

April 30th, 2020

URGENT: FIELD SAFETY NOTICE – IDS-20-1985

BD BBL™ Gram Crystal Violet 250mL & Gram Stain Kit

REF & Lot Numbers: Refer to Table 1 below

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your immediate attention.

Dear Customer,

BD is issuing this Field Safety Notice to remove one specific lot of BD BBL™ Gram Crystal Violet 250mL and one specific lot of BD BBL™ Gram Stain Kit, as listed in Table 1 below. According to our distribution records your organisation may have received these devices which were shipped from BD between December 2019 and March 2020.

REF	Product Description	LOT Number	Date of Manufacture	Expiration Date
212525	BD BBL™ Gram Crystal Violet 250mL	9269800	07-Oct-19	30-Apr-21
212539	BD BBL™ Gram Stain Kit	0007261	29-Jan-20	30-Jun-21

Table 1: List of impacted products

Description of the Problem

Through customer feedback, BD has discovered the specific lots of BD BBL™ Gram Crystal Violet 250mL and BD BBL™ Gram Stain Kit listed in Table 1 above have the potential to exhibit increased levels of artifacts which could be difficult to distinguish from gram positive cocci.

Use of products with increased levels of artifacts could result in a false-positive Gram stain. Gram stain results must be confirmed with additional procedures, but if these protocols are not followed, a false-positive could lead to administration of unnecessary antibiotics or surgical procedures.

Advice on actions to be taken by the Customer:

1. Inspect your inventory, locate, and quarantine any units of the impacted devices listed in Table 1.
2. If you have further distributed the product, please identify those facilities, notify them at once of this product removal and have them return the affected product to your facility.
3. Destroy any unused units of the affected product and complete the customer response form on page 3 indicating:
 - the quantities destroyed **OR**
 - that your organisation does not have any impacted units left in inventory



1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

4. Return the completed Customer Response Form to BDUKFieldAction@bd.com **as soon as possible or no later than May 22nd, 2020.**

Should you have any questions or require assistance relating to this Field Safety Notice, please contact us at BDUKFieldAction@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 and user safety and providing you with quality products. We apologise 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 blue ink, appearing to read 'W. David', is positioned above the printed name.

William David
Senior Director, Quality Compliance EMEA

Customer Response Form – IDS-20-1985

BD BBL™ Gram Crystal Violet 250mL & Gram Stain Kit

REF & Lot Numbers: Refer to the table below

Please read in conjunction with Field Safety Notice IDS-20-1985 and return, completed and signed, as soon as possible or **no later than May 22nd, 2020** to BDUKFieldAction@bd.com.

- I confirm this 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 possession.

OR

☐ We have have 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 following table with the quantities of units destroyed*)

REF	Product Description	LOT Number	Quantity Destroyed
212525	BD BBL™ Gram Crystal Violet 250mL	9269800	
212539	BD BBL™ Gram Stain Kit	0007261	

Account/Organisation Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Signature:	Date:

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