



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

ATB™ Densitometer control Kit - Performance issue

Dear bioMérieux Customer,

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.

Impact to customer:

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

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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).
- Contact your local bioMérieux representative 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.
- 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

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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 ATB™ Densitometer control Kit Reference 15512:

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

DATE

SIGNATURE :

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