Thermo Fisher Scientific
Microbiology
Remel Europe Ltd
Clipper Boulevard West
Dartford
Kent
DA2 6PT
Phone: +44 (0) 1322 295600
Fax: +44 (0) 1322 225413
www.thermofisher.com

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URGENT FIELD SAFETY NOTICE

Thermo Scientific™ Remel™ Wellcolex™ Colour Shigella R30858401 Lots: 1991413, 2130764, 2110576, 2143553 and 2143554

DESCRIPTION

Customers are to be advised of the following:

An internal technical investigation has confirmed that **Thermo Scientific™ Remel™ Wellcolex™ Colour Shigella Reagent 2 Lots: 1980287 and 2131560** sold within product code **R30858401 Lots: 1991413, 2130764, 2110576, 2143553 and 2143554** may not agglutinate in the presence of positive cultures. A negative result indicates that the organisms under test do not belong to the serotypes of *Shigella* species covered by the reagents.

Latex Reagent 2 is used to identify common serotypes of *S. dysenteriae* and *S. boydii.* Continued use of these lots may result in a failure to correctly identify *S. boydii. S.dysenteriae* results are unaffected. Latex Reagent 1 continues to perform correctly and will identify common serotypes of *S. sonnei* and *S. flexneri.*

RISK TO HEALTH

Wellcolex Colour Shigella provides a simple, rapid qualitative procedure for detection and species identification of *Shigella* present on solid culture media. Wellcolex Colour Shigella will identify Shigella isolates to species level. If full serological identification of types within the species is desired, this should be performed by conventional procedures. A negative result in a culture that morphologically appears as Shigella would be subject to further investigation using biochemical testing, serology, or PCR to confirm the identification.

~~A~~ false negative Reagent 2 result should not affect or delay primary treatment. Shigella is an invasive organism and treatment is usually required at the outset. The final species identification is less important for therapy of individual patients so the immediate clinical risk should be considered low.

For public health purposes, it is important to identify *Shigella* species in outbreak situations. In that setting, a false negative result may result in delay in discovery of the outbreak source. This could lead to delays in remediation by public health of the primary cause for an outbreak. The clinical risk is that instance should be considered as moderate.

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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 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.

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 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,

James H Filer
Vice President, Quality and Regulatory, MBD