Rev 1: September 2018
FSN Ref: FSN-2021-0002 FSCA Ref: FSN-2021-0002
Date: 20 May 2021

Urgent Field Safety Notice
RapID NF Plus System, R8311005, Batch 158548

For Attention of*:

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
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	ATCC 19606 (*Acinetobacter baumannii* ATCC® 19606), ATCC 13253 (E*lizabethkingia 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*
	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.	3. Probability of problem arising
	High

2.	4. Predicted risk to patient/users
	The clinical risk to patients is considered as minor. The panels are used for confirmation of the organism and when the panel results are entered into the supportive ERIC database the presumptive result is confirmed, with minimal impact of the overall result despite the NO_3 well failure. The probability of the identification when using ATCC 13253 remains as *Elizabethkingia menigoseptica* regardless if a positive or negative NO_3 result is inputted. However, for ATCC 19606 for the identification of *Acinetobacter baumannii* a higher probability of identification as *Burkholderia cepacia* is received. Here the ERIC database states that the frequency value for the first choice is not within acceptable limits for identification, and instructs the user to recheck coding, test interpretation, Gram stain morphology and test procedures, re-isolation, and reinput results. With this *Acinetobacter* strain discrepancy, the isolate is first reported as a non-fermenting Gram negative bacilli and if clinically important in the specimen then antimicrobial susceptibilities are performed. Patient will already be placed on broad spectrum agents. The clinical risk of the initial "error" in identification is minor with no delay in treatment. The patient treatment will remain unchanged regardless of results.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	One customer complaint had been received. The complaint was 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 11-March-2020 with the expiry of 03-August-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? No Choose an item.		

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	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	..... Vice President, Quality and Regulatory, MBD
	Signature	[redacted]

	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*	FSN-2021-0002			
FSN Date*	20 May 2021			
Product/ Device name*	Remel RapID™ NF Plus System			
Product Code(s)	R8311005			
Batch/Serial Number (s)	158548			
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. **(EDIT WHEN NECESSARY) or N/A**	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*	24 June 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.