FIELD CORRECTIVE ACTION NOTIFICATION AND REPORT FORM

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Rev 1: September 2018
FSN Ref: FSN-2021-0006 FSCA Ref: FSN-2021-0006

Date: 10-JUNE-2021

Urgent Field Safety Notice

ThermoScientific™ Oxoid™ AMC30 Amoxycillin / Clavulanic Acid Antimicrobial Susceptibility Discs CT0223B

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)
ThermoScientific™ Oxoid™ AMC30 Amoxycillin / Clavulanic Acid Antimicrobial Susceptibility Discs CT0223B

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Antimicrobial Susceptibility Discs
1.	2. Commercial name(s)
	ThermoScientific™ Oxoid™ AMC30 Amoxycillin / Clavulanic Acid Antimicrobial Susceptibility Discs CT0223B
1.	3. Unique Device Identifier(s) (UDI-DI)
	05032384006533
1.	4. Primary clinical purpose of device(s)*
	ThermoScientific™ Oxoid™ Antimicrobial Susceptibility Test Discs are used in the semi-quantitative agar diffusion test method for in vitro susceptibility testing. Used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having a microbial infection, these discs are intended to determine susceptibility against microorganisms for which amoxycillin and clavulanic acid have been shown to be active both clinically and in vitro. To be used with a pure, agar grown culture, Oxoid Antimicrobial Susceptibility Test Discs are for professional use only and are neither automated, nor a companion diagnostic.
1.	5. Device Model/Catalogue/part number(s)*
	CT0223B
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range

Lot	Expiry date
2341375	29.05.2021
2343397	03.06.2021
2394162	29.08.2021
2403210	16.09.2021
2408058	02.10.2021
2438023	27.11.2021
2438086	27.11.2021
2457651	06.01.2022
2463120	14.01.2022
2464593	13.01.2022
2491412	14.03.2022
2511707	24.04.2022
2609976	16.07.2022
2832507	05.08.2022
2840771	26.08.2022
2935065	18.02.2023
2958576	15.04.2023
2966037	20.04.2023
2978564	20.05.2023

1.	8. Associated devices
	N/A

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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 lots of CT0223B, ThermoScientific™ Oxoid™ Amoxycillin/Clavulanic Acid Antimicrobial Susceptibility Discs, are giving small zones of inhibition for Quality Control organism *Escherichia coli* ATCC®35218™. The zones of inhibition are outside the specified CLSI/EUCAST 17-22 mm limits.
2.	2. Hazard giving rise to the FSCA*
	Continued use of these lots could produce false resistance results leading to minor delays in overall effective therapy.
2.	3. Probability of problem arising
	The data collected demonstrates that the identified batches would have performed satisfactorily if used within the first year of their allotted shelf-life. Quality control testing in the clinical laboratory should identify out of specification zones readily and clinical tests would not be reported.
2.	4. Predicted risk to patient/users
	No identified risk to user. Potential to exhibit false resistance to clinical strains which may in turn result in a different antimicrobial agent being used for patient treatment. The clinical risk of this setting is considered low as resistance to amoxycillin-clavulanic acid in clinical settings where it is used for oral treatment (e.g. uncomplicated urinary infections) are relatively low (≤15 %). It is currently unknown if smaller concentrations of the two agents in these batches would show false resistance to isolates (particularly ESBLs) with lower MICs to amoxycillin.
2.	5. Further information to help characterise the problem
	If Quality Control testing is performed, this issue will be detected by producing small, out of specification zones of inhibition with *Escherichia Coli* ATCC®35218™.
2.	6. Background on Issue
	This issue is currently suspected to be caused by differing levels of residual moisture in the product, leading to faster rates of degradation of the primary antibiotic and the beta-lactamase inhibitor.
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

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3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes Clinical tests whereby this product has produced a result above the resistance breakpoint 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? *	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	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. *	

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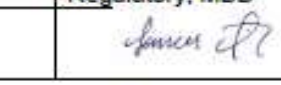
4.	9. List of attachments/appendices:	Customer Response Form
4.	10. Name	James Filer Vice President, Quality and Regulatory, MBD
	Signature	

	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.*

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Customer Reply Form

1. Field Safety Notice (FSN) information				
FSN Reference number*	FSN-2021-0006			
FSN Date*	10 June 2021			
Product/ Device name*	ThermoScientific™ Oxoid™ AMC30 Amoxycillin / Clavulanic Acid Antimicrobial Susceptibility Discs			
Product Code(s)	CT0223B			
Batch/Serial Number (s)	Various – refer to Field Safety Notice			
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			
Deadline for returning the reply form*	**9 July 2021**			

Mandatory fields are marked with *

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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.

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