6th May 2024

URGENT: FIELD SAFETY NOTICE – IDS-24-4957-B

BD SARS-CoV-2 Reagents for BD Max™ Systems

REF: 445003-01 **Lot Numbers:** See Table 1

Type of Action: Product Removal

Attention: Clinical Personnel, Laboratory Managers, Risk Managers, Biomedical Personnel, Purchasing Managers

This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of **BD SARS-CoV-2 Reagents for BD Max™ Systems**. According to our distribution records your organisation may have received the impacted product in Table 1. Product was distributed by BD between 4th December 2023 and 30th January 2024.

Manufacturer's SRN: US-MF-000018910

Product Code (REF)	Lot Number	Expiry Date	UDI
445003-01	3291356	2024-08-03	(01) 60382904450030 (17) 240803 (10) 3291356 (20) 01 (30) 1
	3291358	2024-11-19	(01) 60382904450030 (17) 241119 (10) 3291358 (20) 01 (30) 1
	3327325	2024-12-17	(01) 60382904450030 (17) 241217 (10) 3327325 (20) 01 (30) 1

Table 1: Impacted product

This product removal is limited to the product code / lot numbers listed in Table 1.

Description of the problem

BD has identified, through an internal investigation, that the BD MAX SARS-CoV-2 assays, listed in the table above, may produce false negative results due to decreased activity of the HSQR1 enzyme utilized in the manufacture of this assay's master mix. A review of all products produced with this master mix has been undertaken and no other assays are impacted.

Clinical risk

As a result of this issue, there is the potential for erroneous results, that could cause delayed or absent administration of anti-viral treatment in certain populations or increase the risk of unidentified disease progression. False negative results may also elongate unnecessary broad-spectrum empiric antibiotic therapy and diagnostic testing or increase the risk of viral transmission, especially in the case of asymptomatic patients.

To date, there has been zero (0) complaints or adverse events worldwide related to this issue.

Clinical User Actions

There are no further recommendations for clinical follow-up or review of prior results.

BD Actions:

BD has identified the root cause and is taking corrective actions to prevent recurrence of this issue.

Customer Actions:

- Cease use of any unused affected lots of **BD SARS-CoV-2 Reagents**
- Identify and quarantine all unused affected lots of **BD SARS-CoV-2 Reagents**
- Make a note of the lot numbers and destroy all unused affected units.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 31st May 2024**.
- Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Distributor Actions:

- Cease distribution.
- Identify, quarantine, making a note of the lot numbers then destroy all unused affected lots of **BD SARS-CoV-2 Reagents**
- Identify the facilities where you have distributed affected product and notify them immediately of this notice.
    - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **31st May 2024**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- If you experience any issues, please report as a complaint as per your normal process.

	End User with Inventory	End User with ZERO inventory	Where to send completed form
Purchased **directly** from BD	Complete the form in its entirety Upon receipt, BD will process the response, and you will receive	Complete form and check the box indicating “no inventory”	*EMEAFieldAction@bd.com*

	replacements for unused product		
Purchased from a **distributor/3rd party**	Complete all fields on the form and contact your distributor to arrange for **replacements**	Complete form and check the box indicating "no inventory"	Return the form to your distributor

Contact reference person

If you have any questions about this, please contact your local BD representative or the local BD office or e-mail *EMEAFieldAction@bd.com*.

We confirm that the appropriate regulatory agencies have been informed of these actions.

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,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality

Customer Response Form – IDS-24-4597-B

BD SARS-CoV-2 Reagents for BD Max™ Systems

Return to *EMEAFieldAction@bd.com* as soon as possible or **no later than the 31st May 2024.**

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

Tick the appropriate box below

☐ We do not have any of the affected product as listed in **Table 1** in our facility. Affected product has been used.

All product that is not available for destruction will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.

OR

☐ We have the following units of the affected product as listed in **Table 1** in our possession and I confirm that the units have been destroyed *(Please complete the table below with the lot number and the number of units destroyed.* ***Replacement*** *product will only be sent on completion and return of this form).*

REF:	Lot Number/s:	Units destroyed *(insert quantity below)*

Account/Organisation Name:	
Department *(if applicable)***:**	
Address:	
Postcode:	**City:**
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 Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*