



FDA ADVISORY
No. **2021-3527**

14 DEC 2021

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Uncertified COVID-19 Test Kits:
1. “ICHROMA COVID-19 AG”
2. “HUMASIS COVID-19 AG TEST ONE STEP COVID-19 AG TEST”

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the uncertified COVID-19 test kit:

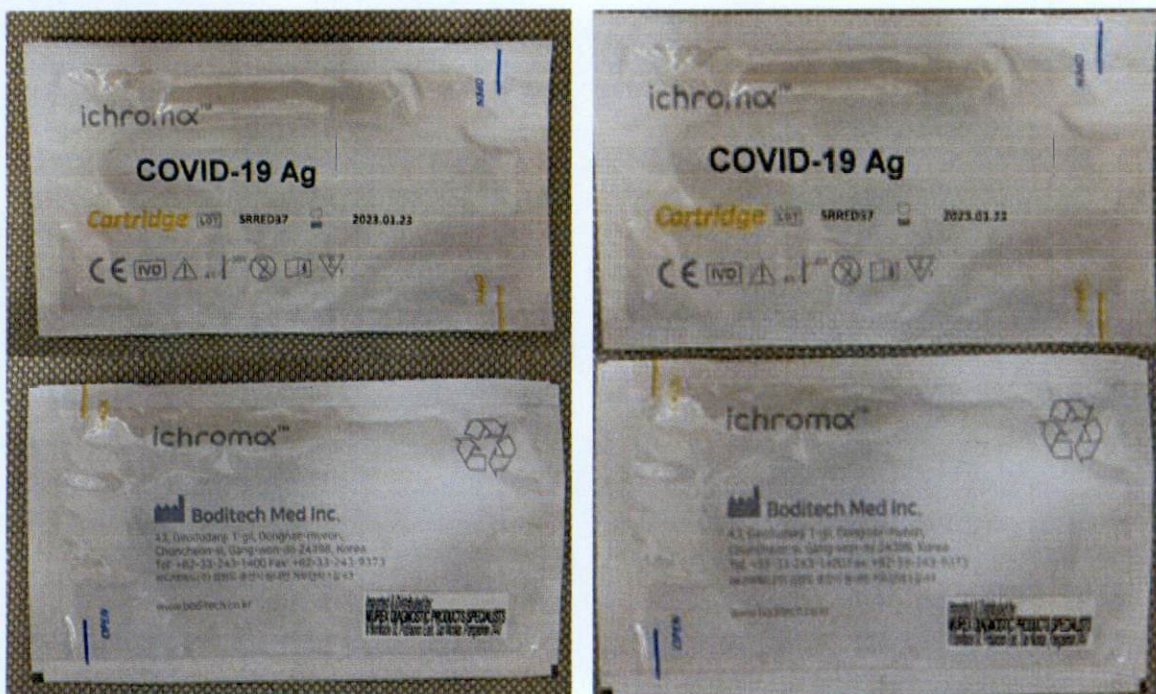


Figure 1. Uncertified Ichroma Covid-19 Ag



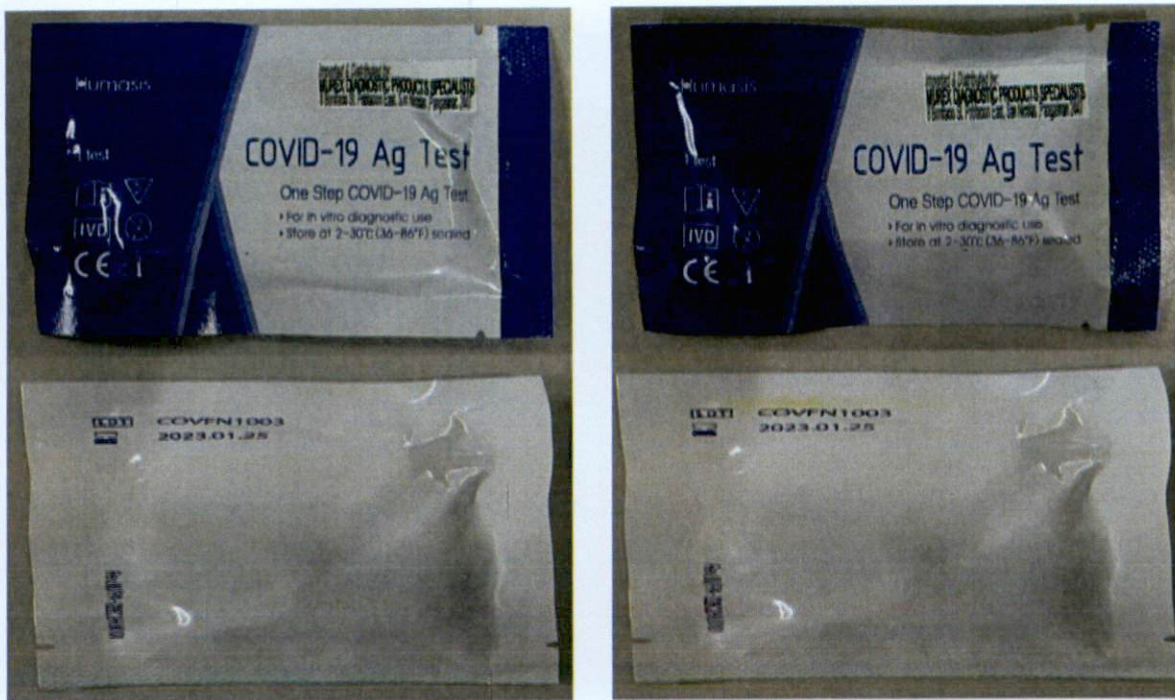


Figure 2. Uncertified Humasis Covid-19 Ag Test One Step Covid-19 Ag Test

The FDA verified through post-marketing surveillance that the abovementioned COVID-19 test kits are not certified and no corresponding Special Certifications have been issued nor applications for renewal have been submitted. Pursuant to the Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since these uncertified COVID-19 test kits have not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative COVID-19 test kit until the FDA Special Certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been certified with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph.

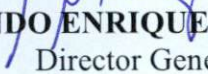
All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that these products are not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of these uncertified products.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at cdrhr@fda.gov.ph indicating on the subject the concerned Advisory, or call (02) 8857-1900 loc. 8301.

To report any sale or distribution of unregistered/uncertified COVID-19 test kit, contact the online reporting facility **eReport** through e-mail at **ereport@fda.gov.ph**.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20211027121647, 20211027121548, 20211027122719 & 20211027122810