

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.

Cont..



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

