Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

**PRESS STATEMENT**

**20 APRIL 2020**

## RITM TO EVALUATE FDA APPROVED COVID-19 RAPID ANTIBODY TEST KITS

The Research Institute for Tropical Medicine (RITM) is now ready to evaluate rapid antibody test kits for COVID-19 disease. In a letter received by the Food and Drug Administration (FDA) on 17 April 2018, RITM Director Dr. Celia Carlos informed FDA Director General Rolando Enrique Domingo that the Institute can now evaluate approved rapid antibody test kits "in the interest of national emergency, health and safety."

"This is a welcome development," said DG Domingo, "so that the reliability of the kits may be tested on local samples. This will guide end users in selecting the kits they will use for testing." The RITM as the National Reference Laboratory (NRL) for Emerging Diseases is mandated to perform the evaluation of infectious disease test kits. In the early weeks of the Institute's response to COVID-19, RITM did not have the capacity to perform this function due to the high volume of Polymerase Chain Reaction (PCR) testing and their laboratory's lack of well- characterized serum samples needed to evaluate the rapid test kits.

While other countries allow the sale of unregistered point of care kits, the Philippine FDA only approves test kits that are registered by reliable National Regulatory Agencies (NRA) and FDA counterparts, pre-qualified by the World Health Organization (WHO), or validated locally. To date, the FDA has approved 16 antibody rapid tests. All concerned stakeholders of registered antibody test kits were directed to submit samples to the RITM Laboratory 30 days from receipt of notice for performance evaluation as part of post marketing surveillance.

"Recent news from other countries reporting poor performance of rapid antibody tests have cast doubts on the accuracy of some kits. As the Philippines embarks on a mass testing strategy using both PCR based and Rapid Antibody test kits, validation of rapid kits by the RITM would be helpful in choosing the best products to use as we go forward now and after the end of the ECQ," DG Domingo said.

**ROLANDO ENRIQUE D. DOMINGO, MD**

Director General

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