Rev 1: September 2018

FSN Ref: FSN-2022-009

Date: 02 September 2022

Urgent Field Safety Notice

SAB GLUC AGAR + Gentam+CHLORAMPH – PO5096A, Lot 4369705

For Attention of*:

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

Kontaktdaten des lokalen Vertreters:
Thermo Fisher Scientific Microbiology Thermo Fisher Diagnostics GmbH Am Lippeglacis 4-8 46483 Wesel
Wenn Sie technische Unterstützung benötigen, kontaktieren Sie bitte unser Technisches Support-Team unter E-Mail: microbiology.techsupport.de@thermofisher.com Telefon: +49 (0) 281 152 266 Für die Rücksendung des beigefügten Fragebogens verwenden Sie bitte E-Mail: microbiology.customerservice.de@thermofisher.com Telefon: +49 (0) 281 152 233 Fax: +49 281 152 214

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Urgent Field Safety Notice (FSN)

SAB GLUC AGAR +GENTAM+CHLORAMPH

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Prepared Microbial Culture Media
1.	2. Commercial name(s)
	SAB GLUC AGAR +GENTAM+CHLORAMPH
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	An acidic pH selective medium for the isolation of dermatophytes, other fungi, and yeasts from skin, hair, nails, genital, respiratory and urine samples from immunocompromised patients.
1.	5. Device Model/Catalogue/part number(s)*
	PO5096A
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot 4369705
1.	8. Associated devices
	None

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	A technical investigation has concluded that there is no inhibition of one target organism (*Pseudomonas aeruginosa*) on this Lot
2.	2. Hazard giving rise to the FSCA*
	If samples contain *Pseudomonas aeruginosa* the customer may see an increased level of undesired growth.
2.	3. Probability of problem arising
	High
2.	4. Predicted risk to patient/users
	Very Low to negligible
2.	5. Further information to help characterise the problem

	None

2.	6. Background on Issue
	A technical investigation following a complaint has concluded that *Pseudomonas aeruginosa* may not be inhibited on this batch of agar. Additional lots have been tested and found to be performing as intended.
2.	7. Other information relevant to FSCA
	Lot number 4369705, Expiry Date - 27th December 2022

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?	Immediately
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Yes Provide further details of patient-level follow-up if required or a justification why none is 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?	Immediately
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:	
	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 46483, Wesel Germany
	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*	2022-009			
FSN Date*	02 September 2022			
Product/ Device name*	SAB GLUC AGAR +GENTAM+CHLORAMPH			
Product Code(s)	PO5096A			
Batch/Serial Number (s)	4369705			
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 Returned (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*	**30 September 2022**			

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.