Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 MAR 2021

FDA ADVISORY
No. 2021-0694

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Misbranded In Vitro Diagnostic (IVD) Medical Device "ABON® H. PYLORI ANTIBODY RAPID TEST IN FOREIGN CHARACTERS"**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the misbranded in-vitro diagnostic medical device "ABON® H. PYLORI ANTIBODY RAPID TEST IN FOREIGN CHARACTERS" in foreign characters:

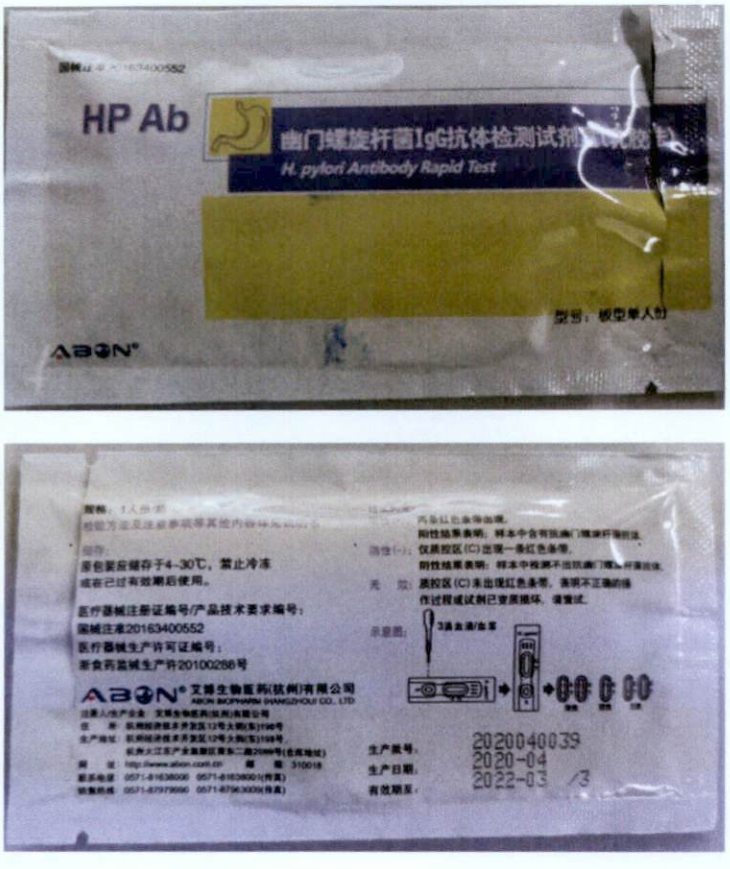

Figure 1. Misbranded ABON® H. pylori Antibody Rapid Test in Foreign Characters

The FDA verified through post-marketing surveillance that the abovementioned medical device product is being offered for sale in the local market.

Section 19(c) of Republic Act (RA) No. 3720 also known as the "Food, Drug, and Cosmetic Act" as amended by RA No. 9711 otherwise known as the "Food and Drug Administration (FDA) Act of 2009" states that "a device shall be deemed misbranded if any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use". The above-mentioned product is considered misbranded and the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is misbranded is prohibited pursuant to Section 10 of RA No. 9711.

The use of the said IVD medical device could lead to inaccurate result; thus, could compromise the health and safety of the user.

In view of the above, all concerned establishments are warned not to distribute, advertise, or sell the said violative medical device products, otherwise, regulatory actions and sanctions shall be strictly pursued.

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

The Bureau of Customs is urged to restrain the entry of this misbranded product.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr-prsdd@fda.gov.ph**, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of the above-mentioned product, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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