



Geneva, 4th November 2019
FSCA 4553

Please deliver to Lab Director or Lab Manager

**IMPORTANT: URGENT FIELD SAFETY NOTICE
Cetrimide Agar (Ref. 43565)**

Acknowledgement required

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.

bioMérieux (Suisse) SA

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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, (Email: ch_support@biomerieux.com; Fax 022 906 57 42).

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 the Customer Service bioMérieux at phone # 022 906 57 96.

Yours faithfully,
bioMérieux (Suisse) SA

Elisabeth Blikø
Marketing Microbiologie

Attachment A: Acknowledgement Form



**Attachment A: Acknowledgement Form
URGENT FIELD SAFETY NOTICE
FSCA 4553 - Ceftriaxone Agar (Ref. 43565)**

Acknowledgement required

**Please, return it to the customer as soon as possible at the following
Email: ch_support@biomerieux.com; or by Fax : 022 906 57 42**

Name of the laboratory: _____

Contact Name: _____

Postal Code, City: _____

Customer number: _____

I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the Ceftriaxone Agar (Ref. 43565) product issue.

Product: Ceftriaxone 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 :

In accordance with the regulatory requirements for traceability, we thank you for completing the present form, even if you no longer have the reagent. Please return the form by fax or e-mail.