

Rev 1: September 2018

FSCA Ref: PB0298A.122019

Date: 30/Dec/2019

Urgent Field Safety Notice
PB0298A
Oxoid™ Streptococcal Selective Agar C.O.B.A

For Attention of*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Email: mbd.vigilance@thermofisher.com
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Urgent Field Safety Notice (FSN)
Oxoid™ Streptococcal Selective Agar C.O.B.A

1. Information on Affected Devices*	
1	1. Device Type(s)* Prepared culture media: Streptococcal Selective Agar C.O.B.A
1	2. Commercial name(s) Oxoid™ Streptococcal Selective Agar C.O.B.A
1	3. Unique Device Identifier(s) (UDI-DI) n/a
1	4. Primary clinical purpose of device(s)* A selective agar for the isolation of Streptococcus species
1	5. Device Model/Catalogue/part number(s)* PB0298A
1	6. Software version n/a
1	7. Affected serial or lot number range 2829729, 2832026, 2832085, 2830579, 2832779, 2835916, 2836870, 2837906, 2838990, 2840119, 2842041, 2844112, 2844949, 2846345
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 there is a reduction in performance for these batches of PB0298A. Testing for Streptococcal spp. may display reduced colony size and a reduction in recovery from what would normally be expected. However, these results remain within QC testing specifications.
2	2. Hazard giving rise to the FSCA* Potential to not identify target organisms should recovery/colony size reduction result in false negative reporting.
2	3. Probability of problem arising High early on in shelf life Lower later in shelf life
2	4. Predicted risk to patient/users There should be no long term health consequences from using this product. With respect to immediate consequences, the poor or lower qualitative growth observed with the affected batches may result in delayed identification of streptococci found in samples from infected patients. While quality control with standard strains may be within specification it is likely that less growth would be observed from previous batches. The 10X concentration of oxolinic acid may well have an inhibitory effect on gram-positive bacteria even though this old fluoroquinolone agent should only be active against gram-negative bacterial species.

Rev 1: September 2018

FSCA Ref: PB0298A.122019

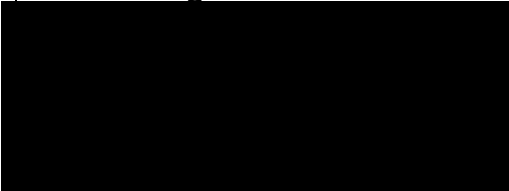
	Delayed observation of infecting strains of <i>S. pneumoniae</i> or beta-haemolytic streptococci may result in strains being missed. The clinical risk should be considered minor to moderate, with the possibilities of inappropriate or inadequate therapy initially.
2	5. Further information to help characterise the problem None
2	6. Background on Issue A technical investigation has confirmed that the below batches of Thermo Scientific™ Streptococcal Selective Agar C.O.B.A, PB0298A have been manufactured with an increased quantity of Oxolinic acid in error.
2	7. Other information relevant to FSCA None

3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input 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 checked="" type="checkbox"/> Other <input type="checkbox"/> None Review patients results
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? * Yes (If yes, form attached specifying deadline for return)
3.	5. Action Being Taken by the Manufacturer <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 checked="" type="checkbox"/> Other <input type="checkbox"/> None Issue was due to incorrect set up of a raw material. The data has been corrected.
3	6. By when should the action be completed? Corrective action complete. Removal action completion date: unknown

Rev 1: September 2018

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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?	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:	
	NA	
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:	
	NA	
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:	Acknowledgement 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>