

10 July 2018

RE: Field Safety Notice –Thermo Scientific™ Remel™ Agglutinating Sera Shigella boydii Polyvalent 2 (7 to 11) R30164001

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

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

1. Item(s) affected

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

2. Reason for notice

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 refer to Field Safety Notice for full details.

3. Actions to be taken


- Review any remaining inventory of the affected lots. Requirement for review of reported test results should be determined by the appropriate technical expert.
- 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: 

Acknowledgement (To be completed by end-user customer)

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.....

Company Name & Stamp:

Microbiology

Blk 33 Marsiling Industrial
Estate Road 3
#07-06
Singapore 739256

+65 6499 9999 tel
+65 6896 2147 fax

www.thermofisher.com