Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

24 MAR 2021

FDA ADVISORY
No. 20210678

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

SUBJECT: **Caution on the purchase and use of certain COVID-19 Test Kits following the performance validation conducted by the RITM**

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the following COVID-19 test kits distributed by the corresponding Market Authorization Holders (MAH) did not meet their declared product specificity and sensitivity after the performance validation conducted by the National Reference Laboratory – Research Institute for Tropical Medicine on COVID-19 Test Kits:

Product Name	Classification	Cert No.	Market Authorization Holder
2019-nCOV/COVID-19 IgG/IgM Rapid Test Device - Hangzhou Realy Tech	RAPID/ RTK	SC-COVID19-2020-242	Medico Exelente Marketing
SARS-CoV-2 Antibody Test (COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY) -Beijing Lepu Medical Technology	RAPID/ RTK	SC-COVID19-2020-351	Serve Diagnostica Inc.
		SC-COVID19-2020-638	Emperial Trading
SARS-COV-2 IGM/IGG ANTIBODY ASSAY KIT (COLLOIDAL GOLD METHOD) -Zybio, Inc.	RAPID/ RTK	SC-COVID19-2020-221	Medlane Diagnostic Solutions, Inc.
COVID-19 IgM Antibody Rapid Test Kit- Hecin Scientific, Inc.	RAPID/ RTK	SC-COVID19-2020-225	Bastion Payment Systems Corporation
SARS-CoV-2 IgG/IgM Antibody Test (Colloidal Gold) -HangZhou Testsea Biotechnology Co., Ltd	RAPID/ RTK	SC-COVID19-2020-305	HealthSolutions Enterprises, Inc.

SARS-CoV-2 IgG/IgM Rapid Test -Zhuhai Encode Medical	RAPID/ RTK	SC-COVID19-2020-328	Iraseth Pharma Incorporated
2019 n-CoV IgG/IgM RAPID TEST CASSETTE - Hangzhou Alltest Biotech Co., Ltd	RAPID/ RTK	SC-COVID19-2020-064	Iraseth Pharma Incorporated

In light of the foregoing, caution should be observed in the purchase and use of the said test kits pending initiation of product recall proceedings.

For more information and inquiries about this advisory, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph** or call **(02) 8857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

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