

3rd July 2018

thermo**scientific**

CUSTOMER NOTIFICATION

Thermo Scientific™ Remel™ Agglutinating Sera

Shigella boydii Polyvalent 2 (7 to 11) R30164001

Product	Bottle lot No.	Carton lot No.
R30164001	2114861	2295417, 2242518, 2286357, 2266013, 2259957
	1821662	1821661, 1868668, 1847188
	1868669	1973576, 1991416, 1973862, 2224850, 2136399
	1737182	1773357, 1737181

DESCRIPTION

Customers are to be advised of the following:

An internal technical investigation has determined that Thermo Scientific™ Remel™ *Shigella boydii* Polyvalent 2 (7 to 11) R30164001 (lots listed above) may fail to agglutinate within the specified minimum reaction time when tested with serogroup 7 bacteria.

Continued use of these lots may result in a failure to correctly identify *Shigella boydii*.serogroup 7 Isolates.

Note: The product Thermo Scientific™ Remel™ *Shigella boydii* Polyvalent 2 (7 to 11) R30164001(lots listed above) continues to correctly identify *Shigella boydii* Groups 8-11.

RISK TO HEALTH

Shigella boydii (7 to 11) serum is intended for use in the qualitative serological identification of *Shigella boydii* Groups 7 to 11 for epidemiological and diagnostic purposes.

We believe the risk is extremely low based on the following rationale:

Identification of a *Shigella boydii* from this polyvalent serum is from culture and covers 7, 8, 9, 10 and 11 groups. Specifically, the group 7 strain is relatively rarely isolated from infections or outbreaks.

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 review any remaining inventory of *Shigella boydii* Polyvalent 2 (7 to 11) R30164001 (lots listed above)

Requirement for review of reported test results should be determined by the appropriate technical expert.

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 product has been transferred.

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

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
Microbiology Products

3rd July 2018

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ACKNOWLEDGEMENT FORM

CUSTOMER NOTIFICATION

Re. Thermo Scientific™ Remel™ Agglutinating Sera *Shigella boydii* Polyvalent 2 (7 to 11) R30164001

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Dear Customer,
Thermo Fisher Scientific, Microbiology, are requesting for customers to be advised of the following:

An internal technical investigation has determined that Thermo Scientific™ Remel™ *Shigella boydii* Polyvalent 2 (7 to 11) R30164001 (lots listed above) may fail to agglutinate within the specified minimum reaction time when tested with serogroup 7 bacteria. Continued use of these lots may result in a failure to correctly identify *Shigella boydii*.serogroup 7 Isolates.

Note: The product Thermo Scientific™ Remel™ *Shigella boydii* Polyvalent 2 (7 to 11) R30164001(lots listed above) continues to correctly identify *Shigella boydii* Groups 8-11.

Please find enclosed a copy of the Customer Notification relating to this product for your records. Accordingly, in keeping with our Quality Policy, we request that you review any remaining inventory of *Shigella boydii* Polyvalent 2 (7 to 11) R30164001 (lots listed above). Requirement for review of reported test results should be determined by the appropriate technical expert.

I would be grateful if you would confirm receipt of this Customer Notification by faxing or emailing a completed, signed copy of this Acknowledgement Form to the Customer Services Department or on Fax no. +44(0)1256 334994 **by 31st July 2018.**

If you require any Technical Assistance please contact our Technical Support Team on 01256 694238 or at microbiology.techsupport.uk@thermofisher.com. Any other assistance, please contact your Customer Services Representative on 01256 841144.

Yours sincerely,

Signed :
Title :
Company :

CONFIRMATION OF RECEIPT

Thermo Fisher Scientific, Microbiology, Customer Notification for Thermo Scientific™ Remel™ Agglutinating Sera Shigella boydii Polyvalent 2 (7 to 11) R30164001

I confirm receipt of the Customer Notification for Thermo Scientific™ Remel™ Agglutinating Sera Shigella boydii Polyvalent 2 (7 to 11) R30164001, dated 3rd July 2018.

Signed.....

Name (please print).....

Position.....

Date..... Email Address/Telephone

Number.....