BIOMÉRIEUX

FIELD ACTION NOTIFICATION

GENERAL INFORMATION

FSCA - FIELD SAFETY CORRECTIVE ACTION			
Field Action Number:	**FA-TWD-000045-1**	**Field Action rev. n°:**	2
CRM Number	FA-035723 | Field Action | Salesforce		
Subject:	VITEK® 2 - False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa		
Type of Required Actions:	**Manufacturer action(s)**	**User action(s)**	
	Other Root cause investigation is ongoing. Customer Notification	Identify Device - On-site modification/inspection All customers using all existing and future cs02n cards should confirm resistant colistin results for multidrug resistant Pseudomonas aeruginosa and Acinetobacter baumannii complex. Customers can set up a custom bioART rule to trigger when resistant colistin results are obtained for multidrug resistant Pseudomonas aeruginosa and Acinetobacter baumannii complex isolates. Based on individual customer policy, customers may determine to perform retrospective review of resistant results.	
Manufacturing Site:	bioMérieux, Inc. 595 Anglum Road Hazelwood, MO 63042		
INV n°:	INV-23044		
INV n°:	INV-25772		
Other FA / CSN n°:	N/A		
Date of decision to take action in the field	6/16/2025		
Issue Date:	**02-JUL-2025**	**Due Date:**	6 months from FSCA issuance date **02-JAN-2026**

SECTION A : DETAILS

Impacted product

System	Product	Ref #	Lot / SN #	Expiry	Software version(s)	Firmware version(s)	Catalog profile	Manufacturing Start & End Date	Shipment Start & End Date	Qty of products released by manuf. site	Unit name	Business unit	GMDN Code	EMDN Code	Unique Device Identifier
VITEK® 2 Reagent	AST-XN25 TEST KIT 20 CARDS	424394	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	03573026630898
VITEK® 2 Reagent	AST-N412 TEST KIT 20 CARDS	423936	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	03573026622695
VITEK® 2 Reagent	AST-N427 TEST KIT 20 CARDS	424196	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	03573026628031
VITEK® 2 Reagent	AST-XN21 TEST KIT 20 CARDS	424197	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	03573026628055
VITEK® 2 Reagent	AST-XN22 TEST KIT 20 CARDS	424199	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	03573026628093
VITEK® 2 Reagent	AST-XN24 TEST KIT 20 CARDS	424351	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	03573026630874
VITEK® 2 Reagent	AST-N438 TEST KIT 20 CARDS	424499	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	03573026632731
VITEK® 2 Reagent	AST-N439 TEST KIT 20 CARDS	424501	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	03573026632779

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VITEK® 2 Reagent	AST-N440 TEST KIT 20 CARDS	424502	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6632793
VITEK® 2 Reagent	AST-N443 TEST KIT 20 CARDS	424541	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6633394
VITEK® 2 Reagent	AST-XN28 TEST KIT 20 CARDS	424586	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6634131
VITEK® 2 Reagent	AST-N444 TEST KIT 20 CARDS	424587	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6634155
VITEK® 2 Reagent	AST-XN29 TEST KIT 20 CARDS	424604	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6634322
VITEK® 2 Reagent	AST-N447 TEST KIT 20 CARDS	424620	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6634551
VITEK® 2 Reagent	AST-N448 TEST KIT 20 CARDS	424633	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6634773
VITEK® 2 Reagent	AST-XN35 TEST KIT 20 CARDS	424810	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6637699
VITEK® 2 Reagent	AST-N462 TEST KIT 20 CARDS	424839	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6638177
VITEK® 2 Reagent	AST-N463 TEST KIT 20 CARDS	424840	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6638191
VITEK® 2 Reagent	AST-N465 TEST KIT 20 CARDS	424842	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6638238
VITEK® 2 Reagent	AST-XN37 TEST KIT 20 CARDS	424888	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6639006

VITEK® 2 Reagent	AST-N475 TEST KIT 20 CARDS	424891	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6639426
VITEK® 2 Reagent	AST-N476 TEST KIT 20 CARDS	424934	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6640156
VITEK® 2 Reagent	AST-N477 TEST KIT 20 CARDS	425019	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Microbiology	All	58605	N/A	0357302 6640804

