



FDA ADVISORY
No. **2020-1080**

15 JUN 2020

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Uncertified COVID-19 Test Kit “WIZ BIOTECH Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2”

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:

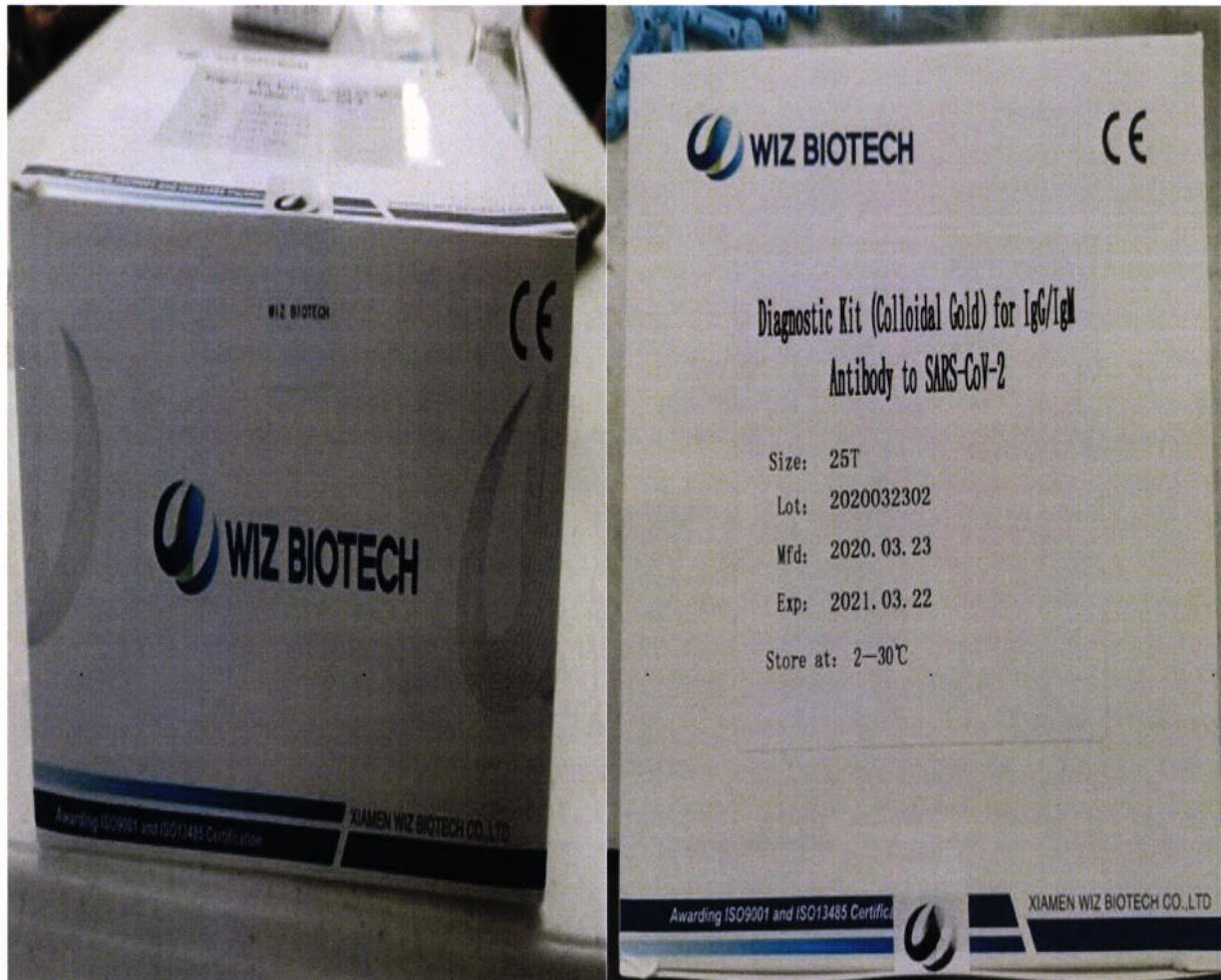


Figure 1. Uncertified WIZ BIOTECH Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2



The FDA verified through post-marketing surveillance conducted on 05 June 2020 that the abovementioned 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 unregistered medical device has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

Furthermore, FDA Circular 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@fda.gov.ph.

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.


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