

25th July 2017

Biosistemi Grupa D.o.o.
Pijavisce 32, 10090 ZAGREB-HR
CROATIA

URGENT FIELD SAFETY NOTICE

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

Dear Matea Gorisek,

Note: In January 2017 a Customer Notification describing this Field Action was issued to all impacted customers. Following a risk assessment discussion with the UK Competent Authority we have decided to reissue the notification as a Field Safety Notice in compliance with European vigilance requirements - MEDDEV 2.12/1 rev 8.

Customers are to be advised of the following:

DESCRIPTION

A technical investigation has identified that some lots of Thermo Scientific™ Remel™ E. coli Polyvalent and Monovalent Agglutinating Sera may produce weaker than expected agglutination reactions with certain serotypes.

Continued use of these lots may result in failure to correctly identify specific *Escherichia coli* serotypes. Full details in Field Safety Notice enclosed.

We request that you inspect your stocks and destroy any remaining inventory of lots listed in the Field Safety Notice.

Customers should be sent a copy of the Field Safety Notice and a Acknowledgment Form to confirm receipt of the notice. We require confirmation of the sold to parties and either a copy of the customer confirmation form or a summary of the sold to parties and customer confirmation.

This information together with replacement requests should be sent to Martyn Rogers European Quality Director **by 22nd August 2017**. If you have any difficulty or delay in complying with this request please contact the Technical Support Department on +44 (0)1256 694238, or at microbiology.techsupport.uk@thermofisher.com.

Please confirm receipt of this notification by e. mail to Martyn.Rogers@thermofisher.com alternatively fax 01256 814626.

Yours sincerely,



Martyn Rogers
European Quality Director
Thermo Fisher Scientific, Microbiology Basingstoke