FDA CIRCULAR
No. _____

SUBJECT: **Specific List of Registrable In Vitro Diagnostic Medical Devices (IVDs) and Revised Technical Requirements for Registration of COVID-19 Test Kits**

I. RATIONALE

On 25 February 2014, FDA Memorandum Circular No. 2014-005 entitled "Updated List of Medical Devices required to be registered prior to sale, distribution and use" was issued to provide the initial list of medical devices including IVDs that are required for registration with the Food and Drug Administration (FDA).

With the occurrence of the pandemic due to COVID-19, FDA Memorandum (FM) No. 2020-006 entitled "Issuance of Special Certification for Imported Test Kits of COVID-19" was issued on 12 March 2020 adding COVID-19 test kits to the list of IVDs that require authorization from the FDA prior to their importation, distribution and sale.

FM No. 2020-006 was issued at the outset of the COVID-19 pandemic. Despite the limited clinical data available at that time to support the performance of the products, FM No. 2020-006 was issued requiring only limited documents to facilitate the issuance of Special Certification to provide access to these products and to enable testing of patients suspected to be afflicted with COVID-19.

Considering that developments have been made in establishing clinical data for COVID-19 test kits and there is already adequate supply of these products in the market, it is prudent to require compliance of these products to the FDA technical requirements for product registration similar with other regulated IVDs to ensure their quality, safety and performance. For COVID-19 test kits that have complied to the said technical requirements, it is appropriate to issue a Certificate of Product Registration (CPR) to the said test kit products in lieu of the Special Certification issued under FM 2020-006.

Majority of the above-mentioned IVDs including COVID-19 test kits are required to undergo performance evaluation by the FDA Common Services Laboratory (FDA-CSL) and by the different National Reference Laboratories (NRLs) depending on the respective capacity of said laboratories. These IVDs should pass such performance evaluation prior to the issuance of required authorization by the FDA.

II. OBJECTIVE

This Circular aims to:

A. Provide the specific list of the different registrable IVDs based on the capacity of FDA-CSL and NRLs.
B. Provide guidelines on the transition from the issuance of Special Certification to CPR for COVID-19 test kits and on the revised technical requirements for the registration of COVID-19 test kits

III. SCOPE

This Circular shall apply to manufacturers and distributors (importers/exporters/wholesalers) of registrable IVDs enumerated in Section B of FDA Memorandum Circular No. 2014-005 and of COVID-19 test kits and reagents.

IV. GUIDELINES

A. The following are the specific list of registrable IVDs that require performance evaluation based on the capacity of FDA-CSL and the different NRLs.

1. **FDA – CSL**
   a. Qualitative immunochromatographic assay Pregnancy Test Kits using urine specimen

2. **NRL - San Lazaro Hospital - STD AIDS Cooperative Central Laboratory**

TEST SYSTEM	TESTING PLATFORM	INTENDED USE
a. HIV (Antibody, antigen)	Screening Test, Confirmatory Test, Supplemental Test, Self-Testing*	Diagnostic Use Only
b. HBV (Antibody, antigen)	Screening Test, Confirmatory Test, Supplemental Test	Diagnostic Use Only
i. Hepatitis Markers (Antibody, antigen)	Screening Test, Disease Monitoring Test	Diagnostic Use Only
c. HCV (Antibody, antigen)	Screening Test, Confirmatory Test, Supplemental Test	Diagnostic Use Only
d. Syphilis (Treponemal, non-treponemal)	Screening Test, Confirmatory Test	Diagnostic Use Only
e. CD4	Disease Monitoring Test	Diagnostic Use Only

* Additional evaluation for HIV self-testing kits shall be done as community research study in coordination with the National AIDS and STD Prevention and Control Program (NASPCP) of the Department of Health.

