Rev 1: September 2018
FSN Ref: FSN-2021-011 FSCA Ref: FSN-2021-011

Date: 15 October 2021

Urgent Field Safety Notice (FSN)
ThermoScientific™ Oxoid™ Egg Yolk Tellurite Emulsion SR0054C

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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1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Culture Media Supplement
1.	2. Commercial name(s)
	ThermoScientific™ Oxoid™ Egg Yolk Tellurite Emulsion
1.	3. Unique Device Identifier(s) (UDI-DI)
	5032384013937
1.	4. Primary clinical purpose of device(s)*
	ThermoScientific™ Oxoid™ Egg Yolk Tellurite Emulsion is an emulsion of egg yolk containing potassium tellurite for use in Baird-Parker Medium CM0275 and Baird-Parker Medium (ISO) CM1127. Baird-Parker Medium is widely used in the food and clinical industries for the detection of pathogenic staphylococci.
1.	5. Device Model/Catalogue/part number(s)*
	SR0054C
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	3292932
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 this batch is showing microbial contamination; this may be presented as black deposits or mould growth within the sealed bottles.
2.	2. Hazard giving rise to the FSCA*
	Continued use of these lots could result in contaminated material being used.
2.	3. Probability of problem arising
	The batch appearance is significantly different from the described specification and not comparable to other batches. The issue is likely to be noticed before opening and the batch would not be used for testing.
2.	4. Predicted risk to patient/users
	There should be no immediate or long-term health consequences of using this defective product. Standard quality control procedures will identify the potential contamination prior to use so the affected bottle will not be applied to diagnostic testing. The clinical risk should be considered negligible.
2.	5. Further information to help characterise the problem
	The microbial contamination should be noticed by users, and the material should not be used for testing.
2.	6. Background on Issue
	Due to the thermal sensitivity of the product, this cannot be terminally sterilised.
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 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?	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	… **Vice President, Quality and Regulatory, MBD**
	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.*