



To the Laboratory Manager  
Cc: the Chairman Medical Board and relevant Head of Departments

Our reference: FSCA 3577

**IMPORTANT:**

**Urgent product removal notice**

**(see table 1)**

Dear valued bioMérieux Customer,

Our records indicate that your laboratory has received one or several products described below:

REF	Product Name	Lot number	Expiry date
533408	ETEST®POLYMYXIN B PO 1024 WW B100	1004767110	08-mar-2021
525518	ETEST®VANCOMYCIN VA 256 WW F100	1004913990	01-jun-2021
412488	ETEST®VANCOMYCIN VA 256 WW S30	1004942890	12-jun-2021
502518	ETEST®BENZYL PENICIL PG 256 WW F100	1004872350	16-may-2019
526308	ETEST®AMPHOTERICIN-B AP 32 WW B100	1004539880	08-dec-2020
55635	OXIDASE 50 AMP	85552401	17-dec-2017

**Description of the issue**

Two specific shipments of products have experienced high temperatures during transportation from our European distribution center to our warehouse located at the Singapore Subsidiary. One shipment was exposed to temperatures of 25°C to 27,5°C for 14 hours and the other shipment was exposed to temperatures of 25°C to 33,7°C for 17 hours. As a result, we cannot guarantee performance of these products since the temperatures sustained during shipping exceeded our maximum allowed shipping conditions.

**Impact to patient/customer:**

There is a possibility that OXIDASE 50 AMP (ref # 55635) could give incorrect results, and that ETEST products (ref #'s 533408, 525518, 412488, 502518 and 526308) could provide falsely high MICs (minimum inhibitory concentrations) leading to false intermediate (I) or resistant (R) results..

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**Required actions:**

We request you 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 one or more of these products, including others to whom you may have transferred these products,
- Please discontinue use and destroy any impacted products remaining in your local inventory and contact your local bioMérieux representative for credit or replacement,
- Please complete the attached Acknowledgement Form and return it to your local bioMérieux representative.

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.

Thank you for your continued use of bioMérieux products,

**Yours sincerely,**

Lukas QUIDENUS  
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**Attachment A: Acknowledgement Form.**

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**FIELD SAFETY NOTIFICATION NOTICE**

**FSCA 3577 – Singapore Shipments – Temperature Out of Range**

**TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE AT THE FOLLOWING**

**FAX NUMBER :** XXXXXXXX

Name of the laboratory:

City:

**Customer number:**

☐ I acknowledge receipt of this bioMérieux Urgent Product Removal Notice regarding this product issue.

☐ I have followed the instructions and implemented the actions as indicated in the Urgent Product Removal Notice.

**Error! Not a valid link.**

Have you received reports of illness or injury related to the identified issue?

☐ Yes or ☐ No

DATE .....

SIGNATURE : .....

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**BIOMERIEUX**

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