Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

25 OCT 2019

FDA ADVISORY
No. 2019-393

TO : **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT : **Voluntary Recall of BD Microtainer**

The Food and Drug Administration (FDA) warns all healthcare professionals on the voluntary recall of the following BD Microtainer® blood collection tubes manufactured by BD Caribe:

Product Name	Product Code	Lot Number
BD Microtainer® Capillary Blood Collection Tube with K2EDTA-Tube Micro w/ Microgard EDTA LAV	21041362	8243545
		8247628
		8288904
		8121979
		8120851
BD Microtainer® Z Capillary Blood Collection Tube (No Additives)- Tube Micro w/ Microgard PLN RD	21041356	8223778
		8268514
BD Microtainer® SST Capillary Blood Collection Tube-Tube Micro w/ Microgard SST GLD	21041357	8170911
		8282848
		8165884
		8117697
BD Microtainer® Amber Capillary Blood Collection Tube-Tube Micro w/ Microgard SST GLD/AMB	21041358	8233967

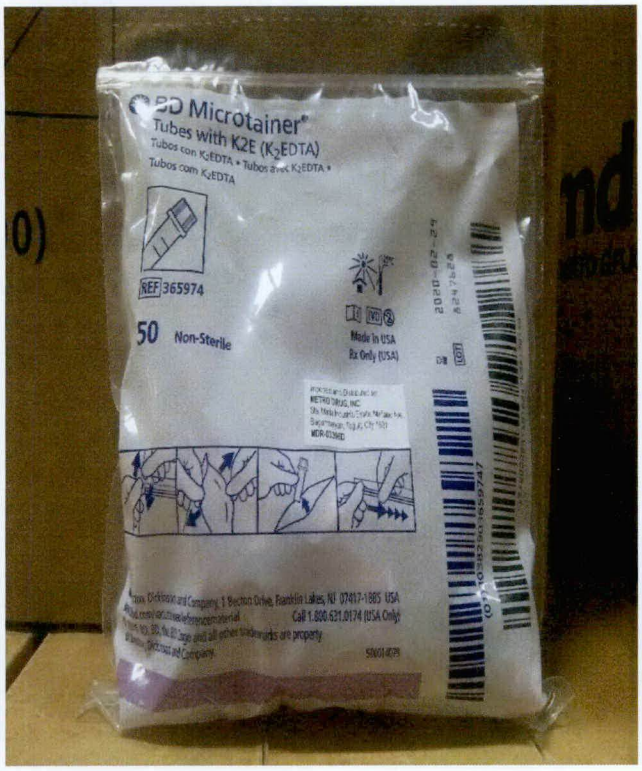

Figure 1. BD Microtainer® Capillary Blood Collection Tube with K2EDTA-Tube Micro w/ Microgard EDTA LAV

Figure 2. BD Microtainer® Z Capillary Blood Collection Tube (No Additives)- Tube Micro w/ Microgard PLN RD

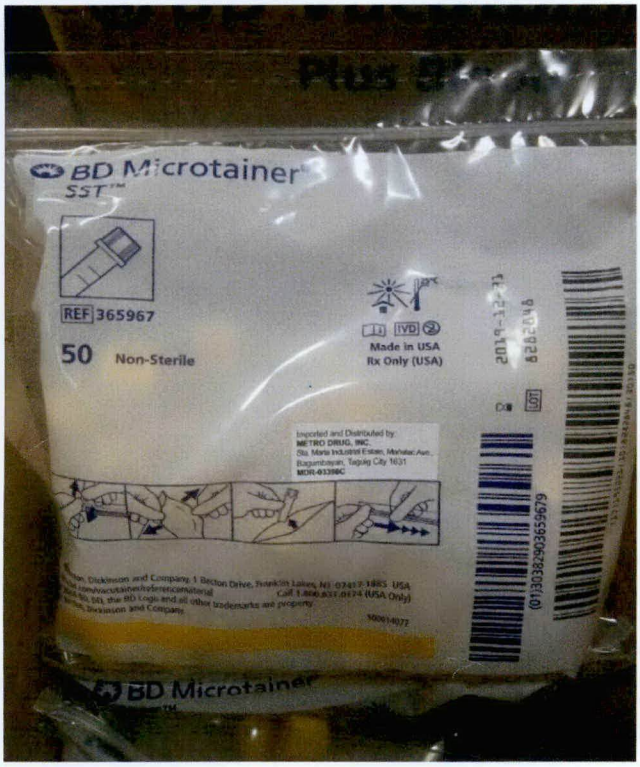

Figure 3. BD Microtainer® SST Capillary Blood Collection Tube-Tube Micro w/ Microgard SST GLD

Figure 4. BD Microtainer® Amber Capillary Blood Collection Tube-Tube Micro w/ Microgard SST GLD/AMB

BD is conducting a voluntary recall for the aforementioned BD Microtainer® products based on the confirmation that these products may have damaged tube reservoirs.

A damaged reserviors may caused insufficient blood sample collection and non-proportional blood-to-additive ratio, hence producing inaccurate results. Moreover, a patient may be required to undergo a repeat blood sample collection and testing on the event that any of theaforementioned BD Microtainer® with damaged reservoir was used during blood collection.

In light of the foregoing, all concerned healthcare professionals, and establishments is warned to discontinue further use, sale, and distribution of the medical device.

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 health products are not sold or made available in the market or areas of jurisdiction.

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport.**

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 857-1900 loc. 8301.**

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 20190625091857