



10th May 2021

URGENT: FIELD SAFETY NOTICE – IDS-21-4116

BD Group B Streptococcus Differential Agar (Granada Medium)

REF & Lot Numbers: See Table 1

Type of Action: Product Removal

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of **BD Group B Streptococcus Differential Agar (Granada Medium)** referenced in Table 1 below. According to our distribution records your organisation may have received the impacted product.

Description of the Problem

Based on customer feedback, BD has identified that the specific lots in Table 1 are not performing as intended. Customers have reported that the agar is not opaque/appears transparent and growth appears of beta-hemolytic strains of *S. agalactiae* could produce white to gray-blue colonies. The root cause has been identified as a misformulation within the manufacturing facility.

This product removal is limited to the product code / lot numbers listed in Table 1 below. No other product codes or lot numbers are affected. Appendix 1 shows the location of the product code/lot number.

Product Name	Catalogue (REF) Number	Lot Number(s)	Expiration Date
Group B Streptococcus Differential Agar (Granada Medium)	257079	1056185	18. May 2021
		1057448	25. May 2021
		1069181	31. May 2021
		1083771	17. Jun. 2021

Table 1: Impacted catalogue Numbers and Lot Numbers

Clinical Risk

This defect could result in a potential misinterpretation of the growth as non-clinically significant.

Advice on actions to be taken by the Customer:

1. Inspect your inventory, locate and quarantine any units of the impacted lot numbers. Destroy all impacted product.



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. BD recommends discussing the content of this letter with your laboratory director regarding the need to review previous test results associated with these impacted lots.
 - If there is any doubt in previous negative test results without any confirmatory results for colorless colonies (such as serological grouping and/or a PYR test) please consider notifying the healthcare provider and recalling the patient for additional testing.
4. Complete the customer response form on page 3 indicating:
 - the quantities destroyed/returned **OR**
 - that your organisation does not have any impacted units left in inventory
5. Return the completed customer response form to <<insert contact details here>> for credit **as soon as possible or no later than 10th June 2021.**

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

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,

[Redacted signature]

[Redacted name]

[Redacted title]

EMEA Quality



Customer Response Form – IDS-21-4116

BD Group B Streptococcus Differential Agar (Granada Medium)

Please read in conjunction with Field Safety Notice IDS-4116 and return completed and signed form as soon as possible or **no later than the 10th June 2021** to <<insert fax/email address here>>.

- 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 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*)

Catalogue (REF) Number	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:
Signature:	Date:

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



Appendix 1 - Product Code / Lot number Identification

BD

Group B Streptococcus Differential Agar (Granada Medium)

REF **257079**

Group B Streptococcus Differential Agar (Granada Medium)

Instructions for Use, Certificates of Analysis, Declarations of Conformity, ISO Certificates and Safety datasheets available on Internet
www.bd.com/europe/regulatory/documents.asp

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REF 257079

1900-01-31
(YYYY-MM-DD)

LOT **1234567**

IVD

CE

Location of catalogue Number (REF)

Location of Lot Number