Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

FDA ADVISORY
No. 2021-1684

06 JUL 2021

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
Novel Coronavirus (2019nCoV) IgG/IgM Test Kit (Colloidal Gold) Mfd by: Genrui Biotech Inc.	RAPID/ RTK	SC-COVID19-2020-414	RTS Express Import and Export
GenBody COVID-19 IgG/IgM RAPID DIAGNOSTIC TEST Mfd by: Genrui Biotech Inc.	RAPID/ RTK	SC-COVID19-2020-654	UC Biosciences Inc.
		SC-COVID19-2020-292	Creative Bakers Company Inc.
COVID-19 (SARS-CoV-2) IgM/IgG Antibody Test Kit Mfd by: Wuhan EasyDiagnosis Biomedicine Co. Ltd.	RAPID/ RTK	SC-COVID19-2020-487	Babyzone Philippines, Inc.
ChekR™ COVID-19 IgM/IgG Rapid Test Kit Mfd by: B-bio, Co. Ltd.	RAPID/ RTK	SC-COVID19-2020-516	Medimax Corporation
SARS-CoV-2 IgG/IgM Kit Mfd by: Goldsite Diagnostics Inc.	RAPID/ RTK	SC-COVID19-2020-442	Labsolution Technologies, Inc.
		SC-COVID19-2020-608	TwinJ3 Sales and Marketing Corporation

FaStep COVID-19 Antigen Rapid Test Device (Nasopharyngeal/ Oropharyngeal Swab) Mfd by: Assure Tech (Hangzhou) Co. Ltd.	ANTIGEN	SC-COVID19-2020-583	Sahar International Trading, Inc.

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, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph** or call **(02) 857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

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