

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

FSCA Ref: FSN-2021-0002

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 : <u>mbd.vigilance@thermofisher.com</u> Telephone: +44(0) 1256 841144 Fax: +44(0) 1256 479525



⁰² FSCA Ref: FSN-2021-0002 Urgent Field Safety Notice (FSN) RapID NF Plus System, R8311005, Batch 158548

	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.	 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.	 Description of the product problem* 				
	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.	Hazard giving rise to the FSCA*				
There should be no immediate or long-term health consequences from using					
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.				
	<i>baumanii</i> and <i>E meningosepticum</i> 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				



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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 <i>Elizabethkingia menigoseptica</i> regardless if a positive or negative NO ₃ result is inputted. However, for ATCC 19606 for the identification of <i>Acinetobacter baumannii</i> a higher probability of identification as <i>Burkholderia cepacia</i> 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 <i>Acinetobacter</i> 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			
	2.	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.			
F	2.	7. Other information relevant to FSCA			
		Lot. 158548 was manufactured in 11-March-2020 with the expiry of 03-August-2021.			
L					



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3. Type of Action to mitigate the Risk*						
3.	1. Action To Be Taken by the User*					
		☑ Identify Device □ Quantify Device	arantine Device 🛛 Return D	Device 🛛 Destroy		
		□ On-site device modificati	on/inspection			
		☑ Follow patient managem	ent recommendations			
		□ Take note of amendment	t/reinforcement of Instructions	For Use (IFU)		
		□ Other □ None				
3.	2.	By when should the action be completed?	Immediately			
3.	3.	Particular considerations for	r: 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 appropria				
3.		Is customer Reply Required		Yes		
3.		yes, form attached specifying				
3.	ວ.	5. Action Being Taken by the Manufacturer				
		☑ Product Removal	On-site device modification	n/inspection		
		Software upgrade	IFU or labelling change	•		
		□ Other				
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 No /lay user?				
3	8.	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.	 For updated FSN, reference number and date of previous FSN 	N/A			
4.	3. For Updated FSN, key new inform	nation as follows:			
	N/A				
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet			
	5. If follow-up FSN expected, what is	s the further advice expected to relate to:			
4	N/A	N/A			
4	6. Anticipated timescale for follow- up FSN	N/A			
4.	 7. Manufacturer information (For contact details of local represent a. Company Name 	tative refer to page 1 of this FSN) Thermo Fisher Scientific			
	b. Address	Clipper Boulevard West, Cross ways industrial estate, Dartford, Kent.			
		DA2 6PT			
	c. Website address	www.thermofisher.com			
4.	 Website address Www.themonster.com 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	Wice President, Quality and 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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Customer Reply Form

FSN Reference number* FSN-2021-0002 FSN Date* 20 May 2021 Product Code(s) Remiel RapID** NF Plus System Product Code(s) R8311005 Batch/Serial Number (s) 158548 2. Customer Details	1. Field Safety Notice (FSN) information						
Product/ Device name* Remel RapID™ NF Plus System Product Code(s) R8311005 Batch/Serial Number (s) 158548 2. Customer Details	FSN Reference number*	FSN-2021-0002					
Product Code(s) R8311005 Batch/Serial Number (s) 158548 2. Customer Details Account Number Organisation Name* Organisation Address* Department/Unit	FSN Date*	20 May 2021					
Batch/Serial Number (s) 158548 2. Customer Details Account Number Organisation Name*	Product/ Device name*	Remel RapID™					
2. Customer Details Account Number Organisation Name* Department/Unit Source action undertaken on behalf of Healthcare Organisation 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. I have returned affected devices - enter number of devices returned and date complete or N/A 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 I Replacement I Comments: Qty: Lot/Serial Number: Date Returned (DD/MM/YY) Qty: Lot/Serial Number: Date Returned (DD/MM/YY) Qty: Lot/Serial Number: </td <td>Product Code(s)</td> <td></td> <td></td> <td>•</td> <td></td>	Product Code(s)			•			
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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 affected devices - enter number destroyed affected devices - enter number (DD/MM/YY) Comments: I have destroyed affected devices - enter number of devices are available for return/ destruction Other Action (Define): 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	Account Number						
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	Telephone Number & Fax						
Fax :+44(0) 1256 479525 Postal Address	Postal Address	гах.+4	++(0) 1200 479020				
	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.