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** 34 **dated** 14/2/2023 **Regarding NCMDR Field Safety Corrective Action 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
ISO 9001:2015 CERTIFIED

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

Sultanate of Oman
Ministry of Health
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مسقط

# Circular No. 34 / 2023

23 -07-1444 H

14 -02-2023

## Field Safety Corrective Action 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=18433 |
| Product | BD Trucount™ Tubes. |
| Description | IVD. |
| Manufacturer | Becton Dickinson & Co. (BD). |
| Local agent | Aston Medical Supplies. |
| The affected products | Refer to Appendix 1 in the attached updated 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).<br>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**

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

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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dgpa_dc Email: dg-padc@moh.gov.om

BD Switzerland Sàrl
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www.BD.com

XX January 2023

**PRODUCT NOTIFICATION – BDB-22-4547-B**

**BD Trucount™ Tubes**

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

**Type of Action**: Advisory

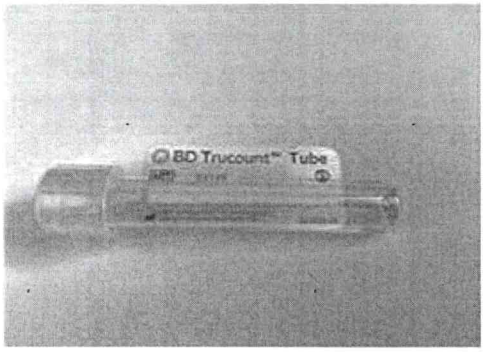
Dear Customer,

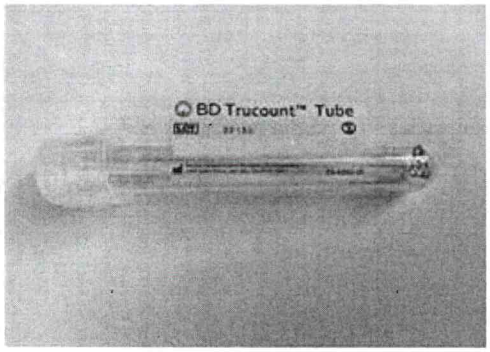
In October 2022, you may have received a Product Notification from BD (Notification Reference: BDB-22-4547) regarding inadequate label adhesion for specific lots of **BD Trucount™ Tubes**. BD is now issuing an expansion to this Product Notification for further lots of BD Trucount™ Tubes as listed in Appendix 1. According to our distribution records, your organisation may have received the additional impacted lots.

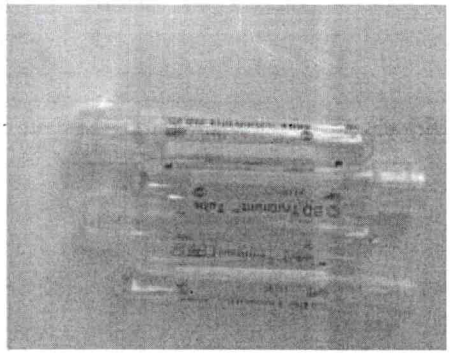
**Please note:** If you previously responded to the October 2022 Product Notification (BDB-22-4547), you must still respond to this Product Notification (BDB-22-4547-B) for reconciliation purposes.

## 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.

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## 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 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 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

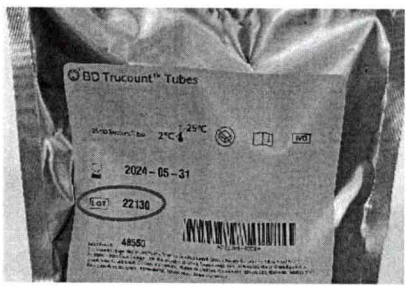
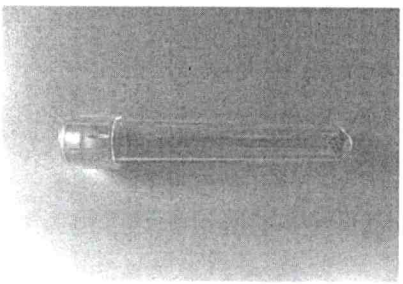
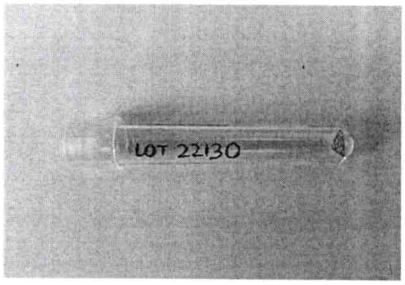
BD has investigated this issue and identified that an adhesive change made by a supplier has resulted in the inadequate label adhesion. BD is working closely with the supplier to resolve this situation expediently.

