



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:

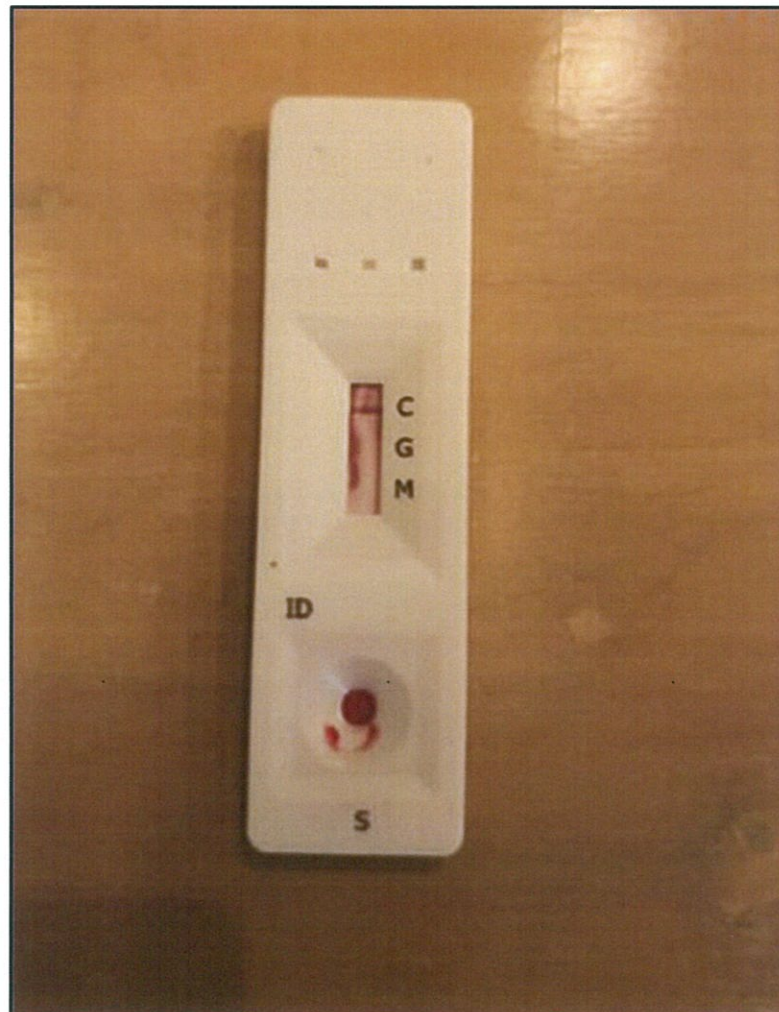


Figure 1. Uncertified Bioeasy 2019-nCoV IgG/IgM GICA Rapid Test



JARC GROUP BIOEASY

FIND IVD CE IVD

2019-Novel Coronavirus (2019-nCoV) IgG/IgM GICA Rapid Test

(Colloidal Gold)(Serum /Plasma/ Whole Blood)

Easier: Quick sampling by fingertip blood
Rapid: Result in 10-15 min
Accurate: Results with IgG and IgM, >94% Accuracy, >99% Specificity
Applications: For suspicious patients with symptoms or mild symptoms; for possible asymptomatic cases; for people in close contact with an infected patient and people under quarantine control

Bioeasy 2019-nCoV IgG/IgM GICA Rapid Test Kit can quickly detect the presence of IgG and IgM, respectively, which can indicate the infection period of patients.

According to the Novel Coronavirus Pneumonia Diagnosis and Treatment Plan (7th Edition) published by the General Office of National Health Committee, serology testing can be used as a diagnostic method of COVID-19 infection.

By differentiating the test results of IgM and IgG, the doctors can determine if the patient is at its early, middle or late stage of infection. With accurate diagnosis, the doctors will be able to prepare the best treatment plan for their patients.

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

JARC GROUP BIOEASY

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Test Procedure

INTERPRETATION OF RESULT
 If either the red IgG or IgM line is visible, it indicates a positive result of the specific line.
 If both the red IgG and IgM lines are visible, it indicates a strong positive result.

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 2100 J. Ellsboro St. Phase V, 8P Holmes, Parsippany City
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LOCALLY DISTRIBUTED BY THE JARC GROUP OF COMPANIES

Kit component: 25 tests/kit
 Storage: 2-8°C

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 cdrhr-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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