Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

20 APR 2020

FDA MEMORADUM
NO. 2020-011

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

SUBJECT: Performance Testing of Antibody Test kits with Issued Special Certification

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All COVID-19 antibody test kits (rapid test, point-of-care, lateral flow, Elisa, GICA, CLIA, among others) with Special Certification shall undergo performance validation by the Research Institute for Tropical Medicine (RITM) as part of the Food and Drug Administration's (FDA) post-marketing surveillance of health products.

Therefore, companies which have been issued Special Certifications for COVID-19 antibody test kits as posted in the FDA website shall be referred to the RITM for performance validation.

Accordingly, companies shall be required to submit to RITM three hundred (300) pieces of their respective antibody test kits within thirty (30) days from the date of the notice of submission from the FDA. Costs for performance validation shall be borne by the respective company.

The FDA shall revoke issued Special Certifications of anti-body 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 anti-body test kits for performance validation by RITM as required.

Lastly, all future approvals of applications for Special Certification for COVID-19 shall be subject to performance validation by RITM as a post-marketing condition.

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