



17 JUL 2020

FDA ADVISORY
No. 2020-1373

TO: ALL CONCERNED HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Uncertified COVID-19 Test Kit “Wondfo® 2019-nCov in Foreign Characters”

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public not to purchase and use of the uncertified COVID-19 test kit:



Figure 1. Uncertified Wondfo® 2019-nCov in Foreign Characters



The FDA verified through post-marketing surveillance that the abovementioned medical device is not certified and/or no FDA Special Certification has been issued as of 08 June 2020. Pursuant to the Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since this uncertified Covid-19 Antibody Test Kit has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative Covid-19 Antibody Test Kit until the FDA Special Certification is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph.

All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that this product is not sold or made available in the market or 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.

To report any sale or distribution of unregistered/uncertified medical devices, 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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