



URGENT PRODUCT RECALL

January 27, 2017

Product Name	UDI	Catalog No.	Lot No.	Expiration Date
BD Vacutainer® Sodium Polyanetholesulfonate 5.95mg Sodium Chloride 14.4mg Blood Collection Tubes For Microbiological Studies (8.3mL • 16 x 100mm)	N/A	364960	6090812	4/30/2017

Dear Customer,

BD is conducting a voluntary recall for BD Vacutainer® Sodium Polyanetholesulfonate 5.95mg Sodium Chloride 14.4mg Blood Collection Tube (SPS tubes), catalog number 364960, lot 6090812.

BD has confirmed that a portion of SPS tubes associated with the above referenced product were incorrectly labeled at the case and shelf pack level. Impacted product will have incorrectly labeled SPS tube **packaging** that includes a label for ACD tubes catalog number 364606, BD Vacutainer® ACD Solution A Blood Collection Tubes 8.5mL • 16 x 100mm (see **Figure 1** below). The ACD tubes label will also reference lot/expiry details associated with the SPS tubes. The correct shelf pack label for the SPS tubes, catalog 364960, is indicated in **Figure 2**.



Figure 1. Shelf Pack (ACD Label)



Figure 2. Shelf Pack (SPS label)

IMPORTANT: ALL SPS/ACD labels with LOT 6090812 MUST BE RETURNED

Individual SPS tubes from lot 6090812 are not impacted and conform fully as the unit level product is correctly labeled; the issue only pertains to the case and shelf pack labelling.

SPS tubes are used in microbiology for blood cultures, whereas ACD tubes are used for cell preservation for HLA phenotyping, DNA and paternity testing. If an SPS tube was unknowingly used instead of an ACD tube, without the necessary preservation the cells would be rendered non-viable for various testing methodologies, potentially resulting in a false negative outcome.

While no adverse events have been reported for this issue, a false negative in HLA testing has the potential of delaying identification of a suitable organ match, delaying organ transplant and extending duration of care and also potentially requiring additional therapeutic intervention/hospitalization. While there is no medical risk with DNA and paternity testing resulting from this labeling issue, there is a risk in not being able to properly identify a biological parent.

Our records indicate you may have been shipped the above-referenced lot of product. BD distributed the affected lot beginning July 19, 2016.

PLEASE TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory for catalog number 364960, lot number 6090812 and quarantine the product subject to the recall.

Important Note: Please ensure you review your inventory as well for any product which entered your facility with catalog number 364606, lot number 6090812.

2. Complete the Customer Recall Response Form and fax it back to BD at **1-888-345-0479** or email to **BD4973@stericycle.com**.
3. Return all affected products using the enclosed packaging instructions and include the completed Recall Response Form with the product. Upon receipt of the returned product, BD will issue replacement product.

NOTE: Even if you do not have any of the affected lot in your inventory, please complete the Customer Recall Response Form indicating you have zero (0) quantity and fax the completed form back to BD at 1-888-345-0479 or email the completed form to BD4973@stericycle.com.

If you have any questions or require assistance with the return of the recalled product and/or availability of replacement product, please contact **1-888-345-8309 between 8AM and 5 PM ET Monday through Friday.**

BD Life Sciences – Preanalytical Systems
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

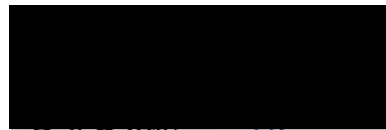
Any adverse health consequences experienced with the use of this product should be reported to BD and may be reported to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/medwatch/report.htm.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with the highest quality products. Thank you for your prompt support on this important matter. BD appreciates your cooperation.

Sincerely,



Aparna Ahuja, MD, PG cert Hospital
Management, IF CAP
Director Medical Affairs
BD Life Sciences – Preanalytical
Systems



Gail Griffiths
Sr. Director Regulatory Compliance
BD Life Sciences

Customer Recall Response Form

BD Vacutainer® Sodium Polyanetholesulfonate 5.95mg Sodium Chloride 14.4mg Blood Collection Tube (8.3mL x 16 x 100mm) Recall

Catalog (Ref) #	Lot Number
364960	6090812

Check inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper or delayed product replacement.* Fax the completed form to BD at 1-888-345-0479 or email the completed form to BD4973@stericycle.com.

Please return only product from the lot referenced in the recall letter; you will only receive product replacement for recalled product that you return.

Facility: _____
 Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ State: _____ Zip: _____

Contact Person: _____

Telephone No.: _____ Email Address: _____

Fax No.: _____

I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

We do not have any of the affected product(s) on hand. (Fill out and return this form to BD at fax or email above)

We have the following units and request replacement(s) (Fill out and return this form to BD at fax or email above and return the product per the packing instruction.)

Product Name	Catalog No.	Lot No.	No. of Units
BD Vacutainer® Sodium Polyanetholesulfonate 5.95mg Sodium Chloride 14.4mg Blood Collection Tube (8.3mL x 16 x 100mm)	364960	6090812	

Please enclose the completed form with the return product shipment.

PACKING INSTRUCTIONS

**BD Vacutainer® Sodium Polyanetholesulfonate 5.95mg Sodium Chloride
14.4mg Blood Collection Tube (8.3mL x 16 x 100mm) Recall**

Product Return Instructions:

1. Please enclose the complete Recall Response Form with the shipment.
2. The simplest way to return product would be to access the following UPS website: <http://returns.upsrow.com>
login: **bdapi**, Password: **bdapi**

When you access the site, you can select among 3 UPS shipping options. If you select the initial option, "Display Return Label Only", you can give the package to a UPS person who stops at your site or drop it off at a UPS location. If you select either of the remaining two options, a UPS person will stop by your location specifically to pick up the package. You need to enter the returned product reorder number, lot number and quantity on the website.

Note: If you are not returning product, also indicate this on the website.

3. If you do not have access to the internet you can call UPS at 1-800-PICK-UPS (742-5877) and arrange for a pick-up using the following charge number specific to this recall: **OER739**.

Product should be returned to:

Returns Team, ref. PAS-17-951-FA

BD Distribution Center

DOOR #2

130 Four Oaks Parkway

Four Oaks, NC 27524

For shipments over 150 pounds - utilize UPS Ground Freight. UPS Freight Customer Service can be contacted at 1-800-333-7400. When arranging the pick-up of freight, please specify 3rd party billing as follows:

Returns Team, ref. PAS-17-951-FA

BD c/o Cass Info Systems

PO Box 67

St. Louis, MO 63166-0067

4. Upon receipt of returned product, BD will provide product replacement. A returned goods authorization is NOT required for this recall return process.

DO NOT SHIP FREIGHT COLLECT
Our warehouse cannot receive products shipped "freight collect".