Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. **2021-1239**

14 MAY 2021

TO: **ALL CONCERNED STAKEHOLDERS AND THE GENERAL PUBLIC**

SUBJECT: **Distribution, Purchase and Administration of FDA Certified COVID-19 Test Kits (RT-PCR, Antibody and Antigen based)**

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 in-vitro diagnostic medical devices in the country so as to protect the health of the Filipino People.

The Food and Drug Administration (FDA) reiterates to all licensed importer/ distributors that all COVID-19 test kits should be strictly distributed to appropriate establishments or institutions.

Subsequently, this should be acquired through a prescription from a licensed physician from licensed hospitals or drugstores/pharmacies. Online sale is strictly prohibited.

FDA Certified Covid-19 test kits such as RT-PCR, Antibody and Antigen based are strictly for medical professional use and not intended for personal use. The administration of the test must be performed by a doctor or a trained health professional. Furthermore, the interpretation of the results must be done by a doctor.

All FDA Regional Offices and Regulatory Enforcement Units are directed to conduct exhaustive monitoring of improper distribution, dispensing and use of all COVID-19 test kits including online platforms to ensure full compliance of this Advisory and to pursue and implement immediate regulatory and enforcement actions as warranted.

For information and guidance.

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