



Please distribute the attached customer letter.

To the Laboratory Manager

To the attention of the Healthcare center Chairman

To the attention of the Reactovigilance correspondent

Our reference: FSCA 3710

IMPORTANT:

Urgent Field Safety notice

ETEST® Teicoplanin 256 (TP) SPB and Foam packaging (Ref: 412461 & 522018)

Dear valued bioMérieux Customer,

This letter is intended for all ETEST Teicoplanin 256 (TP) SPB and Foam packaging (Ref: 412461 & 522018) users; and our records indicate that your laboratory has received one or more of the batches listed in the annex attached.

Description of the issue

Following an assessment of ETEST Teicoplanin with *Staphylococcus* spp., we observed an underestimation of MIC values by at least 1 dilution for Coagulase Negative Staphylococci (CoNS); even though the MIC essential agreement at +/- 1 dilution is > 95% between ETEST® TP256 and the reference method Agar Dilution (AD) for *Staphylococcus* spp.

This underestimation leads to a risk of false Susceptible results linked, in particular to the lack of an Intermediate category interpretation if EUCAST breakpoints are applied for this antibiotic. During the study, the false susceptible rate observed was 37.5% for CoNS, where strains with an MIC at 8 mg/L, by the reference method (Resistant) can be found Susceptible by ETEST Teicoplanin.

Impact to patient/customer:

As a result of these findings, there is a potential performance issue for strains categorization as **CoNS**, which could lead to **False Susceptible** Teicoplanin result if EUCAST breakpoints are applied.

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
- **CoNS should not be tested using ETEST Teicoplanin; Teicoplanin MICs should be obtained using an alternative method.**

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- **Laboratories can continue to use ETEST Teicoplanin for the other microorganisms: *Staphylococcus aureus* and *Enterococcus spp.***
- For tests previously performed, we are asking you to identify any possible false Susceptible results that may have occurred, to analyze the related risks and to determine appropriate actions, if relevant
- Complete the attached Acknowledgement Form in Attachment A 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,

bioMérieux, Inc.

A&B d.o.o.

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Attachment A: Acknowledgement Form.

FIELD SAFETY NOTIFICATION NOTICE

**FSCA 3710 – ETEST® Teicoplanin 256 (TP) SPB and Foam packaging (Ref: 412461 & 522018) -
False susceptible Teicoplanin results for CoNS**

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 this bioMérieux Urgent Field Safety Notice regarding regarding **ETEST Teicoplanin 256 (TP) SPB & Foam packaging (Ref: 412461 & 522018)** product issue.

I have followed the instructions and implemented the actions as indicated in the Urgent Field Safety Notice.

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

Yes or No

DATE

SIGNATURE :

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Table 1- List of impacted products:

Product Name	Reference	Batch	Expiry date (DD/MM/YYYY)
TEICOPLANIN TP 256 WW S30	412461	1005954610	11/09/2022
TEICOPLANIN TP 256 WW S30	412461	1005689670	11/05/2022
TEICOPLANIN TP 256 WW S30	412461	1005629730	10/04/2022
TEICOPLANIN TP 256 WW S30	412461	1005551300	09/03/2022
TEICOPLANIN TP 256 WW S30	412461	1005404850	02/01/2022
TEICOPLANIN TP 256 WW S30	412461	1005201180	02/10/2021
TEICOPLANIN TP 256 WW S30	412461	1004989590	30/06/2021
TEICOPLANIN TP 256 WW S30	412461	1004886930	22/05/2021
TEICOPLANIN TP 256 WW S30	412461	1004637470	02/02/2021
TEICOPLANIN TP 256 WW S30	412461	1004404770	25/10/2020
TEICOPLANIN TP 256 WW S30	412461	1004291010	08/09/2020
TEICOPLANIN TP 256 WW S30	412461	1004107460	22/06/2020
TEICOPLANIN TP 256 WW S30	412461	1003956490	20/04/2020
TEICOPLANIN TP 256 WW S30	412461	1003454920	24/09/2019
TEICOPLANIN TP 256 WW S30	412461	1003313660	27/07/2019
TEICOPLANIN TP 256 WW S30	412461	1003108790	24/04/2019
TEICOPLANIN TP 256 WW S30	412461	1003104300	22/04/2019
TEICOPLANIN TP 256 WW S30	412461	1002933960	09/02/2019
TEICOPLANIN TP 256 WW S30	412461	1002705890	24/10/2018
TEICOPLANIN TP 256 WW S30	412461	1002585250	02/09/2018
TEICOPLANIN TP 256 WW S30	412461	1002355590	30/05/2018
TEICOPLANIN TP 256 WW S30	412461	1002312700	14/05/2018
TEICOPLANIN TP 256 WW S30	412461	1002276240	24/04/2018
TEICOPLANIN TP 256 WW S30	412461	1002221580	08/04/2018
TEICOPLANIN TP 256 WW F100	522018	1005689680	11/05/2022
TEICOPLANIN TP 256 WW F100	522018	1005629740	10/04/2022
TEICOPLANIN TP 256 WW F100	522018	1005408640	02/01/2022
TEICOPLANIN TP 256 WW F100	522018	1005201240	02/10/2021
TEICOPLANIN TP 256 WW F100	522018	1004989600	30/06/2021
TEICOPLANIN TP 256 WW F100	522018	1004886940	22/05/2021
TEICOPLANIN TP 256 WW F100	522018	1004639140	02/02/2021
TEICOPLANIN TP 256 WW F100	522018	1004404740	25/10/2020
TEICOPLANIN TP 256 WW F100	522018	1004291030	08/09/2020
TEICOPLANIN TP 256 WW F100	522018	1004108370	22/06/2020
TEICOPLANIN TP 256 WW F100	522018	1003959520	20/04/2020
TEICOPLANIN TP 256 WW F100	522018	1003759850	03/02/2020
TEICOPLANIN TP 256 WW F100	522018	1003314790	27/07/2019
TEICOPLANIN TP 256 WW F100	522018	1002938960	09/02/2019
TEICOPLANIN TP 256 WW F100	522018	1002830030	18/12/2018
TEICOPLANIN TP 256 WW F100	522018	1002708060	24/10/2018
TEICOPLANIN TP 256 WW F100	522018	1002552490	20/08/2018
TEICOPLANIN TP 256 WW F100	522018	1002358550	30/05/2018
TEICOPLANIN TP 256 WW F100	522018	1002314730	14/05/2018
TEICOPLANIN TP 256 WW F100	522018	1002279440	24/04/2018
TEICOPLANIN TP 256 WW F100	522018	1002222740	08/04/2018
TEICOPLANIN TP 256 WW F100	522018	1002221280	07/04/2018