



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

Address
City, Date

Our reference: FSCA 3329

IMPORTANT:

URGENT FIELD SAFETY NOTICE

ETEST® ETP32 (Ertapenem) (Ref.531640,
531600)

Our records indicate that your laboratory has received the following products. This letter is intended for all ETEST® ETP32 (Ertapenem) (Ref.531640, 531600) blister packaging users (product reference and lot numbers included in annex).

Description of the issue

Based on the strain epidemiology evolution with the detection of some *Streptococcus* resistant strains from clinical specimens (around 1 and 5% according to CLSI breakpoints), that did not exist at the moment of the product registration, and as a part of the Etest® ETP32 Change impact study, bioMérieux initiated an internal study.

The following have been identified:

- ⇒ the investigation results confirmed **a potential performance issue on strain categorization for *S. viridans* group and *S. pneumoniae* based on 2017 CLSI and EUCAST breakpoints, that could lead to False Susceptible result instead of resistant results on ETEST® ETP32 (ertapenem) Blister packaging when comparing to the Broth-Micro Dilution (BMD) reference method.**
- ⇒ This performance issue was not evaluated at the time of product registration because rare or no resistant strains were reported at this time.

Impact to Patient/User:

As a result of the referenced issue, there is a potential **performance issue on strain categorization for *S. viridans* group and *S. pneumoniae* that could lead to False Susceptible Result (False Susceptible result instead of resistant results) when compared to the BMD reference method when using the 2017 CLSI or 2017 EUCAST standards.**

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.

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- **The users of the 2017 CLSI and 2017 EUCAST clinical guidelines can continue the use of ETEST® ETP32 (Ertapenem) (Ref.531640, 531600) blister packaging except for Streptococci group including S. pneumoniae strains. “**
- Among tests previously performed, we are asking you to identify any possible false Susceptible results, analyze the related risks and determine appropriate actions if relevant.
- Contact your local bioMérieux representative for product compensation if needed.
- 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,
Medical Customer Service

Attachment A: Acknowledgement Form.

PLEASE RETURN TO YOUR CUSTOMER SERVICE

Fax :

Name of the laboratory:

City:

Customer number:

I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the **ETEST® ETP32 (Ertapenem) (Ref.531640, 531600) blister packaging** 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

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DATE

SIGNATURE :

Table 1- List of impacted products:

Reference	Description	Lot Number	Expiry date
531600	ERTAPENEM ETP 32 WW B30	1003152970	28-Apr-2017
		1003213910	1-Jun-2017
		1003215220	1-Jun-2017
		1003252370	1-Jun-2017
		1003523980	28-Sep-2017
		1003528910	29-Sep-2017
		1003530750	30-Sep-2017
		1003544500	29-Sep-2017
		1003569060	28-Sep-2017
		1003741390	4-Jan-2018
		1003834210	4-Jan-2018
		1003933880	24-Feb-2018
		1004144790	11-Jun-2018
		1004314330	1-Sep-2018
		1004332810	1-Sep-2018
		1004390590	29-Sep-2018
		1004486980	1-Nov-2018
		1004487990	1-Nov-2018
		1004577410	20-Dec-2018
		1004611460	30-Nov-2018
		1004621450	30-Nov-2018
		1004624930	30-Nov-2018
		1004799720	16-Mar-2019
		1004809490	16-Mar-2019
		1004872750	16-Mar-2019
		1004886970	28-Apr-2019
		1004896590	28-Apr-2019
		1004899420	28-Apr-2019
		1005177360	26-Jul-2019
		1005208910	7-Sep-2019
1005183510	7-Sep-2019		

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		1005353450	15-Nov-2019
		1005437180	20-Dec-2019
		1005439590	20-Dec-2019
531640	ERTAPENEM ETP 32 US B30	1003149850	28-Apr-2017
		1003157690	28-Apr-2017
		1003585350	30-Sep-2017
		1003732380	4-Jan-2018
		1003910410	24-Feb-2018
		1004142070	11-Jun-2018
		1004113370	11-Jun-2018
		1004325260	1-Sep-2018
		1004382730	29-Sep-2018
		1004482780	1-Nov-2018
		1004785720	16-Mar-2019
		1004890160	28-Apr-2019
		1005134380	26-Jul-2019
		1005134390	26-Jul-2019
		1005357180	15-Nov-2019
		1005442470	20-Dec-2019