Name & Address of Legal Manufacturer

Name & Address of Recalling Firm : bioMérieux, Inc.
100 Rodolphe
Durham, NC 27712

Name & Address of Manufacturing site: bioMérieux, Inc.
595 Anglum Road
Hazelwood, MO 63042

SIG Code of Manufacturing site : NA002

Product Intended Use

The VITEK® 2 Gram-negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

Description of the Issue

Investigation Reference No. :

INV-23044
INV-25772

CI/CAPA n° if any :

Associated customer complaint, if any :

CN-671395
CN-734122
CN-674438
CN-675002
CN-693360
CN-702631
CN-705990
CN-707294
CN-713309
CN-719842
CN-725470
CN-739947
CN-754667
CN-807251
CN-820785
CN-807832
CN-807835
CN-807843
CN-840215
CN-575543
CN-575754
CN-635866
CN-671164
CN-671168
CN-747582
CN-589647
CN-671991
CN-759982
CN-576680
CN-580939
CN-643336
CN-643348
CN-643466
CN-643624
CN-649793
CN-653686
CN-656698
CN-658538
CN-659859
CN-662644
CN-662645
CN-666529

CN-668640
CN-674151
CN-676609
CN-678774
CN-688684
CN-694275
CN-702626
CN-703893
CN-706001
CN-707300
CN-714623
CN-718190
CN-727195
CN-727201
CN-736768
CN-740555
CN-785569
CN-790327
CN-807880
CN-809242
CN-817343
CN-818575
CN-824158
CN-824160

Other FA/CSN, if any :
N/A

PSS reference n° and issue date, if any :
N/A

Description of the issue :
Customers are implementing VITEK® 2 AST GN cards with the updated Colistin formula (cs02n) and have reported obtaining false resistant Colistin results primarily with multidrug resistant *Acinetobacter baumannii* and *Pseudomonas aeruginosa*.

A multi-department task force was assembled in early 2025 to determine the root cause of this “hump” and other contributing factors to this issue. This investigation is still in progress.

Additional investigational testing using IUO (Investigation Use Only) VITEK® 2 AST cards and strains being submitted by 3*rd* party laboratories will be conducted to help determine root cause.

Root cause:
No root cause has been identified at this time. Additional investigational testing is ongoing using new IUO (Investigation Use Only) AST cards and strains received from third party laboratories.

CI/CAPA summary:
A CI/CAPA will be initiated as a result of this FSCA.

Description of the actions

bioMérieux has determined that communication to the field is appropriate while the root cause investigation is ongoing. The recommended action will be confirmation testing for resistant colistin results for multidrug resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii complex*

As data from customer sites showed that the rate of occurrence at some sites is elevated in comparison to other regions, the overall risk has been calculated as MINOR by bioMérieux. Taking action in the field will reduce the overall risk; therefore the communication will take the form of a Field Safety Corrective Action (FSCA) and Customer Letter.

A Field Safety Corrective Action (FSCA) with customer letter will be issued to all customers that use all existing and future VITEK 2 AST cards containing the colistin formulation cs02n.

All customers using cs02n cards will be recommended to confirm resistant colistin results for multidrug resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii complex*.

Customers can set up a custom bioART rule to show when resistant colistin results are obtained for multidrug resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii complex* isolates.

Based on individual customer policy, customers may wish to perform retrospective review of resistant results.

At subs/distributors levels:
Confirm the impacted customers in your region.

Translate, if necessary, and distribute the customer letter to each customer in their respective region(s) for customers using VITEK® 2 AST cards containing colistin (cs02n).

Monitor local implementation.

Monitor region for new customers that may be impacted by this issue.

At customers level:
All customers using existing and future cs02n cards should confirm resistant colistin results for multidrug resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii complex*.

Customers can set up a custom bioART rule to show when resistant colistin results are obtained for multidrug resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii complex* isolates.

