Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

23 NOV 2017

FDA ADVISORY
No. 2017-315

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS, ESTABLISHMENTS AND THE GENETAL PUBLIC**

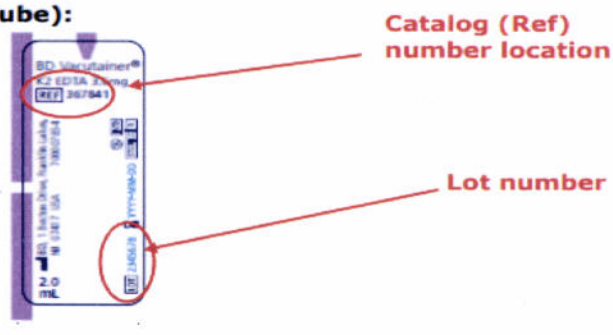
SUBJECT: **Voluntary Recall of BD Vacutainer K2 EDTA (K2E) 3.6mg Blood Collection Tube, 13 x 75mm x 2.0mL**

All concerned healthcare professionals, establishments and the general public are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall of **BD Vacutainer K2 EDTA (K2E)** (see photos of the product below) distributed by Metro Drug, Inc. BD Vacutainer K2 EDTA (K2E) 3.6mg Blood Collection Tube is used for the collection of venous blood.

Product Name	BD Vacutainer K2 EDTA (K2E) 3.6mg Blood Collection Tube
Specifications	13 x 75mm x 2.0mL
Catalog Code	367841
Lot. No.	6279849
Intended Use	For the collection of venous blood
Packaging/Selling Unit	Shelf pack of 100 tubes/Case of 10 Shelf packs
Registration No.	DVR – 3711

BD Vacutainer K2 EDTA (K2E) 3.6mg Blood Collection Tube
(13 x 75mm x 2.0mL)
Recall Catalog (Ref) / Lot Identification Sample

A. Unit (Tube):



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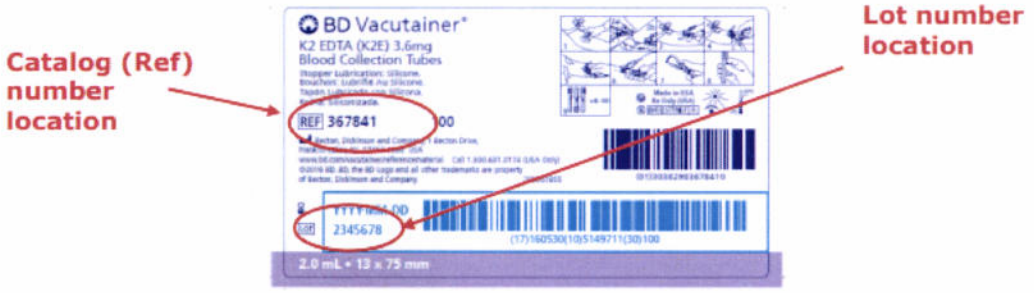
TÜVRheinland CERTIFIED
ISO 9001:2008 Management System
www.tuv.com ID 9105073396

B. Shelf:



C. Case:

The above-stated medical device products are being voluntary recalled by Becton Dickinson and Company (BD). BD has confirmed that a limited portion of the lot was manufactured with less than the required amount of K@EDTA additive, an anticoagulant, which may cause erroneous results that could lead to specimen recollection and potential delay of treatment or misdiagnosis/mismanagement of treatment and serious complications, such as failure to detect thrombocytosis or postponing surgery.

Distributors, retailers, hospitals and all healthcare professionals/users are advised to discontinue further distribution, sale and use of the said affected medical device product.

For more information and inquiries, please email us at cdrrhr_prsdd@fda.gov.ph or call the Product Research and Standards Development Division of the FDA - Center for Device Regulation, Radiation Health and Research at 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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