

31 Jul 2019

RE: Field Safety Notice – Thermo Scientific™ Remel™ Salmonella paratyphi B-H phase 1 Flagellar antigen b Stained Suspension

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 |
|--------------|----------------------------|-------------------|
| R30855201 | 2281770 (Exp: Aug 2020) | 2308921 |
| | | 2404017 |
| | | 2418699 |
| | 2407007 (Exp: Nov 2020) | 2419351 |
| | | 2445422 |

2. Reason for notice

An internal technical investigation has determined that Thermo Scientific™ Remel™ Salmonella paratyphi B-H phase 1 Flagellar antigen b Stained Suspension (R30855201) is showing granularity, before the recommended read end time, which may be misinterpreted as a positive result when used according to the Instructions For Use (IFU).

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 ThermoScientific™ Remel™ Salmonella paratyphi B-H phase 1 Flagellar antigen b Stained Suspension, dated 18th July 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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