



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



21 JAN 2021

**FDA ADVISORY**  
No. **2021-0104**

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

**SUBJECT: Public Health Warning Against the Purchase and Use of Uncertified COVID-19 Test Kits intended for Self-Administration**

The Food and Drug Administration (FDA) informs all concerned stakeholders and the general public that to date, there is **no FDA Certified COVID-19 Test Kits for Self-Administration**.

In light of the foregoing, all healthcare professionals and the general public are advised not to purchase and use these in-vitro devices.

All concerned establishments are warned not to distribute, advertise, or sell the said Uncertified medical device until FDA Special Certification is issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

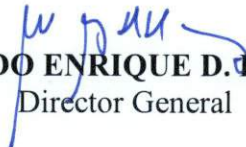
All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that this product is not sold or made available in the market or their areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this uncertified product.

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](mailto: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](http://www.fda.gov.ph/ereport).

Dissemination of this advisory to all concerned is hereby requested.

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

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