3. **NRL - East Avenue Medical Center**

ANALYTE	IVD TYPE / SPECIMEN	CUT-OFF VALUES
a. Shabu (Methamphetamine)	Rapid Test Kits; Assay Reagents / Urine	1000ng/mL; 500ng/mL
b. Marijuana (THC)	Rapid Test Kits; Assay Reagents / Urine	50ng/mL
c. Amphetamine	Rapid Test Kits; Assay Reagents / Urine	1000ng/mL; 500ng/mL
d. Cocaine/Benzoylecgonine	Rapid Test Kits; Assay Reagents / Urine	300ng/mL
e. Ecstasy (MDMA)	Rapid Test Kits; Assay Reagents / Urine	500ng/mL
f. Opiates (Morphine/Codeine)	Rapid Test Kits; Assay Reagents / Urine	2000ng/mL
g. Benzodiazepine (Nordiazepam/Oxazepam)	Rapid Test Kits; Assay Reagents / Urine	300ng/mL

4. **NRL - National Kidney and Transplant Institute**

All platforms/technologies including but not limited to manual, semi-automated and automated platforms.

a. **Anti-A Reagents**
   i. Anti-A1
   ii. Anti-A2
   iii. Anti-A3
   iv. All other Anti-A Sub Types
   v. Anti-A for Tube Technology
   vi. Anti-A for Phase Contrast Technology
   vii. Anti-A for Column Agglutination Technology
   viii. Anti-A for Erythrocyte Magnetized Technology
   ix. Anti-A for Solid Phase Technology
   x. Anti-A Card Technology
   xi. All other Anti-A Technologies
   xii. Anti-A Control
   xiii. Neutral reagents
   xiv. Dolichos Biflorus Lectin (A1 Lectin) Reagent
   xv. Anti-A,B
   xvi. All other Anti-A reagents and controls

b. **Anti-B Reagents**
   i. Anti-B
   ii. All other Anti-B Sub Types
   iii. Anti-B for Tube Technology
   iv. Anti-B for Phase Contrast Technology
   v. Anti-B for Column Agglutination Technology

vi. Anti-B for Erythrocyte Magnetized Technology
vii. Anti-B for Solid Phase Technology
viii. Anti-B Card Technology
ix. All other Anti-B Technologies
x. Anti-B Control
xi. Neutral reagents
xii. Anti-A,B
xiii. All other Anti-B reagents and controls

c. **Anti-D/Rh Reagents**
i. Anti-D/Rh
ii. Anti-DW
iii. Anti-DP
iv. Anti-DVI+
v. Anti-DVI-
vi. Anti-E
vii. Anti-e
viii. Anti-C
ix. Anti-c
x. Anti-CW
xi. All Other Anti-Rh Sub Types
xii. Anti-D/Rh For Tube Technology
xiii. Anti-D/Rh For Phase Contrast Technology
xiv. Anti-D/Rh For Column Agglutination Technology
xv. Anti-D/Rh For Erythrocyte Magnetized Technology
xvi. Anti-D/Rh For Solid Phase Technology
xvii. Anti-D/Rh Card Technology
xviii. All other Anti-D/Rh Technologies
xix. Anti-D/Rh Control
xx. Neutral reagents
xxi. All other Anti-D reagents and controls

d. **Known Cells or Reverse Cells**
i. Known A1 and Control
ii. Known A2 and Control
iii. Known B and Control
iv. Known O and Control
v. Neutral
vi. All other antigens for minor blood groups and controls

e. **Anti-Human Globulin (AHG) Reagents**
i. Polyspecific Anti-human Globulin
ii. Anti-IgG
iii. Anti-C3
iv. Anti-C3b
v. Anti-C3d
vi. Anti-C3d C3b
vii. Anti-C4b
viii. Anti-C4d

ix. All other anti complement antibodies
x. Coombs' control
xi. Check cells

f. **Potentiators**
i. Low Ionic Strength Saline (LISS)
ii. LISS and Additives
iii. Albumin
iv. Albumin based additives
v. Enzymes (all Proteoloytic enzymes used in Immunohemotology included)
vi. Polyethelyne Glycol
vii. Polybrene
viii. Control
ix. Neutral
x. All other methods using potentiators
xi. All other technologies using potentiators

