Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

18 APR 2020

FDA ADVISORY
No. 2020-671

TO: **The General Public**

SUBJECT: **Varying Specifications and Use of COVID-19 Rapid Antibody Test Kits**

The Food and Drug Administration (FDA) has approved sixteen (16) COVID-19 Rapid Antibody test kits for commercial use as of April 16, 2020. These applications have completed necessary documentary requirements and have undergone review and evaluation by the FDA. As part of FDA's mandate to ensure safety and quality of these products, surveillance measures are in place to monitor performance and effectiveness.

These test kits are independent from each other and each product has different specifications. These are manufactured by different companies, in various countries and settings. Each uses a technology and validation technique which may vary from others. The rapid test kits detect the presence of antibodies in an individual's blood or serum.

Antibodies detected by these types of test kits are identified as Total Antibody, IgG antibody and IgM antibody. Total antibody signifies the collective response of the patient's immune system. IgM antibodies represent response to a current or recent infection while IgG antibodies represent response from a past infection. Some of the kits detect only one antibody – either IgM or IgG. Some kits detect total antibodies – IgM and IgG together in one result. Other kits detect both IgG and IgM at the same time but give a separate result for each.

It is important to consider the timing of the infection and the condition of the patient during the time of specimen collection. The selection of the type of kit to be used is also dependent on the indication, the information the doctor wants to obtain, and the specifications of the kit. Interpretation must be done with caution and clinical correlation.

The FDA encourages the public to take into consideration that these kits have technical specifications unique from each other. These are rapid kits that are packaged as easy to use but they should be administered by trained health professionals. The agency reiterates that these kits are strictly for medical professional use only and not intended for personal use. The test should be administered by trained health professionals and the results should be interpreted by licensed physicians. Confirmatory PCR based testing is still the gold standard.

The FDA stands firm in safeguarding the public against unregistered and substandard health products amidst the COVID-19 pandemic. The agency continuously conducts post marketing surveillance and evaluation despite the stringent and expedited measures imposed on these approvals. For any reports on FDA approved COVID-19 health products, send an email to covidresponse@fda.gov.ph

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