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MICROBIOLOGY
Acquired from
Thermo Fisher Scientific

Remel Europe Ltd.
Remel House
Clipper Boulevard West
Dartford
DA2 6PT

www.thermofisher.com/microbiology

FSN Ref: FSN-2026-010 FSCA Ref : FSN 2026-010

Date: 5 November 2026

Urgent Field Safety Notice

Thermo Scientific™ Streptex™ Latex Agglutination Test (R30950501)

For Attention of*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
E.mail : mbd.vigilance@thermofisher.com Telephone: +44(0) 1256 841144 Fax: +44(0) 1256 479525

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Urgent Field Safety Notice (FSN)

Thermo Scientific™ Streptex™ Latex Agglutination Test (R30950501)

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD
1.	2. Commercial name(s)
	Thermo Scientific™ Streptex™ Latex Agglutination Test
1.	3. Unique Device Identifier(s) (UDI-DI)
	05056080501376
1.	4. Primary clinical purpose of device(s)*
	Streptex™ is a rapid, qualitative latex agglutination test for the identification of Streptococcus Lancefield groups A, B, C, D, F and G isolates grown on agar. Used in a diagnostic workflow to aid clinicians in treatment options for patients suspected of having bacterial infections. The device is not automated, is for professional use only and is not a companion diagnostic.
1.	5. Device Model/Catalogue/part number(s)*
	R39050501
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Kit Lot Number: 6416336
1.	8. Associated devices
	N/A

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2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Extraction Enzyme Lot 6339390 (contained within the product R30950501 Lots 6416336) may provide atypical performance when used with Streptex D Latex reagent Lot 6408670.
2.	2. Hazard giving rise to the FSCA*
	Cross reactions with the Extraction Enzyme Lot. 6339390 and D Latex Lot. 6408670
2.	3. Probability of problem arising
	High
2.	4. Predicted risk to patient/users
	There should be no immediate or long-term health consequences from using the following lots of Thermo Scientific™ R30950501 Streptex Lots 6416336.The Group D reagent in the lot 6416336 may exhibit some deterioration over time. Users should include positive and negative controls in any event as standard quality controls. Further, Streptex is only a confirmatory test. Gram smear, bile esculin. haemolysis on blood agar, etc., are required for identification of enterococci from appropriate clinical specimens. Patient monument should not be affected by a failure to identify this serogroup. The clinical risk should be considered very low to negligible.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Cross reaction has been identified and causing false negative reactions.
2.	7. Other information relevant to FSCA
	N/A

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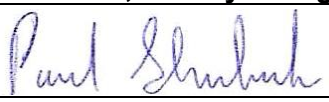
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	3. Type of Action to mitigate the Risk*	
3.	1. Action To Be Taken by the User* ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No None is required.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	Immediately
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

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4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	N/A
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	N/A
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Thermo Fisher Scientific
	b. Address	Remel Europe Ltd, Clipper Boulevard West Dartford Kent DA26PT
	c. Website address	www.thermofisher.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * **YES**	
4.	9. List of attachments/appendices:	Customer response form
4.	10. Name	**Paul Sherlock** **Vice President, Quality & Regulatory, MBD**
	Signature	

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

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Required Customer Reply Form

1. Notification information	
Notification Date	5 November 2026
Product/ Device name	Thermo Scientific™ Streptex™ Latex Agglutination Test
Product Code(s)	R30950501
Batch/Serial Number (s)	6416336
2. Customer Details	
Account Number	
Customer Name	
Customer Address	
3. Customer Actions (Tick all that apply)	
I confirm receipt of the Notice and that I read and understood its content.	☐
I have identified customers that received or may have received this device and they have been notified.	☐
By entering my name below, I acknowledge that the required actions have been taken in accordance with this notice.	
Print Name*:	
Signature*:	
Date*:	

4. Destruction / Replacements / Credit				
I have destroyed affected devices ☐ Number destroyed …… Date completed: ……	CREDIT (pack/each)	Qty :	REPLACEMENT (pack/each)	Qty:
No Replacement available: ☐ (sender to amend: N/A if not applicable)				
No affected devices are available for destruction ☒	**INSPECT & REVIEW STOCK ☐**			

5. Technical Support Information
If you require any Technical Assistance please contact our Technical Support Team on 01256 694238 or at microbiology.techsupport.uk@thermofisher.com. Any other assistance, please contact your Customer Services Representative on 01256 841144.

6. Return acknowledgement to sender	
Email	MBD.vigilance@thermofisher.com.
Deadline for returning the customer reply form	**3 December 2026**