Rev 1: September 2018
FSN Ref: FSN-2020-0005 FSCA Ref: FSN-2020-0005

Date: 7th May 2020

Urgent Field Safety Notice
Thermo Scientific™ Oxoid™ Legionella MWY Selective medium

For Attention of*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
Oxoid Deutschland GmbH **Am Lippeglacis 4-8** **D-46483 Wesel (Germany)** **Norbert Benning** **Sr. Site Quality Manager / Prokurist** **Tel.: +49 (0) 281 152-320** **Mobil: 01520-2722498** **Email: norbert.benning@thermofisher.com**

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Urgent Field Safety Notice (FSN) Thermo Scientific™ Oxoid™ Legionella MWY Selective medium Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Media in plates / IVD
1.	2. Commercial name(s)
	Thermo Scientific™ Oxoid™ Legionella MWY Selective medium
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	A selective medium for the isolation of Legionellaceae
1.	5. Device Model/Catalogue/part number(s)*
	PO5071a
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot 2948201
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	A technical investigation has concluded that contamination may be present within the medium following incubation.
2.	2. Hazard giving rise to the FSCA*
	There is a risk that the target Legionella species will either be supressed or overgrown by the contaminating organism and false negative results may be observed.
2.	3. Probability of problem arising
	Very high
2.	4. Predicted risk to patient/users
	Misdiagnosis due to false negative results of the target organism
2.	5. Further information to help characterise the problem
	Legionella species are macroscopically distinguishable from pathogens of the Pseudomonas group, but there is a risk of suppressing the target organism.
2.	6. Background on Issue
	Contamination may not be observed before use.
2.	7. Other information relevant to FSCA
	2948201 Expiry 2020-04-29

	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?	As soon as possible
3.	3. Particular considerations for: IVD The customer should have the previous test results checked professionally and repeat the test if necessary and given the opportunity 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?	24.05.2020
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	Oxoid Deutschland GmbH
	b. Address	Am Lippeglacis 4-8 – D-46483 Wesel
	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:	N/A
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*	FSN-2020-0005
FSN Date*	7th May 2020
Product/ Device name*	Thermo Scientific™ Oxoid™ Legionella MWY Selective medium
Product Code(s)	PO5071A
Batch/Serial Number (s)	2948201

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:	Lot/Serial Number:
		Date:	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 Service Tel. & Fax Number	Fax : +44(0)1256 334 994
Deadline for returning the reply form*	**4th 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.