

IMPORTANT:

URGENT FIELD SAFETY NOTICE

False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for *Acinetobacter baumannii* complex and *Pseudomonas aeruginosa*

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-000045-1

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

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-XN25 TEST KIT 20 CARDS	424394		
AST-N412 TEST KIT 20 CARDS	423936		
AST-N427 TEST KIT 20 CARDS	424196		
AST-XN21 TEST KIT 20 CARDS	424197		
AST-XN22 TEST KIT 20 CARDS	424199		
AST-XN24 TEST KIT 20 CARDS	424351		
AST-N438 TEST KIT 20 CARDS	424499		
AST-N439 TEST KIT 20 CARDS	424501		
AST-N440 TEST KIT 20 CARDS	424502		
AST-N443 TEST KIT 20 CARDS	424541		
AST-XN28 TEST KIT 20 CARDS	424586		
AST-N444 TEST KIT 20 CARDS	424587		
AST-XN29 TEST KIT 20 CARDS	424604		
AST-N447 TEST KIT 20 CARDS	424620		

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

AST-N448 TEST KIT 20 CARDS	424633		
AST-XN35 TEST KIT 20 CARDS	424810		
AST-N462 TEST KIT 20 CARDS	424839		
AST-N463 TEST KIT 20 CARDS	424840		
AST-N465 TEST KIT 20 CARDS	424842		
AST-XN37 TEST KIT 20 CARDS	424888		
AST-N475 TEST KIT 20 CARDS	424891		
AST-N476 TEST KIT 20 CARDS	424934		
AST-N477 TEST KIT 20 CARDS	425019		

Dear bioMérieux Customer,

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

This communication is to inform you that you may encounter false resistant colistin (formulation cs02n) results when testing strains of *Pseudomonas aeruginosa* and *Acinetobacter baumannii* complex.

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

Required actions

bioMérieux recommends you confirm any resistant colistin (cs02n) results for multidrug resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii* complex isolates via an alternate method for all existing and future AST cards with cs02n.

If appropriate for your laboratory, create a custom bioART rule to show when resistant colistin (cs02n) results are obtained for *Pseudomonas aeruginosa* and *Acinetobacter baumannii* complex isolates (refer to the VITEK® 2 Software User Manual for instructions).

Based on individual facility policy, you may wish to perform retrospective review of resistant results.

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 the product.

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.

Description of the issue

VITEK® 2 users, who are using VITEK® 2 GN-AST cards with Colistin formulation, cs02n, have reported obtaining false resistant Colistin results with *Acinetobacter baumannii* complex and *Pseudomonas aeruginosa* isolates.

Impact to User/Customer/Patients

Potential for overestimated MIC / Over-calling resistance, leading to a Major Error, erroneous antibiotic category interpretation.

False resistant results may lead to the use of less effective antibiotic treatment or the association of multiple antibiotics having negative side effects, with potential consequences to the patients' health.

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



Colistin (cs02n) is a polymyxin (polymyxin E) that is frequently used as a last-resort antimicrobial treatment for multidrug resistant Gram-negative infections.

Patients infected by multidrug resistance *Acinetobacter baumannii* and *P. aeruginosa* are usually critical patients, patients in ICU, patients requiring ventilator's support, immunocompromised patients that have been exposed to multiple antibiotic treatments and/or healthcare visits/hospitalizations, elderly and infant patients.

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

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



Attachment A: Acknowledgement Form.

Urgent Field Safety Corrective Notice

FSCA - FIELD SAFETY CORRECTIVE ACTION FA-TWD-000045-1
False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for
Acinetobacter baumannii complex and *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 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.

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



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