



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



12 MAR 2020

FDA CIRCULAR
No. 2020-004

TO: ALL CONCERNED STAKEHOLDERS AND PARTIES

SUBJECT: Prohibition of Selling of COVID-19 Testing Kit without Authorization from FDA

In view of the ongoing concern on the spread of coronavirus disease (COVID-19) which has placed the country under state of public health emergency, all healthcare professionals, stakeholders and the general public are hereby advised not to distribute, sell or use COVID-19 Testing Kit without authorization from the Food and Drug Administration (FDA). This is to ensure the provision of accurate and reliable information regarding result of the COVID-19 test to be conducted.

All concerned establishments are warned not to distribute, advertise, or sell COVID-19 testing kit until a corresponding authorization has been issued by FDA; otherwise, regulatory actions and sanctions shall be strictly pursued.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that only COVID-19 testing kit with FDA authorization is sold or made available in the market or their areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of COVID-19 testing kit without FDA authorization.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at cdrhr@fda.gov.ph, or call (02) 8857-1900 loc. 8301.

To report any sale or distribution of unauthorized medical device, the online reporting facility, **eReport** can be accessed at www.fda.gov.ph/ereport.

Dissemination of this advisory to all concerned is hereby requested.


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Director General

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