Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

14 MAY 2020

FDA ADVISORY
No. 2020-812

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

SUBJECT: **Public Health Warning Against the Sale and Purchase of the Uncertified COVID-19 Test Kit "Bioeasy 2019-nCoV IgG/IgM GICA Rapid Test"**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the sale and purchase of the uncertified Covid-19 test kit:

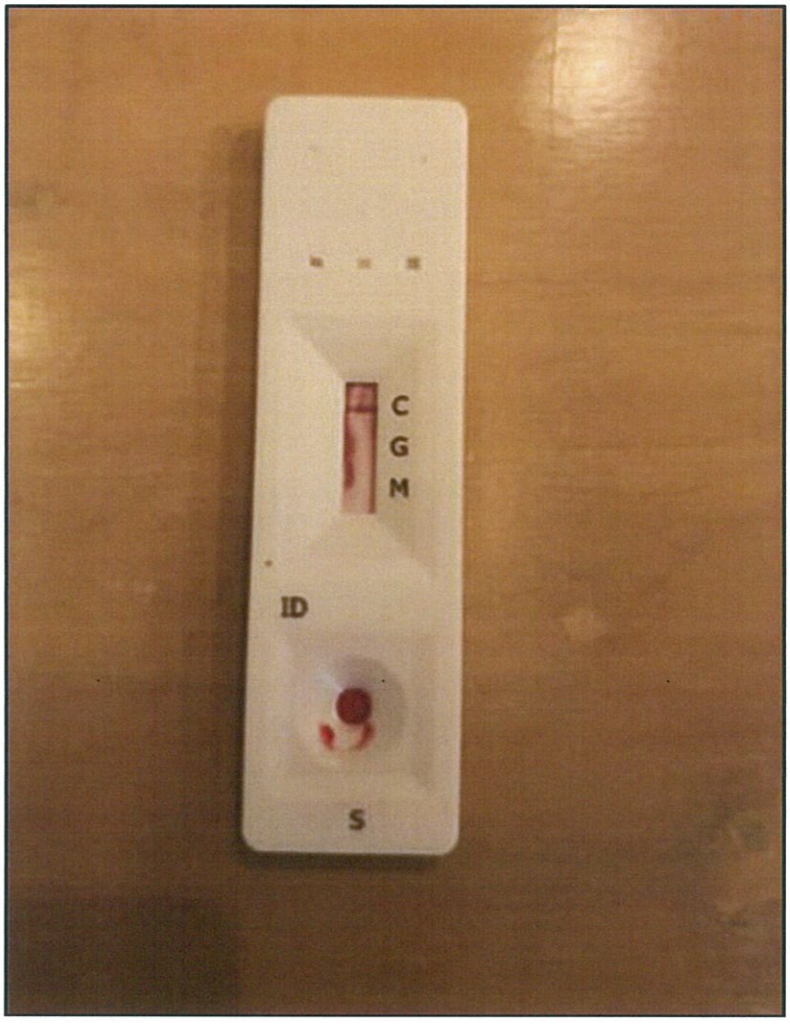

Figure 1. Uncertified Bioeasy 2019-nCoV IgG/IgM GICA Rapid Test

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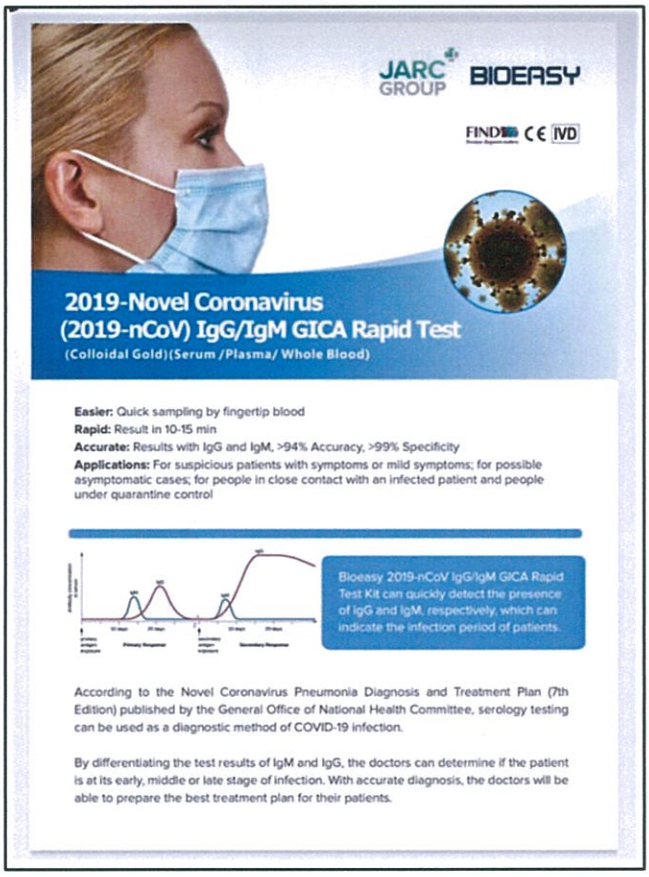

Figure 2. Uncertified Bioeasy 2019-nCoV IgG/IgM GICA Rapid Test

Figure 3. Uncertified Bioeasy 2019-nCoV IgG/IgM GICA Rapid Test

The FDA verified through post-marketing surveillance conducted on 20 March 2020 that the above mentioned medical device is not certified and/or no 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 has not gone through the evaluation process of the FDA, the agency cannot assure its quality and safety.

Furthermore, FDA Circular No. 2020-016 entitled "Prohibition of Online Selling of FDA Certified Covid-19 Antibody Test Kits" prohibits online selling and commercial use of such products.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr-prsdd@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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