

11th April 2013

FIELD SAFETY NOTICE

Remel Streptex™ Group D Latex Reagent Lot 1154057

Customers are to be advised of the following:

An internal technical investigation has confirmed that **Streptex Group D Latex Lot: 1154057** sold separately as **R30950901 Lot: 1149576** and contained within the kits detailed below, may give weak or false negative test results:

Streptex Latex Agglutination Test (200 tests)	R30164701 Lot: 1187912
Streptex Latex Agglutination Test (50 tests)	R30950501 Lot: 1192181
Streptex Latex Agglutination Test (50 tests)	R30950901 Lot: 1149576

The positive control reagent continues to react satisfactorily with the latex and will not indicate that the reagent is weak.

Continued use of these kits may result in false negative test results with some cultures.

Customers who have used this lot of Streptex Group D Reagent (1154057) should review results reported and consider retesting and/or seek appropriate expert advice.

Please note that Streptex Latex Group A, B, C, F and G Reagents continue to perform satisfactorily.

Accordingly, in keeping with our Quality Policy, we request that you destroy any remaining inventory of the Streptex Group D latex lot 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.

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 via our main switchboard on +44 (0)1256 841144.

Yours faithfully,



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