ATB™ Densitometer control Kit

Please distribute the attached customer letter.

To the Laboratory Manager

To the attention of the Healthcare center Chairman

To the attention of the Reactovigilance correspondent

Address
City, Date

Our reference: FSCA 2692

IMPORTANT:

URGENT PRODUCT REMOVAL NOTICE

Densimat Ref. 99234 - Calibration failure

Dear bioMérieux Customer,

Our records indicate you have received the following product: Densitometer Densimat (reference 99234 – Serial number from IDN016182 to IDN016268 except IDN016242).

Please read this information regarding an issue that could impact your laboratory.

Description of the issue

During an internal investigation, bioMérieux observed a product non-conformance on the reagent (ATB™ Densitometer control) used to calibrate Densitometer Densimat instruments.

As a result, there is a shift in instrument performance; leading to under-estimation of the actual McFarland value.

Impact to customer:

The investigation concluded the reported issue could cause false identifications results or false susceptibility testing results on the following strips:
- Strips using 2 McF: API 20C AUX, ID 32 C, API 50 CH, ATB FUNGUS 3 and ATB for Staphylococci
- Strips using 3 McF: API CANDIDA, API 20 A, ATB for Anaerobic
- Strips using 4 McF: rapidID 32 A, rapidID 32 STREP, API NH, API 20 STREP
- Strips using 6 McF: API Coryne, API Campy

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 the impacted Densimat instrument.

- Contact your local bioMérieux representative for product replacement.
  - While waiting on product replacement, the Mc Farland standard product (Ref. 70900) may be used as a temporary back-up solution.
  - You should be updated about the availability of new instrument.

- Discuss any concerns you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

- Complete and return the Acknowledgement Form in Attachment A by Fax 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.

Yours faithfully,
Customer Service

Attachment A: Acknowledgement Form.

PLEASE RETURN TO YOUR CUSTOMER SERVICE

Fax : …….
Name of the laboratory:

City:

Customer number:

❑ I acknowledge the receipt of bioMérieux Urgent Product Removal Notice informing this laboratory on the Densimat instrument Reference 99234.

❑ I have followed the instructions and implemented the actions as indicated in the Urgent Product Removal Notice.

Have you received reports of illness or injury related to the identified issue?
❑ Yes or ❑ No

DATE …….. **SIGNATURE : ……..**