

16 Aug 2017

RE: Field Safety Notice – Streptex Kit (R30950501) and Streptex Extraction Enzyme (R30951001)

Dear Customer,
(cc Chairman Medical Board and Relevant Head of Departments)

Please be informed of the product recall for the batches below.

1. Item(s) affected

Streptex Rapid Latex Agglutination Test (R30950501) Lots: 1959920, 1987862, 2106328
Streptex Extraction Enzyme (R30951001) Lots: 1981815, 2105975, 2106329
- Products above contain Extraction Enzyme Bottle Lots: 1960420 and 1960621

2. Reason for notice

An internal technical investigation has confirmed that Extraction Enzyme lots 1960420 and 1960621 (contained in the product lots listed above) may provide atypical performance when used with Streptex G Latex reagent. False positive results may be seen within the one minute reaction time detailed in the Instruction for Use.

Continued use of these lots of extraction enzyme with G latex reagent (only) may result in incorrect results reporting.

All other Latex and Extraction Enzyme combinations have been confirmed to meet IFU criteria.

3. Actions to be taken

- Discontinue the use and destroy any remaining inventory of the lots of enzyme listed above
- Kindly fill up the acknowledgement section below and send back to us.

Please refer to attached memo for more information and feel free to contact us should you have any queries regarding this notice.

Thank you for your prompt attention.

Yours Sincerely,



Ji Wenxin
Tel: 6499 9992
Email: wenxin.ji@thermofisher.com

Acknowledgement (To be completed by end-user customer)

I confirm receipt of the F.S.N. for Thermo Scientific™ Remel™ Streptex Rapid Latex Agglutination Test (R30950501) Lots: 1959920, 1987862 and 2106328 & Streptex Extraction Enzyme (R30951001) Lots: 1981815, 2105975 and 2106329

I confirm that the product has been destroyed. Please confirm No. of units destroyed.....

I require replacement packs/Credit to be issued (Please indicate if none required)

Signed.....

Name (please print).....

Position.....

Date.....

Email Address/Telephone Number.....

Company Name & Stamp:

Microbiology

Blk 33 Marsiling Industrial
Estate Road 3
#07-06
Singapore 739256

+65 6499 9999 tel
+65 6896 2147 fax

www.thermofisher.com

8th August 2017

URGENT FIELD SAFETY NOTICE

Thermo Scientific™ Remel™

Streptex Rapid Latex Agglutination Test (R30950501) Lots: 1959920, 1987862 and 2106328

Streptex Extraction Enzyme (R30951001) Lots: 1981815, 2105975 and 2106329

Products above contain Extraction Enzyme Bottle Lots: 1960420 and 1960621

DESCRIPTION

Customers are to be advised of the following:

An internal technical investigation has confirmed that Extraction Enzyme lots 1960420 and 1960621 (contained in the product lots listed above) may provide atypical performance when used with Streptex G Latex reagent. False positive results may be seen within the one minute reaction time detailed in the Instruction for Use.

Continued use of these lots of extraction enzyme with **G latex reagent (only)** may result in incorrect results reporting.

All other Latex and Extraction Enzyme combinations have been confirmed to meet IFU criteria.

RISK TO HEALTH

Streptex is a rapid latex test system for use in the qualitative detection and identification of the Lancefield group of streptococci. Reagents are provided for groups A, B, C, D F and G covering the majority of clinical isolates, group E streptococci are rarely isolated.

We believe the clinical risk is low for the following reasons.

- Group A and B Streptococci are the most critical groups for patient management.
- A false positive report of Group G Streptococci should not impact on patient management as the diagnosis will be based on a Gram smear results, beta-haemolysis on blood agar plates, clinical symptomatology and epidemiology.
- Organisms of groups A, B, C, F and G are normally beta-haemolytic. If an alpha or non-haemolytic organism appears to belong to one of these groups then the species identification should be confirmed by biochemical tests.

- A similar strength of agglutination of more than one latex suspension (but not all) indicates that the extract may contain a mixture of streptococcal groups or other bacteria containing cross-reacting antigens and further isolation procedures and/or biochemical tests should be performed.
- Some strains of group D streptococci have been identified which appear to possess group G antigen. These strains will react with both group D and group G latex reagents and may be confirmed as group D if desired by the bile esculin test.
- User quality control should readily show the appearance of apparent false positive reactions.

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 the lots of enzyme listed above and contact Customer Services or your local distributor who will issue replacements.


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