



FIELD SAFETY NOTICE – BDB-22-4547
BD Trucount™ Tubes and Kits
 Type of Action: Advisory Notice

31 October 2022

Dear Customer,

BD is conducting a product advisory of BD Trucount™ tubes and kits containing these tubes as listed in the table.

Product Name	Catalog (Ref) Number	Lot Number	Expiration Date
BD Multitest™ 6-Color TBNK Reagent	337166	11589	06/30/2023
		28743	03/31/2023
		45907	06/30/2023
		59833	04/30/2023
		89140	05/31/2023
		89148	07/31/2023
		89150	08/31/2023
BD Trucount™ Tubes	340334	2031144	12/31/2023
		2034642	12/31/2023
		2035110	12/31/2023
		2035121	12/31/2023
		2060660	01/31/2024
		2073297	01/31/2024
		2073298	01/31/2024
		2095186	02/29/2024
		2101458	02/29/2024
		2108676	02/29/2024
		2112862	03/31/2024
		2152055	03/31/2024
		2152064	03/31/2024
		2152068	04/30/2024
		2152075	04/30/2024
		2152080	04/30/2024
		2203024	04/30/2024
		2208091	05/31/2024
		2215812	05/31/2024
		2223229	06/30/2024
2235269	05/31/2024		
2236782	05/31/2024		
2236783	06/30/2024		
2236934	06/30/2024		
2237008	06/30/2024		
BD Leucocount™ Kit	340523	2073863	01/31/2024
		2123451	03/31/2024
		2213828	02/29/2024



BD™ Stem Cell Enumeration Kit	344563	2097468 2097469 2097470 2124891 2192079 2192083	01/31/2024 11/30/2023 12/31/2023 02/29/2024 05/31/2024 04/30/2024
BD Leucocount™ Kit	662415	2026676 2195942	05/31/2023 02/29/2024
BD Multitest™ 6-Color TBNK	662995	11568 31905 45905 53637 88003 89111	06/30/2023 07/31/2023 06/30/2023 04/30/2023 07/31/2023 05/31/2023

Description:

BD has confirmed through internal investigation that the labels applied to the BD Trucount™ tubes are becoming detached as shown in the pictures below:



Our investigation has identified an adhesive change made at a supplier resulting in the inadequate adhesion. BD is working closely with the supplier to resolve this situation expediently.

BD Trucount™ Tubes can cause automation errors when used with the automated loader for the FACSCalibur™, the FACSCanto™, and the FACS™ Lyse Wash Assistant. In these instruments, the loader moves the tube to the probe, the tube is lifted from its position in the loader for sampling, and then it is replaced into its position in the loader. If the label is partially detached, the tube cannot be fully replaced into its position in the loader.

The Trucount product performance is not impacted by the label detachment issue. As a result, for any patient testing completed, no further action is warranted.

Our records indicate you have been shipped the affected product which was distributed beginning February 11, 2022.

Please Take the Following Actions:

1. Immediately review your inventory for the specific catalog and lot numbers listed above.
2. For any tube where label detachment is observed, BD recommends that the clinician remove the label from the tube and, using a permanent marker, record the tube lot number as well as any other relevant information directly on the tube as shown below:

1) Use one BD Trucount™ Tube lot at a time	2) Remove label from the tube	3) Write lot number and relevant information on the tube
		

Removal of the label prevents it from interfering with any auto-loading sample preparation and analysis systems, as well as from sticking to other tubes.

3. Distribute this notice to all those who need to be aware of the Field Safety Notice within your organization.
4. Complete the attached Customer Response Form and return to the BD contact noted on the form so that BD may acknowledge your receipt of this notification.

Actions Taken by BD:

1. Corrective and preventive action was initiated to investigate root cause and identify actions to prevent recurrence.



2 International Business
Park Road
The Strategy #08-08
Singapore 609930
Registration No.
201114149N
bd.com

Contact Information:

There are other identifiers and/or lots affected globally and please verify with local BD representative if in doubt. For all other inquiries please contact your local BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

BD is committed to advancing the world of health. Our primary objective is providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours Sincerely,

A handwritten signature in black ink, appearing to be 'EY', written in a cursive style.

Erwin Yap
Quality Director, Southeast Asia



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bd.com

Customer Acknowledgement Form
BDB-22-4547
BD Trucount™ Tubes and Kits
Type of Action: Advisory Notice

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to SEA_Quality SEA_Quality@bd.com / **local BD contact** by 30 November 2022.

Please tick as appropriate.

- I have read and understood the attached notice & will share this Field Safety Notice with all users within my facility.

Completed by:

Name:	
Signature:	
Date:	
Facility / Address / Telephone Number:	