

NHSBT Reagents Field Safety Notice-URGENT

Product Titration cell 1

Lot R407 5188 **Expiry** 2017/07/06

Date of Notification 22/06/17

Details of problems with this device:

As per our telephone communication on 22/06/17 It has come to our attention that titration cell 1, lot number R407 5188 issued by Reagents on 13/06/17 has a reduced E antigen strength, and as a result, titration endpoints for samples containing anti-E may be 1 or 2 dilutions lower than expected. The replacement product R407 3190 is included with this notice.

Action to be taken by user

Please start to use batch R407 3190 immediately and discard any remaining product of batch R407 5188 (including cell 2 labelled R407 3188, though this product is not affected). Please review anti-E titration results obtained using cell 1 from batch R407 5188. We suggest that you consider re-test if the titration endpoint is 4, 8, or 16; if there was no archive sample tested in parallel as per BSH guidelines 2016; or if there is a discrepancy between the archive result when tested with the previous and current samples. Please confirm that you have taken the relevant action and inform us of any potential patient impact this has had and the action you have taken.

This notice needs to be passed on to all those who need to be aware within your organisation and to any organisation where this device has been transferred
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of this corrective action.

NHSBT Reagents confirms that the appropriate Regulatory Agency has been notified.

Issued for NHSBT Michelle Weston **Title** Reagents Manager
Reagents by

Contact details NHSBT Reagents Customer Services
NHSBT, 14 Estuary Banks, Speke, Liverpool, L24 8RB
Tel: 0151 268 7157 Fax: 0151 268 7156

User contact - Please return this slip to the above address or fax it to number above.

I confirm that I have received the field safety notice regarding the device below and have taken the required action

Hospital..... **Pulse Code**.....

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|--------------|------------------|-------------|
| Name | Signature | Date |
| Product Name | Lot Number | Expiry |

(Template Version 01/04)

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