Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

31 MAR 2021

FDA ADVISORY
No. 2021-0700

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the following Unregistered In-Vitro Diagnostic (IVD) Medical Device Products in Foreign Characters:**

1. **ABON® HBV HEPATITIS B VIRUS COMBO RAPID TEST**
2. **INTEC HIV TEST KIT**
3. **INTEC ABO BLOOD TYPING TEST KIT**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the unregistered IVD medical device products:

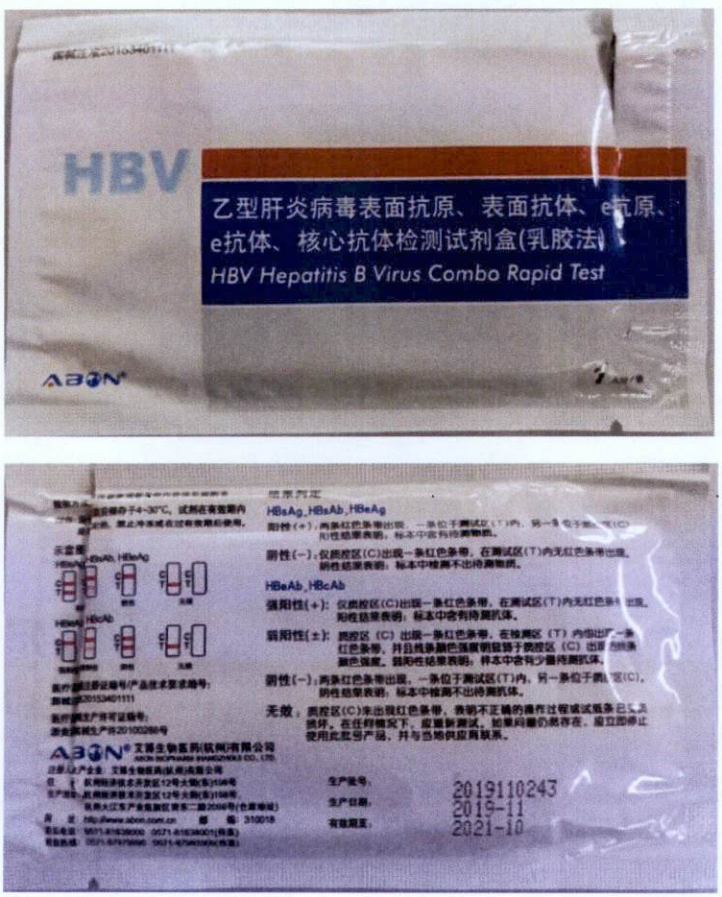

Figure 1. Unregistered ABON® HBV Hepatitis B Virus Combo Rapid Test (in foreign characters)

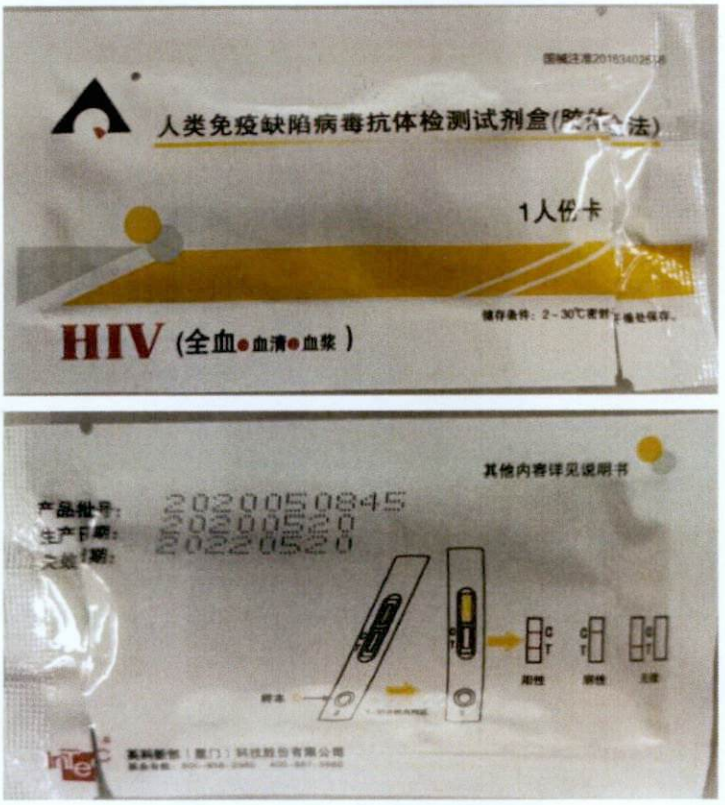

Figure 2. Unregistered Intec HIV Test Kit (in foreign characters)

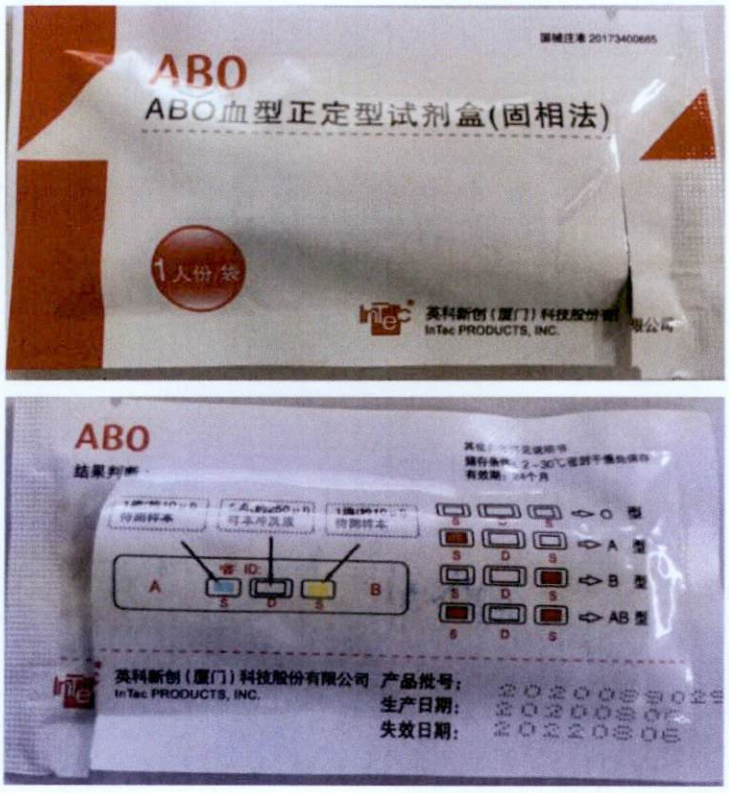

Figure 3. Unregistered Intec ABO Blood Typing Test Kit (in foreign characters)

The FDA verified through post-marketing surveillance that the above-mentioned IVD medical device products are not registered and no corresponding Product Registration Certificates have been issued. 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 unregistered IVD medical device products have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative IVD medical device products until the Product Registration Certificates are issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label in the form of either IVDR-xxx or RR-xxx.

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 unregistered products.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr@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 medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

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Director General

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