

21 June 2016

Our reference: FSCA 2995

Dear

IMPORTANT : URGENT FIELD SAFETY NOTICE
Mueller Hinton +5% horse blood + 20 mg/l beta-NAD (MH-F) ref: 43901 and 43919

Our records indicate that your laboratory has received one or more of the following products. This letter is intended for all Mueller Hinton +5% horse blood + 20 mg/l beta-NAD (MH-F) (Ref. 43901-43919) users (product reference and lot numbers included below).

Table 1:

Product Number	Description	Lot Number	Expiry Date
43901	Mueller Hinton +5% horse blood + 20 mg/l beta-NAD	1004762720	16-JUN-2016
43901		1004772690	21-JUN-2016
43901		1004826400	13-JUL-2016
43901		1004844500	20-JUL-2016
43919		1004743960	08-JUN-2016
43919		1004773480	20-JUN-2016
43919		1004775060	22-JUN-2016
43919		1004809210	06-JUL-2016
43919		1004855130	27-JUL-2016

Description of the issue

Based on a false susceptible results for *Streptococcus pneumoniae* strains with the Cotrimoxazole antibiotic (= Triméthoprime-sulfaméthoxazole) (SXT) on plates of M.HINTON HORSE BLOOD NADX20PLT (MH-F) (Ref. 43901) reported from the field, bioMérieux initiated a complaint investigation to confirm product performance and determine root cause. While the investigation is still ongoing, the following have been identified:

- ⇒ The use of the medium Mueller Hinton +5% horse blood+ 20 mg/l bêta NAD with the SXT antibiotic could lead to a false susceptible result for a patient strain with a disc diffusion method when comparing to the Broth Micro-dilution method (BMD) recommended by EUCAST



- ⇒ The use of MH-F lots from the middle of their shelf-life could lead to **False Susceptible** results with the SXT antibiotic with a disc diffusion method.

Impact to Patient/User:

As the result of the referenced issue there is a potential of False Susceptible results on Mueller Hinton +5% horse blood + 20 mg/l beta-NAD (MH-F) (Ref. 43901-43919 and 43904), Lots listed Table 1, with the SXT antibiotic with a disc diffusion method.

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.
- Discontinue using and discard any remaining inventory False Susceptible results on Mueller Hinton +5% horse blood + 20 mg/l beta-NAD (MH-F) (Ref. 43901-43919 and 43904), Lots listed Table 1
- Among tests previously performed with these batches, we are asking you to identify any possible false Susceptible results, analyze the related risks and determine appropriate actions if relevant.
- **Complete and return the Acknowledgement Form in Attachment A for the attention of Customer Service Department on 0044 (0) 1256 816863 to confirm receipt of this notice and for product compensation. In order to comply with Competent Authority Regulations it is important that you complete and return this form**

We can confirm that the Competent Authority has been advised of this Notice

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact our Technical Service Department on 0044 (0) 1256 461881.

Yours sincerely

Customer Service Department





Attachment A: Acknowledgement Form – FSCA 2995

**Please return for the attention of Customer Service Department to fax number
0044 (0) 1256 816863**

**In order to comply with Competent Authority Regulations it is important that you complete
and return this acknowledgement form**

I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the Mueller Hinton +5% horse blood + 20 mg/l beta-NAD (MH-F) product issue.

Product : Mueller Hinton +5% horse blood + 20 mg/l beta-NAD (MH-F)				
43901	Mueller Hinton +5% horse blood + 20 mg/l beta-NAD	1004762720	Number of kits received	
			Number of kits destroyed	
		1004772690	Number of kits received	
			Number of kits destroyed	
		1004826400	Number of kits received	
			Number of kits destroyed	
1004844500	Number of kits received			
	Number of kits destroyed			
43919	Mueller Hinton +5% horse blood + 20 mg/l beta-NAD	1004743960	Number of kits received	
			Number of kits destroyed	
		1004773480	Number of kits received	
			Number of kits destroyed	
		1004775060	Number of kits received	
			Number of kits destroyed	
		1004809210	Number of kits received	
			Number of kits destroyed	
		1004855130	Number of kits received	
			Number of kits destroyed	

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 :

