Rev 1: September 2018
FSN Ref: FSN-2023-001 FSCA Ref: FSN-2023-001
Date: 31 January 2023

Urgent Field Safety Notice
Thermo Scientific™ Oxoid™ MacConkey Agar without Salt (Dehydrated) CM0507B

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)
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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Dehydrated Culture Media
1.	2. Commercial name(s)
	Thermo Scientific™ Oxoid™ MacConkey Agar without Salt (Dehydrated)
1.	3. Unique Device Identifier(s) (UDI-DI)
	5032384003327
1.	4. Primary clinical purpose of device(s)*
	MacConkey Agar without Salt devices are differential media for the isolation of Gram-negative organisms whilst suppressing the swarming of Proteus species from clinical samples, including urine samples. MacConkey Agar without Salt devices are used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having bacterial infections including urinary tract infections (UTIs). Can also be used for testing food and environmental samples
1.	5. Device Model/Catalogue/part number(s)*
	CM0507B
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	3449738
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	An internal investigation by Oxoid Limited, part of Thermo Fisher Scientific, has confirmed that the above lot of CM0507B, Thermo Scientific™ Oxoid™ MacConkey Agar without Salt (Dehydrated) does not supress the swarming of *Proteus mirabilis*, ATCC®29906™.
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 supress the swarming of *Proteus mirabilis*, ATCC®29906™.
2.	4. Predicted risk to patient/users
	There should be no significant immediate or long-term consequences from use of this product. MacConkey agar used for urine culture is usually accompanied by other electrolyte deficient agars. The likelihood of serious complications with use of the affected batch appears to be very low to negligible. There is no evidence of consistent observation, no other complaints have been recorded, and only one batch appears to be affected.
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

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?	Without undue delay
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes Clinical tests should be reviewed and retested as required.	
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?	Without undue delay
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	

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	Thermo Fisher Scientific
	b. Address	Wade Road, Basingstoke, Hampshire RG24 8PW
	c. Website address	www.thermofisher.com/microbiology
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
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*	2023-001
FSN Date*	31 January 2023
Product/ Device name*	Thermo Scientific™ Oxoid MacConkey Agar without Salt
Product Code(s)	CM0507B
Batch/Serial Number (s)	3449738
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	Qty:	Lot/Serial Number:	Date Completed (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*	**28 February 2023**

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.