Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

FDA Advisory No. 2021-3382

10 DEC 2021

TO: **ALL CONCERNED MEDICAL DEVICE ESTABLISMENTS AND HEALTHCARE PROFESSIONALS AND ALL OTHER CONCERNED GOVERNMENT OFFICES**

SUBJECT: **Clarification on the Conduct of Performance Evaluation by the RITM on COVID-19 related IVD Medical Devices.**

The COVID-19 pandemic allowed the emergence of various in-vitro diagnostic products in the Philippine market which are used for detecting the COVID-19 virus.

The Food and Drug Administration (FDA) has regulated the distribution and sale of COVID-19 test kits to ensure the quality of this novel product developed to detect the presence of the COVID-19 virus in humans. The authorization of the COVID-19 test kits to allow the marketing of the product is granted through the issuance of a Special Certification. However, prior to FDA's issuance of Special certification, the performance of the test kits should be evaluated by the Research Institute of Tropical Medicine (RITM), which serves as the National Reference Laboratory for these types of products.

All concerned stakeholders are reminded that only COVID-19 test kits (nucleic acid amplification tests, rapid antigen tests, and antibody tests) are required to be evaluated by RITM. These are the COVID-19 related medical devices currently regulated by the FDA. Class A or Low risk IVDs such as collection tubes, collection kits, transport media, and respiratory swabs are not regulated at this time.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

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