

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

FSCA Ref: FSN-2020-0004

**Date:** 13-May-2020

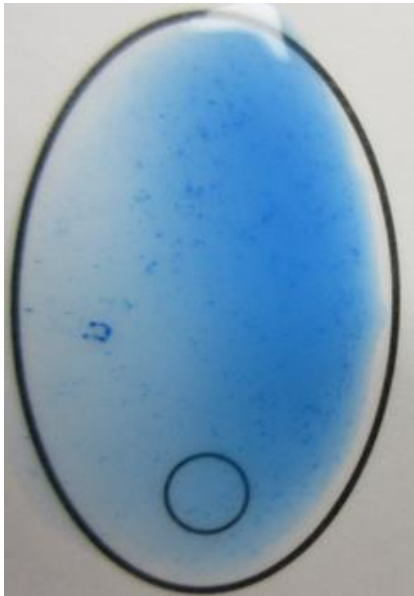
**Urgent Field Safety Notice**  
**Thermo Scientific™ Oxoid™ DrySpot Staphytest Plus**

For Attention of\*: Lab Managers



Contact details of local representative (name, e-mail, telephone, address etc.)*
<a href="mailto:mbd.vigilance@thermofisher.com">mbd.vigilance@thermofisher.com</a>
Fax : +44(0)1256 334 994

**Urgent Field Safety Notice (FSN)**  
**Thermo Scientific™ Oxoid™ DrySpot Staphytest 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 Staphytest Plus
1	3. Unique Device Identifier(s) (UDI-DI)
.	05032384029297
1	4. Primary clinical purpose of device(s)*
.	DrySpot Staphytest Plus™ is a latex slide agglutination test for the differentiation of <i>Staphylococcus aureus</i> by detection of clumping factor, Protein A and certain polysaccharides found in methicillin- resistant <i>S. aureus</i> (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

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2 .	<p><b>1. Description of the product problem*</b></p> <p>An internal technical investigation has determined that Thermo Scientific™ Oxoid™ DrySpot Staphytest Plus (DR0100M) may show variable levels of granularity with the Test Reagent, before the recommended read end time, as illustrated in the photograph below.</p> 
2 .	<p><b>2. Hazard giving rise to the FSCA*</b></p> <p>This granularity may be misinterpreted as a positive result when used according to the Instructions For Use (IFU).</p>
2 .	<p><b>3. Probability of problem arising</b></p> <p>High</p>
2 .	<p><b>4. Predicted risk to patient/users</b></p> <p>The clinical consequence of a false positive result could potentially result in unwarranted antimicrobial therapy and a potential delay in getting the correct therapy.</p>
2 .	<p><b>5. Further information to help characterise the problem</b></p> <p>None</p>
2 .	<p><b>6. Background on Issue</b></p> <p>Internal investigation following Quality Control failure of product release for second part of split batch.</p>
2 .	<p><b>7. Other information relevant to FSCA</b></p> <p>2916980 Expiry 30-Apr-2022</p>

3. Type of Action to mitigate the risk*		
3.	<b>1. Action To Be Taken by the User*</b>  <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device  <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other <input type="checkbox"/> 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.	<b>5. Action Being Taken by the Manufacturer</b>  <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> 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	
	Signature	

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

## Customer Reply Form

<b>1. Field Safety Notice (FSN) information</b>			
FSN Reference number*		FSN-2020-0004	
FSN Date*		13 <sup>th</sup> May 2020	
Product/ Device name*		Thermo Scientific™ Oxoid™ Dryspot Staphytest Plus	
Product Code(s)		DR0100M	
Batch/Serial Number (s)		2916980	
<b>2. Customer Details</b>			
Account Number			
Organisation Name*			
Organisation Address*			
Department/Unit			
Shipping address if different to above			
Contact Name*			
Title or Function			
Telephone number*			
Email*			
<b>3. Customer action undertaken on behalf of Healthcare Organisation</b>			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.		
<input type="checkbox"/>	I performed all actions requested by the FSN.		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.		
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Date:	Comments: Credit <input type="checkbox"/> Replacement <input type="checkbox"/>
<input type="checkbox"/>	No affected devices are available for destruction		
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).		
Print Name*			
Signature*			
Date*			
<b>4. Return acknowledgement to sender</b>			
Email		<a href="mailto:mbd.vigilance@thermofisher.com">mbd.vigilance@thermofisher.com</a>	
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.