Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 JUN 2018

FDA ADVISORY
No. 2018-206

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

SUBJECT: **VOLUNTARY RECALL OF THE PATHFAST CK-MB AND PATHFAST NTproBNP REAGENTS**

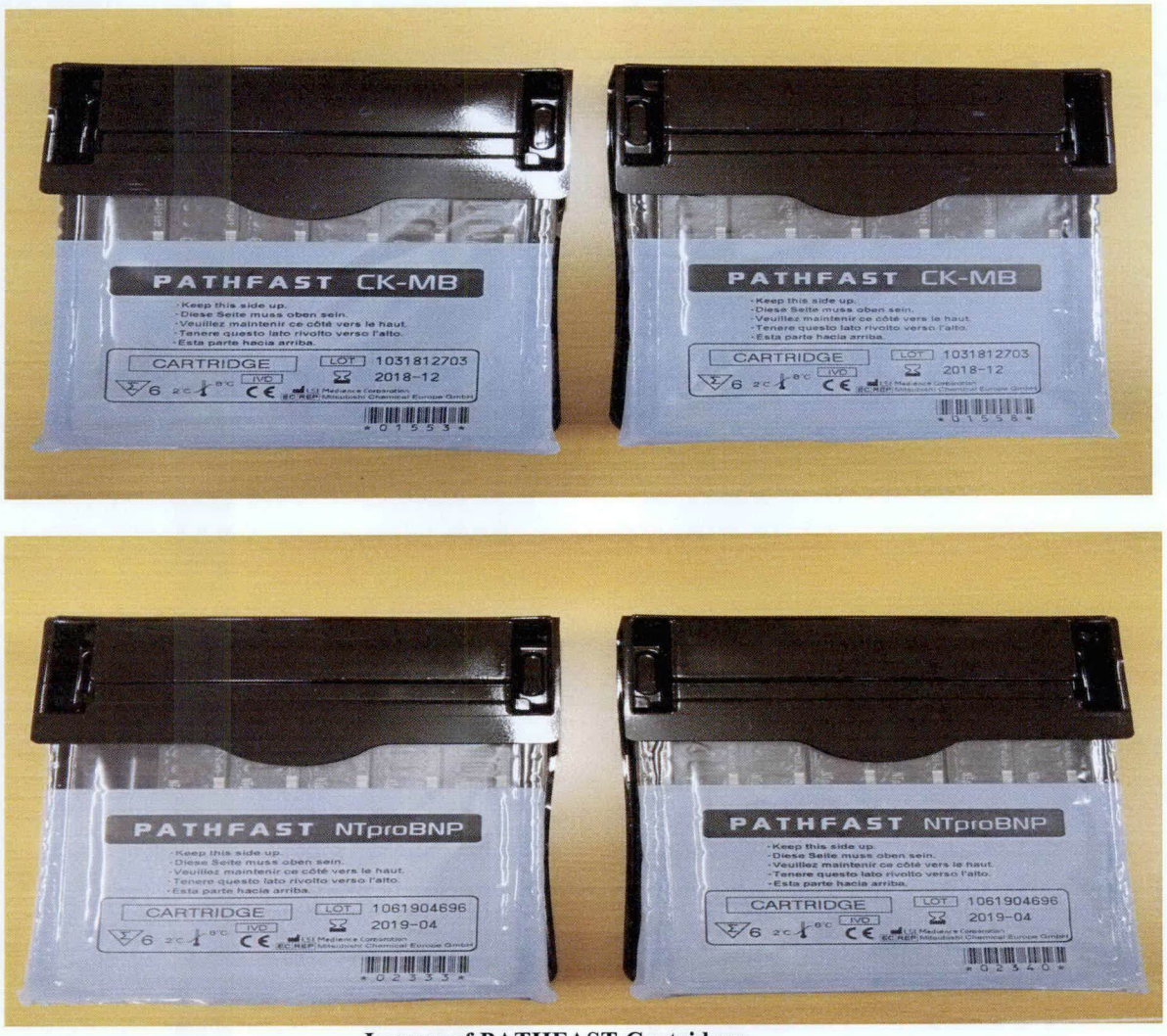
All are hereby advised by the Food and Drug Administration (FDA) on the voluntary recall of **PATHFAST CK-MB** with **LRD/CDRRHR_EXEMP-2015-6374** and **PATHFAST NTproBNP** with **LRD/CDRRHR_EXEMP-2015-6372** distributed by Global Medical Solutions, Inc., with business address at 3/F 14 Economia St., Bagumbayan, Quezon City with the following information:

Product Name	Catalogue No.	Lot No.
PATHFAST CK-MB	PF1031-K	0769
PATHFAST NTproBNP	PF1061-K	0768
PATHFAST NTproBNP	PF1061-K	0769

The cited medical device was voluntarily recalled by Global Medical Solutions, Inc. due to the several reagent cartridges had tiny pinhole on the Aluminum seal at the well position of alkaline phosphatase labelled antibody reagent which was generated during the filling process. In case the reagent leaked through the pinhole, the appropriate result may not be obtained. The above recalled medical device products might results in deviation of accuracy of the data if reagent leakage occurs through the pinhole.

Image of PATHFAST Reagents

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph



Images of PATHFAST Cartridges

Distributors, retailers, hospitals that have any lot of the stated medical device product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots.

Any suspected adverse reaction experienced or any incident of the same cases from the use of the device but not limited to the lots stated above, should be reported immediately to FDA at telephone no. (02) 857-1900 loc. 8301 or email us at cdrrhr_prsdd@fda.gov.ph.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General

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