



Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Healthcare center Chairman

Zagreb, 04.01.2022.

Our reference: FSCA 5488

IMPORTANT:
URGENT FIELD SAFETY NOTICE
ID 32 C (Reference 32200)
Thermoforming defect

Dear valued bioMérieux Customer,

This letter is intended for ID 32 C strips (Reference 32200) users and our records indicate that your laboratory has received the lot number listed below:

Product Name	Reference	Lot number	Expiry date
ID 32 C	32200	1008781060	11 June 2022

Description of the issue

ID 32 C is a qualitative standardized system for the identification of yeasts. It uses miniaturized tests as well as a specially adapted database. After manual inoculation of the strip, reading can be performed either automatically or manually and the identification is obtained using an identification software.

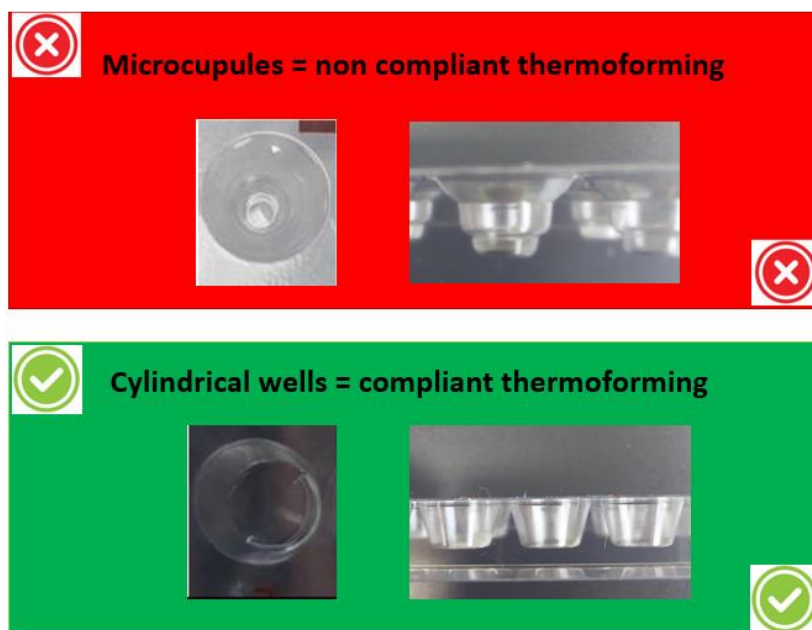
Following an internal complaint, a thermoforming defect has been detected in strips of product ID 32 C, Reference 32200, lot 1008781060: well's shape observed was "microcupules" instead of "cylindrical".

According to bioMérieux Research & Development experts, there could be a risk of misidentification or of delayed results with the absence of identification.

Even though the number of ID 32 C strips, Reference 32200, lot 1008781060 potentially affected by this issue is low (less than 0.25%), bioMérieux has decided to inform you of this issue for product quality assurance and patient safety reasons.

Please see below correct and incorrect reading table illustrating strip well thermoforming:

Well's thermoforming illustration:



Impact to customer:

The thermoforming defect (microcupules) in ID 32 C strips could lead to delayed results with the absence of identification and in the worst case incorrect results (misidentifications) with the lot of ID 32 C strips mentioned above.

Required actions:

We request that you perform 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.
- **You can continue to use ID 32 C strips if well's shape is "cylindrical".**
- **However, bioMérieux requests you to stop using and destroy ID 32 C strips with "microcupule" wells.**
- For tests previously performed using ID 32 C, lot 1008781060, we recommend that you identify any possible misidentifications, to analyze the related risks and to determine appropriate actions, if relevant.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative 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.

Thank you for your continued use of bioMérieux products,

bioMérieux, Inc.

Attachment A: Acknowledgement Form.



URGENT FIELD SAFETY NOTICE

FSCA 5488 - ID 32 C Ref. 32200 – Thermoforming defect

**TO BE RETURNED TO YOUR bioMÉRIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : 01/2396 899**

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “ID 32 C Ref. 32200 – Thermoforming defect”
- I will implement the required actions indicated in the Urgent Field Safety Notice.
- Have you encountered impact on patients’ results, or reports of illness or injury related to the identified issue ?
 - Yes No Not applicable

DATE

SIGNATURE :