Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Advisory No. 2021-1270

16 JUN 2021

TO: **THE GENERAL PUBLIC AND HEALTHCARE PROFESSIONALS**

SUBJECT: **USE OF COVID-19 ANTIBODY TEST KITS FOR ASSESSMENT OF IMMUNITY AFTER COVID-19 VACCINATION**

The Food and Drug Administration (FDA) reminds the public on the use of the different COVID-19 Antibody Test kits authorized for use in the Philippines.

The COVID-19 infection initiates a humoral immune response that produces antibodies against specific viral antigens such as the Nucleocapsid protein (N protein) and Spike protein (S protein). The S protein has subunit proteins, S1 and S2 subunits. S1 subunit contains the receptor binding domain (RBD). Antibodies such as IgM, IgG and IgA form immune responses to these antigens. However, it is only the RBD that binds with angiotensin converting enzyme-2 (ACE2) receptor of humans which elicit immune response during vaccination. This is the common targeted antigen-antibody complex by vaccine development.

As testing remains to be an important aspect of COVID-19 mitigation and surveillance, it is important to be familiar with the various test kits available in the market. Serologic based test kits, such as rapid antibody test kits (lateral flow and immunoassays) and neutralization test kits can be used to detect presence of antibodies caused by prior COVID-19 infection. It is however important to consider the phase or severity of the disease, the time of specimen collection and the vaccination status prior to its use. Current authorized antibody tests have not been evaluated to assess the level of protection provided by an immune response to COVID-19 vaccination.

There are no currently available FDA approved COVID-19 test kits in the Philippines that differentiate the antibody protection gained from natural COVID-19 infection and the immunity from vaccination. These kits have varying specifications and indications independent from each other which are helpful in specific circumstances and settings. The complexity of the immune responses from COVID-19 infection and COVID-19 vaccination is not limited to the humoral response stated above as T-cell immunity, seroconversion, asymptomatic cases and cross reactivity reactions are to be considered in the utilization of these test kits.

Hence, the use and interpretation of results of these kits should be under the supervision of trained health professionals and laboratories accredited by the Department of Health-Research Institute for Tropical Medicine. The FDA encourages the public to be vigilant with the use and claims of these kits in the market to avoid false information and undue misconception.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

Source:https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html