Rev 1: September 2018
FSN Ref: FSN-2022-001 FSCA Ref: FSN-2022-001

Date: 28 January 2022

Urgent Field Safety Notice

Remel™ Culti-Loops™ E. floccosum ATCC™ 52066™ PK/5 R4601977

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

Rev 1: September 2018
FSN Ref: FSN-2022-001 FSCA Ref: FSN-2022-001

Urgent Field Safety Notice (FSN)

Remel™ Culti-Loops™ E. floccosum ATCC™ 52066™ PK/5 R4601977

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD
1.	2. Commercial name(s)
	Remel™ Culti-Loops™ E. floccosum ATCC™ 52066™ PK/5 R4601977
1.	3. Unique Device Identifier(s) (UDI-DI)
	00848838012075
1.	4. Primary clinical purpose of device(s)*
	This product is a ready to use, disposable bacteriological loop containing stabilized viable microorganisms and is recommended for use in the performance testing of culture media, stains, diagnostic kits and reagents, for the maintenance of stock cultures and in the evaluation of bacteriological procedures.
1.	5. Device Model/Catalogue/part number(s)*
	R4601977
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	255302
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	An internal technical investigation has confirmed that Remel™ Culti-Loops™ E. floccosum ATCC™ 52066™ PK/5 R4601977 Lot 255302 may exhibit lower than expected or no growth of *E. floccosum.*
2.	2. Hazard giving rise to the FSCA*
	Lower than expected or no growth of *E. floccosum.*
2.	3. Probability of problem arising
	Low to medium
2.	4. Predicted risk to patient/users
	There should be no immediate or long term health consequences from use of this product. The *Epidermophyton floccosum* Culti-Loop is a quality control strain that should not affect the ability to culture the suspected organism from clinical samples. The clinical risk should be considered negligible.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	An internal investigation has found that R4601977 lot 255302 is not performing as expected.
2.	7. Other information relevant to FSCA
	Lot. 255302 with the expiry of 27-Oct-2022

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 Provide further details of patient-level follow-up if required or a justification why 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?	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?		
	N/A		

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	Remel Inc.
	b. Address	12076 Santa Fe Trail Drive Lenexa KS 66215
	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	…

	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.*

Rev 1: September 2018
FSN Ref: FSN-2022-001 FSCA Ref: FSN-2022-001

Required Customer Reply Form

1. Notification information	
Notification Date	January 28, 2022
Product/ Device name	Remel™ Culti-Loops™ E. floccosum ATCC™ 52066™ PK/5
Product Code(s)	R4601977
Batch/Serial Number (s)	255302

2. Customer Details	
Account Number	
Customer Name	
Customer Address	

3. Customer Actions	
I confirm receipt of the Recall Notice and that I read and understood its content.	☐
I performed all actions requested by the notification including destroying any remaining units. Qty_____. I prefer credit ☐ replacement ☐	☐
The information and required actions have been brought to the attention of all relevant users and executed.	☐
By entering my name below, I acknowledge that the required actions have been taken in accordance with this notice.	
Print Name*:	
Signature*:	
Email or phone*:	
Date*:	

***required information**

4. Return acknowledgement to sender	
Email	MBD.vigilance@thermofisher.com
Telephone	Tel : +44(0) 1256 841144 Fax :+44(0) 1256 479525
Deadline for returning the customer reply form	**February 25, 2022**

IT IS IMPORTANT THAT YOUR ORGANIZATION TAKES THE ACTIONS DETAILED IN THE NOTIFICATION AND CONFIRMS THAT YOU HAVE RECEIVED THE NOTICE.