FSCA
FIELD SAFETY CORRECTIVE ACTION

BIOMÉRIEUX

IMPORTANT:

URGENT FIELD SAFETY NOTICE

VITEK 2 Cards AST-N447 - 0853293604 Pouch Foil Fractures Leading to False Resistant Carbapenem and/or Cephalosporin Results

Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Laboratory Medical Director

Date

bMx local contact information

(to be adapted at local level)

Our reference: FSCA - FIELD SAFETY CORRECTIVE ACTION - FA-TWD-000077

Impacted products ***(to be adapted at local level if necessary including for names and ref #, local license #, name and address of manufacturer)***			
Product Name	**Reference Number**	**Lot Number/Serial Number/ Product version**	**Product Expiration Date (if applicable)**
AST-N447 TEST KIT	424620	0853293604	02Dec2026

Dear bioMérieux Customer,

This communication is to inform you of a potential risk of false resistant carbapenem and/or cephalosporin results when using the VITEK® 2 AST-N447 (Ref 424620, Lot 0853293604) manufactured using one pouching device (P7).

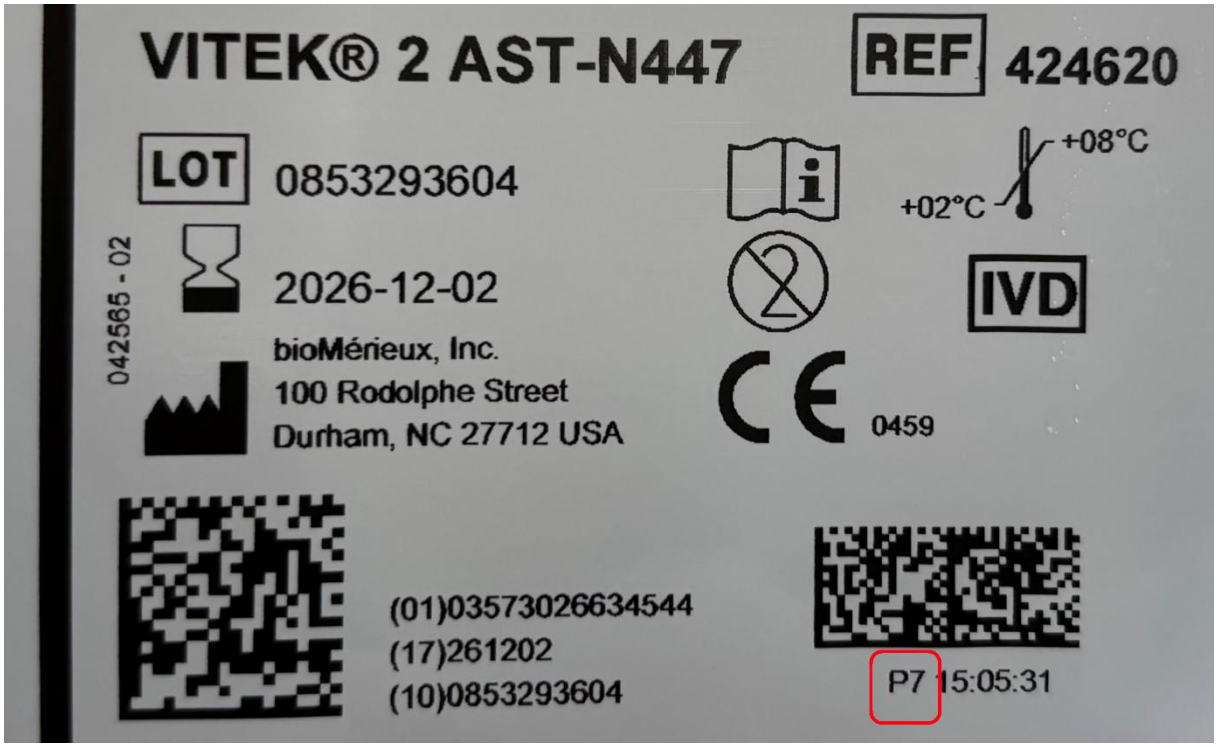
Our records indicate that your laboratory received the product listed in Table 1 below.

TABLE 1

REF #	Product Name	Batch #
424620	AST-N447 TEST KIT	0853293604

Description of the issue

The issue is related to card pouch damage associated with a portion of the lot which was produced on a specific card pouching device (P7). Cards manufactured on other pouching devices are not impacted. The pouching device number is indicated on the lower right of the card pouch. See example image below.



Impact to User/Customer/Patients

False resistant results of patient isolates due to overcalling of the MIC value: False resistant results may lead to the use of less effective antibiotic treatments or the association of multiple antibiotics having negative side effects, which could potentially impact patient's health.

Required actions

Dispose of any remaining inventory VITEK 2 AST-N447 TEST KIT (Ref 424620, Lot 0853293604) that were manufactured with Poucher 7, as identified by product labeling. Inspect each pouch in inventory and dispose of cards with "P7" on the label. Alternatively, dispose of all cards from Lot 0853293604 remaining in inventory.

In accordance with your facility's policies, you may consider performing a retrospective review of clinically significant resistant results. Among tests previously performed, identify any possible false resistant results that may have occurred, analyze the related risks, and determine appropriate actions, if applicable.

Please ensure that this information is communicated to all relevant personnel within your laboratory, retain a copy in your records, and forward this information to all parties that may use this product, including those to whom you may have transferred the product. Please complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice. It is important that you return the acknowledgement form to bioMérieux even if you determine that this product correction notice does not impact your facility.

As a reminder, please visit the Resource Center to confirm if a reference package insert is associated with a Field Corrective Action or Field Safety Corrective Action.
https://resourcecenter.biomerieux.com/

Local legal mentions to be added if necessary at local level (e.g. in case of recall, reporting to NCA, recall methods)

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 (to be adapted at local level)*.

Yours faithfully,

Customer Service

Attachment A: Acknowledgement Form.

Urgent Field Safety Corrective Notice

FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000077 VITEK 2 Cards AST-N447 - 0853293604 Pouch Foil Fractures Leading to False Resistant Carbapenem and/or Cephalosporin Results

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TO BE RETURNED TO *YOUR BIOMERIEUX CUSTOMER SERVICE (TO BE ADAPTED AT LOCAL LEVEL)*
AT THE FOLLOWING
FAX NUMBER: XXXXXXXX OR EMAIL ADDRESS: XXXXXXX

Name and Address of the laboratory	
Contact information	
Customer Account Number	

Local legal mentions to be added if necessary at local level)

☐ I am not impacted by the issue. Please provide rationale: ……

☐ I have implemented the required actions.

Table to be added and adapted if necessary to monitor quantities received/discarded (products names and ref.# to be adapted at local level if necessary) depending on the required actions.

REF #	Product Name	Batch #	Quantity received	Quantity used	Quantity destroyed	Quantity returned*
424620	AST-N447 TEST KIT	0853293604				

** Quantity returned to bioMérieux or distributor*

If you have encountered impact on patients' results, or reports of illness or injury related to the identified issue and have not yet reported to bioMérieux, please contact your local bioMérieux representative.

DATE…….....SIGNATURE……

It is important that you complete this Acknowledgement Form and return it to bioMérieux