

6<sup>TH</sup> November 2019

**URGENT FIELD SAFETY NOTICE**

**Thermo Scientific™ Remel™ *E. coli* Polyvalent Agglutinating Sera**

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

**DESCRIPTION**

Customers are to be advised of the following:

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.

**RISK TO HEALTH**

We believe the clinical risk is extremely low based on the following rationale: Patient management should not be affected by a failure to identify the correct serotype. In particular infants with apparent diarrhoea or haemolytic uremic syndrome would be treated and managed in the same way long before any serotype of *E. coli* was recovered. The risks associated with incorrect identification of *E. coli* serotypes is related primarily to epidemiology specifically that a suspected outbreak might not be linked correctly. There has been a move to use specific chromogens to identify probable serotypes associated with Shiga-like *E. coli* infections and serotyping of *E. coli* may well be superseded by more rapid ways of identifying specific pathogenic types.

**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 destroy any remaining inventory of *E. coli* Polyvalent Agglutinating Sera (R30954901), lots as indicated in the table.

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

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

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.

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 Acknowledgement 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,

A handwritten signature in blue ink, appearing to read 'James H Filer'.

**James H Filer**  
**Vice President, Quality and Regulatory, Microbiology Products.**

6<sup>th</sup> November 2019

**ACKNOWLEDGEMENT FORM**

**Re. Thermo Scientific™ Remel™ E. coli Polyvalent and Monovalent Agglutinating Sera**

Dear Customer,

Thermo Fisher Scientific, Microbiology, has taken the decision to recall Thermo Scientific™ Remel™ E. coli Polyvalent Agglutinating Sera, manufactured and sold between March 2019 – October 2019.

To meet regulatory requirements of the IVD Directive, I would be grateful if you would confirm receipt of this Notification by emailing a completed, signed copy of this Acknowledgement Form to the new vigilance email, [mbd.vigilance@thermofisher.com](mailto:mbd.vigilance@thermofisher.com), or Customer Services Department at Fax no. +44(0)1256 479525 by **4<sup>th</sup> December 2019**.

If you require any Technical Assistance please contact our Technical Support Team on 01256 694238 or at [microbiology.techsupport.uk@thermofisher.com](mailto:microbiology.techsupport.uk@thermofisher.com). Any other assistance, please contact your Customer Services Representative on **Contact No.**

Yours sincerely,

**Signed :**  
**Title :**  
**Company :**

**CONFIRMATION OF RECEIPT**

I confirm receipt of the F.S.N. for Thermo Scientific™ Remel™ E. coli Polyvalent Agglutinating Sera, dated 6<sup>th</sup> November 2019.

I confirm that the product has been destroyed. **Please confirm No. of units destroyed.....**

Please contact your local Customer Services representative for Credit, as replacements are unavailable.

Signed..... Name (please print).....

Position..... Date.....

Email Address/Telephone Number.....