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 : mbd.vigilance@thermofisher.com 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, 168222 and 168235
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 (*Acinetobacter baumannii* ATCC® 19606), ATCC 13253 (*Elizabethkingia menigoseptica* ATCC® 13253) and blank (NF reagent) gave a positive reaction where it should have given a negative reaction within the NO_3 well of the panel.
2.	2. Hazard giving rise to the FSCA*
	The NO_3 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 *A. baumanii* and *E meningosepticum* that are positive for NO_3, 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

2.	6. Background on Issue
	A preventive action from a previous product recalled lot 158548 found that the monitored lots 143096, 158586, 168222 and 168235 are now failing whilst performing this internal investigation four customer complaints had been received. The complaints were confirmed as the transferred retained sample replicated the issue. This product was manufactured at a Thermo Fisher Scientific manufacturing site which is no longer in existence.
2.	7. Other information relevant to FSCA
	Lot. 158548 was manufactured in Mar 2020 with the expiry of 03-August-2021. Lot. 143096 was manufactured in Nov 2020 with the expiry of 27-July-2021. Lot. 158586 was manufactured in Dec 2020 with the expiry of 10-August-2021. Lot. 168222 was manufactured in Jan 2021 with the expiry of 07-Sept-2021. Lot. 168235 was manufactured in Jan 2021 with the expiry of 14-Sept-2021.

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? Yes We request that the requirement for review of reported test results should be determined by the appropriate technical expert	
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?	As soon as possible
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.

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 6PT
	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	…
	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*	2021-0007
FSN Date*	11 August 2021
Product/ Device name*	Remel RapID™ NF System
Product Code(s)	R8311005
Batch/Serial Number (s)	158548, 143096, 158586, 168222 and 168235
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 or **N/A**	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 Returned (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
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.