Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Advisory
No. 2021-0450

05 MAR 2021

TO: **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 the 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 of Tropical Medicine on COVID-19 Test Kits:

Product Name	Classification	Certificate No.	Market Authorization Holder
Cellex qSARS-Cov-2 IgG/IgM Cassette Rapid Test	Rapid/RTK	SC-COVID-19-2020-114	Labx Corp.
		SC-COVID-19-2020-130	Gepp Lab Solutions Inc
		SC-COVID-19-2020-286	Allied Hospital Supply International Corporation
		SC-COVID-19-2020-206	Labsolution Technologies, Inc
		SC-COVID-19-2020-300	Phil. Pak Pharma Inc
QuickProfileTM COVID-19 Antigen Test	Antigen	SC-COVID-19-2020-627	Murex Diagnostic Products Specialists
Abbott Panbio™ COVID-19 IgG/IgM Rapid Test Device	Rapid/RTK	SC-COVID19-2020-177	Sunfu Solutions Inc
Innovita 2019-nCoV Antibody Test (Colloidal Gold)	Rapid/RTK	SC-COVID19-2020-037	Fas Diagnostic Group Inc
		SC-COVID19-2020-133	Lifecore Bio Integrative Inc
		SC-COVID19-2020-035	Sahar International Trading Inc
Camtech COVID-19 IgM/IgG (CamTech-LFART)	Rapid/RTK	SC-COVID19-2020-136	Keli Devices Distribution Inc

HighTop SARS-CoV-2 IgM/IgG Antibody Rapid Test	Rapid/RTK	SC-COVID19-2020-082	Biotecnica Diagnostics Inc.
Diagnostic Kit for IgM/IgG Antibody to Corona Virus (SARS-CoV-2) Colloidal Gold) -Livzon	Rapid/RTK	SC-COVID19-2020-184	Philippine Blue Cross Biotech Corporation
COVID-19 IgM/IgG Test Kit (Dry Fluorescence Immunoassay) (NL-CA002-2020-50668)-Lansion Biotechnology	Rapid/RTK	SC-COVID19-2020-316	Basemed Kare Inc.
		SC-COVID19-2020-436	Labx Corporation
		SC-COVID19-2020-408	Diamed Kinetics Healthcare On the Go
Standard™ Q COVID-19 Ag TEST	Antigen	SC-COVID19-2020-314	Worldwidelink Trading Corporation
		SC-COVID19-2020-398	Trulaboratories Corporation
		SC-COVID19-2020-445	H & B Pharma International Inc.
Maglumi 2019-nCoV IgM (CLIA) Maglumi 2019-nCoV IgG (CLIA)	Rapid/RTK	SC-COVID19-2020-134 SC-COVID19-2020-135	Labsolution Technologies, Inc.
		SC-COVID19-2020-153 SC-COVID19-2020-152	Pharmastar Int'l Trading
		SC-COVID19-2020-306 SC-COVID19-2020-307	Medasia Medical Products Corportion

In light of the foregoing, caution should be observed in the purchase and use of 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.

ROLANDO ENRIQUE D. DOMINGO
Director General