



19 August 2015

Our reference: FSCA 2624

Dear Sir / Madam

IMPORTANT : URGENT FIELD SAFETY NOTICE

chromID S.aureus Range PPM – Anomaly

Our records indicate that your laboratory has received one or more kits of our chromID™ S. aureus range products:

Product chromID™ S.aureus reagents				
43371	chromID™ S.aureus agar	1004044190	Number of kits received	
			Number of kits destroyed	
43371	chromID™ S.aureus agar	1004085400	Number of kits received	
			Number of kits destroyed	
43466	chromID™ MRSA agar / chromID™ S. aureus agar (MRSA/SAID)	1004091980	Number of kits received	
			Number of kits destroyed	

Description of the issue:

During an internal investigation, bioMérieux observed an anomaly on three (3) lots of chromID™ S. aureus manufactured with the same semi-finished lot.

This anomaly is causing a delayed coloration of the colonies which appear white/light green instead of green resulting in a potential false negative result. Per the instructions for use, biochemical and/or immunological tests must be performed to identify colonies other than green ones (white, pink or mauve): therefore, the risk to deliver a false negative result is excluded.

CAPA 900257 has been initiated in order to determine the root cause and define corrective and preventive actions to prevent the issue from recurring.

Impact:

The investigation concluded the reported issue could cause a potential false negative result due to the delayed coloration. Considering the intended use of the product and the instructions for use, the risk to deliver a false negative result is excluded.

Cont....



Required actions:

We request you to take the following actions at this time:

- 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 the impacted product and discard any remaining inventory of the chromID™ S. aureus reagents References 43371 and 43466 referenced in the table above.
- Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.
- **Complete and return the Acknowledgement Form in Attachment A for the attention of Customer Service Department to fax number 0044 (0) 1256 816863 to confirm receipt of this notice and for credit on any destroyed stock.**

We can confirm that the Competent Authorities have been informed of this action.

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 faithfully

Customer Service Department
bioMérieux UK Ltd



Attachment A: Acknowledgement Form

FSCA: 2624

In order to comply with Competent Authority Regulations it is important to complete the acknowledgement form and return it to bioMérieux UK Ltd

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

I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the chromID™ S. aureus range.

Product chromID™ S.aureus reagents				
43371	chromID™ S.aureus agar	1004044190	Number of kits received	
			Number of kits destroyed	
43371	chromID™ S.aureus agar	1004085400	Number of kits received	
			Number of kits destroyed	
43466	chromID™ MRSA agar / chromID™ S. aureus agar (MRSA/SAID)	1004091980	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

NAME : **SIGNATURE :** **DATE:**
(Block Capitals)

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Upon receipt of this completed form a credit will be provided on any destroyed stock