Rev 1: September 2018
FSN Ref: FSN-2022-003

Date: 8 March 2022

Urgent Field Safety Notice

Thermo Scientific™ ProSpecT™ STEC
(Shiga Toxin E. coli) Microplate Assay (R2474096)

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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Thermo Scientific ProSpecT STEC
(Shiga Toxin E. coli) Microplate Assay

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD
1.	2. Commercial name(s)
	Thermo Scientific ProSpecT STEC (Shiga Toxin E. coli) Microplate Assay
1.	3. Unique Device Identifier(s) (UDI-DI)
	05056080501673
1.	4. Primary clinical purpose of device(s)*
	The Thermo Scientific ProSpecT STEC (Shiga Toxin E. coli) Microplate Assay is intended for the qualitative detection of Shiga Toxin (Stx1 and Stx2) in aqueous extracts of faecal specimens and broth enriched faecal cultures. The test is intended for use as an aid in the diagnosis of enterohemorrhagic *E. coli* infections.
1.	5. Device Model/Catalogue/part number(s)*
	R2474096
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	3282613 3301257
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 R2474096 ProSpecT Shiga Toxin E.coli (STEC) Microplate Assay Lots. 3282613 and 3301257 are failing to meet IFU criteria with multiple wells failing for the positive control (PCK) which would invalidate the test, however, where borderline results are obtained a loss in sensitivity of the conjugate may lead to false negative results.
2.	2. Hazard giving rise to the FSCA*
	Delay to patient treatment
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 R2474096 ProSpecT Shiga Toxin E.coli (STEC) Microplate Assay Lots. 3282613 and 3301257. 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 complaint (ref: 9000052657) has been received. A customer stated that the positive control is 'too low' for the Lot. 3301257.
2.	7. Other information relevant to FSCA

Lot	DOM (YYYY-MM-DD)	Exp. Date (YYYY-MM-DD)
3282613	2021-06-22	2202-05-31
3301257	2021-08-31	2022-05-31

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 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*	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:	[redacted]
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*	2022-003			
FSN Date*	8 March 2022			
Product/ Device name*	Thermo Scientific ProSpecT STEC (Shiga Toxin E. coli) Microplate Assay			
Product Code(s)	R2474096			
Batch/Serial Number (s)	3282613 & 3301257			
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*	**05 April 2022**			

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.