Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Advisory
No. 2020-1394

24 JUL 2020

TO: **ALL LICENSED IMPORTERS / DISTRIBUTORS OF COVID-19 TEST KITS**

SUBJECT: **PRESCRIBED QUANTITY OF PRODUCTS FOR EVALUATION**

The Food and Drug Administration (FDA) informs all COVID-19 test kit Distributors / Importers which were granted a Special Certification starting 22 April 2020 to be guided by the issuance released by the Research Institute for Tropical Medicine (RITM) regarding validation of test kits.

For Serologic Based (Rapid Antibody and Immunoassay) test kits and Antigen based test kits, performance testing is required by FDA as part of post marketing surveillance. Failure to subject test kits to validation may lead to revocation of certification.

It was initially required that 300 test kits must be submitted to RITM, however, based on the *"Guidelines on the Evaluation of In Vitro Diagnostics Medical Devices and Other Related Laboratory Diagnostoc Supplies for COVID-19"* released and published in the RITM website on 13 July 2020, the prescribed quantity of product for evaluation of **SARS-CoV-2/ COVID-19 Antibody/ Antigen Kit must be good for 100 tests**.

Please be guided that for subsequent approvals of Serologic based test kits and Antigen test kits, guidelines on the submission of documents to FDAC within 30 days from the issuance of the Special Certification stated in the letter provided to you with subject, "Performance Testing as Post Marketing Surveillance of COVID-19 Rapid Antibody Test Kits with Issued Special Certification" remains in effect.

For your information and guidance.

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