



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 2995

IMPORTANT:

URGENT FIELD SAFETY NOTICE

Mueller Hinton +5% horse blood + 20 mg/l beta-NAD (MH-F) (Ref. 43901-43919 and 43904)

Dear bioMérieux Customer,

Our records indicate that your laboratory has received the following products. This letter is intended for all Mueller Hinton +5% horse blood + 20 mg/l beta-NAD (MH-F) (Ref. 43901-43919 and 43904) users (product reference and lot numbers included below).

Table 1:

Product Ref. Number	Description	Lot Number	Expiry date
43901	Mueller Hinton +5% horse blood + 20 mg/l beta-NAD	1004743950	08-JUN-2016
43901		1004762720	16-JUN-2016
43901		1004772690	21-JUN-2016
43901		1004809200	06-JUL-2016
43901		1004826400	13-JUL-2016
43901		1004844500	20-JUL-2016
43901		1004855120	27-JUL-2016
43901		1004874250	04-AUG-2016
43904		Mueller Hinton +5% horse blood + 20 mg/l beta-NAD	1004754730
43904	1004762260		17-JUN-2016
43904	1004775180		22-JUN-2016
43904	1004811770		07-JUL-2016
43904	1004829120		14-JUL-2016

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43904		1004859380	28-JUL-2016
43904		1004870760	03-AUG-2016
43904		1004874270	04-AUG-2016
43904		1004888730	10-AUG-2016
43904		1004888740	10-AUG-2016
43919	Mueller Hinton +5% horse blood + 20 mg/l beta-NAD	1004743960	08-JUN-2016
43919		1004762270	16-JUN-2016
43919		1004773480	20-JUN-2016
43919		1004775060	22-JUN-2016
43919		1004809210	06-JUL-2016
43919		1004826410	13-JUL-2016
43919		1004844510	20-JUL-2016
43919		1004855130	27-JUL-2016
43919		1004874260	04-AUG-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.
- Contact your local bioMérieux representative for product compensation.
- 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

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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 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	1004743950	Number of kits received	
			Number of kits destroyed	
		1004762720	Number of kits received	
			Number of kits destroyed	
		1004772690	Number of kits received	
			Number of kits destroyed	
		1004809200	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	
		1004855120	Number of kits received	
			Number of kits destroyed	
		1004874250	Number of kits received	
			Number of kits destroyed	
43904	Mueller Hinton +5% horse blood + 20	1004754730	Number of kits received	
			Number of kits destroyed	
		1004762260	Number of kits received	
			Number of kits destroyed	
		1004775180	Number of kits received	
			Number of kits destroyed	
		1004811770	Number of kits received	
			Number of kits destroyed	

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			Number of kits destroyed	
		1004829120	Number of kits received	
			Number of kits destroyed	
		1004859380	Number of kits received	
			Number of kits destroyed	
		1004870760	Number of kits received	
			Number of kits destroyed	
		1004874270	Number of kits received	
			Number of kits destroyed	
		1004888730	Number of kits received	
			Number of kits destroyed	
		1004888740	Number of kits received	
			Number of kits destroyed	
		43919	Mueller Hinton +5% horse blood + 20 mg/l beta-NAD	1004743960
Number of kits destroyed				
1004762270	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			
1004826410	Number of kits received			
	Number of kits destroyed			
1004844510	Number of kits received			
	Number of kits destroyed			
1004855130	Number of kits received			
	Number of kits destroyed			
1004874260	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 :

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