



4 November 2015

Dear

Our reference: FSCA 2692

IMPORTANT :

URGENT FIELD SAFETY NOTICE

Densimat Ref. 99234 – Calibration failure

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:

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

Cont..

bioMérieux UK Ltd



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.

In order to comply with Competent Authority Regulations it is important that you complete and return the acknowledgement form in Attachment A. Please return for the attention of Customer Service by Fax to 01256 816863 to confirm receipt of this notice.

We can confirm that the Competent Authority has been advised of this notification.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise 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 sincerely

Customer Service Department

Attachment A: Acknowledgement Form.

☐ I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the Densimat instrument Reference 99234.

☐ 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 :.....

In order to comply with Competent Authority Regulations it is important that you complete and return this acknowledgement form

**Please complete and return for the attention of
Customer Services to fax number: 01256 816863**



4 November 2015

Dear

Our reference: FSCA 2692

IMPORTANT: URGENT FIELD SAFETY NOTICE

ATB™ Densitometer control kit – Performance issue

Our records indicate you have received the following product: ATB™ Densitometer control Kit (reference 15512).

Name	Reference	Lot number	Expiry date
ATB™ Densitometer control Kit	15512	1003780430	05-Feb-16
ATB™ Densitometer control Kit	15512	1003838260	24-Feb-16
ATB™ Densitometer control Kit	15512	1003848040	03-Mar-16
ATB™ Densitometer control Kit	15512	1003883560	17-Mar-16
ATB™ Densitometer control Kit	15512	1003990940	26-Apr-16
ATB™ Densitometer control Kit	15512	1004040130	03-May-16
ATB™ Densitometer control Kit	15512	1004089920	10-Jun-16
ATB™ Densitometer control Kit	15512	1004121270	14-Jun-16
ATB™ Densitometer control Kit	15512	1004149420	22-Jun-16

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

Description of the issue

During an internal investigation, bioMérieux observed performance non-conformity on 9 lots of ATB™ Densitometer control Kits.

The product non-conformance is causing a loss of performance on the product and may lead to the calibration control failure of your Densitometer instrument.

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Impact:

The investigation concluded the reported issue could cause a calibration control failure of your Densitometer instrument; potentially leading to false susceptible or misidentification results.

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 product and discard any remaining inventory of the ATB™ Densitometer control Kit (refer to the above table regarding lot numbers impacted).
- Complete and return the Acknowledgement Form in Attachment A for product compensation.
 - Until additional lots are manufactured, the Mc Farland standard product (Ref. 70900) may be used as a temporary back-up solution.
 - A new batch of product has been released to replace non-conforming product. Additional batches will be available for allocation until the back-order situation is resolved.

In order to comply with Competent Authority Regulations it is important that you complete and return the acknowledgement form in Attachment A. Please return for the attention of Customer Service Department by Fax to 01256 816863 to confirm receipt of this notice.

We can confirm that the Competent Authority has been advised of this notification.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise 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 sincerely

Customer Service Department

Attachment A: Acknowledgement Form.

☐ I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the ATB™ Densitometer control Kit Reference 15512:

Ref 15512	ATB™ Densitometer control Kit	Lot 1003780430	Number of kits received	
			Number of kits destroyed	
Ref 15512	ATB™ Densitometer control Kit	Lot 1003838260	Number of kits received	
			Number of kits destroyed	
Ref 15512	ATB™ Densitometer control Kit	Lot 1003848040	Number of kits received	
			Number of kits destroyed	
Ref 15512	ATB™ Densitometer control Kit	Lot 1003883560	Number of kits received	
			Number of kits destroyed	
Ref 15512	ATB™ Densitometer control Kit	Lot 1003990940	Number of kits received	
			Number of kits destroyed	
Ref 15512	ATB™ Densitometer control Kit	Lot 1004040130	Number of kits received	
			Number of kits destroyed	
Ref 15512	ATB™ Densitometer control Kit	Lot 1004089920	Number of kits received	
			Number of kits destroyed	
Ref 15512	ATB™ Densitometer control Kit	Lot 1004121270	Number of kits received	
			Number of kits destroyed	
Ref 15512	ATB™ Densitometer control Kit	Lot 1004149420	Number of kits received	
			Number of kits destroyed	

☐ 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

NAME:..... DATE..... SIGNATURE :

In order to comply with Competent Authority Regulations it is important that you complete and return this acknowledgement form

**Please complete and return for the attention of Customer Services to
fax number: 01256 816863**