



To the Laboratory Manager
Cc: to the Chairman Medical Board and relevant Head of Departments

[27 Aug 2018]

MRSA Safety Alert

Our Ref: 4018 FSCA

Dear Valued bioMérieux customer,

Our records indicate that your laboratory uses the VITEK® 2 system for AST (antimicrobial susceptibility testing).

Description of Issue:

It has come to our attention that testing of certain strains of *Staphylococcus aureus* at customer facilities are resulting in the non-detection of methicillin resistance. bioMérieux has recently received reports from European and US clinical laboratories, in which testing with the VITEK 2 reports methicillin susceptibility, while additional confirmatory testing demonstrates resistance. The investigation of approximately twenty *S. aureus* isolates is ongoing to identify the root cause of these non-detection occurrences, assess the prevalence of a possible new strain of *S. aureus* and determine whether updated testing recommendations may be necessary.

At present time, the internal investigation initiated by bioMérieux confirmed that these methicillin resistant *Staphylococcus aureus* (MRSA) strains are slow-growing with VITEK 2, and demonstrate cefoxitin zone sizes close to or at the resistant breakpoint with the cefoxitin disk reference, but are all *mecA* positive by PCR.

Extensive testing of the VITEK 2 AST Gram positive (GP) oxacillin (OX) and cefoxitin screen (OXSF) with VITEK 2 with additional *S. aureus* isolates indicated that the overall performance of the tests is within established performance characteristics for typical clinical strains of *S. aureus*.

MRSA detection with the VITEK 2 is determined based on the combination of the oxacillin MIC, and the cefoxitin screen results. As such, bioMérieux recommends the following actions to further aid in mitigating potential non-detection of MRSA when testing oxacillin (OX) and cefoxitin screen (OXSF) on VITEK 2.

1. Implement a Custom VITEK 2 System Software BIOART™ Rule

In order to optimize the detection of MRSA strains with specific profiles, bioMérieux is providing criteria for the creation of a VITEK 2 System BIOART rule which will be triggered in the presence of a strain with the following results on the VITEK 2 System:

If organism is *S. aureus*,

- and an oxacillin MIC of 1 or 2 µg/ml,
- and a negative result for the Cefoxitin Screen Test

Then: create a user-defined comment on the lab report to guide the user for further instruction regarding additional testing, such as *mecA* gene testing, PBP2a latex agglutination testing or other appropriate testing. Include the action "Stop for Review".



Triggering of the BIOART rule (when the conditions as listed above are observed) will alert the user via a user-defined message on the lab report.

For instructions to create this BIOART Rule, please refer to the VITEK 2 Technology Online Software User Manual, Chapter 13, Advanced Reporting Tool.

2. Additional VITEK 2 System Software Tools

Forcing Rule:

- For *S. aureus*, if the oxacillin MIC is R, or the cefoxitin screen is positive (POS), then the oxacillin status is resistant, and all beta-lactams (except anti-MRSA beta-lactams) are forced R (if not already R).
- This oxacillin forcing rule is enabled by default in any VITEK 2 System parameter set that includes CLSI (except Global CLSI-based). For the full benefit of the VITEK 2 Systems software in all other parameter sets the user should assure that AES is enabled as it will automatically suggest the same therapeutic corrections as the forcing rule. [Refer below to AES section]

ADVANCED EXPERT SYSTEM™:

- If the parameter set of Global CLSI-based, EUCAST or Global European-based is utilized, the VITEK 2 ADVANCED EXPERT SYSTEM™ (AES) will suggest the same therapeutic corrections (i.e. change the beta-lactams, except anti-MRSA beta-lactams to R if not already R) when the Modified PBP phenotype is recognized. [Modified PBP phenotype is proposed when oxacillin MIC is resistant (R) or cefoxitin screen is positive, and organism is *S. aureus*.]

With the BIOART rule activated, under the prescribed conditions, you will be alerted by a comment on the laboratory report, and the software will stop the report for review by the user (for the possible presence of a *S. aureus* strain that does not fully express oxacillin resistance). In this case, it is suggested to confirm the potential MRSA.

