



10 SEP 2019

**FDA ADVISORY**  
No. 2019-287

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

**SUBJECT: Public Health Warning Against the Purchase and Use of the following Unregistered Snibe Diagnostic Maglumi™ Medical Devices:**

1. Syphilis
2. HBsAg
3. Anti-HBs
4. HIV Ab/Ag Combi
5. Anti-HCV

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the unregistered medical devices:

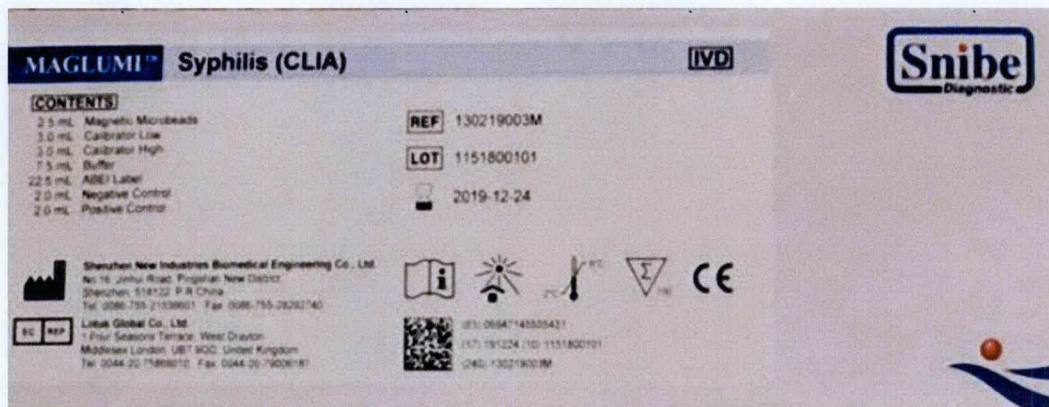


Figure 1. Unregistered Snibe Diagnostic Maglumi™ Syphilis (CLIA)

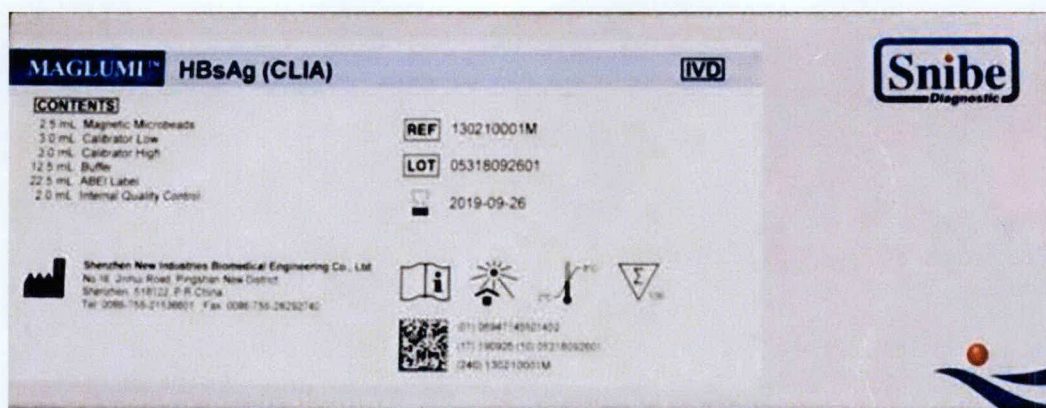


Figure 2. Unregistered Snibe Diagnostic Maglumi™ HBsAg (CLIA)



