



October 31st, 2019

URGENT: FIELD SAFETY NOTICE – BDDS-19-1857

BD CHROMagar™ Orientation Medium

REF & Lot Numbers: Refer to Table 1

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

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

Dear valued Customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of BD CHROMagar™ Orientation Medium from the market. The specific product code (REF) / lot number combinations affected by this product removal are outlined in Table 1. According to our distribution records your organisation may have received the impacted product.

| Product Name | REF | Lot No. | Exp. Date | Product Package Size |
|----------------------------------|--------|---------|-------------|----------------------|
| BD CHROMagar™ Orientation Medium | 254107 | 9197107 | 07-Nov-2019 | 120 cpu |
| | 257481 | 9197107 | 07-Nov-2019 | 20 cpu |

Table 1: Affected product information

Description of the Problem

BD has recently become aware through customer feedback of bacterial contamination on the above listed lots of non-sterile prepared plated BD CHROMagar™ Orientation media. Contaminants may appear as blue or beige/natural pigmentation.

Contamination of BD CHROMagar™ Orientation Medium has the potential to lead to reporting of an incorrect result which could lead to possible misdiagnosis, potentially resulting in a patient not being treated appropriately. Often contamination is recognized by the laboratory, however, if it is not discovered prior to use it is possible that the contamination may be reported as patient results.

BD would like to reinforce the need to visually inspect all non-sterile prepared media prior to use. Plates should not be used if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

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

Advice on actions to be taken by the Customer:

1. Confirm previous patient results of blue or beige/natural pigmented colonies from the affected lots (Table 1) if patient confirmatory tests were not previously conducted. Please note that per



the product insert, beige colonies could be perceived to be organisms from the *Proteus-Morganella-Providencia* group or yeast and would require confirmatory testing before reporting. Blue colonies could be equated to organisms related to the *Klebsiella-Enterobacter-Serratia* group or *Streptococcus agalactiae* and would require confirmatory testing before reporting. However, if the colonies were perceived to be small blue-green colonies, they could be perceived to be *Enterococcus spp.* and per the product insert would not require confirmatory testing before reporting. If repeat testing is required, please follow your laboratory protocol.

2. Inspect your inventory, locate and quarantine any units of the impacted product as listed in Table 1.
3. 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.
4. Destroy any unused units of the affected product and complete the customer response form on page 3 indicating:
 - o the quantities destroyed **OR**
 - o that your organisation does not have any impacted units left in inventory
5. Return the completed customer response form to BDUKFieldAction@bd.com **as soon as possible or no later than November 7th, 2019.**

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,

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.....



Customer Response Form - BDDS-19-1857

BD CHROMagar™ Orientation Medium

REF & Lot Numbers: Refer to Table 1

Please read in conjunction with Field Safety Notice BDDS-19-1857 and return completed and signed form as soon as possible or **no later than November 7th, 2019** 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 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 | Lot No. | Quantity Destroyed |
|--------|---------|--------------------|
| 254107 | 9197107 | |
| 257481 | 9197107 | |

| | |
|------------------------------------|--------------------------------|
| 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.