3. VITEK 2 Systems Software Version 8.01

Enhancements in the VITEK 2 Systems Software Version 8.01 Knowledge Base provide for updated analysis parameters for the cefoxitin screen test which improve detection of slow-growing organism. bioMérieux will continue implementation of this software version at customer sites.

Impact to customer/patient:

In the event of non-detection of MRSA, a patient could receive inappropriate therapy, resulting in potential treatment failure.

As the investigation continues additional recommendations may become available, and will be communicated.

Actions:

Please take the following actions as appropriate for your laboratory:

- Confirm this letter has been distributed and reviewed by all appropriate personnel within your organization.



- Apply the VITEK 2 Systems BIOART rule criteria as previously mentioned (i.e., using the criteria as listed below for *S. aureus* isolates).
 - *Staphylococcus aureus*,
 - oxacillin MIC of 1 or 2 µg/ml, and
 - negative Cefoxitin Screen test.
- Enable AES to ensure the appropriate forcing rules are applied to test results regardless of the parameter set in use.
- Store this letter with your bioMérieux system documentation.
- Complete the attached Acknowledgement Form (Attachment A) and return it to your local bioMérieux representative.

As part of an ongoing investigation, if your laboratory observes a suspect strain of *S. aureus*, please utilize the existing strain submission system to send the isolate to bioMérieux for additional testing.

bioMérieux is committed to providing our customers with the highest quality products, and we apologize for any inconvenience this may cause 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

Kok Ling LAI
Clinical Application Specialist
bioMérieux Singapore Pte Ltd





Attachment A: Acknowledgement Form

MRSA Safety Alert

4018 - FSCA - VITEK® 2 – MRSA Detection

Customer Information:

Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____ Contact Title: _____

Phone Number: _____



Product Information: All lot numbers of the listed are affected.

REF #	Description		REF #	Description
22226	AST-GP67		412645	AST-P622
22304	AST-GP69		412603	AST-P623
22340	AST-GP70		413042	AST-P624
410750	AST-GP71		413727	AST-P625
414491	AST-GP73		413863	AST-P626
415670	AST-GP75		414124	AST-P627
418424	AST-GP76		414534	AST-P628
421051	AST-GP78		414576	AST-P629
421825	AST-GP79		414697	AST-P630
421826	AST-GP80		414961	AST-P631
421827	AST-GP81		415059	AST-P632
22207	AST-P573		414994	AST-P633
22218	AST-P577		415671	AST-P634
22233	AST-P580		416911	AST-P635
22252	AST-P584		417951	AST-P636
22263	AST-P585		418583	AST-P637
22284	AST-P591		418423	AST-P638
22287	AST-P592		418662	AST-P639
22288	AST-P593		418579	AST-P640
22296	AST-P595		418604	AST-P642
22297	AST-P596		418673	AST-P644
22298	AST-P597		419602	AST-P645
22314	AST-P601		420144	AST-P646
22320	AST-P603		420610	AST-P647
22321	AST-P604		420857	AST-P648
22325	AST-P605		420858	AST-P649
22336	AST-P608		421296	AST-P650
22349	AST-P609		421586	AST-P651
22351	AST-P610		421857	AST-P652
22358	AST-P611		421858	AST-P653
22359	AST-P612		421912	AST-P654
410027	AST-P613		421829	AST-P656
410806	AST-P618		422072	AST-P657
411944	AST-P619		423050	AST-P659



Questions:

	Yes	No
1. Have you read the enclosed MRSA Safety Alert regarding VITEK 2 AST MRSA detection?		
2. Have you followed the instructions and implemented the actions as indicated in this MRSA Safety Alert? If no, please indicate the reason in the Comments section below.		
3. Have you received reports of illness or injury related to VITEK 2 AST MRSA detection?		
Comments:		

Signature: _____

Date: _____

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

Please fax this form to: [\[Kok Ling LAI\]](#) To the attention of: [\[Kok Ling LAI\]](#)