

12 Nov 2019

RE: Thermo Scientific™ Remel™ E. coli Polyvalent and Monovalent Agglutinating Sera

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 Code	Bottle Lot Number	Carton Lot Number
R30954901/ZA01 E. coli Polyvalent 2	2479722	2458666
		2527762
		2510252
		2514882
		2832563

2. Reason for notice

A technical investigation has determined that specific lots of Thermo Scientific™ Remel™ E. coli Polyvalent Agglutinating Sera may produce weaker than expected agglutination reactions with certain serotypes when used in accordance to the Instructions For Use (IFU).

Continued use of these lots may result in failure to correctly identify specific *Escherichia coli* serotypes. Please refer to Field Safety Notice for full details.

3. Actions to be taken

- Destroy any remaining inventory of the lot listed above.
- Review reported test results as necessary.
- 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: [Redacted]

Acknowledgement (To be completed by end-user customer)

I confirm receipt of the F.S.N. for Thermo Scientific™ Remel™ E. coli Polyvalent Agglutinating Sera, dated 12 November 2019.

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:

Microbiology

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