Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

18 APR 2018

FDA ADVISORY
No. 2018-149

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

SUBJECT: **Public Health Warning Against the Purchase and Use of Unregistered In-Vitro Diagnostic Medical Devices (Fujibio HIV Test Kit and Diagnos Pregnancy Test Kit)**

The Food and Drug Administration (FDA) advises all concerned healthcare professionals and the public against the purchase and use of the following in-vitro diagnostic medical device products:

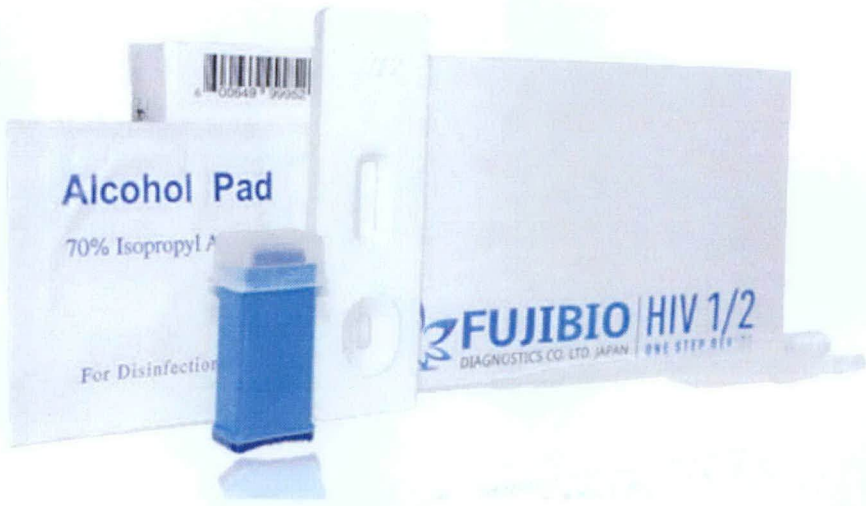

Figure 1. Fujibio HIV Test Kit

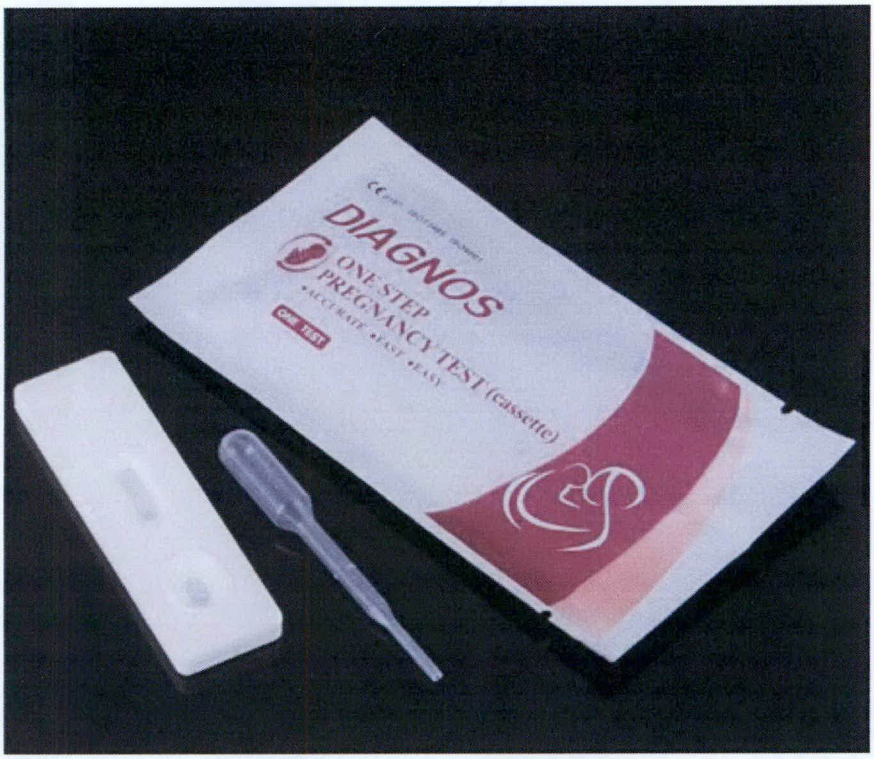

Figure 2. Diagnos Pregnancy Test Kit

FDA post-marketing surveillance activities have verified that Fujibio HIV Test Kit (see Figure 1) and Diagnos Pregnancy Test Kit (see Figure 2) have not gone through the registration process of the agency and have not been issued with Certificate of Product Registration (CPR).

Pursuant to the provisions of Republic Act 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 any health product without the proper authorization are prohibited.

Since the abovementioned products did not undergo the evaluation process of the FDA, the agency cannot guarantee their quality and safety.

In this regard, the public is hereby advised not to purchase the above-mentioned violative products. All concerned establishments are warned not to advertise, sell or distribute the said products until such have been issued with the corresponding Cerificate of Product Registration, otherwise, regulatory actions and sanctions shall be strictly pursued.

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

For more information and inquiries, please email us at **info@fda.gov.ph.** To report continuous sale or distribution of the above medical devices, utilize our online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**, or email us via **report@fda.gov.ph**, or call the Center for Device Regulation, Radiation Health, and Research at (02) 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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