Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20201054

10 JUN 2020

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Uncertified COVID-19 Test Kit "Testsealabs® One Step Rapid Test – SARS-cov-2 IgG/IgM Test Cassette"**

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

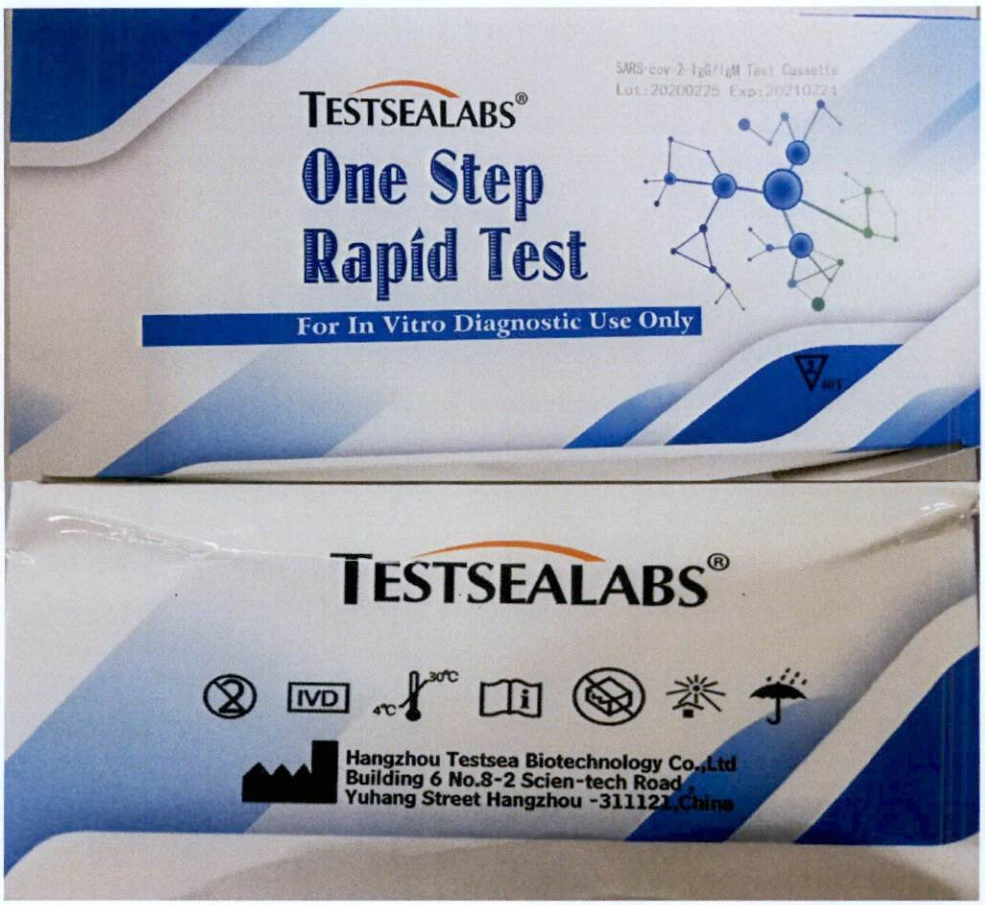

Figure 1. Uncertified Testsealabs® One Step Rapid Test – SARS-cov-2 IgG/IgM Test Cassette

---

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

The FDA verified through post-marketing surveillance that the abovementioned medical device is not certified and/or no FDA Special Certification has been issued as of 27 May 2020. 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 evaluation process of the FDA, the agency cannot assure its quality and safety.

Furthermore, FDA Circular No. 2016-016 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 about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr-prsdd@fda.gov.ph**, 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

DTN: 20200520112805