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URGENT FIELD SAFETY NOTICE

Thermo Scientific™ Remel™ R30166601 - Neisseria meningitidis Poly A-D

and

Thermo Scientific™ Remel™ R30167001 - Neisseria meningitidis Group D

Product	Bottle lot No.	Carton lot No.
R30166601	1873510	2239498 & 2177820
R30167001	1873513	2239861
R30167001	1739964	1773410 & 1739963

DESCRIPTION

Customers are to be advised of the following:

An internal technical investigation has determined that Thermo Scientific Remel *Neisseria meningitidis Poly A-D (R30166601) and - Neisseria meningitidis Group D (R30167001)* (lots listed above) may fail to agglutinate within the specified minimum reaction time when tested with Group D Neisseria meningitidis bacteria.

Continued use of these lots may result in a failure to correctly identify isolates as Group D Neisseria meningitidis bacteria.

Note: The product Thermo Scientific Remel Neisseria meningitidis Poly A-D (R30166601) continues to correctly identify *Neisseria meningitidis* Groups A, B and C.

RISK TO HEALTH

Meningococcus Agglutinating Sera are intended for use in the qualitative serological identification of *Neisseria meningitidis* Groups A, B, C, D, X, Y, Z and W135 for epidemiological and diagnostic purposes.

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

Identification of a *Neisseria meningitidis* is from culture and primarily cover A, B, C, D, X, Y, Z and W135 serogroups. Group D strains are rarely isolated and these behave biochemically like other meningococci, resulting in them being denoted as non-typeable (from an epidemiological perspective).

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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 destroy any remaining inventory of *R30167001 Neisseria meningitidis Group D (*lots listed above).

Any remaining inventory of *R30166601 Neisseria meningitidis Poly A-D* (lots listed above) may still be used for identification of *Neisseria meningitidis* Groups A, B and C, otherwise please destroy.

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.

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,

[redacted]

James H Filer
Vice President, Quality and Regulatory
Microbiology Products