Based on individual customer policy, customers may wish to perform retrospective review of resistant results.

At manufacturing site level:
Continue investigation into root cause of the identified issue.
Implement additional actions as necessary.

Initiate CAPA / CI

At International/regional Distribution Center(s) level:
N/A

At other internal level, if any:
N/A

Hazard Assessment

Summary of the impact on customer/patient:
Hazard (6.38) Erroneous AST result - Overestimated MIC / Over-calling resistance, leading to a Major Error, erroneous antibiotic category interpretation.

Potential Impact: 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 serious consequences to the patients' health.

Probability of Occurrence (P1): Occasional
Severity: Serious
Probability of Harm (P2): Remote
Overall Probability (P): Remote
Overall Risk: Minor

Med. Affairs office name & function: Cecilia Carvalhaes Completion date: 13 Jun 2025

Immediate and Long Range Health Consequences:
A. Describe the Immediate and Long Term Health Consequences (Injuries or Illnesses) That May Result from Use of or Exposure to the Defective Device and Assess the Severity Related to Patients and Users. (Include Known Off Label Uses).

Colistin (cs02n) is a polymyxin (polymyxin E) that is frequently used as a last-resource antimicrobial treatment for **multidrug resistant** Gram-negative infections, such as those caused by Pseudomonas aeruginosa, Acinetobacter spp. and Enterobacterales species.

It is a CLSI M100 Tier 4 drug - antimicrobial agent that may warrant testing and reporting by clinician request if antimicrobial agents in other tiers are not optimal because of various factors - for *Acinetobacter baumannii complex*, and not recommended as monotherapy for *Pseudomonas aeruginosa* or Enterobacterales isolates. Alternative agents are strongly recommended. However, in the lack of alternative option or availability, it is used as a last-resource antimicrobial therapy for infections ranging from bloodstream infections to urinary tract infection caused by **multidrug resistance** pathogens. Therefore, accurate results are critical for patient care.

The current issue identified with the select lots of VITEK® 2 cards is a risk associated with the potential for an increase in false resistant results for the colistin (cs02n) test due to overcalling of MIC results, and potentially leading to the use of less effective antibiotic treatment or the association of multiple antibiotics favoring deleterious side effects, with potential serious consequences to the patients' health.

Erroneous AST result - Overestimated MIC / Over- calling resistance, leading to a Major erroneous antibiotic category (BMX.1.034873 - VITEK 2" Systems Hazard Definition and Impact - Rev 5) - Major Error (ME): a susceptible (S) result is interpreted as resistant (R) leading to a false resistance AST result. Negative influence on the medical diagnosis and treatment requiring professional medical intervention. A resistant result eliminates the drug as a choice for treatment. A false resistant result could have a negative influence on the treatment decision, as resistant results limit the treatment options available to the clinician.
The patient may not receive the most effective antimicrobial. The patient could receive an alternative antibiotic and experience more side effects (e.g. toxicity, invasive administration route, more expensive treatment). The severity of harm to the patient is SERIOUS.

Although the overall risk assessment is irrelevant, based on a calculation of probability that spreads the likelihood of false resistance results across all customers evenly, the data from specific sites showed that this estimated rate of occurrence does not represent what is likely actually happening at some sites. Therefore, the intent is to communicate the issue and propose mitigation to reduce risk at those sites which are impacted.

B. Describe Any Factors That May Mitigate the Risk. Include An Assessment of P2.

Recommend using an alternative method if a resistant result is obtained using colistin (cs02n) against multidrug resistant *Acinetobacter spp*. and *P. aeruginosa* in VITEK 2 systems.
P2 is defined in BMX.1.034873 - VITEK® 2" Systems Hazard Definition and Impact - Rev 6 as REMOTE for a hazard of false resistance.

C. What Segment of the Population is Most at Risk? (e.g. Infants, Elderly, Pregnant Women, Critically Ill Patients, Immunocompromised Patients, etc.)

Patients infected by multidrug resistance *Acinetobacter baumannii complex* 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.

