date of completion

4.2 A summary of the study findings including a conclusion that clarifies how the study objectives have been met

4.3 The study protocol and full report, which incorporates at a minimum, the following information:

4.3.1 study objectives, study design, the methodology used and data collected
4.3.2 the site where the study was performed (for example, Manufacturers R&D laboratory, hospital laboratory, health care clinic)
4.3.3 operator of the assay
4.3.4 the reference standard, if applicable
4.3.5 specimen acceptance criteria, specimen characterization
4.3.6 specimen type (serum, plasma, finger stick whole blood, venous whole blood) and numbers of each type
4.3.7 actual test result summaries with their acceptance criteria and not just pass/fail statements
4.3.8 all data is clearly labeled, and clearly linked to the study report
4.3.9 details of statistical methods, estimations and calculations applied
4.3.10 the study conclusion
4.3.11 when performed by a party other than the manufacturer, details of this party and the relationship to the manufacturer

4.4 If using other brand name

4.4.1 Analytical studies

4.4.1.1 Specimen type

4.4.1.1.1 Detailed information for each matrix and anticoagulant, when applicable
4.4.1.1.2 Provide studies and information supporting the use of each specimen type (and where applicable, anticoagulant).
4.4.1.1.3 Provide studies and information in support of stability claims, storage claims and, where applicable, claims for transport conditions for each applicable specimen type, including:

4.4.1.1.3.1 Duration

4.4.1.1.3.2 Temperatures
4.4.1.1.3.3 Number of allowable freeze/thaw cycles
4.4.1.1.3.4 Specimen stability claims
4.4.1.2 Analytical performance characteristics
4.4.1.2.1 Accuracy of measurement
4.4.1.2.1.1 Trueness of measurement
4.4.1.2.1.2 Precision of measurement
4.4.1.2.1.2.1 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.
4.4.1.2.1.2.2 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.
4
4.4.1.2.2 Analytical sensitivity

4.4.1.2.2.1 For a quantitative assay, identify the following parameters and provide details on how they were derived:

4.4.1.2.2.1.1 Limit of blank (LoB)

4.4.1.2.2.1.2 Limit of detection (LoD)

4.4.1.2.2.1.3 Limit of quantitation (LoQ)

4.4.1.2.3 Analytical specificity

4.4.1.2.3.1 Interference studies

4.4.1.2.3.2 Cross reactivity studies

4.4.1.2.4 Traceability of calibrators and control material values

4.4.1.2.5 Measuring range of the assay

4.4.1.2.6 Validation of assay cut-off

4.4.1.2.7 Validation of assay procedure – reading time

4.5 Stability (excluding specimen stability)

4.5.1 Claimed shelf life

4.5.1.1 Testing is done on at least three different lots manufactured under conditions that are equivalent to routine production conditions

4.5.1.2 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.

4.5.1.3 The conclusions must clearly identify claimed shelf life stability.

4.5.2 In-use stability

4.5.2.1 Studies should be submitted for each assay component (for example, test cartridge, buffer, conjugate, substrate, acid).

4.5.2.2 For each component, testing is required on a minimum of one lot.

4.5.2.3 Open vial stability and/or on-board stability.

4.5.2.4 If calibration stability is claimed, then supporting data should be included.

4.5.2.5 The conclusions must clearly identify the claimed in-use stability.

4.5.3 Shipping stability

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

4.6 Robustness Studies

4.7 Clinical evidence (clinical or diagnostic sensitivity and specificity)

4.7.1 Clinical evaluation – Manufacturer

4.7.2 Clinical evaluation - Independent study

4.7.3 Additional requirements for self-testing and near-patient testing, if applicable

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

4.9 Software Verification and Validation

4.9.1 Specify the version of the software to be supplied.

4.9.2 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.

4.9.3 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).

4.10 Electrical Safety and Electromagnetic Compatibility

4.10.1 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.

