FIELD CORRECTIVE ACTION NOTIFICATION AND REPORT FORM

ThermoFisher SCIENTIFIC
The world leader in serving science

Rev 1: September 2018
FSN Ref: FSN-2021-012 FSCA Ref: FSN-2021-012

Urgent Field Safety Notice (FSN)

Thermo Scientific™ Remel™ Shigella dysenteriae polyvalent

1. Information on Affected Devices*		
1.	1. Device Type(s)*	
	IVD	
1.	2. Commercial name(s)	
	Thermo Scientific™ Remel™ Shigella dysenteriae polyvalent	
1.	3. Unique Device Identifier(s) (UDI-DI)	
	05056080500904	
1.	4. Primary clinical purpose of device(s)*	
	Shigella Polyvalent Agglutinating Sera are suitable for use in slide agglutination tests to identify Shigella cultures presumptively for epidemiological and diagnostic purposes. Antisera provide serological identification only; full identification of an organism must be made in conjunction with biochemical testing.	
1.	5. Device Model/Catalogue/part number(s)*	
	R30163701	
1.	6. Software version	
	N/A	
1.	7. Affected serial or lot number range	
	2971158	
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 R30163701 Shigella dysenteriae polyvalent Lot. 2971158 is failing to agglutinate with Sero type 9 and therefore lead to false negative results.	
2.	2. Hazard giving rise to the FSCA*	
	False Negatives	
2.	3. Probability of problem arising	
	High	
2.	4. Predicted risk to patient/users	
	Quality Control testing using Shigella dysenteriae group 9 positive cultures may identify this failure mode before use on clinical samples. We believe the clinical risk is extremely low based on the following rationale: Patient management should not be affected by a failure to identify the correct serotype. Patients would be treated and managed in the same way long before any serotype of Shigella dysenteriae was recovered. The risks associated with incorrect identification of the serotypes are related primarily to epidemiology, specifically that a suspected outbreak might not be linked correctly. However, Serotype 9 is rarely, if ever, recovered from clinical specimens, even in area where shigellosis is common.	

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2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	An internal investigation has found that R30163701 lot 2971158 is not performing to IFU criteria.
2.	7. Other information relevant to FSCA
	Lot. 2971158 was manufactured on 16-11-2020 with the expiry of 31-Oct-2023

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	

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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	**James Filer** **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.*

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2021-012
FSN Date*	3 November 2021
Product/ Device name*	ThermoScientific™ Remel™ Shigella dysenteriae polyvalent
Product Code(s)	R30163701
Batch/Serial Number (s)	2971158
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*				

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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*	**30 November 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.