g. **Antibody Screen Reagents**
i. Pooled cells
ii. 2 cell antibody screen panel
iii. 3 cell antibody screen panel
iv. Antibody screen reagents for Tube method
v. Antibody screen reagents for Column Agglutination Technology
vi. Antibody screen reagents for Erythrocyte Magnetized Technology
vii. Antibody screen reagents for Solid Phase Method (Plate Method)
viii. LISS cards/cassettes for antibody screening using Column Agglutination Technology
ix. AHG cards/cassettes for antibody screening using Column Agglutination Technology
x. All other methods and technologies for antibody screening reagents and controls
xi. All other cards/cassettes for antibody screening reagents and controls

h. **Antibody Identification Reagents**
i. 11 or more cell antibody identification panel
ii. Antibody identification reagents for Tube method
iii. Antibody identification reagents for Column Agglutination Technology
iv. Antibody identification reagents for Erythrocyte Magnetized Technology
v. Antibody identification reagents for Solid Phase Method (Plate Method)
vi. LISS cards/cassettes for antibody identification using Column Agglutination Technology
vii. AHG cards/cassettes for antibody identification using Column Agglutination Technology

viii. All other methods and technologies for antibody identification reagents
ix. All other cards/cassettes for antibody identification reagents and controls

i. **Phenotyping Reagents**
   i. Anti-C
   ii. Anti-c
   iii. Anti-Cw
   iv. Anti-e
   v. Anti-E
   vi. Anti-Fya
   vii. Anti-Fyb
   viii. Anti-Jka
   ix. Anti-Jkb
   x. Anti-K
   xi. Anti-k
   xii. Anti-Kpa
   xiii. Anti-Kpb
   xiv. Anti-Lea
   xv. Anti-Leb
   xvi. Anti-M
   xvii. Anti-N
   xviii. Anti-P1
   xix. Anti-S
   xx. Anti-s
   xxi. Anti-Lua
   xxii. Anti-Lub
   xxiii. Neutral card for Phenotyping
   xxiv. Phenotyping reagents for Tube Method
   xxv. Phenotyping reagents for Column Agglutination Technology
   xxvi. Phenotyping reagents for Erythrocyte Magnetized Technology
   xxvii. Phenotyping reagents for Solid Phase Method (Plate Method)
   xxviii. LISS cards/cassettes for phenotyping using Column Agglutination Technology
   xxix. AHG cards/cassettes for phenotyping using Column Agglutination Technology
   xxx. Neutral cards/cassettes for phenotyping
   xxxi. All other methods and technologies for phenotyping reagents
   xxxii. All other cards/cassettes for antibody identification reagents

j. **Miscellaneous Reagents**
   i. LISS cards/cassettes for crossmatching using column Agglutination Technology
   ii. AHG cards/cassettes for crossmatching using column Agglutination Technology
   iii. Crossmatching reagents using Erythrocyte Magnetized Technology
   iv. Crossmatching reagents using Solid Phase Technology

v. All other reagents and methods used for crossmatching
vi. All other technologies for crossmatching

5. **NRL - Research Institute for Tropical Medicine**
   a. COVID-19 test kits and reagents

B. The following IVDs shall not undergo performance evaluation by the NRL but shall undergo documentary review by the FDA:
   1. Leptospirosis test kits/reagents
   2. Pregnancy test kits/reagents using specimen other than urine

C. Above-identified registrable IVDs including COVID-19 test kits shall comply with the FDA technical requirements for registration of IVDs (See Annex A).

D. IVDs including COVID-19 test kits that complied with the requirements shall be issued a CPR. The validity of CPR for COVID-19 test kits shall follow the existing validity of CPR for registrable IVDs.

E. The registration fee for COVID-19 test kits shall follow the registration fee for the registrable IVDs specified in FDA Memorandum Circular No. 2014-005:
   1. Php1,000.00 + 1% Legal Research Fee (LRF) for initial with one (1) year validity
   2. Php5,000.00 + 1% LRF for renewal with five (5) years validity

V. SEPARABILITY CLAUSE

In the event that any provision or part of this Circular is declared invalid, the other provisions hereof shall not be affected.

VI. REPEALING CLAUSE

Provisions of FM No. 2020-006 and FM No. 2021-009 entitled "Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection" that are inconsistent with this Circular are hereby modified, withdrawn, repealed, and/or revoked accordingly.

