FIELD CORRECTIVE ACTION NOTIFICATION AND REPORT FORM

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Rev 1: September 2018
FSN Ref: FSN-2021-010 FSCA Ref: FSN-2021-010

Date: 5 October 2021

Urgent Field Safety Notice
Pathodxtra Strep Group D Latex

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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Urgent Field Safety Notice (FSN)
Pathodxtra Strep Group D Latex

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD
1.	2. Commercial name(s)
	Pathodxtra Strep Group D Latex
1.	3. Unique Device Identifier(s) (UDI-DI)
	05032384519866
1.	4. Primary clinical purpose of device(s)*
	PathoDxtraTM supplementary Strep Grouping reagents are intended for use in the PathoDxtra Strep Grouping Kits, which contain all components necessary for the various systems. These reagents are provided as replacement items. For complete information and correct use of this product, please refer to the Instructions for Use which accompanies the PathoDxtra kits (Strep Grouping Kits [DR0700M and DR0710M]).
1.	5. Device Model/Catalogue/part number(s)*
	DR0704G
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	3312966 & 3312967
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 DR0704G Pathodxtra Strep Group D Latex Lots. 3312966 and 3312967 may fail to agglutinate with Sero type D 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
	There should be no immediate or long-term health consequences from use of this Group D streptococcal testing product. This was found from an internal investigation. Primary quality control would identify failure to agglutinate with the standard quality control strains of enterococci, thus preventing use on clinical isolates. Other standard tests as well (e.g. gram smear, bile esculin etc.) would identify the failure of the defective PathoDx Group D reagent. 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

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	An internal investigation has found that DR0704G lots 3312966 & 3312967 are not performing to IFU criteria.
2.	7. Other information relevant to FSCA
	Lot. 3312966 was manufactured on 21-Jul-2021 with the expiry of 30-Jun-2022. Lot. 3312967 was manufactured on 24-Aug-2021 with the expiry of 30-Jun-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? 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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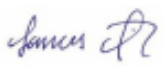
4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what 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*	FSN-2021-010			
FSN Date*	05 October 2021			
Product/ Device name*	Pathodxtra Strep Group D Latex			
Product Code(s)	DR0704G			
Batch/Serial Number (s)	3312966 & 3312967			
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. **(EDIT WHEN NECESSARY) or N/A**	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*	02 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.

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