D. Does the Health Consequence Have Significant Public Health Impact? No

Summary of the overall risk before implementing a Field Action:

Product name - Ref	Associated risk	P1 (Probability of hazardous situation occurring)	P2 (Probability of hazardous situation leading to harm)	P (Overall probability)	Severity	OVERALL RISK
VITEK 2 AST-GN Cards containing Colistin (cs02n)	Hazard (6.38) Erroneous AST result - Overestimated MIC / Over-calling resistance, leading to a Major	Occasional	Remote	Remote	Serious	Minor

Notification to Regulatory Authority

Manual creation of Local Field Actions for management of reporting to health authorities are required for the countries that are required to assess/report to health authorities for FCA-FSCA implemented outside of their country per 000584 – Field Action Reporting Matrix

Attachments

Customer Letter FA-TWD-000045-1 Click on the papperclip below :

SECTION B : REQUIRED ACTIONS

1. **Please immediately acknowledge receipt (AR) of this FA.**

- Subsidiaries and plants using CRM: Please manage the Acknowledgment of this FA in CRM by changing the local field action status from “new” to “Acknowledged”. Please refer to CRM 360 – Service – Global user manual – Field action 065826 for more details.
- Subsidiaries not using CRM, Export Distributors and other entities: Please complete the Acknowledgment of receipt, sign and date where indicated, then send it by email to fieldactions@biomerieux.com.

2. **Identify all customers for which you are responsible that are impacted by the scope of this notification.**

3. **Implement the following required actions (when applicable) :**

Service tasks	Subsidiaries	Export distributors and other entities	Due date
Send Initial Notification to Customer: Recipients of this notification must notify all impacted customers using translated customer letter (if applicable). Initial customer notification should be completed before the indicated due date unless local regulation specifies earlier due date. Translate, if necessary, and distribute the customer letter to each customer in their respective region(s) for customers purchasing VITEK® 2 AST cards containing colistin (cs02n). Identify customers that have received VITEK® 2 Test kits containing colistin cs02n.	CRM users: Complete the date of initial customer notification and close the Service Task “Send Initial Notification to customer” from your **Local Field Action.** Please refer to the CRM 360 – Service – Global user manual – Field action 065826 for more details. Not CRM users: Complete the paragraph “Send initial notification to customer” of the acknowledgment of completion, then send it by email to fieldactions@biomerieux.com.	Complete the paragraph “Send initial notification to customer” of the acknowledgment of completion, then send it by email to fieldactions@biomerieux.com.	One (1) month from FSCA issuance date **02-AUG-2025**

Service tasks	Subsidiaries	Export distributors and other entities	Due date
Send reminder for customer letter: Recipients of this notification must define a customer reminder according to their local procedure. The customer reminder should be completed before the indicated due date unless local regulation specifies earlier due date.	CRM users: Complete the date of reminder customer notification and close the Service Task "Send Reminder for customer letter" from your **Local Field Action.** Please refer to the CRM 360 – Service – Global user manual – Field action 065826 for more details.	*Refer to your local procedure - No need to provide information in AOC*	**Refer to your local requirements**
	Not CRM users: Complete the paragraph "Send reminder for customer letter" of the acknowledgment form then send it by email to fieldactions@biomerieux.com.		

Service tasks	Subsidiaries	Export distributors and other entities	Due date
Report to Health Authority: Recipients of this notification must assess the product issue and any associated patient risk in accordance with local regulations to determine if it is reportable to their local regulatory authority. Notification to their regulatory authority must include device classification when required. Reporting decision and Initial reporting to health authorities should be completed before the indicated due date unless local regulation specifies earlier due date. If required by the local procedures and regulation, recipient of this notification must send to their regulatory authority final/closure reports before the due date specified in their local regulation.	CRM users: Complete the date and information requested in the Service task "Report to Health Authority" from your **Local Field Action.** Then, create the appropriate Health Authority Action(s) (HAA) in CRM including "Health Authority - Reporting decision" which is mandatory. NB: If reportable, the service task "Report to health Authority" must be closed when the "Health Authority - Initial report" has been completed. If not reportable, the service task "Report to health Authority" must be closed after the "Health Authority - Reporting decision" has been completed. Please refer to the CRM User Guide - Field Action - Regulatory Reporting 063702 - for more details. Not CRM users: Complete the paragraph "Report to Health Authority" of the acknowledgement form, then send it by email to fieldactions@biomerieux.com.	Complete the paragraph "Report to Health Authority" of the acknowledgement form, then send it by email to fieldactions@biomerieux.com.	One (1) month after issuance. **02-AUG-2025**

