



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

Address
City, Date

Our reference: FSCA 5290

IMPORTANT:

URGENT FIELD SAFETY NOTICE

Ref. 50300 - API® 50 CH Lot 1008603700

Dear valued bioMérieux Customer,

This letter is intended for all API® 50 CH Ref. 50300 lot# 1008603700 users; and our records indicate that your laboratory has received one or more shipments of this batch.

Description of the issue

API® 50 CH is a standardized system, associating 50 biochemical tests for the study of the carbohydrate metabolism of microorganisms.

API® 50 CH is used in conjunction with API® 50 CHL Medium for the identification of *Lactobacillus* and related genera and with API 50 CHB/E Medium for the identification of *Bacillus* and related genera, *Enterobacteriaceae* and *Vibrionaceae*.

The complete list of those organisms that it is possible to identify with this system can be found in the Identification Table at the end of the package inserts of the associated media.

PRINCIPLE

The API® 50 CH strip consists of 50 microtubes used to study fermentation of substrates belonging to the carbohydrate family and its derivatives (heterosides, polyalcohols, uronic acids).

The fermentation tests are inoculated with API® 50 CHL Medium or API® 50 CHB/E Medium, which rehydrates the substrates.

During incubation, fermentation is revealed by a color change in the tube, caused by the anaerobic production of acid and detected by the pH indicator present in the chosen medium.

API® 50 CH is used for clinical and other specimens (veterinary, pharma and food samples). The microorganisms to be identified must first be isolated on a suitable culture medium according to standard microbiological techniques.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



During an internal investigation it was confirmed that test 19 of API® 50 CH lot# 1008603700 contains a mix of sorbitol (SOR) and 5-ketogluconic acid (5KG) instead of sorbitol only. Whereas all the other tests of the gallery were confirmed to be conform.

Retain samples of lot 1008603700 were tested using bacterial strains selected among the more impacted species by a test SOR containing 5KG and for some strains a false positive reaction on test 19 was obtained that led to a doubtful profile.

Impact to customer:

Based on the investigation results there is a potential to obtain doubtful profile and, in the worst case scenario, incorrect identification test result due to the false positive reaction on test 19.

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 and discard any remaining inventory of API® 50 CH Lot 1008603700
- For tests previously performed using API® 50 CH Ref. 50300 lot# 1008603700, we are asking you to identify any possible incorrect identification test result due to a false positive reaction of test 19, analyze the related risks and to determine appropriate actions, if relevant.
- Contact your local bioMérieux representative for product compensation
- 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.

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

Attachment A: Acknowledgement Form.

Subsidiary name (if applicable) / Nom de la filiale (si approprié)



URGENT FIELD SAFETY NOTICE

FSCA 5290 - API® 50 CH ref 50300 Lot 1008603700 - Test 19 Mix-up of solutions

**TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : XXXXXXXX**

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “API® 50 CH ref 50300 Lot 1008603700– Test 19 Mix-up of solutions”
- I will implement the required actions, stop using and destroy the concerned lot as 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

Product	Reference	Lot #	Quantity Received	Quantity Destroyed
API® 50 CH	50300	1008603700		

DATE

SIGNATURE :

Subsidiary name (if applicable) / Nom de la filiale (si approprié)