



Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Healthcare center Chairman

Address
City, Date

Our reference: FSCA 5722

IMPORTANT:

URGENT FIELD SAFETY NOTICE

MUELLER HINTON E AGAR-Multiple reference

no growth of *S. capitis*

Dear valued bioMérieux Customer,

This letter is intended for MUELLER HINTON E AGAR-Multiple (reference) users and our records indicate that your laboratory has received one of the lot numbers listed below (Table 1):

Product	Reference	Batch Number	Product Expiration Date
M HINTON E AGAR 90 20PL	413822	1009473200	26/09/2022
M HINTON E AGAR 90 100PL	413824	1009476030	28/09/2022
M HINTON E AGAR 90 20PL	413822	1009483750	03/10/2022
M HINTON E AGAR 90 20PL	413822	1009488990	04/10/2022
M HINTON E AGAR 90 20PL	413822	1009495800	07/10/2022
M HINTON E AGAR 90 20PL	413822	1009495790	07/10/2022
M HINTON E AGAR 120X120 20PL	413825	2135690	10/10/2022
M HINTON E AGAR 90 20PL	413822	1009491230	10/10/2022
M HINTON E AGAR 90 100PL	413824	1009491200	10/10/2022
M HINTON E AGAR 90 20PL	413822	1009497090	10/10/2022
M HINTON E AGAR 90 MM	417680	1009506880	10/10/2022
MHE 145 LA BALME 20P	421528	2134210	11/10/2022
M HINTON E AGAR 90 20PL	413822	1009498630	11/10/2022
M HINTON E AGAR 90 100PL	413824	1009507120	17/10/2022
M HINTON E AGAR 120X120 20PL	413825	2139200	25/10/2022
MHE 145 LA BALME 20P	421528	2141460	01/11/2022
M HINTON E AGAR 120X120 20PL	413825	2143450	08/11/2022

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



M HINTON E AGAR 120X120 20PL	413825	2145690	10/11/2022
M HINTON E AGAR 120X120 20PL	413825	2143750	15/11/2022
M HINTON E AGAR 90 100PL	413824	1009554280	16/11/2022
M HINTON E AGAR 120X120 20PL	413825	2147110	17/11/2022

Table 1

Description of the issue

Mueller Hinton E Agar is a medium for disk diffusion antimicrobial susceptibility testing and the determination of Minimal Inhibitory Concentrations (MIC) using the ETEST® method.

Following customer complaints, a growth performance limitation with *S. capitis* on MUELLER HINTON E AGAR has been confirmed for all the Lot number listed.

Impact to customer:

The absence of *Staphylococcus capitis* growth could result in no AST result and delayed AST result.

Required actions:

We request that you perform the following actions at this time:

-Stop using MUELLER HINTON E AGAR- **MUELLER HINTON E AGAR - Ref. 413822; Ref. 413824 ; Ref. 417680 ; Ref. 421528 ; Ref. 413825** - batches (table 1) when testing with *Staphylococcus capitis* based on growth performance issue

- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative 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.

Thank you for your continued use of bioMérieux products,

bioMérieux, Inc.

[\[Enter Local Contact\]](#)

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5722- MUELLER HINTON E AGAR – Growth Performance with S. capitis

**TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : XXXXXXXX**

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “MUELLER HINTON E AGAR – Growth Performance with S. capitis
- I will implement the required actions indicated in the Urgent Field Safety Notice.
- Have you encountered impact on patients’ results, or reports of illness or injury related to the identified issue ?
 - Yes No Not applicable

DATE

SIGNATURE :

Subsidiary name (if applicable) / Nom de la filiale (si approprié)