Service tasks	Subsidiaries	Export distributors and other entities	Due date
Perform Delta Management: Recipients of this notification must identify if new customers are impacted until the due date indicated.	CRM users: Complete the date and close the service task "Perform Delta Management" from your **Local Field Action.** Please refer to the CRM 360 – Service – Global user manual – Field action 065826 for more details. Not CRM users: Complete the paragraph "Perform delta management" of the acknowledgment of completion, then send it by email to fieldactions@biomerieux.com.	*Refer to your local procedure - No need to provide information in AOC*	Four (4) months after issuance of FSCA **02-NOV-2025**

4. After all actions are completed, please:

- Subsidiaries and plants using CRM: Close the Local Field Action. Please refer to the CRM 360 – Service – Global user manual – Field action 065826
- Subsidiaries not using CRM, Export Distributors and other entities: Complete the acknowledgment of completion at the time of each ACTION, sign it and return it by email to fieldactions@biomerieux.com.

SECTION C : CONTACT

Benjamen Jost
Specialist - Vigilance Operational Team - Microbiology
595 Anglum Road
Hazelwood, MO 63042
ben.jost@biomerieux.com

SECTION D : REVISION HISTORY

Revision #	Description of change
1	Creation of FA notification
2	Correction of P1 to Occasional per the HHA and removal of product received/removed/destroyed table from the customer letter. This edit cancels and replaces the initial notification.

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000045-1	CRM number: FA-035723 | Field Action | Salesforce	FA type/Title: FSCA- VITEK® 2 - False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa

A/ ACKNOWLEDGEMENT OF RECEIPT (AR)

Location

Account #:

Group Company or Export Distributor Name(s):

Country:

Please assess if the Field Action is applicable to your entity and fill the document, accordingly.

*If you are an Export **DISTRIBUTOR:** both Acknowledgement of Receipt and the Acknowledgement of Completion – Part 1 must be sent back to bioMérieux **within 1 month** after receiving the Field Action communication. Then, the Acknowledgment of Completion Part 2 should be fulfilled and returned **at the time of each action completion**.*

*If you are part of bioMérieux, as **SUBSIDIARY OR OTHER ENTITY not CRM users**, the Acknowledgement of Receipt must be sent back **immediately** after receiving the Field Action communication. Then, the Acknowledgment of Completion Part 1 and Part 2 should be fulfilled and returned **at the time of each action completion**.*

☐ Field Action Not Applicable

Provide justification: ……

Please, provide a justification, sign, and return the document.

☐ Field Action Applicable

If applicable, please sign and return the document.

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000045-1	CRM number: FA-035723 | Field Action | Salesforce	FA type/Title: FSCA- VITEK® 2 - False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa

Print Name:

Sign Name:

Position:

Date (dd/MMM/yyyy):

B/ ACKNOWLEDGMENT OF COMPLETION (AC) – Part 1

Location

Account #:

Group Company or Export Distributor Name(s):

Country:

*If you are an **Export DISTRIBUTOR**: both Acknowledgement of Receipt and the Acknowledgement of Completion – Part 1 must be sent back **within 1 month** after receiving the Field Action communication.*

If you are part of bioMérieux, as SUBSIDIARY OR OTHER ENTITY not CRM users, the Acknowledgment of Completion Part 1 and Part 2 should be fulfilled and returned at the time of each action completion (before the due date indicated in the table).

