

26<sup>th</sup> April 2018

**URGENT FIELD SAFETY NOTICE**

**Thermo Scientific™ Remel™ Agglutinating Sera**

**R30161201 - Salmonella H (gm)**

**R30161301 - Salmonella H (gp)**

**R30161401 - Salmonella H (gq)**

Product	Bottle lot No.	Carton lot No.
R30161201	1889091	1941642, 1978786, 2115840 & 2286353
R30161201	1669174	1669173 & 1750538,
R30161201	1821666	1821665
R30161301	1620804	1620459 & 1778756
R30161401	1772909	1772908

**Description**

Customers are to be advised of the following:

An internal technical investigation has determined that Thermo Scientific™ Remel™ Agglutinating Sera *Salmonella H (gm)* (R30161201), *Salmonella H (gp)* (R30161301) and *Salmonella H (gq)* (R30161401) (lots listed above) may produce negative results with positive cultures with the tube agglutination method when used according to the IFU.

The performance of these lots continues to be within specification when used following the slide agglutination method.

Continued use of these lots with the tube agglutination method may result in a failure to correctly identify the subtypes with the gp, gm and gq flagella antigens.

**Note: The Thermo Scientific™ Remel™ Agglutinating Sera *Salmonella H (gm)* (R30161201), *Salmonella H (gp)* (R30161301) and *Salmonella H (gq)* (R30161401) products continue to correctly identify *Salmonella H*.**

**Risk to Health**

Salmonella Agglutinating Sera are intended for use in slide and tube agglutination tests for serological identification of Salmonella cultures for epidemiological and diagnostic purposes.

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

The tube agglutination method is performed primarily for epidemiologic purposes, and will not have any direct clinical effect critical to patient care. The slide agglutination continues to correctly identify the isolate as *Salmonella H*.

Any risk to patients is indirect, in that epidemiology in a population may not be profiled accurately.

**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 *Salmonella H (gm) (R30161201)*, *Salmonella H (gp) (R30161301)* and *Salmonella H (gq) (R30161401) Agglutinating Sera* (lots listed above) and note that they are only to be used for slide agglutination for the identification of *Salmonella H*.

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](mailto: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**