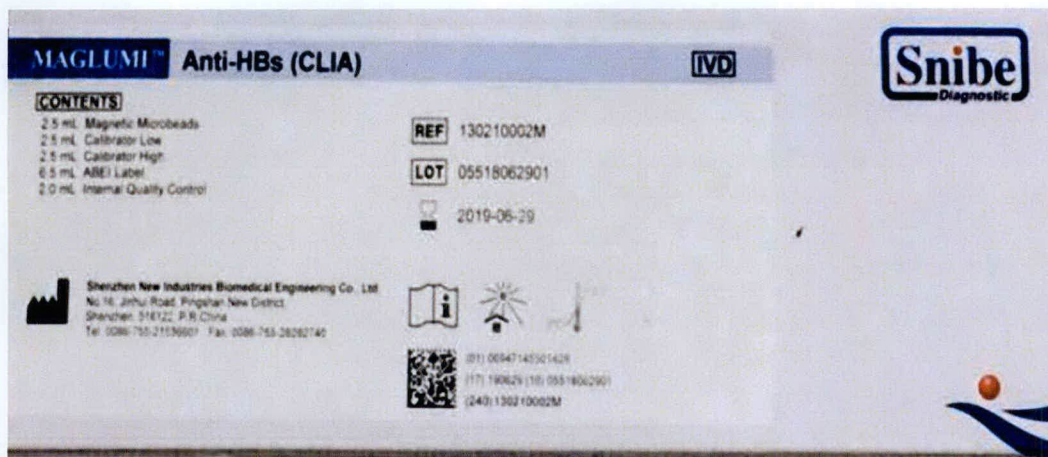


Figure 3. Unregistered Snibe Diagnostic Maglumi™ Anti-HBs (CLIA)



Figure 4. Unregistered Snibe Diagnostic Maglumi™ HIV Ab/Ag Combi (CLIA)

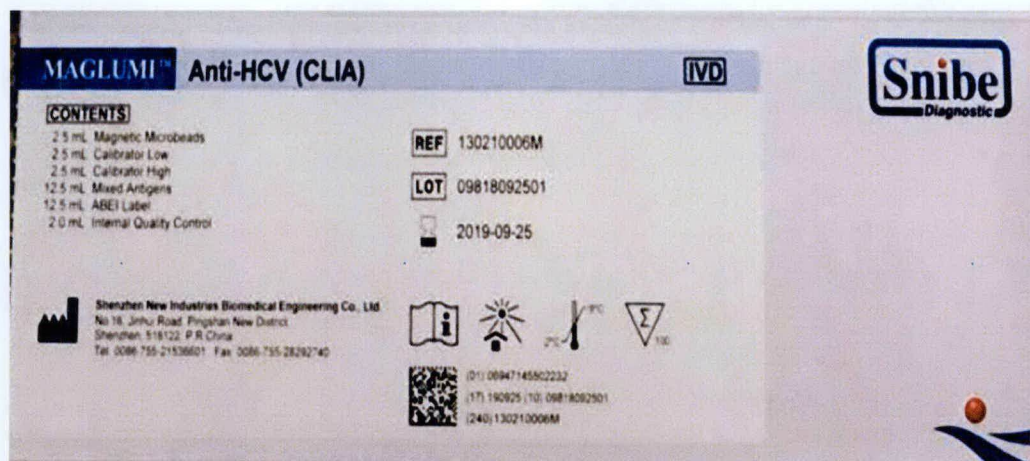


Figure 5. Unregistered Snibe Diagnostic Maglumi™ Anti-HCV (CLIA)

The FDA verified through post-marketing surveillance that the abovementioned medical devices are not registered and the Certificate of Product Registration (CPR) have not yet 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 medical devices have not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

In light of the foregoing, the public is advised not to purchase the violative products in the market.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical devices until CPR are issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

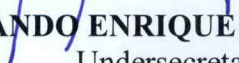
All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that these products are not sold or made available in the market or their areas of jurisdiction.

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

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at [cdrhr@fda.gov.ph](mailto:cdrhr@fda.gov.ph), or call **(02) 857-1900 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](http://www.fda.gov.ph/ereport).

Dissemination of this advisory to all concerned is hereby requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD, DPBO**  
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Officer-in-Charge, Director General

DTN: 20190424154227