



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



08 MAY 2020

**FDA CIRCULAR**  
No. 2020-016

**TO: ALL CONCERNED STAKEHOLDERS AND PARTIES**

**SUBJECT: Prohibition of Online Selling of FDA Certified COVID-19 Antibody Test kits**

Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, and its Implementing Rules and Regulations, declares that it is the policy of the state to ensure the safety, efficacy and quality of IVD medical devices in the country so as to protect the health of the Filipino people.

The FDA issued FDA Advisory No. 2020-497 reiterating the Market Authorization Holder (MAH) of all COVID-19 antibody test kits (rapid test, point-of-care, lateral flow, Elisa, GICA, CLIA among others) with FDA special certification are strictly for medical professional use and not intended for personal use. Furthermore, FDA Advisory No 2020-498 was issued to inform the general public on purchase and administration of all FDA certified COVID-19 antibody test kits.

In view of the foregoing, all concerned stakeholders and parties are strongly reminded that online selling of FDA certified COVID-19 antibody test kits is **strictly prohibited**.

All FDA Regional Field Offices and Regulatory Enforcement Units are directed to conduct exhaustive monitoring of all online platforms to ensure full compliance of this Circular and to pursue and implement immediate regulatory and enforcement actions as warranted.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

DTN 20200429115922

