Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

14 APR 2021

FDA ADVISORY
No. 2021-0760

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of the Uncertified Medical Device Product "CLUNGENE® COVID-19 ANTIGEN RAPID TEST CASSETTE (SALIVA)"**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the uncertified medical device product:

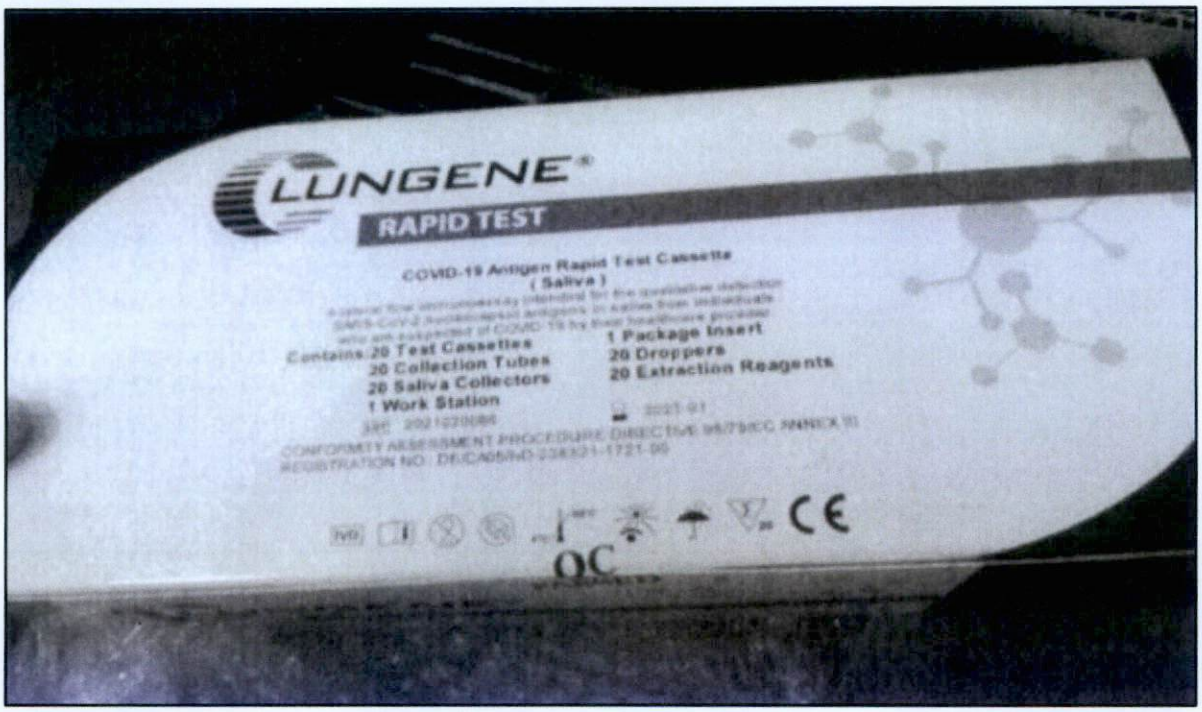

Figure 1. Uncertified Clungene® COVID-19 Antigen Rapid Test Cassette (Saliva)

The FDA verified through post-marketing surveillance that the abovementioned medical device product is not certified and no corresponding Special Certification has been issued. 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 medical device product 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 medical device product until the FDA Special Certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been certified 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 about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr@fda.gov.ph** indicating on the subject the concerned Advisory, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unregistered/uncertified 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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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