



Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Healthcare center Chairman

Address
City, Date

Our reference: FSCA 4360

IMPORTANT:

URGENT FIELD SAFETY NOTICE

**Chocolate agar + PolyViteX™ (PVX) ref 43109 - lot
1007089110- growth defect**

Dear bioMérieux Customer,

Our records indicate that your laboratory is using bioMérieux Chocolate agar + PolyViteX™ (PVX) ref 43109 lot 1007089110, expiry date 21-May-2019.

Description of the issue

This Chocolate agar + PolyViteX™ (PVX) medium is an isolation medium particularly recommended for the growth of fastidious strains belonging to the genera *Neisseria* and *Haemophilus*, and *Streptococcus pneumoniae*.

This medium is composed of a nutritive base enriched with factors X (hemin) and V (NAD) provided by the hemoglobin and PolyViteX™ which allow the growth of fastidious strains belonging to the genera *Haemophilus*.

Customers complained about growth defect (low or absence) for the following strains:

Haemophilus influenzae ATCC strains (ATCC 10211, ATCC 49247 and ATCC 49766) and *Haemophilus influenzae patients strains*.

These complaints concerned the same lot 1007089110 of Chocolate agar + PolyViteX™ (PVX) ref43109 and described false negative results.

Impact to customer:

The risk associated with the detected problem is a risk of false negative results with *Haemophilus influenzae* strains in patient's samples.

BIOMERIEUX



Required actions:

We request you to take the following actions at this time:

- 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.
- Stop using the lot affected (1007089110 ref 43109) and to destroy the remaining products,
- Discuss any concerns they may have regarding previously reported patient results obtained with their Laboratory Medical Director to determine the appropriate course of action. Results should be reviewed and interpreted in the context of the overall clinical picture.
- Contact your local customer service if you have observed the issue and if you have a doubt regarding your results.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative 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 faithfully,
Customer Service



Attachment A: Acknowledgement Form.

FIELD SAFETY NOTICE
Chocolate agar + PolyViteX™ (PVX) ref 43109 - lot 1007089110- growth defect

**TO BE RETURNED TO YOUR BIO MÉRIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : XXXXXXXX**

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “**Chocolate agar + PolyViteX™ (PVX) ref 43109 – lot 1007089110- growth defect**”

- I will implement the required actions as indicated in the Urgent Product Safety Correction Notice.

REF #	Product Name	Lot #	Quantity received	Quantity discarded
43109	Chocolate agar + PolyViteX™ (PVX)	1007089110		

DATE

SIGNATURE :