Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA MEMORANDUM
No. 2020-022

03 SEP 2020

TO: **ALL MEDICAL DEVICE MANUFACTURERS, IMPORTERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES**

SUBJECT: **Performance Testing of Antigen Based Test Kits with Issued Special Certification**

This is to inform all concerned that COVID-19 Antigen Based test kits with Special Certification shall likewise undergo performance validation by the Research Institute for Tropical Medicine (RITM) as a part of FDA's post marketing surveillance.

The companies shall be required to submit to RITM one hundred (100) pieces of their respective antigen test kits for performance testing (see FDA Advisory No. 2020-1394: Prescribed Quantity of Products for Evaluation). Cost for performance validation shall be borne by the company.

FDA shall revoke issued Special Certifications of antigen test kits which are not compliant with the standards according to the performance validation conducted by RITM. Also, the FDA shall revoke the Special Certifications of companies which did not subject their antigen test kits for performance validation by RITM as required.

This is following the previously released memorandum on performance testing of antibody test kits (FDA Memorandum No. 2020-011: Performance Testing of Antibody Test Kits with Issued Special Certification).

For your compliance.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General