

IMPORTANT:

URGENT FIELD SAFETY NOTICE

False Resistant Antibiotic results (cza02n, ipm05n, ipr01n, mev01n, pb02n) in VITEK® 2 AST GN cards for Enterobacterales species and/or *Pseudomonas aeruginosa*

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

Our reference: FA-TWD-000064- FSCA - FIELD SAFETY CORRECTIVE ACTION

Dear bioMérieux Customer,

This communication is to inform you of a potential risk of Quality Control failures and/or false resistant antibiotic results when testing isolates of Enterobacterales/*Enterobacteriaceae* species and/or *Pseudomonas aeruginosa* with the following antibiotic formulations: Ceftazidime/Avibactam (cza02n), Imipenem (ipm05n), Imipenem/Relebactam (ipr01n), Meropenem/Vaborbactam (mev01n), and Polymyxin B (pb02n).

Our records indicate that your laboratory received one or more products listed in table 1 below.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

Table 1: List of impacted cards

Product Name	Reference	Drug Impacted
VITEK® 2 AST-N399	423701	ipm05n
VITEK® 2 AST-N402	423644	ipm05n
VITEK® 2 AST-N403	423645	cza02n/ipm05n
VITEK® 2 AST-N404	423664	ipm05n
VITEK® 2 AST-N405	423864	ipm05n
VITEK® 2 AST-N406	423869	ipm05n
VITEK® 2 AST-N407	423870	cza02n
VITEK® 2 AST-N409	423925	cza02n
VITEK® 2 AST-N412	423936	ipm05n
VITEK® 2 AST-N413	423928	ipm05n
VITEK® 2 AST-N414	423933	ipm05n
VITEK® 2 AST-N415	423934	ipm05n
VITEK® 2 AST-N416	423935	ipm05n
VITEK® 2 AST-N417	423880	ipm05n
VITEK® 2 AST-N419	423948	cza02n/ipm05n
VITEK® 2 AST-N421	424055	cza02n/ipm05n
VITEK® 2 AST-N428	424320	ipm05n
VITEK® 2 AST-N429	424321	ipm05n
VITEK® 2 AST-N430	424322	ipm05n
VITEK® 2 AST-N433	424389	ipm05n
VITEK® 2 AST-N439	424501	cza02n/ipr01n/mev01n
VITEK® 2 AST-N440	424502	cza02n/ipm05n/ipr01n
VITEK® 2 AST-N443	424541	cza02n/ipm05n/ipr01n
VITEK® 2 AST-N444	424587	cza02n/ipm05n/ipr01n
VITEK® 2 AST-N467	424857	cza02n/ipr01n
VITEK® 2 AST-N476	424934	cza02n
VITEK® 2 AST-N478	425052	cza02n
VITEK® 2 AST-N480	425084	cza02n
VITEK® 2 AST-N481	425085	cza02n
VITEK® 2 AST-N485	425182	cza02n
VITEK® 2 AST-N496	425265	cza02n
VITEK® 2 AST-N800	423310	cza02n
VITEK® 2 AST-N802	423706	ipm05n
VITEK® 2 AST-N804	424634	cza02n/ipr01n
VITEK® 2 AST-N808	424711	ipm05n
VITEK® 2 AST-N810	424712	cza02n
VITEK® 2 AST-N811	424713	cza02n
VITEK® 2 AST-N813	424722	cza02n/ipr01n
VITEK® 2 AST-N815	425054	cza02n/mev01n
VITEK® 2 AST-XN09	423425	cza02n

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

VITEK® 2 AST-XN15	423829	cza02n/mev01n
VITEK® 2 AST-XN17	423673	cza02n
VITEK® 2 AST-XN18	423874	cza02n
VITEK® 2 AST-XN20	423947	cza02n/mev01n
VITEK® 2 AST-XN21	424197	cza02n/mev01n
VITEK® 2 AST-XN22	424199	cza02n/mev01n
VITEK® 2 AST-XN23	424198	caz02n/ipr01n/mev01n/pb02n
VITEK® 2 AST-XN24	424351	cza02n/ipr01n/mev01n
VITEK® 2 AST-XN26	424500	cza02n/ipm05n/ipr01n/mev01n
VITEK® 2 AST-XN28	424586	cza02n/ipr01n/mev01n
VITEK® 2 AST-XN29	424604	cza02n/ipr01n
VITEK® 2 AST-XN30	424639	cza02n/ipm05n/ipr01n/mev01n/pb02n
VITEK® 2 AST-XN31	424640	ipm05n/ipr01n/mev01n/pb02n
VITEK® 2 AST-XN32	424678	cza02n/ipr01n/mev01n
VITEK® 2 AST-XN33	424723	cza02n/ipm05n/ipr01n/mev01n
VITEK® 2 AST-XN34	424752	cza02n/ipr01n/mev01n/pb02n
VITEK® 2 AST-XN35	424810	cza02n/ipr01n/mev01n
VITEK® 2 AST-XN36	424860	cza02n/ipr01n/mev01n
VITEK® 2 AST-XN37	424888	cza02n/ipr01n
VITEK® 2 AST-XN38	425074	cza02n/ipr01n/mev01n
VITEK® 2 AST-XN39	425086	ipr01n/mev01n
VITEK® 2 AST-XN40	425095	cza02n/ipr01n/mev01n
VITEK® 2 AST-XN41	425204	cza02n
VITEK® 2 AST-XN42	425309	cza02n/ipr01n/mev01n

