



Please distribute the attached customer letter.

To the Laboratory Manager

To the attention of the Healthcare center Chairman

Address
City, Date

Our reference: FSCA#4553

IMPORTANT:

URGENT FIELD SAFETY NOTICE

Cetrimide Agar (Ref. 43565)

Dear bioMérieux Customer,

Our records indicate that your laboratory has received the product described below in Table 1, and this letter is intended for all customers using this specific lot of product.

Table 1:

Product Ref. Number	Description	Lot Number	Expiry date
43565	Cetrimide Agar (CET)	1007530990	04-NOV-2019

Description of the issue

Based on fertility issues with Cetrimide Agar (Ref. 43565) reported from the field, bioMérieux initiated a complaint investigation to confirm product issue and determine root cause.

The following have been identified:

- ⇒ The investigation confirmed a fertility issue on lot.#1007530990 of Cetrimide Agar (Ref. 43565). We observed a low growth of *Pseudomonas aeruginosa* ATCC 10145
- ⇒ No false negative results were observed during testing for *Pseudomonas aeruginosa* ATCC 10145.
- ⇒ We did not receive any complaints from clinical customers due to referenced issue.
- ⇒ The impacted lot was conform to the specifications during the Quality Control release testing, therefore the issue appears over the product shelf life and could be related to a stability issue.



Impact to customer:

- Based on the investigation results, there is a potential risk for False negative results for *Pseudomonas aeruginosa* with lot. # 1007530990 of Cetrimide Agar (Ref. 43565) – in Table 1 when used in Medical bacteriology.

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 lot. #1007530990 of Cetrimide Agar (Ref. 43565) – not already expired remaining in your inventory
- 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,

Customer Service

BIOMERIEUX



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 Cetrimide Agar (Ref. 43565) product issue.

Product: Cetrimide Agar			
43565	1007530990	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.

DATE

SIGNATURE :

BIOMERIEUX