



To the Laboratory Manager
To the attention of the Healthcare center Chairman
To the attention of the Reactovigilance correspondent

Address
City, Date

Our references:
43301, 43302, 43309, 43511, 41864, 51075.
All lots.
IMPORTANT: Product Correction

Dear Madam, Dear Sir,
bioMérieux's records indicate that you use our products Mueller Hinton 2 Agar media and we thank you for choosing bioMérieux solution. We would like to inform you that a problem of non-detection of resistance to cefoxitin in methicillin-resistant *Staphylococcus aureus* (MRSA *mecC* genotype) has been detected for the Mueller Hinton 2 agar – references:

Part Number	Media Description
43301	Mueller Hinton 2 (2X10 plates 90 mm)
43302	Mueller Hinton 2 (4X5 plates 145 mm)
43309	Mueller Hinton 2 (10X10 plates 90 mm)
43511	Mueller Hinton 2 (4X5 plates 120X120 mm)
41864	Mueller Hinton 2 (6X200 ml bottles)
51075	Mueller Hinton 2 (Dehydrated medium)

Description of Issue

bioMérieux has registered some customer complaints about a problem of non-detection of resistance to cefoxitin in methicillin-resistant *Staphylococcus aureus* (MRSA *mecC* genotype) with the Mueller Hinton 2 Agar media. The *mecC* genotype (LGA 251 variant) is a new counterpart of the *mecA* gene. This *mecC* genotype is rarely isolated from samples of human origin. However, some strains of *Staphylococcus aureus* containing *mecC* genotype (LGA 251 variant) are methicillin-resistant *S.aureus* strains. These strains are resistant to cefoxitin.

Studies with several *Staphylococcus aureus* strains containing *mecC* genotype have been performed by our Quality Control laboratory and R&D department and the study results show that the resistance to cefoxitin is not detected for some methicillin resistant *S.aureus* strains *mecC* genotype on the Mueller Hinton 2 Agar media with the disc diffusion. The root cause is not defined yet. Some investigations are still on going.

However, based on the study results obtained for methicillin-resistant *Staphylococcus.aureus* strains (*mecC* genotype), it was decided to add a limitation test in all the packaging insert of involved products in order to alert the users about the non-detection of resistance to cefoxitin in methicillin-resistant *Staphylococcus aureus* strains containing *mecC* genotype (LGA251 variant). The limitation test is as following:

«Some strains of *Staphylococcus aureus* containing *mecC* genotype (LGA251 variant), new counterpart of the *mecA* gene, can be susceptible to cefoxitin on this medium, particularly with the disc method. However, this variant is rarely isolated from samples of human origin».



In addition and in order to find a solution for the detection of resistance to ceftazidime in methicillin-resistant *Staphylococcus aureus* strains containing *mecC* genotype, a new Mueller Hinton E (MHE) has been developed by our R&D department. The internal studies showed that the resistance to ceftazidime was well detected for this kind of *Staphylococcus aureus mecC* genotype with this new Mueller Hinton E.

Impact

Based on the bioMérieux Health Risk Assessment, the two potential risk associated to this issue are:

1. Susceptibility testing of a clinical isolate (diagnosis of infection).
The non-detection of MRSA corresponds to a false sensitive result for the given antibiotic. Then, the risk is to prescribe an antibiotic that will not be efficient (inappropriate treatment) and to delay the correct treatment. However the result of a test is coupled with the clinician's independent judgment and additional information (local epidemiology, patient demographics, medical history, patient status, symptoms, and other tests performed by the clinician).
2. Confirmation of methicillin resistance when MRSA has been isolated during a screening process.
This is a confirmation of a positive screening test. So, a false negative test will alert the microbiologist and will lead to additional testing because the false sensible result (obtained with the Mueller Hinton 2 medium) will be in discordant with the first screening positive result (usually obtained with a screening medium as chromID MRSA). The risk for the patient would be to delay the report to the physician, to provide a provisional report or postponing the right patient management. However, in the case of use of screening, a first testing has already been done and will alert the microbiologist.

Actions

Please complete the following actions:

1. Take immediately into account the limitation test described above as soon as you receive this customer letter and each time, you use the Mueller Hinton 2 Agar- References: 43301, 43302, 43309, 43511, 41864, 51075.
2. Please complete and return the Attachment A: Acknowledgement Form to your local bioMérieux Customer Service representative. (FAX number: xxxxx)
3. A bioMérieux information and the new package insert version of each Mueller Hinton 2 agar will be sent to you as soon as the package inserts are implemented.
4. If you wish have more information regarding the new Mueller Hinton E, please contact your local bioMérieux Customer Service representative. (Phone number:xxxxx)
5. Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Yours sincerely,

Customer Service

[Enter Local Contact Address and telephone]

www.biomerieux.com



Attachment A: Acknowledgement Form

TO BE RETURNED TO YOUR CUSTOMER SERVICE

fax :

Name of the laboratory:

City:

Customer number:

I acknowledge the receipt of bioMérieux letter informing about a problem of non-detection of resistance to cefoxitin in methicillin-resistant *Staphylococcus aureus* (MRSA *mecC* genotype) has been detected for the Mueller Hinton 2 agar – references:

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DATE

SIGNATURE :