

4th October 2017

URGENT FIELD SAFETY NOTICE

Thermo Scientific™ Remel™ Vibrio Cholerae Inaba Agglutinating Serum R30165101
Lots: 1669210, 1669212, 1763660, 1800977, 1839368, 1873045

DESCRIPTION

Customers are to be advised of the following:

An internal technical investigation has determined that **Thermo Scientific™ Remel™ Vibrio cholerae inaba Agglutinating Serum (Bottle Lot number: 1669211)** sold as product code **R30165101** Lots: **1669210, 1669212, 1763660, 1800977, 1839368, 1873045** may produce negative results with positive cultures using the tube and slide agglutination methods.

Continued use of these lots may result in a failure to correctly identify the subtype *Vibrio cholerae inaba*.

RISK TO HEALTH

Vibrio cholerae agglutinating sera are intended for the serological identification of *V. cholerae* for epidemiological and diagnostic purposes. Specifically, *Vibrio cholerae inaba* agglutinating serum (R30165101) is intended for the serological identification of subtype *Vibrio cholerae inaba*. This serological test is intended for screening purposes and should augment, not replace culture and biochemical procedures.

From a clinical risk perspective, patient management should not be affected by a failure to identify the correct subtype. The primary determination of *V. cholerae* infection will be carried out using alternative standard microbiological methods and it is these results that will help inform therapeutic decisions. The risk associated with incorrect identification of *V. cholerae* subtypes is related primarily to epidemiology specifically that suspected outbreaks may not be correctly associated.

ACTION TO BE TAKEN

Our records indicate that you have received the above product.

Accordingly, in keeping with our Quality Policy, we request that you destroy any remaining inventory of the lots listed above. Requirement for review of reported test results should be determined by the appropriate technical expert.

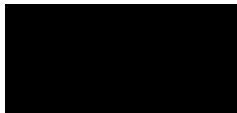
The Medicines and Healthcare products Regulatory Agency (MHRA) have been informed of this Field Safety Corrective Action.

This notice needs to be passed on to all who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. If you have any questions, please contact our Technical Support Department on +44 (0)1256 694238, or at microbiology.techsupport.uk@thermofisher.com.

You should complete the accompanying Acknowledgment Form in regard to inventory you have received and/or which is still in stock.

We appreciate your immediate attention to this matter and apologise for any inconvenience this may have caused.

Yours sincerely,



James H Filer
Vice President, Quality and Regulatory, MBD

05 October 2017

RE: Field Safety Notice – Vibrio cholerae Inaba 2ml/VL, R30165101

Dear Customer,
(cc Chairman Medical Board and Relevant Head of Departments)

Please be informed of the product recall for the batches below.

1. Item(s) affected

Product: Vibrio cholerae Inaba 2ml/VL, R30165101

Affected Lots: 1669210, 1669212, 1763660, 1800977, 1839368, 1873045

2. Reason for notice

An internal technical investigation has determined that Thermo Scientific™ Remel™ Vibrio cholerae inaba Agglutinating Serum (Bottle Lot number: 1669211) sold as product code R30165101 Lots: 1669210, 1669212, 1763660, 1800977, 1839368, 1873045 may produce negative results with positive cultures using the tube and slide agglutination methods.

Continued use of these lots may result in a failure to correctly identify the subtype Vibrio cholerae inaba. Please refer to Field Safety Notice for full details.

3. Actions to be taken

- Discontinue the use and destroy any remaining inventory of the affected lots
- Kindly fill up the acknowledgement section below and send back to us.

Please refer to attached memo for more information and feel free to contact us should you have any queries regarding this notice.

Thank you for your prompt attention.

Yours Sincerely,


Ji Wenxin
Tel: 6499 9992
Email: wenxin.ji@thermofisher.com

Acknowledgement *(To be completed by end-user customer)*

I confirm receipt of the Urgent Field Safety Notice for Thermo Scientific™ Remel™ Vibrio Cholera Inaba Agglutinating Serum, R30165101 Lots: 1669210, 1669212, 1873045, 1839368, 1800977 and 1763660, dated 5th October 2017.

I confirm that the product has been destroyed. Please confirm No. of units destroyed.....

I require replacement packs/Credit to be issued (Please indicate if none required)

Signed.....

Name (please print).....

Position.....

Date.....

Email Address/Telephone Number.....

Company Name & Stamp: