



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 2624

IMPORTANT:

URGENT FIELD SAFETY NOTICE

chromID™ S. aureus Range PPM – Anomaly

Dear bioMérieux Customer,

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

Name	Reference	Lot number	Expiry date
chromID™ S.aureus agar	43371	1004119200	20-Oct-15
chromID™ S.aureus agar	43371	1004044190	22-Sep-15
chromID™ S.aureus agar	43371	1004085400	07-Oct-15
chromID™ MRSA agar / chromID™ S. aureus agar (MRSA/SAID)	43466	1004158090	01-Oct-15
chromID™ MRSA agar / chromID™ S. aureus agar (MRSA/SAID)	43466	1004091980	03-Sep-15
chromID™ MRSA agar / chromID™ S. aureus agar (MRSA/SAID)	43466	1004113000	11-Sep-15
chromID™ MRSA agar / chromID™ S. aureus agar (MRSA/SAID)	43466	1004141170	23-Sep-15
chromID™ MRSA agar / chromID™ S. aureus agar (MRSAV1/SAID) (for US only)	414524	1004141270	23-Sep-15
chromID™ MRSA agar / chromID™ S. aureus agar (MRSAV1/SAID) (for US only)	414524	1004105600	09-Sep-15

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Description of the issue

During an internal investigation, bioMérieux observed an anomaly on nine (9) 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 to customer:

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.

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, 43466 and 414524 referenced in the table above.
- Contact your local bioMérieux representative for product compensation.
- 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 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 faithfully,
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 chromID™ S. aureus range.

Product chromID™ S.aureus reagents				
43371	chromID™ S.aureus agar	1004119200	Number of kits received	
			Number of kits destroyed	
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)	1004158090	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	
43466	chromID™ MRSA agar / chromID™ S. aureus agar (MRSA/SAID)	1004113000	Number of kits received	
			Number of kits destroyed	
43466	chromID™ MRSA agar / chromID™ S. aureus agar (MRSA/SAID)	1004141170	Number of kits received	
			Number of kits destroyed	
414524	chromID™ MRSA agar / chromID™ S. aureus agar (MRSAV1/SAID)(for US only)	1004141270	Number of kits received	
			Number of kits destroyed	
414524	chromID™ MRSA agar / chromID™ S. aureus agar (MRSAV1/SAID)(for US only)	1004105600	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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