Please distribute the attached customer letter.

To the Laboratory Manager

To the attention of the Healthcare center Chairman

To the attention of the Reactovigilance correspondent

Address
City, Date

Our reference: FSCA 3532

IMPORTANT:

URGENT FIELD SAFETY NOTICE

Mueller Hinton E Agar (MHE) (Ref. 413822, 413823, 413824 and 413825)

Our records indicate that your laboratory has received the following products. This letter is intended for all Mueller Hinton E Agar (MHE) (Ref. 413822, 413823, 413824 and 413825) users (product reference and lot numbers included in annex).

Description of the issue

Following QC failures (diameter out of range - too high) when testing ATCC strains for antibiotic susceptibility test by disk diffusion method when using MHE agar reported from the field, bioMérieux initiated a complaint investigation to check product performance and determine the root cause of the issue observed by a customer.

It could be determined that the use of the medium MHE by **disk diffusion** method with the antibiotics belonging to cyclines and aminosides classes could potentially lead to failure to quality control test (out of range high) and **false susceptible** result for clinical isolates (whatever the strain that could be tested) instead of resistant results.

The investigation states that the identified non-conformity concerns all lots manufactured using a specific formulation. As a consequence new lots produced using new formulations perform within the expected specifications and those new lots are not affected by the above issue.

Impact to Patient/User:

As a result of the referenced issue, there is a potential **performance issue on strain categorization that could lead to False Susceptible Result** for antibiotics belonging to cyclines and aminosides classes when testing patients' samples' for antibiotic suceptibiity test by disk mehtod using MHE agar ref. 413822, 413823, 413824 and 413825 lots listed on Table 1.

Required actions:

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.

Until new lots from the new formulation will be available, laboratories can continue to use MHE agar ref. 413822, 413823, 413824 and 413825 lots listed on Table 1 only when applying the following recommendations:

- Laboratory should continue to follow their current QC procedure;
- Cyclines and aminosides Susceptible results (whatever the clinical strain that could be tested), should be confirmed by an alternative method;
- Results of all the other antibiotics classes can be directly reported.
- Among tests previously performed, we are asking you to identify any possible false Susceptible results, analyze the related risks and determine appropriate actions if relevant.
- Contact your local bioMérieux representative for product compensation if needed.
- Complete and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

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,
Medical Customer Service

Attachment A: Acknowledgement Form.

PLEASE RETURN TO YOUR CUSTOMER SERVICE

Fax : ……
Name of the laboratory:

City:

Customer number:

❑ I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the **MHE agar ref. 413822, 413823, 413824 and 413825** product issue.

❑ I have followed the instructions and implemented the actions as indicated in the Urgent Field Safety Notice.

Have you received reports of illness or injury related to the identified issue?
❑ Yes or ❑ No

DATE ..... **SIGNATURE** : .....

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