



Address
City, Date

Our reference: FSCA 5201

IMPORTANT:

Urgent Field Safety notice

Sabouraud 2 agar (SAB2-T) (reference 42037)

Dear valued bioMérieux Customer,

Our records indicate that your laboratory has received the products described below:

Table 1:

Reference	Product Name	Lot number	Expiry date
42037	Sabouraud 2 agar (SAB2-T)	1008262940	01 MAR 2022
		1008342620	13 APR 2022
		1008472120	14 JUL 2022
		1008545830	04 AUG 2022
		1008615520	15 SEP 2022

Description of the issue

During internal testing, a growth defect was observed for *Candida* on the product Sabouraud 2 agar tubes (SAB2-T), (reference 42037) for the lots listed in Table 1.

The following results were obtained:

- No growth was observed for *C. albicans* ATCC10231 on lots 1008342620 and 1008262940
- Growth conforms to specifications for *C. albicans* ATCC10231 on lots 1008472120, 1008545830 and 1008615520
- Growth conforms to specifications on all lots tested for *C. tropicalis* ATCC 9968, *C. glabrata* DSM6425, *C. kefyr* ATCC4922, *A. brasiliensis* ATCC16404 and *T. mentagrophytes* ATCC 9533.

As a result, the growth defect was confirmed for reference 42037 lots 1008342620 and 1008262940. To date, the product issue is not confirmed for lots 1008472120, 1008545830 and 1008615520. However, as a precautionary measure they are included in the scope of this FSCA as the no growth defect may be observed later during the shelf-life of the products.

Please note that for lot 1008342620, *C. albicans* ATCC 10231 was confirmed to be within specification on 31 March 2021. Therefore tests performed using lot 1008342620 after this date are impacted by this FSCA.



Impact to patient/customer:

The absence of growth of *Candida albicans* ATCC strains could result in false negative results for the isolation of Candida species with the medium. There is a failure to recover organisms normally expected to grow in/on the media.

Required actions:

We request you 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 one or more of these products, including others to whom you may have transferred these products,
- **Please discontinue use and destroy any impacted products listed in Table 1 remaining in your local inventory and contact your local bioMérieux representative for credit or replacement,**
- Discuss any concerns you may have regarding previously reported patient results obtained with the impacted products listed in Table 1 with your Laboratory Medical Director to determine the appropriate course of action,
- Complete the attached Acknowledgement Form and return it to your local bioMérieux representative.

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.

Thank you for your continued use of bioMérieux products,

bioMérieux

[\[Enter Local Contact\]](#)

BIOMERIEUX

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Attachment A: Acknowledgement Form.

FIELD SAFETY NOTIFICATION NOTICE

FSCA 5201 - Sabouraud 2 Agar (ref. 42037) - Growth issue for C. Albicans

TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE AT THE FOLLOWING

FAX NUMBER : XXXXXXXX

Name of the laboratory:

City:

Customer number:

☐ I acknowledge receipt of this bioMérieux Urgent Field Safety Notice regarding Sabouraud 2 Agar (ref. 42037) product issue.

☐ I have followed the instructions and implemented the actions as indicated in the Urgent Field Safety Notice.

Products : See below				
42037	Sabouraud 2 Agar	1008262940	Number of boxes received	
			Number of boxes destroyed	
42037	Sabouraud 2 Agar	1008342620	Number of boxes received	
			Number of boxes destroyed	
42037	Sabouraud 2 Agar	1008472120	Number of boxes received	
			Number of boxes destroyed	
42037	Sabouraud 2 Agar	1008545830	Number of boxes received	
			Number of boxes destroyed	
42037	Sabouraud 2 Agar	1008615520	Number of boxes received	
			Number of boxes destroyed	

Have you received reports of illness or injury related to the identified issue?

☐ Yes or ☐ No

DATE

SIGNATURE :

BIOMERIEUX