Rev 1: September 2018
FSN Ref: FSN-2020-0004 FSCA Ref: FSN-2020-0004

Date: 13-May-2020

Urgent Field Safety Notice
Thermo Scientific™ Oxoid™ DrySpot Staphytect Plus

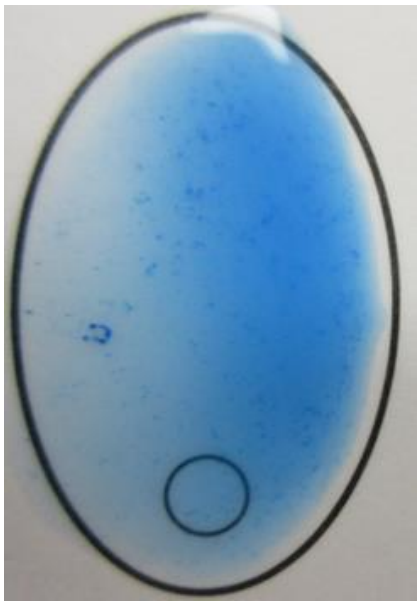
For Attention of*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
mbd.vigilance@thermofisher.com Fax : +44(0)1256 334 994

Rev 1: September 2018
FSN Ref: FSN-2020-0004 FSCA Ref: FSN-2020-0004

Urgent Field Safety Notice (FSN)
Thermo Scientific™ Oxoid™ DrySpot Staphytect Plus
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD
1.	2. Commercial name(s)
	Thermo Scientific Oxoid DrySpot Staphytect Plus
1.	3. Unique Device Identifier(s) (UDI-DI)
	05032384029297
1.	4. Primary clinical purpose of device(s)*
	DrySpot Staphytect Plus™ is a latex slide agglutination test for the differentiation of *Staphylococcus aureus* by detection of clumping factor, Protein A and certain polysaccharides found in methicillin- resistant *S. aureus* (MRSA) from those staphylococci that do not possess these properties.
1.	5. Device Model/Catalogue/part number(s)*
	DR0100M
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	2916980
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 Thermo Scientific™ Oxoid™ DrySpot Staphytect Plus (DR0100M) may show variable levels of granularity with the Test Reagent, before the recommended read end time, as illustrated in the photograph below. 
2.	2. Hazard giving rise to the FSCA*
	This granularity may be misinterpreted as a positive result when used according to the Instructions For Use (IFU).
2.	3. Probability of problem arising
	High
2.	4. Predicted risk to patient/users
	The clinical consequence of a false positive result could potentially result in unwarranted antimicrobial therapy and a potential delay in getting the correct therapy.
2.	5. Further information to help characterise the problem
	None
2.	6. Background on Issue
	Internal investigation following Quality Control failure of product release for second part of split batch.
2.	7. Other information relevant to FSCA
	2916980 Expiry 30-Apr-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?	
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?	
	No 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	Wade Road, Basingstoke, Hampshire RG24 8PW
	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
	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-2020-0004 FSCA Ref: FSN-2020-0004

Customer Reply Form

1. Field Safety Notice (FSN) information			
FSN Reference number*		FSN-2020-0004	
FSN Date*		13th May 2020	
Product/ Device name*		Thermo Scientific™ Oxoid™ Dryspot Staphytect Plus	
Product Code(s)		DR0100M	
Batch/Serial Number (s)		2916980	
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 destroyed affected devices – enter number destroyed and date complete.	Qty: Date:	Lot/Serial Number: Comments: Credit ☐ Replacement ☐
☐	No affected devices are available for destruction		
☐	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	
Customer Services Tel. & Fax		Fax : +44(0)1256 334 994	
Deadline for returning the reply form*		9th June 2020	

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.