ACKNOWLEDGEMENT FORM		
FA number: FA-TWD-000045-1	**CRM number: FA-035723 | Field Action | Salesforce**	**FA type/Title: FSCA-** VITEK® 2 - **False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa**

Actions to be completed by all stakeholders

ACTIONS	Due Date	Description
Initial Notification to Customers	One (1) month after issuance of FSCA 02-AUG-2025	☐ If applicable, please indicate the date when all customers have been notified (DD/MM/YYYY):…….. ☐ If not applicable, please provide a justification: …….
Report to Health Authority	One (1) month after issuance of FSCA 02-AUG-2025	**REPORTING DECISION** ⇨ *Please refer to your local regulation to determine if the field action must be reported to your National competent authority and indicate the decision below:* ☐ REPORTABLE ☐ NON-REPORTABLE ⇨ Please indicate when the reporting decision has been taken (DD/MM/YYYY): …… If non-reportable, please provide a justification of the decision: …… …… ……
	IF REPORTABLE, PLEASE COMPLETE THE SECTION BELOW	

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000045-1	**CRM number: FA-035723 | Field Action | Salesforce**	**FA type/Title: FSCA-** VITEK® 2 - **False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa**

ACTIONS	Due Date	Description
	One (1) month after issuance of FSCA 02-AUG-2025	**INITIAL REPORT** ⇨ *Please indicate the following information as soon as your initial report has been sent to your National Competent Authority (NCA)* Country: ……. National Competent Authority Name: …….. Reference number from your NCA, if any: …….. Date of submission to your NCA (DD/MM/YYYY): …… ⇨ *In case of shorter timelines for reporting requested by your local regulation, please indicate this due date: (DD/MM/YYYY): ……..* ⇨ *Please provide the evidence of submission in attachment to this Acknowledgement of Completion*

Please sign and return the fulfilled Acknowledgement of Completion form:

Print Name:

Sign Name:

Position:

Date (DD/MM/YYYY):

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000045-1	CRM number: FA-035723 | Field Action | Salesforce	FA type/Title: FSCA- VITEK® 2 - False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa

B/ ACKNOWLEDGMENT OF COMPLETION (AC) – Part 2

Location

Account #:

Group Company or Export Distributor Name(s):

Country:

*Please complete the **Acknowledgment of Completion – Part 2 at the time of each ACTION completion**. The due date indicates the date when the action must be completed and when the Acknowledgment of Completion must be returned to bioMérieux.*

NB 1: There is no need to complete the Acknowledgment of Completion – Part 2 if you have assessed the field action as "not applicable".

NB 2: For Export DISTRIBUTOR, it is acceptable to return the Acknowledgment of Completion – Part 2 once all the remaining actions are completed.

Actions to be completed by all stakeholders

ACTIONS	Due Date	Description
Action on Product	N/A	☐ If applicable, please indicate the date when the action on product has been completed (DD/MM/YYYY): ……. ⇨ Please complete the following table related to the impacted products: ✓ *If reagent, please use the following table:*

REF #	Product Name	Batch #	Quantity received	Quantity used	Quantity destroyed	Quantity returned*
N/A	N/A	N/A	N/A	N/A	N/A	N/A

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000045-1	CRM number: FA-035723 | Field Action | Salesforce	FA type/Title: FSCA- VITEK® 2 - False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa

ACTIONS	Due Date	Description
		** Quantity returned to bioMérieux subsidiary or export distributor* ✓ *If instrument/software, please use the following table:* REF # | Product Name | Serial number # / Version number | Quantity received | Quantity corrected** | Quantity returned* N/A | N/A | N/A | N/A | N/A | N/A ** Quantity returned to bioMérieux subsidiary or export distributor* *** Quantity corrected include software updates or instruments corrections* ☐ If not applicable, please provide a justification: …….....
Report to Health Authority	Refer to your local regulation	**FINAL REPORT** ⇨ *Please refer to your local regulation to determine if a final report is required:* **FINAL REPORT REQUIRED: ☐ YES ☐ NO** ⇨ *If required, please refer to your local regulation to determine the local due date the final report must be sent to your NCA, if any: (DD/MM/YYYY) ……..* ⇨ *If required, please indicate the date when the final report has been submitted to your NCA (DD/MM/YYYY): ……..* ⇨ *Please, provide the evidence of submission in attachment to the Acknowledgement of Completion*
	Refer to your local regulation	**CLOSURE** ⇨ *Please indicate if your local procedure requires a closure of the field action.* **CLOSURE REQUIRED: ☐ YES ☐ NO**

