



Address
City, Date

Our reference: FSCA 5172

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)	1007856360	28-APR-2021
		1007724190	18-MAY-2021
		1008001290	03-OCT-2021
		1008112720	06-DEC-2021

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 for *C. albicans* ATCC 10231 on all lots listed in Table 1.
- Growth does not conform to specifications (low growth) for *C. tropicalis* ATCC 9968 on lot 1007856360 only, growth conforms to specifications for the three other lots listed in Table 1.
- Growth conforms to specifications for the other strains tested: *C. kefyr* ATCC 4922, *T. mentagrophytes* ATCC 9533, *C. glabrata* DSM 6425 and *A. brasiliensis* ATCC 16404 on all lots listed in Table 1.

Please note that for lot 1007724190, *C. albicans* was confirmed to be within specification on 18 December 2020. Therefore tests performed using lot 1007724190 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

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

BIOMÉRIEUX

5 rue des Aqueducs - B.P. 10 - 69290 Craaponne - Pays - France
Tél. / Phone : + 33 (0) 820 22 9090 - Fax : + 33 (0) 04 78 87 73 07 - www.biomerieux.com
bioMérieux SA au capital de 12 029 370 € - RCS 673 620 399 Lyon – Siège social : 69280 Marcy l'Etoile - France



Attachment A: Acknowledgement Form.

FIELD SAFETY NOTIFICATION NOTICE

FSCA 5172 – 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	1007724190	Number of boxes received	
			Number of boxes destroyed	
42037	Sabouraud 2 Agar	1007856360	Number of boxes received	
			Number of boxes destroyed	
42037	Sabouraud 2 Agar	1008001290	Number of boxes received	
			Number of boxes destroyed	
42037	Sabouraud 2 Agar	1008112720	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