4.11 Other Evidences

4.11.1 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:

4.11.1.1 Cybersecurity vulnerabilities and risks analysis

4.11.1.2 Cybersecurity control measures

4.11.1.3 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.

4.11.2 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.

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

5.1. Photographs of all kit components (packaged and individually).

5.2. Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable.

5.3. For any additional product claims on the label, submit studies or tests supporting the claims.

5.4. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and Intellectual Property Office (IPO) approval of the said brand name.

5.5. For local manufactured products, IPO approval of the said brand name

5.6. If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark.

5.7. Pictures and text of the label should be clear and not be pixelated when the view is increased in size.

5.8. Lot No., Batch No., Serial No., whichever is applicable, should be reflected.

5.9. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected.

5.10. Storage condition, sterilization method should be reflected if applicable.

5.11. Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number.

5.12. Suggested Retail Price (SRP) in Philippine peso.

6. RISK ANALYSIS/RISK ASSESSMENT

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

7. PHYSICAL MANUFACTURER INFORMATION

7.1. 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.
7.2. A brief summary of the sterilization method should be included.
7.3. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation.
7.4. If the sterilization of the device is contracted out, submit a copy of valid ISO Certificate of the contracted sterilizing company.
7.5. For non-sterile devices:
   7.5.1. Submit Non-sterile declaration from the manufacturer
   7.5.2. If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer

ANNEX D

Summary List of Requirements for the Initial Registration of Class B, C and D IVD

Requirements	CLASS B	CLASS C	CLASS D
Legal Documents			
1. Notarized application form	√	√	√
2. 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.	√	√	√
3. 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.	√	√	√
4. For imported IVD, the CIVDN or 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.	√	√	√
5. Colored picture of the device from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.	√	√	√
Technical Requirements			
6. Executive Summary	√	√	√
7. Essential Principle Checklist	√	√	√
8. Device Description	√	√	√ Detailed information on the material specification would be provided
9. Summary of Design Verification and Validation Documents (whichever is applicable)			

9.1 Declaration of Conformity	√	√	√
9.2 Summary of each study conducted	√	√	√
9.3 Analytical Studies	√	√	√
9.3.1 Specimen type	Summary information	Summary information	Detailed information including formatted raw data must be submitted
9.3.2 Analytical performance characteristics	√	√	√
● Accuracy measurement	Summary information	Detailed information	Detailed information
● Analytical Sensitivity	Summary information	Detailed information	Detailed information
● Analytical Specificity	Summary information	Detailed information	Detailed information
● Traceability of calibrators and control material values	Summary report	Summary report	Detailed report
● Measuring range of the assay	Summary information	Detailed information	Detailed information
● Validation of assay cut-off	Summary information	Detailed information	Detailed information
● Validation of assay procedure-reading time	Summary information	Detailed information	Detailed information
9.4 Stability Studies	√	√	√
9.4.1 Claimed shelf life	Summary information	Detailed information	Detailed information
9.4.2 In-use stability	Summary information	Detailed information	Detailed information
9.4.3 Shipping stability	Summary information	Detailed information	Detailed information
9.5 Robustness Studies	√ Summary information	√ Summary information	√ Detailed information
9.6 Clinical Evidence	√ Summary information	√ Summary information	√ Detailed information including formatted raw data must be submitted
9.7 Software Verification and Validation	√ Summary information	√ Summary information	√ Detailed information
9.8 Electrical Safety and Electromagnetic Compatibility	√	√	√
9.9 Other Evidences ● 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 requirements are in ANNEX C

ANNEX E

3

Requirements for the Renewal of Notification/Registration of IVD for All Classifications

1. For Automatic Renewal
   1.1 Notarized Application Form
   1.2 Payment
   1.3 A sworn statement indicating no change or variation whatsoever in the product is attached to the application

