Thermo Fisher Scientific
Microbiology
Remel House
Clipper Boulevard West
Dartford
Kent
DA2 6PT
United Kingdom

Phone: +44 (0) 1322 295600
Fax: +44 (0) 1322 225413
www.thermoscientific.com

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URGENT CUSTOMER NOTIFICATION

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

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.

The following Product codes/lots are affected by the notice.

Product Code	Kit Lot Number	Bottle Lot Number	Kit Expiry Date
R30955101/ZA03 E. coli Polyvalent 4	1641803	1664129	2018-04
	1289222	1311006	2017-02
	1465530	1465531	2017-08
	1641520	1545834	2018-04
	1641519	1545834	2018-04
	1545835	1545834	2018-04
	1641802	1545834	2018-04
	1735261	1735263	2019-07
	1931163	1735263	2019-07
	1807794	1735263	2019-07

R30954901/ZA01 E. coli Polyvalent 2	1456728	1563978	2017-10
	1574369	1758810	2018-11
	1734760	1758810	2018-11
R30955001/ZA02 E. coli Polyvalent 3	1439232	1369501	2017-05
	1544395	1544397	2019-02
	1645544	1544397	2019-02
	1842646	1842647	2019-08
R30955301/ZA12 E. coli Type O44:K74 (L)	1329820	1375387	2017-03
R30955401/ZA13 E. coli Type O55:K59 (B5)	1414001	1414002	2017-09
R30956201/ZA21 E. coli Type O126:K71 (B16)	1401661	1401662	2016-12
R30956301/ZA22 E. coli Type O127:K63 (B8)	1373954	1373955	2016-16

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RISK TO HEALTH

Patient management should not be affected by a failure to identify the correct *E.coli* serotype. Infants with apparent diarrhoea or haemolytic uremic syndrome would be treated and managed in the same way before the *E. coli* serotype was identified. The risks associated with incorrect identification of *E.coli* serotypes is primarily related 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to identify probable serotypes associated with Shiga-like *E. coli* infections and serotyping of *E. coli* may well be superseded by more rapid ways of identifying specific pathogenic types.

ACTIONS TO BE TAKEN

Our records indicate that you have received the above product.

Accordingly, in keeping with our Quality Policy, we request that you inspect your stocks, destroy any remaining inventory of the lots listed above and contact Customer Services or your local distributor regarding any necessary replacements. 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 devices have 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.

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,

Martyn Rogers
European Quality Director
Thermo Fisher Scientific, Microbiology Basingstoke