Rev 1: September 2018
FSN Ref: FSN-2021-014 FSCA Ref: FSN-2021-014

Date: 4 January 2022

Urgent Field Safety Notice (FSN)
Cefiderocol on Sensititre plates

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)*
	Sensititre plates: EUMDROXF DEUGNGOE NONAG8 MDRGN2F (USA only) In combination with: CAMHB with TES Broth (T3462)
1.	2. Commercial name(s)
	Cefiderocol on Sensititre plates
1.	3. Unique Device Identifier(s) (UDI-DI)
	+M578 EUMDROXF +M578 DEUGNGOE +M578 NONAG8 +M578 MDRGN2F (USA only) For T3462 = 00848838003356
1.	4. Primary clinical purpose of device(s)*
	The Sensititre MIC and Breakpoint Susceptibility system is an *in vitro* diagnostic product for clinical susceptibility testing of non-fastidious Gram negative isolates, comprising of *Enterobacteriaceae*, *Pseudomonas aeruginosa,* and other non-*Enterobacteriaceae* and of non-fastidious Gram positive isolates, comprising of *Staphylococcus* sp., *Enterococcus* sp., and Beta haemolytic *Streptococci* other than *S. pneumoniae*. The Sensititre ESBL confirmatory test plate is an *in vitro* diagnostic product for detection of ESBLs in clinical isolates of *Klebsiella pneumoniae, Klebsiella oxytoca* and *Escherichia coli.* MIC and ESBL plates can either be read manually or automatically on the Sensititre Autoreader / OptiRead and/or ARIS. Thermo Scientific manufactured broths have only been validated with Sensititre products
1.	5. Device Model/Catalogue/part number(s)*
	EUMDROXF DEUGNGOE NONAG8 T3462
1.	6. Software version
	N/A

1.	7. Affected serial or lot number range
	Plates: • EUMDROXF Lot numbers: B0464A, B1052, B1101A, B1151A, B1183A, B1273, B1395A • DEUGNGOE Lot number: B1205B • NONAG8 Lot number: B1253B • MDRGN2F (USA only) Lot number: B0164B, B0361, B1161A, B1211, B1315A, B1402A Broths: from 267261 to 402775
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Potential for False Susceptibility for some Gram-Negative species due to broth performance variation.
2.	2. Hazard giving rise to the FSCA*
	Potential for False Susceptibility for some Gram-Negative species
2.	3. Probability of problem arising
	High probability for the broth lot numbers identified in this notification
2.	4. Predicted risk to patient/users
	Limited/negligible risk as immediate impact and no long-term consequences from using this product.
2.	5. Further information to help characterise the problem
	Low MIC results
2.	6. Background on Issue
	Formulation changes to the broth
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 Do not report results of Cefiderocol with these the impacted broth lots highlighted in this notification. Note all other antimicrobics on the plate are not impacted. As part our IFU the standard QC test results will indicate low out of range MICs.	
3.	2. By when should the action be completed?	Immediate
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Immediate results would have been confirmed if effective or not to the patient. Alternative therapies should have been selected	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	5. Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Broth resolution on-going	
3.	6. By when should the action be completed?	1 month
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?	
	No Choose an item.	

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	Trek Diagnostic Systems Ltd
	b. Address	Units 17/19 Willard Way Birches Industrial Estate East Grinstead West Sussex RH19 1XZ
	c. Website address	https://www.thermofisher.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendic	[redacted]
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*	FSN-2021-014			
FSN Date*	4 January 2022			
Product/ Device name*	Cefiderocol on Sensititre plates			
Product Code(s)	EUMDROXF DEUGNGOE NONAG8 T3462			
Batch/Serial Number (s)	Various – Refer to Notification			
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 **N/A**	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY)
		Comments:		
☐	I have destroyed affected devices – enter number destroyed and date complete. **N/A**	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*	**1 February 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.