Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2022-0017-A

09 DEC 2022

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

SUBJECT: **Lifting of the FDA Advisory No. 2022-0017 entitled Public Health Warning Against the Purchase and Use of the Uncertified Self-Administered COVID-19 Test Kit " ARIA SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)"**

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product, Uncertified Self-Administered COVID-19 Test Kit "ARIA SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), has been issued an FDA Special Certificate to the Market Authorization Holder (MAH), LABX Corp., in accordance to existing FDA rules and regulations.

Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2022-0017 dated 13 January 2022 is hereby lifted.

The public health warning imposed on the remaining product listed in FDA Advisory No. 2022-0017 shall remain to be upheld and shall not be affected by the issuance of this advisory. Furthermore, the issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to the existing laws, rules, and regulations.

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.**

To report any sale or distribution of unnotified medical device, contact the online reporting facility, **eReport**, through e-mail at **ereport@fda.gov.ph**.

Dissemination of this advisory to all concerned is hereby requested.

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Director General

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