2. For Regular Renewal
   2.1 Notarized Application Form
   2.2 Payment
   2.3 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.
   2.4 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.
   2.5 Colored picture of the IVD from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.
   2.6 Clear and complete colored pictures of commercial label from all sides of the packaging.
   2.7 Real-time aging stability test data and results which shall include:
      - shelf life
      - in-use stability
      - shipping stability studies to justify claimed shelf life
      - shall be performed on at least three (3) different product lots manufactured under conditions that are essentially equivalent to routine production conditions.
   2.8 Documents to comply the Post Approval Commitments

ANNEX F

Requirements for Application for the Certificate of IVD Listing

1. Notarized Application Form

2. Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health, and Research, stating that the IVD will be used solely for research, analysis, or is being donated by a certain organization and is not intended for sale. The letter should contain the following information:
   2.1 Complete list of the IVD indicating the quantity, brand and the name of the manufacturer of the product
   2.2 Declaration that the organization shall be the sole entity responsible for the IVD and that the CDRRHR - FDA, DOH will not be held liable for any safety issue concerning the product.
3. Certificate of In-Vitro Diagnostic Notification or 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.
4. For a donated IVD (brand new), a certified true copy of the deed of donation, the deed of acceptance, and the packing list or any document that will show the quantity of the product.
5. Copy of SEC or DTI registration, when applicable

ANNEX G

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

1. **East Avenue Medical Center**
   - 1.1 National Reference Laboratory for Environment and Occupational Health
   - 1.2 National Reference Laboratory for Toxicology
   - 1.3 National Reference Laboratory for Micronutrient Assay
   - 1.4 National Reference Laboratory for Industrial and Chemical Emergencies

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

3. **National Kidney and Transplant Institute**
   - 3.1 National Reference Laboratory for Hematology
   - 3.2 National Reference Laboratory for Immunohematology
   - 3.3 National Reference Laboratory for Urinalysis
   - 3.4 National Reference Laboratory for Anatomic Pathology for Renal Diseases and other Unassigned Organ Systems
   - 3.5 National Reference Laboratory for Cellular-Based Product Testing

4. **Philippine Heart Center**
   - 4.1 National Reference Laboratory for Anatomic Pathology for Cardiac Diseases
   - 4.2 National Reference Laboratory for Cardiac Makers

5. **Research Institute for Tropical Medicine**
   - 5.1 National Reference Laboratory for Antimicrobial Resistance
   - 5.2 National Tuberculosis Reference Laboratory
   - 5.3 National Reference Laboratory for Transfusion-Transmissible Infections
   - 5.4 National Reference Laboratory for Dengue and Other Arboviruses
   - 5.5 National Reference Laboratory for Influenza and Other Respiratory Viruses
   - 5.6 National Reference Laboratory for Emerging and Re-Emerging Bacterial Diseases
   - 5.7 National Reference Laboratory for Leptospirosis
   - 5.8 National Reference Laboratory for Special Pathogens
   - 5.9 National Reference Laboratory for Mosquito Vectors of Human Diseases
   - 5.10 National Reference Laboratory for Malaria and Other Parasites
   - 5.11 National Reference Laboratory for Schistosomiasis
   - 5.12 National Reference Laboratory for Rabies and Other Lyssaviruses
   - 5.13 National Reference Laboratory for Polio and Other Enteroviruses
   - 5.14 National Reference Laboratory for Measles and Other Exanthems
   - 5.15 National Reference Laboratory for Invasive Bacterial Vaccine Preventable Diseases
   - 5.16 National Reference Laboratory for Rotavirus and Other Enteric Viruses
   - 5.17 National Reference Laboratory for Bacterial Enteric Diseases
   - 5.18 National Reference Laboratory for Mycology

6. **San Lazaro Hospital - STD AIDS Cooperative Central Laboratory (SACCL)**
   - 6.1 National Reference Laboratory for HIV/AIDS
   - 6.2 National Reference Laboratory for Hepatitis B and Hepatitis C
   - 6.3 National Reference Laboratory for Syphilis and Other Sexually-Transmitted Infections

7. **Food and Drug Administration – Common Services Laboratory**
   - 7.1 Testing Laboratory for Pregnancy Test Kit

ANNEX H

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