**VITEK 2 Gram Positive AST Cards Recalled Due to False Results for Some MRSA Strains: What Can Your Laboratory Do?**

**ISSUE:**
The FDA has notified the public of a class I recall of all lots of VITEK 2 Gram-positive antimicrobial susceptibility testing (AST) cards manufactured since February 8, 2017. [https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm618135.htm](https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm618135.htm)

**Recalled Product:**
- Name: VITEK 2 Gram Positive Cefoxitin Screen; VITEK 2 Gram Positive AST for Oxacillin
- Lot Numbers: All lots of gram positive AST cards with oxacillin and cefoxitin tests
- Manufacturing and Distribution Dates: February 8, 2017 to present

The ASM Clinical Laboratory Practice Subcommittee is providing the following guidance to aid laboratories with this issue.

**BACKGROUND:**
This recall was prompted by the discovery that some strains of methicillin-resistant *Staphylococcus aureus* (MRSA) are incorrectly categorized as methicillin-susceptible by the VITEK 2. Specifically, these strains demonstrate oxacillin minimum inhibitory concentration (MIC) values in the susceptible range and produce a negative cefoxitin screen result by VITEK 2 (1, 2). It is estimated that almost 14,000,000 devices have been affected by this recall.

Most MRSA strains can express a heterogenous oxacillin resistance phenotype. So-called oxacillin-susceptible meca-positive *S. aureus* (OS-MRSA) have been previously described but are typically resistant to cefoxitin. In contrast, the strains that led to the issuance of this recall can appear susceptible to cefoxitin, by both the VITEK 2 and other methods. These strains are meca-positive and have thus far been mecc-negative. The prevalence of these strains is not yet known. Laboratories should consult with their institutional risk management group in order to determine what steps, if any, should be taken regarding patient notification.

**Questions:**

**“Can I continue to use VITEK 2 GP AST cards?”**
Yes, but additional testing must be performed for *S. aureus* isolates that are cefoxitin screen negative by the VITEK 2 with an oxacillin MIC of 1 or 2 μg/mL.

**“What additional testing must be performed on these isolates?”**
Either penicillin-binding protein 2a (PBP2a) latex agglutination testing, or meca PCR testing should be performed on all cefoxitin screen negative *S. aureus* isolates with oxacillin MIC values of 1 or 2 μg/mL by VITEK 2. For those laboratories without access to these tests, isolates that meet these criteria should be sent to a reference laboratory for PBP2a testing or meca PCR.
There are currently two PBP2a assays cleared for use on *S. aureus* isolates:

- Alere™ PBP2a SA (Abbott)
- Oxoid™ PBP2' Latex Agglutination Test Kit (ThermoFisher Scientific™)

There are currently no FDA-cleared *mecA* PCR assays for testing *S. aureus* isolates, although several FDA-cleared molecular assays are available for a variety of clinical specimen types (e.g. nares, positive blood culture, etc.). Use of any these assays for testing of clinical isolates would be considered off-label, and thus require laboratory validation.

**“Can I instead just test cefoxitin by disk-diffusion or gradient diffusion?”**

At this time, the CLP does **not** recommend cefoxitin disk or gradient diffusion testing, as these strains are believed to be somewhat slow growing and can produce false-negative cefoxitin test results.

Emerging data suggests these isolates may also test susceptible by cefoxitin disk diffusion (*i.e.*, zone of growth inhibition near the breakpoint). These results are being confirmed by additional parties.

Of note, CLSI recently reviewed the performance of disk diffusion for isolates of *S. aureus* that grow poorly on MHA, using alternative media, and found cefoxitin disk diffusion often results in false-susceptible zone sizes (3). **Laboratories should not test such isolates using alternative methodologies, including use of media other than MHA.**

**“Can I instead use an MRSA-selective chromogenic agar to detect these isolates?”**

The ability of MRSA-selective media (e.g. chromogenic agar) to detect these strains is unknown and thus not recommended by the CLP to detect these strains at the time of writing.

**“What additional recommendations have been made?”**

BioMérieux is recommending that laboratories also take the following measures:

- Use version 8.01 software and implement the flagging (BIOART) rule for these isolates as outlined in the bioMérieux MRSA Safety Alert letter sent to customers (3).
- Enable the Advanced Expert System on the VITEK 2 Systems software to ensure that the appropriate forcing rules are applied to test results regardless of the parameter set in use. If laboratories encounter strains that have an oxacillin MIC =1 or 2, are FOX screen-negative but PBP2a or *mecA* positive, use the existing strain submission system to send isolates to bioMérieux for further characterization.

**“Is this recall being extended to other commercial AST systems?”**

At the time of writing, this has not occurred. However, all laboratories should be aware of the existence of potential OS-MRSA strains.
References:

1. BioMérieux Recalls VITEK 2 Gram Positive Antimicrobial Susceptibility Testing (AST) Cards Due to False Results for some strains of methicillin-resistant *Staphylococcus aureus* (MRSA) [https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm618135.htm](https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm618135.htm)


3. The BioMérieux MRSA Safety Alert [letter](https://www.biomerieux.com/) sent to customers

**Contact Information for BioMérieux:**

BioMérieux, Inc.
595 Anglum Road
Hazelwood, MO 63042-2320

Technical Support Center:

Clinical Accounts
[CustomerService-IDAST@biomerieux.com](mailto:CustomerService-IDAST@biomerieux.com)
(800) 682-2666

Industry Accounts
[CSI.STL@biomerieux.com](mailto:CSI.STL@biomerieux.com)
(800) 634-7656