Rev 1: September 2018
FSN Ref: FSN-2026-007

Date: 12 August 2026

Urgent Field Safety Notice

R30166901 Neisseria meningitidis Gp C 2ml/VL

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)

R30166901 Neisseria meningitidis Gp C 2ml/VL

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD
1.	2. Commercial name(s)
	Neisseria meningitidis Gp C 2ml/VL
1.	3. Unique Device Identifier(s) (UDI-DI)
	05056080501161
1.	4. Primary clinical purpose of device(s)*
	Meningococcus Agglutinating Sera are intended for use in the qualitative serological identification of *Neisseria meningitidis* Groups A, C, D, X, Y, Z and W135 for epidemiological and diagnostic purposes. Serological tests are intended for screening purposes and should augment, not replace, culture procedures. For professional use only.
1.	5. Device Model/Catalogue/part number(s)*
	R30166901
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range

Kit Lot Number R30166901	Filled Lot Number W75BZM39M
6214791	6205702
6175327	***6152380***
6148809	6135107
6002010	6002011

Note: Product box/packaging will have the kit lot and physical bottle will state the filled lot.

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*
	A technical investigation as a result of a customer complaint has determined that the following lots of R30166901 Neisseria meningitidis Gp C 2ml/VL are not performing to IFU criteria not positive to ATCC13102 within 60 Seconds.
2.	2. Hazard giving rise to the FSCA*
	False NEGATIVE results for ATCC 13102.
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 use of the following lots of R30166901 Neisseria meningitidis Gp C 2ml/VL The clinical risk should therefore be considered as negligible.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Failing to agglutinate with homologous cultures within a minute.
2.	7. Other information relevant to FSCA
	N/A

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?	
	No Not appended to this FSN	

4. General Information*		
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN-2026-007 15 July 2026
4.	3. For Updated FSN, key new information as follows:	
	Updated batch number previously stated as 3800004 should be 6152380 – the information has been updated in section 1.7 and highlighted bold and italic	
4.	4. Further advice or information already expected in follow-up FSN? *	No The issue has been isolated to a single lot of serum used in the manufacture of the impacted lots.
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	
	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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Customer Reply Form

1. Field Safety Notice (FSN) information				
FSN Reference number*	2026-007			
FSN Date*	12 August 2026			
Product/ Device name*	Thermo Scientific™ Remel™ Neisseria meningitidis Gp C 2ml/VL			
Product Code(s)	R30166901			
Batch/Serial Number (s)	4 Batches (Refer to Notification)			
2. Customer Details				
Account Number				
Organisation Name*				
Organisation Address*				
Department/Unit				
Shipping address if different to above				
Contact Name*				
Title or Function				
Telephone number*				
Email*				
3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.			
☐	I performed all actions requested by the FSN.			
	The information and required actions have been brought to the attention of all relevant users and executed.			
☐	I have returned affected devices - enter number of devices returned and date complete	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY)
		Comments:		
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	Date Completed (DD/MM/YY)
		Qty	Credit ☐ Replacement ☐	
		Comments:		
	No affected devices are available for return/ destruction			
	Other Action (Define):			
☐	I do not have any affected devices.			
☐	I have a query please contact me (e.g. need for replacement of the product).			
Print Name*				
Signature*				
Date*				
4. Return acknowledgement to sender				
Email		MBD.vigilance@thermofisher.com		
Deadline for returning the reply form*		**10 September 2026**		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.