**PRODUCT RECALL****IDS-25-5245****BD BBL™ TB Stain Kit K**

14 February 2025

Dear BD Distributor,

**Type of Field Action:**

**Removal (Recall)**

**Affected Product**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product Name** | **Catalog** | **Lot No.** | **UDI-DI** | **Expiration Date** |
| BD BBL™ TB Stain Kit K | 212522 | 4191205 | (01)00382902125228 | 2025/04/30 |

**Description of the Problem:**

BD identified through customer complaints, that the TB CARBOLFUCHSIN KF 250ML component of the BD BBL™ TB Stain Kit K (catalog number 212522) was shipped with an expiration date of 30 Sep 2024 while the Certificate of Analysis (COA) indicated an expiration date of 30 Apr 2025.

**Clinical Risk Statement:**

If the expired product is used, there is a low potential risk of erroneous smear microscopy results, which could impact time to diagnosis and possibly delay initiation of treatment or lead to unnecessary treatment. No reports of patient harm or diagnostic inaccuracies have been received to date. The risk associated with use of the expired product is mitigated by good laboratory practice as well as the availability and use of additional diagnostic testing and clinical correlation in ascertaining a patient's true disease status.

**Complaint & Adverse Event Statement:**

To date, there have been no adverse events worldwide related to this event.

**Actions for Clinical Users:**

1. Immediately inspect your inventory for the specific catalog and lot number listed to determine if the lot in your possession are impacted and immediately discontinue use of any remaining inventory of the affected product.
2. Customers should verify product expiration dates on the reagent prior to use to prevent the use of expired materials. All other components of the BD BBL™ TB Stain Kit K are labeled with the correct expiration date of 30 Apr 2025.
3. Ensure the contents of this notification are read and understood.
4. Share and post this customer letter within your facility network and forward to any customers to whom you may have distributed the product to ensure awareness.

**Action To be Taken by BD:**

BD is investigating the root cause and will implement appropriate corrective actions to prevent recurrence of this issue.

**Please Take the Following Actions:**

1. Please discontinue distribution of catalogue listed in this letter, and immediately quarantine and dispose all affected product remaining in your possession in accordance with your local facility’s process.
2. Identify all customers within your distribution network that purchased the affected product as defined in this notification. Provide a copy of the attached customer letter to all customers to advise them of this field action notification on BD’s behalf.
3. Coordinate customers product return and destruction following your institution’s process of destruction.
4. Complete and return the attached Distributor Response Form even if you no longer have any inventory remaining in your facility so that BD may acknowledge your receipt of this notification.
5. Return the signed and completed Distributor Response Form with Distributor Overview, as well as the signed Customer Response Form from all the impacted customers to the BD contact noted on the form.
6. Report any adverse health consequences experienced with the use of this product to BD.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and 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,

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| --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Karena HanQuality Manager, Southeast Asia |
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**DISTRIBUTOR RESPONSE FORM
IDS-25-5245
BD BBL™ TB Stain Kit K**

Please fill in the information below so that we may acknowledge your receipt of this notification.
Complete and return the completed form to **SEA\_Quality** **SEA\_Quality@bd.com** **/ local BD representative** by **21 February 2025.**

Please tick as appropriate.

|  |  |
| --- | --- |
|  | I have read and understood the attached notice taken appropriate actions  |
|  | We do not have affected product(s) in our inventory. |
|  | We have identified the affected product(s) in our inventory. Affected products have been quarantined until disposal. Upon disposal, we will provide a copy of the Certificate of Destruction/proof of destruction to BD.The expected date of destruction is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |
|  | We have identified all customers that purchased the affected catalog numbers and will notify theaffected customers of this notice. The overview of the distribution to the customers are as attached in the Distribution Overview. |

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| --- | --- | --- | --- | --- | --- |
| **Product Description** | **Catalog No.** | **Lot No.** | **Quantity Received (EA)** | **Quantity Sold** **(EA)** | **Remaining Quantity in inventory to be \*destroyed (EA)** |
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**\* Please provide a copy of the Destruction Certificate/ Proof of Destruction for the disposal of all affected units.**

**Completed by:**

|  |  |
| --- | --- |
| **Name:**  |  |
| **Signature:** |  |
| **Date:** |  |
| **Facility / Address /Telephone Number:** |  |