25 May 2017

«Title» «First_Name» «Last_Name»
«Company_Name»
«Address_line_1»
«Address_line_2»
«Address_line_3»
«City»
«County»
«Postal_Code»

Urgent Product Correction Notice – FSCA 3490

Dear «First_Name»

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 reported[1] 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:
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 organisation.

- 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 fax number 0044 (0) 1256 816863 or scan and email to ukvigilance@biomerieux.com **. It is a requirement of the Competent Authority that this form is returned by you.**

bioMérieux, is committed to providing our customers with the highest quality products, and we apologise for any inconvenience this has caused your business. If you have any questions or concerns, please contact our Technical Service Department on 0044 (0) 1256 480711.

Thank you for your continued use of bioMérieux products

Yours sincerely

UKVIGILANCE

bioMérieux UK Ltd

Grafton Way, Basingstoke, Hampshire, RG22 6HY
Tel.: +44 (0)1256 461881 - Fax: +44 (0)1256 816863 - www.biomerieux.co.uk
Registered Office: Grafton Way, Basingstoke, Hampshire, RG22 6HY – Registered in England No. 1061914

Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE
FSCA - 3490 (Addendum) – VITEK® 2 - Colistin (cs01n) Performance

Please complete and return for the attention of UKVIGILANCE to fax number 0044 (0) 1256 816863 or scan and email to ukvigilance@biomerieux.com

It is a requirement of the Competent Authority that this form be returned by you

---

Customer Information:

«Title» «First_Name» «Last_Name»
«Company_Name»
«Address_line_1»
«Address_line_2»
«Address_line_3»
«City»
«County»
«Postal_Code»

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?		
2. 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.		
3. Have you received reports of illness or injury related to the VITEK 2 colistin issue?		
Comments:		

Signature: _____ Date: _____

bioMérieux UK Ltd

Grafton Way, Basingstoke, Hampshire, RG22 6HY
Tel.: +44 (0)1256 461881 - Fax: +44 (0)1256 816863 - www.biomerieux.co.uk
Registered Office: Grafton Way, Basingstoke, Hampshire, RG22 6HY – Registered in England No. 1061914

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			

bioMérieux UK Ltd

Grafton Way, Basingstoke, Hampshire, RG22 6HY
Tel.: +44 (0)1256 461881 - Fax: +44 (0)1256 816863 - www.biomerieux.co.uk
Registered Office: Grafton Way, Basingstoke, Hampshire, RG22 6HY – Registered in England No. 1061914