

# FIELD CORRECTIVE ACTION NOTIFICATION AND REPORT FORM

Rev 1: September 2018

FSN Ref: FSN-2021-0007

FSCA Ref: FSN-2021-0007

Date: 11 August 2021

## Urgent Field Safety Notice (FSN) Remel RapID™ NF System

For Attention of: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)* E.mail : <a href="mailto:mbd.vigilance@thermofisher.com">mbd.vigilance@thermofisher.com</a> Telephone: +44(0) 1256 841144 Fax: +44(0) 1256 479525
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1. Information on Affected Devices*	
1.	1. Device Type(s)* IVD
1.	2. Commercial name(s) RapID NF Plus System
1.	3. Unique Device Identifier(s) (UDI-DI) 00848838058158
1.	4. Primary clinical purpose of device(s)* Remel RapID™ NF Plus System is a qualitative micromethod employing conventional and chromogenic substrates for the identification of medically important glucose non-fermenting, Gram-negative bacteria and other select glucose-fermenting, Gram-negative bacteria not belonging to the family Enterobacteriaceae, which have been isolated from human clinical specimens. A complete listing of the organisms addressed by the RapID NF Plus System is provided in the RapID NF Plus Differential Chart (found in the IFU).
1.	5. Device Model/Catalogue/part number(s)* R8311005
1.	6. Software version N/A
1.	7. Affected serial or lot number range 158548, 143096, 158586, 188222 and 188235
1.	8. Associated devices N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* A technical investigation has determined ATCC 19606 ( <i>Acinetobacter baumannii</i> ATCC® 19606), ATCC 13253 ( <i>Elizabethkingia meningoseptica</i> ATCC® 13253) and blank (NF reagent) gave a positive reaction where it should have given a negative reaction within the NO <sub>3</sub> well of the panel.
2.	2. Hazard giving rise to the FSCA* The NO <sub>3</sub> well is giving the incorrect reaction with certain strains.
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 this product. The determination of nitrate in the affected species are not the sole determinant for identification of these species. There are some strains of both <i>A. baumannii</i> and <i>E. meningosepticum</i> that are positive for NO <sub>3</sub> , so the entire range of biochemical tests should be considered in the identification of clinical specimens. In this context of a single false positive test, the clinical risk should be considered negligible
2.	5. Further information to help characterise the problem N/A

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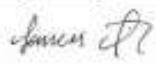


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3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? <small>Choose an item.      Choose an item.</small>
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4. General Information*		
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN-2021-0002
4.	3. For Updated FSN, key new information as follows: Failure for further four lots is identical to the original product recall.	
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	Clipper Boulevard West, Cross ways industrial estate, Dartford, Kent. DA2 8PT
	c. Website address	www.thermofisher.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Customer response form
4.	10. Name	James Filer, Vice President, Quality and Regulatory, MBD
	Signature	

Transmission of this Field Safety Notice
<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

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### Customer Reply Form

<b>1. Field Safety Notice (FSN) information</b>			
FSN Reference number*		2021-0007	
FSN Date*		11 August 2021	
Product/ Device name*		Remel RapID™ NF System	
Product Code(s)		R8311005	
Batch/Serial Number (s)		158548, 143096, <del>158586</del> , 168222 and 168235	
<b>2. Customer Details</b>			
Account Number			
Organisation Name*			
Organisation Address*			
Department/Unit			
Shipping address if different to above			
Contact Name*			
Title or Function			
Telephone number*			
Email*			
<b>3. Customer action undertaken on behalf of Healthcare Organisation</b>			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.		
<input type="checkbox"/>	I performed all actions requested by the FSN.		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete or N/A	Qty:	Lot/Serial Number:      Date Returned (DD/MM/YY)
		Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:      Date Returned (DD/MM/YY)
		Qty	Credit <input type="checkbox"/> Replacement <input type="checkbox"/>
		Comments:	
<input type="checkbox"/>	No affected devices are available for return/ destruction		
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.		
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).		
Print Name*			
Signature*			
Date*			
<b>4. Return acknowledgement to sender</b>			
Email		MBO.vigilance@thermofisher.com	
Telephone Number & Fax		Tel : +44(0) 1256 841144 Fax :+44(0) 1256 479525	
Postal Address			
Deadline for returning the reply form*		11 September 2021	

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.**

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FSCA Ref: FSN-2021-0007

Quality Procedure: Field Corrective Action And Field Safety Notice Procedure QP-QC-11	Form No.: QC-11-02 Effective Date: 05/03/2021	Rev:0	Page 11 of 11
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