Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 MAY 2021

FDA ADVISORY
No. 2021-1154

TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall and Revocation of FDA Special Certification of Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall and revocation of FDA Special Certification of Cellex qSARS-CoV-2 imported and distributed by Gepp Lab Solutions, Inc.:

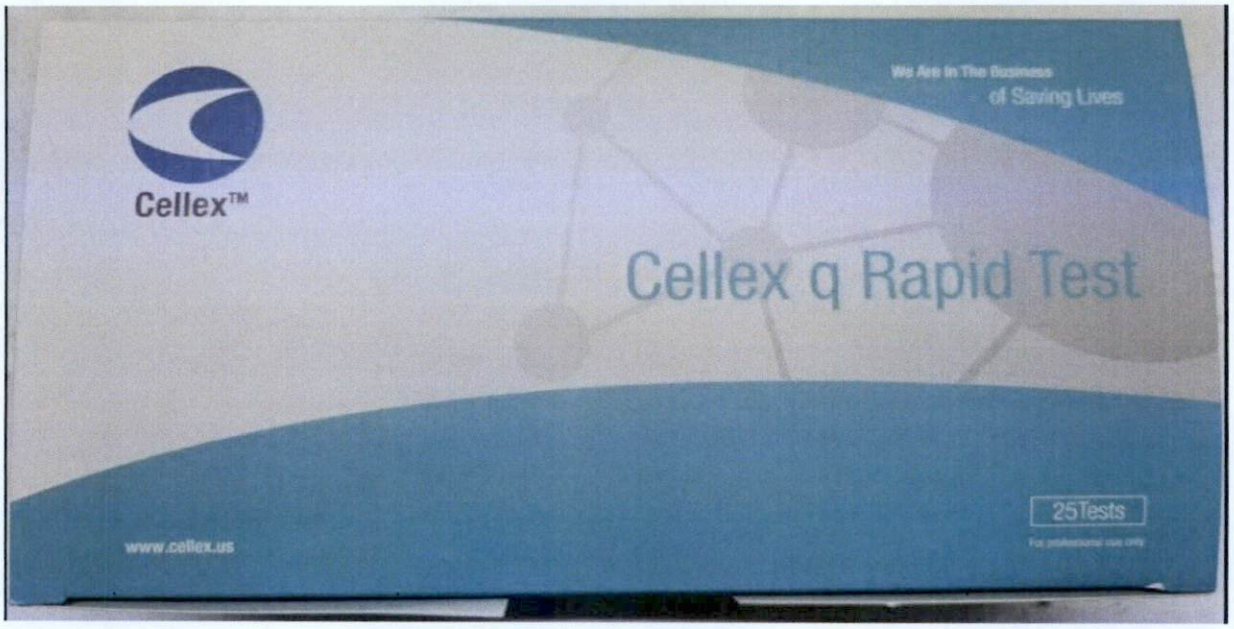

Figure 1. Photo of Cellex qSARS-CoV-2- IgG/IgM Cassette Rapid Test

The abovementioned COVID-19 test kit was non-compliant to the standards for performance validation conducted by the Research Institute for Tropical Medicine (RITM). Based on the FDA Memorandum No. 2020-011 the FDA shall revoke the issued Special Certification of COVID-19 anti-body test kits which are not compliant with the standards according to the performance

validation conducted by the RITM. Thus, FDA issued Special Certification to Cellex qSARS-CoV-2 IgG/IgM Cassette Rapid Test is already revoked.

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 Cellex qSARS-CoV-2-IgG/IgM Cassette Rapid Test.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is 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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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