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000045-1	CRM number: FA-035723 | Field Action | Salesforce	FA type/Title: FSCA- VITEK® 2 - False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa

ACTIONS	Due Date	Description
		⇨ *If required, please indicate the date when the closure has been completed (DD/MM/YYYY):* …… ⇨ *Please indicate the criteria of closure:* ……
Other	N/A	☐ If applicable, please indicate the completion date (DD/MM/YYYY): …… ☐ If not applicable, please provide a justification: ……

Please sign and return the fulfilled acknowledgement of completion form:

Print Name:

Sign Name:

Position:

Date (DD/MM/YYYY):

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000045-1	CRM number: FA-035723 | Field Action | Salesforce	FA type/Title: FSCA- VITEK® 2 - False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa

Actions to be completed only by bioMérieux entities

ACTIONS	Due Date	Description
Send reminder for customer letter	Refer to your local regulation	⇨ *Please refer to your local procedure to determine if a reminder must be sent to your customer(s)* ☐ If applicable, please complete the following table:

Reminder customer notification	Due date (as per your local procedure) (DD/MM/YYYY)	Reminder Customer Notification date (DD/MM/YYYY)	% customer answers after the reminder
Reminder #1			
Reminder #2			
Reminder #3			

☐ If not applicable, please provide a justification: ……..

Delta Management	Four (4) months after issuance of FSCA 02-NOV-2025	⇨ *Please refer to your local procedure to determine if a delta management must perform.* ☐ If applicable, please indicate the date when it has been completed (dd/MMM/yyyy): …….. ☐ If not applicable, please provide a justification: ……..

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000045-1	CRM number: FA-035723 | Field Action | Salesforce	FA type/Title: FSCA- VITEK® 2 - False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa

ACTIONS	Due Date	Description
Report to Health Authority	Refer to your local regulation	**FOLLOW UP REPORT** ⇨ *Please refer to your local regulation to determine if a follow up report is required* **FOLLOW UP REPORT REQUIRED: ☐ YES ☐ NO** ⇨ *If required, please indicate the following information as soon as your report has been sent to your NCA:*

Follow-up report	Due date (as per your local procedure/ local regulation) (DD/MM/YYYY)	Submission Date(s) (DD/MM/YYYY)
Follow up #1		
Follow up #2		
Follow up #3		

⇨ *Please, provide the evidence of reporting in attachment to the Acknowledgement of completion.*

Report to Health Authority		**QUESTIONS/COMMUNICATION FROM NCA** ⇨ *Please indicate if you have received any question/ communication from your National Competent Authority* Questions/ Communication from NCA? ☐ YES ☐ NO ⇨ *If applicable, please indicate the date when you have answered to your NCA (DD/MM/YYYY): ……* ⇨ *Please, provide supporting documentation in attachment to the Acknowledgement of Completion, as applicable.*

ACKNOWLEDGEMENT FORM

FA number: FA-TWD-000045-1	CRM number: FA-035723 | Field Action | Salesforce	FA type/Title: FSCA- VITEK® 2 - False Resistant Colistin (cs02n) in VITEK® 2 AST GN cards for Acinetobacter baumannii complex and Pseudomonas aeruginosa

ACTIONS	Due Date	Description
		CHANGE REQUESTS FROM NCA ⇨ *Please indicate if you have received any change request from your National Competent Authority* Change request from NCA? ☐ YES ☐ NO *If yes, please indicate the date when you have answered to your NCA (DD/MM/YYYY): :……* ⇨ *Please, provide supporting documentation in attachment to the Acknowledgement of Completion as applicable.*

Please sign and return the fulfilled Acknowledgement of Completion form:

Print Name:

Sign Name:

Position:

Date (DD/MM/YYYY):