Address
City, Date

Our reference: FSCA 4085

IMPORTANT:

Urgent Field Safety notice

(see table 1)

Dear valued bioMérieux Customer,

Our records indicate that your laboratory has received one or several products described below:

Table 1:

REF	Product Name	Lot number	Expiry date
10400	API NH 10GALERIES+10MILIEUX	1006274720	13-NOV-2018
		1006275060	13-NOV-2018
		1006462930	20-NOV-2018
		1006463100	08-JAN-2019
		1006598510	08-JAN-2019
		1006598550	15-MAY-2019

Description of the issue

A mistake has been observed in the Italian version of the instruction for use (07487) on the shelf life of ZYM B reagent after opening and reconstitution: the shelf life indicated in the Italian version is two months while it should be kept up to two weeks after opening.

This mistake is present in the Italian version of the IFU revisions O and P of the IFU available since March 2016.

Impact to patient/customer:

A poor storage condition of the reagent ZYM B (for example storage > 2 weeks after reconstitution) may lead to a degradation of the reagent.

In the worst case, this degradation will lead to incorrect results (false positive or false negative) for the 2 tests revealed with the ZYM B reagent (ProA and GGT), thus possible errors of identification or absence of identification.

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,
- **Continue to use ZYM B reagent with a restriction: The ZYM B reagent may be kept for up to 2 weeks after the ampules have been opened and the reagents reconstituted in the dropper-vials (or until the expiry date if this comes first)**.
- Discuss any concerns you may have regarding previously reported patient results obtained with your Laboratory Medical Director to determine the appropriate course of action. Results should be reviewed and interpreted in the context of the overall clinical picture.
- 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]

Attachment A: Acknowledgement Form.

FIELD SAFETY NOTIFICATION NOTICE

FSCA 4085 - API NH (ref. 10400) - mistake in Italian IFU

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 Product Removal Notice regarding API NH (ref. 10400) product issue.

❑ 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** : .....

Table 1 – Lot numbers Manufacturing & expiry dates

REF	Product Name	Lot number	Expiry date	Release date
10400	API NH 10 GALERIES + 10 MILIEUX	1006274720	13-NOV-2018	06-FEB-2018
		1006275060	13-NOV-2018	06-FEB-2018
		1006462930	20-NOV-2018	23-APR-2018
		1006463100	08-JAN-2019	24-APR-2018
		1006598510	08-JAN-2019	25-JUN-2018
		1006598550	15-MAY-2019	26-JUN-2018