Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 197 **dated** 23/10/22 **Regarding NCMDR Field Safety Notice of BD Trucount™ Tubes from (mfr: Becton Dickinson & Co. (BD)).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Circular No. 197 / 2022

27 -03-1444 H

23 -10-2022

Field Safety Notice of BD Trucount™ Tubes from Becton Dickinson & Co. (BD).

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17286
Product	BD Trucount™ Tubes.
Description	IVD.
Manufacturer	Becton Dickinson & Co. (BD).
Local agent	Aston Medical Supplies LLC.
The affected products	REF/Lot: See Appendix 1 in the attached FSN.
Reason	An adhesive change made at a supplier that results in the inadequate adhesion of the labels applied to the BD Trucount™ Tubes. This results in the BD Trucount™ Tube labels becoming detached.
Action	1. For any tube where label detachment is observed, BD recommends that the user removes the label from the tube and, using a permanent marker, record the tube lot number as well as any other identification numbers directly on the tube (See attached for more information). 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

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www.BD.com

2nd – Oct – 2022

PRODUCT NOTIFICATION – BDB-22-4547

BD Trucount™ Tubes

REF: See Appendix 1 **Lot Numbers:** See Appendix 1

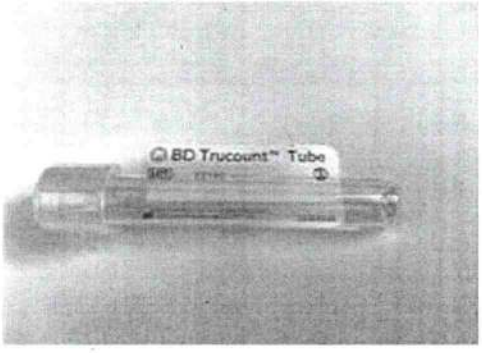
Type of Action: Advisory

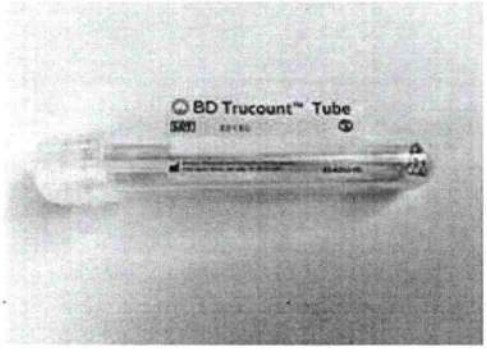
Dear Customer,

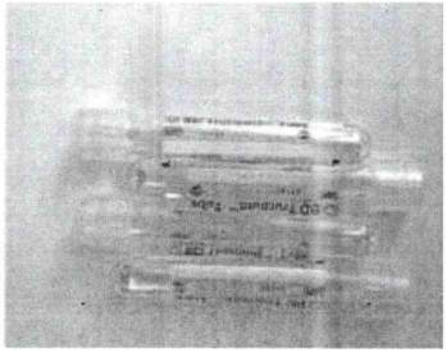
BD is issuing this product notification for specific lots of **BD Trucount™ Tubes** as listed in Appendix 1. According to our distribution records your organisation may have received the impacted product. Affected product was distributed by BD from February 2022.

Description of the Problem

Based on customer feedback, BD has identified an adhesive change made at a supplier that results in the inadequate adhesion of the labels applied to the **BD Trucount™ Tubes.** This results in the **BD Trucount™ Tube** labels becoming detached as shown in the pictures below:







Note: The BD Trucount™ Tube product performance is not impacted by the label detachment issue.

This product notification is limited to the product codes and lot numbers listed in Appendix 1. No other product codes or lot numbers are affected by this product notification.

Potential risk

The issue could potentially cause automation errors when BD Trucount™ Tubes are used with the automated loader for the BD FACSCalibur™, the BD FACSCanto™, and the BD 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

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partially detached, the tube cannot be fully replaced into its position in the loader. Please refer to Appendix 2 for information on what is included on the label.

There are no additional follow-up activities recommended for any patient samples tested with these tubes. To date, BD has not received any adverse events worldwide related to this issue.

There is no requirement for customers to return any BD Trucount™ Tubes to BD. These products can continue to be used in accordance with the guidance in this Product Notification.