Description of the issue

bioMérieux has identified an increase in complaints for out-of-range high (OORH) quality control (QC) results for the following antibiotic formulations: Ceftazidime/Avibactam (cza02n), Imipenem (ipm05n), Imipenem/Relebactam (ipr01n), Meropenem/Vaborbactam (mev01n), and Polymyxin B (pb02n). During the investigation we identified that a small number of VITEK® 2 GN-AST cards users, have also reported false resistant antibiotic results with the same antibiotics when testing strains of *Enterobacterales/Enterobacteriaceae species* and/or *Pseudomonas aeruginosa*. Please note that the internal investigation is still ongoing, and the root cause has not yet been fully determined.

Impact to User/Customer/Patients

There are two potential impacts: QC failure and/or 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.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

Required actions

bioMérieux recommends that **clinically significant isolates** of Enterobacterales/*Enterobacteriaceae* species and *Pseudomonas aeruginosa* with resistant results to Ceftazidime/Avibactam (cza02n), Imipenem (ipm05n), Imipenem/Relebactam (ipr01n), Meropenem/Vaborbactam (mev01n), or Polymyxin B (pb02n) be considered for confirmation using an alternative method for all VITEK® 2 GN-AST cards. The determination of clinical significance should be made by each laboratory based on the antimicrobial susceptibility profile and the local availability of alternative antibiotics.

If appropriate for your laboratory, create a custom bioART rule (regionally specific as listed in Table 2) when using a VITEK® 2 GN-AST card with the impacted antibiotics. The following are the bioART rule criteria:

- If:
 - Organism is [SPECIES] (“Enterobacterales/Enterobacteriaceae” or “*P. aeruginosa*”)
 - Antibiotic is [DRUG VERSION], Interpretation R (Resistant)
- Then:
 - Stop for Review
 - Create a user-defined comment on the lab report to guide the user for further instruction regarding alternate testing (i.e. Per FA-TWD-000064 FSCA, confirm [DRUG NAME] ([DRUG VERSION]) resistance with an alternative method before reporting; only when needed for patient care.
- **Note: For Enterobacterales/*Enterobacteriaceae* if software version is 9.03 or prior apply for *Enterobacteriaceae*, if software version is 9.04 or after apply Enterobacterales.**

For assistance with bioART rule creation, please contact your local bioMérieux representative.

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.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



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/>

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

Table2. Recommended Actions by Region/Country:

Antibiotic	Organism	Perform alternate method in case of resistant result for clinically significant isolates? (NO, means no bioART rule is needed)		
		USA	EMEA, CANADA and ASPAC	LATAM
Ceftazidime/avibactam (cza02n)	Enterobacterales /Enterobacteriaceae***	YES	YES	YES
	<i>P. aeruginosa</i>	NO, Existing limitation*	YES	YES
Imipenem (ipm05n)	Enterobacterales/ Enterobacteriaceae***	YES	YES	YES
	<i>P. aeruginosa</i>	YES	YES	YES
Imipenem/relebactam (ipr01n)	Enterobacterales /Enterobacteriaceae***	YES	YES	NO**
	<i>P. aeruginosa</i>	YES	YES	NO**
Meropenem/vaborbactam (mev01n)	Enterobacterales/ Enterobacteriaceae***	YES	YES	NO**
	<i>P. aeruginosa</i>	NO, not FDA cleared	YES	NO**
Polymyxin B (pb02n)	Enterobacterales/ Enterobacteriaceae***	NO, not FDA cleared	NO**	NO**
	<i>P. aeruginosa</i>	YES	NO**	NO**

* Existing limitation for MIC values of ≥ 16 $\mu\text{g/mL}$: resistant results should not be reported

** No cards exist with the impacted drugs, rule to apply if drug is available or new card is created with impacted drugs in future

*** For Enterobacterales/Enterobacteriaceae if software version is 9.03 or prior apply for Enterobacteriaceae, if software version is 9.04 or after apply Enterobacterales.

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,

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



Customer Service

Subsidiary name (if applicable) / Nom de la filiale (si approprié)

Company address / Adresse de la société émettrice - Zip Code City / Code postal Ville - Country / Pays
Phone / Tél.: + 33 (0)0 00 00 00 00 - Fax: + 33 (0)0 00 00 00 00 - www.biomerieux.com
Legal notice / Mentions légales de la société émettrice



Attachment A: Acknowledgement Form.

Urgent Field Safety Corrective Notice

FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000064
False Resistant Antibiotic results (ipm05n, pb02n, cza02n, mev01n, ipr01n) in
VITEK® 2 AST GN cards for *Enterobacterales/Enterobacteriaceae* species and/or
Pseudomonas aeruginosa

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

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 am impacted by the issue.

Impacted References: Reference

 Reference

 Reference

 Other

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.

Have you encountered an impact on patients' results, or reports of illness or injury related to the identified issue? *(to be completed based on FSCA issue)*

Yes No

DATE.....SIGNATURE.....

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

Subsidiary name (if applicable) / Nom de la filiale (si approprié)