Rev 1: September 2018
FSN Ref: FSN-2021-013 FSCA Ref: FSN-2021-013

Date: 16 November 2021

Urgent Field Safety Notice

Thermo Scientific™ Campylobacter Test Kits

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-2021-013 FSCA Ref: FSN-2021-013

Urgent Field Safety Notice (FSN)

Thermo Scientific™ Campylobacter Test Kits

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD
1.	2. Commercial name(s)
	Thermo Scientific™ Campylobacter Test
1.	3. Unique Device Identifier(s) (UDI-DI)
	05032384027705
1.	4. Primary clinical purpose of device(s)*
	Thermo Scientific™ Campylobacter Test is a rapid latex agglutination test intended for confirmatory identification of enteropathogenic, thermophilic campylobacters cultured on selective solid media. The kit is intended for professional laboratory use only.
1.	5. Device Model/Catalogue/part number(s)*
	DR0155M
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	18512, 18711, 18102, 18003 and 18411
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 determined that DR0155M Thermo Scientific™ Campylobacter Test Lots. 18512, 18711, 18102, 18003 and 18411 are auto-agglutinating in all the test latexes with + to ++ reactions.
2.	2. Hazard giving rise to the FSCA*
	False Positive
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 use of this *Campylobacter* testing product. Primary identification of *Campylobacter species* is performed first by culture on selective media, and then on Gram smear of the isolate (curved bacilli), phenotypic and biochemical tests. Agglutination tests are used only for confirmation and for species identification (which is first done with biochemical tests). Primary quality control should identify auto-agglutination of the test latex. Patient management and treatment as necessary will have been started and is based on specific antimicrobial susceptibility testing. The clinical risk should therefore be considered as negligible.
2.	5. Further information to help characterise the problem
	N/A

2.	6. Background on Issue
	One customer complaint received concerning lot. 18711. The complaint was confirmed as the retained sample and previously passed samples replicated the failure.
2.	7. Other information relevant to FSCA
	Lot. 18711 was manufactured 2021-06 with the expiry of 2022-11 Lot. 18512 was manufactured 2021-05 with the expiry of 2022-10 Lot. 18411 was manufactured 2021-04 with the expiry of 2022-09 Lot. 18102 was manufactured 2020-06 with the expiry of 2021-12 Lot. 18003 was manufactured 2020-04 with the expiry of 2021-10

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. 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	Thermo Fisher Scientific
	b. Address	Remel Europe Ltd, Clipper Boulevard West Dartford Kent DA26PT
	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.*