Actions taken by BD

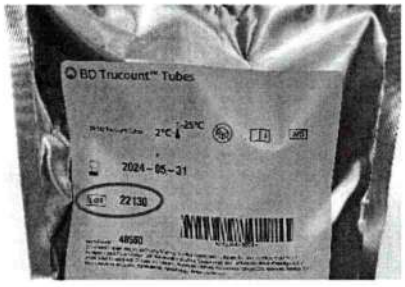
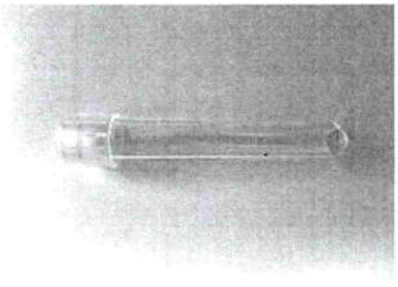
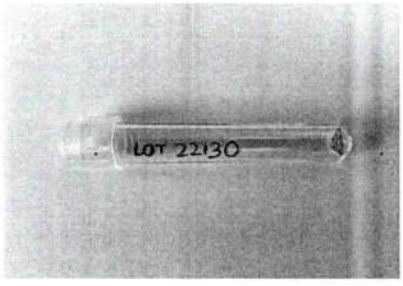
BD is working with the supplier to identify the root cause and implement corrective actions to prevent recurrence.

Actions for Customers to take:

1. Circulate this product notification to all those within your organisation that may use the **BD Trucount™ Tubes**.

2. If you have further distributed the product, please identify those users and notify them at once of this advisory. Ensure they follow the instructions listed in this Product Notification.

3. For any tube where label detachment is observed, BD recommends that the user removes the label from the tube and, using a permanent marker, record the tube lot number as well as any other identification numbers directly on the tube as shown:

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.

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4. Complete the customer response form on page 4 and return it to Ahmed.Shebah@bd.com **as soon as possible or no later than 31st October 2022.** If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on Ahmed.Shebah@bd.com

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

Lorna Darrock
Sr. Manager, Post Market Quality
EMEA Quality

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Customer Response Form - BDB-22-4547

BD Trucount™ Tubes

REF: See Appendix 1 **Lot Numbers:** See Appendix 1

Return to Ahmed.Shebah@bd.com as soon as possible or **no later than the 31st October 2022.**

- **I confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

Account/Organisation Name:		
Department *(if applicable)*:		
Address:		
Postcode:	**City:**	**Country:**
Contact Name:	**Job Title:**	
Contact Telephone Number:		
Contact E-mail Address:		
Name of your supplier for this product*: *(if not direct from BD)*		
Signature:	**Date:**	

This form must be returned to BD before this action can be considered closed for your account.

**If you were forwarded this Product Notification via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*

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Appendix 1 - Product Code / Lot number Identification

Product Code (REF)	Product Name	Lot Number	Expiry Date
333185	BD Multitest™ CD8/CD38/CD3/HLA-DR (50 tests with BD Trucount tubes)	48325	20230331
337166	BD Multitest™ 6-Color TBNK Reagent with BD Trucount™ Tubes	11589	20230630
		28743	20230331
		45907	20230630
		59833	20230430
		89140	20230531
		89148	20230731
		89150	20230831
338331	BD® Plasma Count Kit	2138823	20221031
		2201159	20230131
		2201171	20230131
		2201174	20230131
		2213297	20230131
340523	BD Leucocount™ Human Reagent Kit	2073863	20240131
		2123451	20240331
		2213828	20240229
342443	BD Tritest™ CD3/CD19/CD45 (50 Tests per kit with BD Trucount™ Tubes)	53881	20230731
342444	BD Tritest™ CD3/CD4/CD45 (50 Tests with BD Trucount Tubes)	16101	20230731
		25956	20230531
		59291	20230731
		73302	20230930
		80204	20230531
		80213	20230531
342445	BD Tritest™ CD4/CD8/CD3 (50 Tests per kit with BD Trucount™ Tubes)	01670	20240131
		09981	20240131
		48322	20231130
		57189	20231130
		78515	20240531
342446	BD Multitest™ CD3/CD16+CD56/CD45/CD19 (50 Tests per kit with BD Trucount™ Tubes)	01689	20231031
		57191	20230430
		74245	20230430
		74250	20230430
		80415	20231031
342447	BD Multitest™ CD3/CD8/CD45/CD4 (50 Tests per kit with BD Trucount™ Tubes)	22998	20240331
		27834	20240531
		33863	20240229

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		36951	20240531
		59139	20240131
		59301	20240331
		80232	20240131
663028	BD Trucount™ Absolute Counting Tubes	2031238	20231231
		2063994	20240131
		2095615	20240229
		2145791	20240331
		2221697	20240531
664231	BD® Stem Cell Enumeration Kit	2089518	20240131
		2104929	20231231
		2140813	20240331
		2200100	20240331
		2213825	20240331

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Appendix 2 – Label details