VII. TRANSITORY PROVISION

A. For COVID-19 test kits with pending application for initial Special Certification prior to the effectivity of this Circular, Special Certification shall still be issued for approved applications. However, after the validity of the issued Special Certification, CPR shall be required for the said COVID-19 test kits in accordance with this Circular.

B. For COVID-19 test kits with pending application for re-issuance of Special Certification pursuant to the provisions of FM No. 2021-009 prior to the effectivity

of this Circular, Special Certification shall still be issued for approved applications. However, after the validity of the re-issued Special Certification, CPR shall be required for the said COVID-19 test kits in accordance with this Circular.

C. For COVID-19 test kits with valid Special Certification prior to the effectivity of this Circular, CPR shall be required for the said COVID-19 test kits after the expiration of the Special Certification. The Marketing Authorization Holder may apply for the CPR pursuant to this Circular six (6) months prior to the expiration of the Special Certification.

VIII. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified true copies with the University of the Philippines Law Center – Office of the National Administrative Register.

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

DTN: 20211006131213

Annex A

CHECKLIST OF REQUIREMENTS FOR THE REGISTRATION OF AN IN VITRO DIAGNOSTIC MEDICAL DEVICE

REQUIREMENTS	TYPE OF APPLICATION	
	INITIAL	RENEWAL
1. Table of Contents (with page number)	√	√
2. Notarized Application Form from Distributor (Importer/Exporter/Wholesaler)/Local Manufacturer/ Trader)	√	√
3. Certificate of Brand Name Clearance (for branded products, if applicable)	√	
4. Valid License to Operate (LTO) of an IVD Distributor (Importer/Exporter/Wholesaler)/ Local Manufacturer/ Trader	√	√
5. Valid Government Certificate of Clearance and Free Sale/Registration approval of the Product from the country of origin issued by the Health Authority and duly authenticated by the territorial Philippine Consulate for Imported Product	√	
6. Valid Government Certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities or valid ISO Certification for Imported Product. For imported products, certificate must be and duly authenticated by the territorial Philippine Consulate	√	√
7. Copy of or Special Certification for COVID-19 test kits issued under FDA Memorandum No. 2020-006, as applicable or latest Certificate of Product Registration	N/A	√
8. Certificate of Foreign Agency Agreement between the manufacturer and trader/distributor/importer regarding the product involved duly authenticatedby the territorial Philippine Consulate	√	√
9. Intended use and Directions for Use	√	
10. List of all raw materials used as components of the reagents/test kit	√	
11. Technical specifications and physical description of the Finished Product	√	
12. Process-control/Test Procedure and expected performance specification	√	
13. Brief description of the methods used in the facility and the controls in themanufacture, processing, packaging of the IVD and the process flowchart showing an overview of production	√	
14. Risk analysis with control measures	√	

15. A. For INITIAL: Stability test data and results describing the shelf life, in-usestability, and the shipping stability studies to justify claimed shelf life. The testing should be performed on at least three (3) different product lots manufactured under conditions that are essentially equivalent to routine production conditions. B. For RENEWAL: Stability test data and results describing the shelf life.The testing should be performed on at least three (3) different product lots manufactured under **REAL TIME CONDITION**.	√	√
16. A. For INITIAL: Labeling materials to be used for the product: Immediatelabel, secondary packaging, box label and package insert/brochure. B. For renewal, submit clear and readable commercial product label specimen of all labeling materials (outer, immediate, package insert)	√	√
17. For pregnancy test kit, 15 samples of the same lot with at least nine (9) months expiration date. For other IVD applications, samples will be submitteddirectly to the respective NRLs. No. of samples required will depend on the requirement of each NRL.	√	√
18. Evidence of registration fee/payment (charge slip/official receipt)	√	√

- *Application should be filed **six (6) months** prior to the expiration of the validity of the CPR.*
- *Submit an electronic/scanned copy (in PDF searchable format of at least 150dpi).*
- *The soft copy should be arranged according to the checklist of requirements. The file name should consist of thename of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements.*
- *Bring hard copy of the assessment slip.*