

28th April 2015

URGENT FIELD SAFETY NOTICE

Remel PathoDx Strep B Group Latex Lot 1437729

This reagent is contained within the following products:

Remel PathoDx Strep B Grouping Latex (R62031) – Lot 1463129

Remel PathoDx Strep Grouping Kit 60 Test (R62025) – Lot 1470133

Customers are to be advised of the following:

An internal technical investigation has confirmed that PathoDx Strep B Group Latex Lot 1437729 may produce weak or slow reactions.

Continued use of this lot may result in a failure to identify beta-haemolytic streptococci group B isolates potentially leading to a delay in result reporting and/or a delay to delivering appropriate therapy.

Customers, who have used these lots should review results reported and consider retesting and/or seek appropriate expert advice.

Accordingly, in keeping with our Quality Policy, we request that you destroy any remaining inventory of the lots listed above and contact Customer Services or your local distributor who will issue a replacement.

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.

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

If you experience any problems complying with this notice or you require any further information, please contact our Technical Support Department on +44 (0)1256 694238, or at microbiology.techsupport.uk@thermofisher.com

Yours Sincerely,



Colin Booth
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