Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20220064

25 JAN 2022

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

SUBJECT: **Reiteration of FDA Advisory No. 2021-3195 and FDA Advisory No. 2021-3523 entitled Public Health Warning Against the Purchase and Use of the Uncertified COVID-19 Test Kit "CLUNGENE RAPID TEST COVID-19 ANTIGEN RAPID TEST CASSETTE"**

The Food and Drug Administration (FDA) reiterates its advisory to all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the uncertified COVID-19 test kit "Clungene Rapid Test COVID-19 Antigen Rapid Test Cassette."

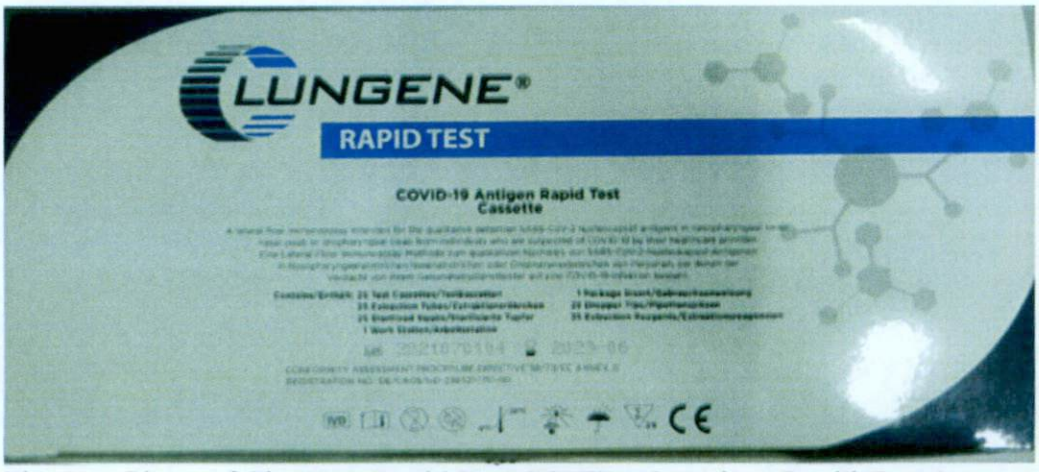

Figure 1. Photo of Clungene Rapid Test COVID-19 Antigen Rapid Test Cassette

Figure 2. Clungene Rapid Test COVID-19 Antigen Rapid Test Cassette

To date, the abovementioned COVID-19 test kit is not certified and no corresponding Special Certification has been issued nor application for renewal has been submitted. 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 test kit has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

The FDA reiterates to all concerned establishments not to distribute, advertise, or sell the said violative COVID-19 test kit 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.

Furthermore, FDA Order Nos. 2021-2683 and 2021-2993 are still in effect for the inventory and seizure of the aforestated violative health 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 COVID-19 test kit, contact the online reporting facility **eReport** through e-mail at **ereport@fda.gov.ph**.

Dissemination of this advisory to all concerned is hereby requested.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge, Director General

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