Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

02 AUG 2021

FDA ADVISORY
No. 2021-1896

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

SUBJECT : **Recall of COVID-19 Test Kits with Low Results of Performance Validation Conducted by the Research Institute of Tropical Medicine (RITM)**

The Food and Drug Administration (FDA) informs all concerned healthcare professionals and the general public on the recall of the following COVID-19 test kits distributed by the corresponding Market Authorization Holders (MAHs) which did not meet their declared product specificity and sensitivity after the low results of performance validation conducted by the RITM on the said in vitro diagnostic test kits:

	Product Name	Certificate No.	Market Authorization Holder
1	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	SC-COVID19-2020-286	Allied Hospital Supply International Corporation
2	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	SC-COVID19-2020-206	Labsolution Technologies, Inc.
3	Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test	SC-COVID19-2020-300	Phil. Pak Pharma Inc.
4	Innovita 2019-nCoV Antibody Test (Colloidal Gold)	SC-COVID19-2020-037	Fas Diagnostic Group Inc.
5	Innovita 2019-nCoV Antibody Test (Colloidal Gold)	SC-COVID19-2020-133	Lifecore Bio Integrative Inc.
6	Innovita 2019-nCoV Antibody Test (Colloidal Gold)	SC-COVID19-2020-035	Sahar International Trading Inc.
7	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2 Colloidal Gold) -LIVZON	SC-COVID19-2020-184	Philippine Blue Cross Biotech Corporation
8	COVID-19 IgM/IgG Test Kit (Dry Fluorescence Immunoassay) (NL-CA002-2020-50668) -Lansion Biotechnology	SC-COVID19-2020-408	Diamed Kinetics Healthcare On The Go
9	Standard™ Q COVID-19 Ag Test	SC-COVID19-2020-445	H&B Pharma International Inc.

10	SARS-CoV-2 Antibody Test (Colloidal Gold Immunochromatography) -Beijing Lepu Medical Technology	SC-COVID19-2020-638	Emperial Trading
11	COVID-19 IgM Antibody Rapid Test Kit-Hecin Scientific, Inc.	SC-COVID19-2020-225	Bastion Payment Systems Corporation

The above-mentioned MAHs were notified by the FDA and were given ample time to explain in writing about the non-conformance of their product to the declared specifications. However, this Office did not receive any response from the said companies resulting to this recall.

Further, in compliance to FDA Memorandum No. 2021-009, all other MAHs, particularly with the same product as listed above, who have not submitted their documents for performance validation conducted by RITM are reminded to comply with prescribed period of thirty (30) days from the date of notice of submission from FDA to avoid revocation of issued special certification.

In light of the foregoing, all concerned healthcare professionals, establishments, and the general public are warned to discontinue further use, sale, and distribution of the identified COVID-19 test kits.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that these products are not sold or made available in the market or areas of jurisdiction.

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) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.

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