Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

31 JAN 2022

FDA ADVISORY
No. 2021-3527-A

TO: **THE GENERAL PUBLIC**

SUBJECT: **Lifting of the FDA Advisory No. 2021-3527 entitled Public Health Warning Against the Purchase and Use of the Uncertified COVID-19 Test Kit "ICHROMA COVID-19 AG"**

The Food and Drug Administration (FDA) informs the public that **Ichroma COVID-19 Ag, with Registration No. SC-2022-001,** has been registered by the Market Authorization Holder (MAH), VITALINE HEALTHCARE INC., in accordance to existing FDA rules and regulations.

Accordingly, the warning against the purchase and use of the aforementioned medical device as mentioned in FDA Advisory No. 2021-3527 is hereby lifted.

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 unregistered medical device products, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

The public health warning imposed on the remaining products listed in FDA Advisory No. 2021-3527 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.

Dissemination of this advisory to all concerned is hereby requested.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN 20220118150455