## 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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# Appendix 1 - Product Code / Lot number Identification

| Product Name | UDI-DI | Catalog (Ref) No. | Lot No | Trucount™ Pouch/Tube Lot No. | Expiration Date (YYYYMMDD) |
|---|---|---|---|---|---|
| BD Multitest™ 6-Color TBNK Reagent | 00382903371662 | 337166 | 26349 | 22270 | 20231031 |
| BD® Plasma Count Kit | 00382903383313 | 338331 | 2270435 | 22231 | 20230228 |
| | | | 2278452 | 22231 | 20230228 |
| | | | 2297963 | 22270 | 20230331 |
| BD Trucount™ Tubes | 00382903403349 | 340334 | 2242378 | 22231 | 20240831 |
| | | | 2258317 | 22242 | 20240831 |
| | | | 2264596 | 22242 | 20240831 |
| | | | 2279430 | 22242 | 20240831 |
| | | | 2286870 | 22242 | 20240831 |
| | | | 2298418 | 22270 | 20240930 |
| | | | 2306759 | 22231 | 20240831 |
| BD Procount™ Progenitor Cell Enumeration Kit | 00382903404988 | 340498 | 2258522 | 22231 | 20230228 |
| BD Leucocount™ Kit | 00382903405237 | 340523 | 2271455 | 22231 | 20240229 |
| BD Tritest™ CD4/CD8/CD3 | 00382903424450 | 342445 | 42625 | 22231 | 20240531 |
| | | | 97189 | 22242 | 20240831 |
| BD Multitest™ CD3/CD16+CD56/CD45/CD19 | 00382903424467 | 342446 | 42615 | 22231 | 20240229 |
| | | | 97193 | 22242 | 20240331 |
| BD Multitest™ CD3/CD8/CD45/CD4 | 00382903424474 | 342447 | 30050 | 22270 | 20240930 |
| | | | 63638 | 22231 | 20240331 |
| | | | 66395 | 22242 | 20240831 |
| | | | 80038 | 22242 | 20240831 |
| BD® Stem Cell Enumeration Kit | 00382903445639 | 344563 | 2258491 | 22231 | 20240831 |
| | | | 2306163 | 22270 | 20240930 |
| BD Multitest™ 6-Color TBNK | 00382906629951 | 662995 | 31905 | 22231 | 20230731 |
| | | | 76844 | 22231 | 20231130 |
| BD Trucount™ Tubes | 00382906630285 | 663028 | 2258067 | 22231 | 20240831 |
| | | | 2298251 | 22270 | 20240930 |
| | | | 2315776 | 22270 | 20240930 |

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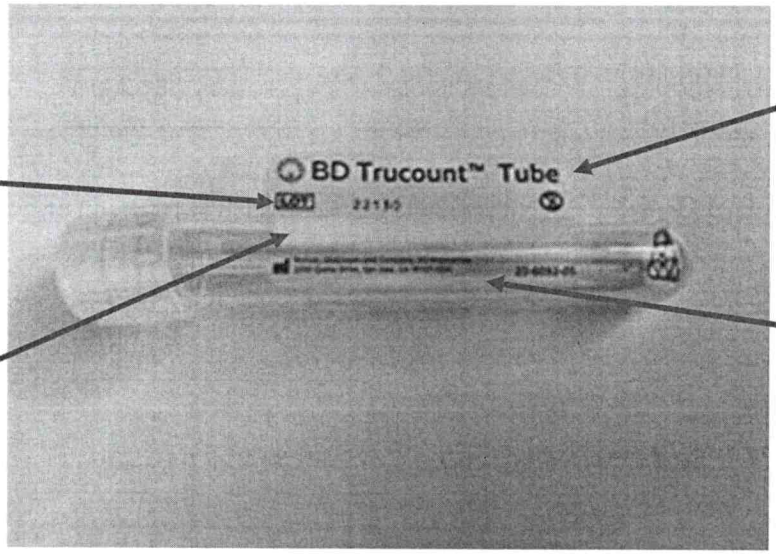
## Appendix 2 – Label details



Kingdom of Saudi Arabia
Saudi Food & Drug Authority

**Medical Devices Sector**

قطاع الأجهزة الطبية

# NCMDR

**National Center for Medical Devices Reporting**

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية



## NCMDR Recall

**Reference Number:** mdprc 002 10 22 001

**Date submitted:** 1/29/2023

Back

| | |
|---|---|
| **Manufacturer:** | Becton Dickinson & Co. (BD) |
| **Device Type:** | BD Trucount™ Tubes |
| **Description:** | IVD |
| **Medical Device Identifier:** | REF/Lot: See Appendix 1 in the attached FSN. |
| | ..... |
| | **NCMDR update codes:** |
| | Refer to Appendix 1 in the attached updated FSN |
| **Reason of Field Safety Corrective Action:** | 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. |
| **Remedy Action:** | 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) |
| **Athorized Representative/Importer/Distributor:** | Becton Dickinson B.V. |
| **Report Source:** | NCMDR |
| **Source Ref. Number:** | 41F1140041187, 94EA5E053D21E |
| **SFDA Comments:** | SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company. |
| **Attachments:** | **Becton Dickinson & Co. (BD).pdf** |

View History