



Please distribute the attached customer letter.

To the Laboratory Manager

To the attention of the Healthcare center Chairman

Zagreb, 19.08.2020.

Our reference: FSCA#4864

**IMPORTANT:**

**URGENT FIELD SAFETY NOTICE**

**CHOCOLATE POLYVITEX (Ref. 43109 -43101)**

Dear bioMérieux Customer,

Our records indicate that your laboratory has received the product described below in Table 1, and this letter is intended for all customers using those specific product references.

Table 1:

Product Ref. Number	Description
43109	CHOCOLATE POLYVITEX 100 BTE
43101	CHOCOLATE POLYVITEX 20 BTE

### **Description of the issue**

Based on complaints from the field regarding a low or lack of growth of *S. aureus* strains and *Corynebacterium striatum* strain on CHOCOLATE POLYVITEX 100PLATES – (Ref. 43109), lot. #1008049150, bioMérieux initiated a complaint investigation to confirm product issue and determine root cause.

The following have been identified:

- ⇒ The issue was confirmed for 5 out of 13 of the lots tested available on the market in date of investigation, we observed no or low growth of some ATCC *Staphylococci* strains (ATCC® 29213, ATCC® 6538, ATCC® 29971), *Staphylococcus* strains from patient isolates and *Corynebacterium diphtheriae* ATCC® 27010 depending on the lot.
- ⇒ The issue is localized on a part of each lot concerned corresponding to ¼ of each lot.
- ⇒ *S. aureus* ATCC® 29213 is part of the final Quality Control testing and results were within the specifications at release, therefore issue seems to appear over the product shelf-life



- ⇒ On lots for which the issue was confirmed, we observed a good growth of the fastidious Quality Control release strains: *Neisseria gonorrhoeae* ATCC® 43069, *Neisseria gonorrhoeae* ATCC® 49226, *Neisseria meningitides* ATCC® 13090, *Haemophilus influenzae* ATCC® 10211, *Streptococcus pneumoniae* ATCC® 6305, *Candida albicans* ATCC® 60193.
- ⇒ Therefore, this issue seems not related to a specific lot but only to a specific part of each lot. Also, the issue could appear over the product shelf-life, then we cannot exclude that all lots of the product references listed table 1 could be impacted.

**Impact to customer:**

- Based on the investigation results, there is a potential risk of false negative results for Staphylococci and Corynebacterium species when using CHOCOLATE POLYVITEX – (Ref. 43109 and Ref.43101) in Medical bacteriology

**Required actions:**

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- The intended use of the impacted product references is to detect fastidious bacteria belonging to *Neisseria* and *Haemophilus*, and *Streptococcus pneumoniae* and for other strains, we require you to perform systematically in addition a non-selective media (For example: Columbia agar + 5% sheep blood)
- Complete and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Yours sincerely,

Customer Service Medical

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