

Rev 1: September 2018

FSN Ref: FSN-2024-005

FSCA Ref: FSN-2024-005

Date: 20 November 2024

**Urgent Field Safety Notice**  
**Thermo Scientific™ Yersinia Selective Agar**  
**PO5044A Lot 6190052 Exp. 27-December-2024**

For Attention of\*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)\*

E.mail : [mbd.vigilance@thermofisher.com](mailto:mbd.vigilance@thermofisher.com)

Telephone: +44(0) 1256 841144

Fax: +44(0) 1256 479525

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**Thermo Scientific™ Yersinia Selective Agar**  
**PO5044A Lot 6190052 Exp. 27-December-2024**

<b>1. Information on Affected Devices*</b>	
1.	1. Device Type(s)* Prepared Plate Media (IVD)
1.	2. Commercial name(s) Thermo Scientific™ Yersinia Selective Agar
1.	3. Unique Device Identifier(s) (UDI-DI) 5032384129140
1.	4. Primary clinical purpose of device(s)* A selective medium for the isolation of <i>Yersinia enterocolitica</i> . Can also be used for testing food samples.
1.	5. Device Model/Catalogue/part number(s)* PO5044A
1.	6. Software version N/A
1.	7. Affected serial or lot number range 6190052
1.	8. Associated devices N/A

<b>2. Reason for Field Safety Corrective Action (FSCA)*</b>	
2.	1. Description of the product problem* An internal investigation has identified that <i>Pseudomonas aeruginosa</i> may not be inhibited on this batch of agar. Additional lots have been tested and found to be performing as intended.
2.	2. Hazard giving rise to the FSCA* Continued use of this lot may result in delay to patient treatment.
2.	3. Probability of problem arising High. The data collected demonstrates that the identified batch does not inhibit <i>Pseudomonas aeruginosa</i> .
2.	4. Predicted risk to patient/users No serious adverse health consequences should be observed. Yersiniosis is primarily a gastrointestinal infection that occurs in persons who have ingested shellfish or who have been exposed from brackish waters. Cefsulodin is present to prevent growth of <i>P. aeruginosa</i> , which is very uncommon in these types of faecal samples. It is not likely, that the use of the affected batch will cause any adverse events.
2.	5. Further information to help characterise the problem N/A
2.	6. Background on Issue The root cause of this issue is yet to be determined.
2.	7. Other information relevant to FSCA N/A



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? *	No
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	[REDACTED]
	c. Website address	[REDACTED]
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	[REDACTED]
	Signature	[REDACTED]

#### 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*	2024-005		
FSN Date*	20 November 2024		
Product/ Device name*	Thermo Scientific™ Yersinia Selective Agar		
Product Code(s)	PO5044A		
Batch/Serial Number (s)	6190052		
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			
<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.		
	The information and required actions have been brought to the attention of all relevant users and executed.		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete	Qty:	Lot/Serial Number:      Date Returned (DD/MM/YY)
		Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete	Qty:	Lot/Serial Number:      Date Completed (DD/MM/YY)
		Qty	Credit <input type="checkbox"/> Replacement <input type="checkbox"/>
		Comments:	
	No affected devices are available for return/ destruction		
	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.		
<input type="checkbox"/>	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	<a href="mailto:MBD.vigilance@thermofisher.com">MBD.vigilance@thermofisher.com</a>		
Telephone Number & Fax	Tel : +44(0) 1256 841144 & Fax :+44(0) 1256 479525		
Postal Address			
Deadline for returning the reply form*	18 December 2024		

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.**