**[to be date of distribution]**

**Urgent Product Correction Notice**

Dear Valued bioMérieux Customer,

Our records indicate that your laboratory performs VITEK® 2 Antimicrobial Susceptibility Testing (AST) using one or more of the VITEK® 2 Gram-Negative AST cards types listed in Appendix A. A performance issue has been identified with colistin (cs01n).

**Description of Issue:**

EUCAST and CLSI recently issued a joint recommendation that broth-microdilution (BMD) is the only reference method validated for antimicrobial susceptibility testing (AST) of colistin. As the VITEK® 2 AST-GN colistin (cs01n) was developed to agar dilution (AD), an internal bioMérieux investigation was conducted to identify any shift in performance for colistin (cs01n) since the VITEK® 2 colistin (cs01n) test was developed.

Investigational testing included VITEK® 2, broth-microdilution and agar dilution using 290 isolates with varying degrees of susceptibility and resistance to colistin. Two QC organisms (*E.coli* ATCC® 25922™ and *P. aeruginosa* ATCC® 27853™) were also included in the testing. MIC results from the three methods were compared and evaluated.

The investigation demonstrated a high rate of very major errors (resistant isolates calling susceptible) with the VITEK® 2 AST-GN colistin (cs01n) compared to agar dilution (the reference method used for cs01n development) and compared to broth-microdilution (recommended method by EUCAST/CLSI).

Since the development of VITEK® 2 AST-GN colistin (cs01n), higher resistance rates have been reported. In November 2015 plasmid mediated transferable colistin resistance (mcr-1 gene) was reported1 and resistance due to other mechanisms is reported more frequently.

1 *"Emergence of plasmid-mediated colistin resistance mechanism MCR-1 in animals and human beings in China: a microbiological and molecular biological study.". The Lancet. Infectious diseases. (Liu YY et al., Lancet Infect Dis, 2015).*

**Impact to patient/customer:**

Evaluation of the identified issue indicates the potential for false susceptible colistin results. A false susceptible result could have a negative influence on the treatment decision as the drug may be chosen for therapy. Inappropriate treatment could be prescribed resulting in treatment failure.

**Actions:**

We request you take the following action at this time:

* Please confirm this letter has been distributed to and reviewed by all appropriate personnel within your organization.
* For the referenced test kits (see Appendix A), please perform an alternate method of testing prior to reporting susceptible colistin (cs01n) results.
	+ Please note that a VITEK® 2 bioART rule can be created to suppress reporting of colistin (cs01n) susceptible results (reference VITEK® 2 Online Software User Manual) if required by your facility's procedures.
* Please store this letter with your bioMérieux instrument documentation.
* Complete the Acknowledgement Form and return it to your local bioMérieux representative.

bioMérieux, Inc. is committed to providing our customers with the highest quality products, and we apologize for any inconvenience this has caused your business. If you have any questions or concerns, please contact your local bioMérieux representative.

Thank you for your continued use of bioMérieux products,

**bioMérieux, Inc.**

**[Enter Local Contact]**

**Attachment A: Acknowledgement Form.**

**URGENT PRODUCT CORRECTION NOTICE**

FSCA - 3490 (Addendum) – VITEK® 2 - Colistin (cs01n) Performance

**Customer Information:**

Customer Account Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Organization Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Street Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City, State and Postal Code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Product Information:**

|  |  |
| --- | --- |
| **Catalog Number** | **Description** |
| Multiple | See Appendix A |

**Questions:**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| 1. Did you read the enclosed Urgent Product Correction Notice regarding VITEK® 2

 colistin performance? |  |  |
| 1. Have you followed the instructions and implemented the actions as indicated in this

 Urgent Product Correction Notice? If no, please indicate the reason in the Comments  section below. |  |  |
| 1. Have you received reports of illness or injury related to the VITEK® 2 colistin issue?
 |  |  |
| **Comments**: |

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Please fax this form to: **[Enter Local Contact]** To the attention of:  **[Enter Local Contact]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **REF #** | **Description** |  | **REF #** | **Description** |
| 418114 | AST-GN94 |  | 416914 | AST-N309 |
| 22258 | AST-N102 |  | 417426 | AST-N315 |
| 412605 | AST-N194 |  | 417952 | AST-N318 |
| 412921 | AST-N199 |  | 418204 | AST-N320 |
| 412862 | AST-N201 |  | 418489 | AST-N322 |
| 412863 | AST-N202 |  | 418513 | AST-N325 |
| 412924 | AST-N205 |  | 418514 | AST-N326 |
| 412918 | AST-N210 |  | 418630 | AST-N328 |
| 413061 | AST-N212 |  | 418631 | AST-N329 |
| 413083 | AST-N222 |  | 418675 | AST-N331 |
| 413112 | AST-N225 |  | 418676 | AST-N332 |
| 413171 | AST-N236 |  | 418985 | AST-N335 |
| 413172 | AST-N237 |  | 419077 | AST-N338 |
| 413204 | AST-N239 |  | 419341 | AST-N339 |
| 413205 | AST-N240 |  | 420063 | AST-N343 |
| 413391 | AST-N242 |  | 420440 | AST-N344 |
| 413394 | AST-N245 |  | 420867 | AST-N347 |
| 413397 | AST-N248 |  | 420856 | AST-N348 |
| 413572 | AST-N249 |  | 421258 | AST-N352 |
| 413722 | AST-N253 |  | 421297 | AST-N353 |
| 413724 | AST-N255 |  | 421350 | AST-N354 |
| 413725 | AST-N256 |  | 421351 | AST-N355 |
| 413753 | AST-N261 |  | 421451 | AST-N357 |
| 414164 | AST-N272 |  | 421441 | AST-N358 |
| 414286 | AST-N276 |  | 421583 | AST-N360 |
| 414492 | AST-N279 |  | 421584 | AST-N361 |
| 414531 | AST-N280 |  | 421585 | AST-N362 |
| 414532 | AST-N281 |  | 421692 | AST-N363 |
| 414972 | AST-N288 |  | 421693 | AST-N364 |
| 415063 | AST-N292 |  | 421830 | AST-N365 |
| 415369 | AST-N293 |  | 421853 | AST-N366 |
| 415433 | AST-N295 |  | 421854 | AST-N367 |
| 416005 | AST-N299 |  | 421855 | AST-N368 |
| 416241 | AST-N300 |  | 410025 | AST-XN01 |
| 416590 | AST-N303 |  | 413230 | AST-XN05 |
| 416913 | AST-N308 |  |  |  |