Rev 1: September 2018
FSN Ref: FSN 2025-002 FSCA Ref: 2025-002
21 November 2025

Urgent Field Safety Notice

CAMHB W/LHB, MANUAL, 11ML, 10/BOX YCP112-10
BRUCELLA BROTH, 11ML, 10/BOX

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

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Urgent Field Safety Notice (FSN)

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1. Information on Affected Devices*		
1.	1.	Device Type(s)*
		Sensititre™ test program
1.	2.	Commercial name(s)
		CAMHB W/LHB, MANUAL, 11ML, 10/BOX YCP112-10 BRUCELLA BROTH, 11ML, 10/BOX
1.	3.	Unique Device Identifier(s) (UDI-DI)
		848838018831 848838091353
1.	4.	Primary clinical purpose of device(s)*
		The Cation Adjusted Mueller-Hinton Broth w/ TES w/ Lysed Horse Blood (CP112-10) is a medium for the suspension of pure isolates of microorganisms for the inoculation of the Sensititre™ plates for testing Streptococcus species as part of the Thermo Scientific™ Sensititre™ System which is a semi-quantitative test intended for in vitro antimicrobial susceptibility testing within a diagnostic workflow. The device is for professional use only and is not intended for self-testing. This device is not automated and is not a companion diagnostic.
1.	5.	Device Model/Catalogue/part number(s)*
		YCP112-10 YT3450
1.	6.	Software version
		N/A
1.	7.	Affected serial or lot number range
		YCP112-10 lots 305529, 311228, 316019, 320993 YT3450 lot 317287
1.	8.	Associated devices
	N/A	
2. Reason for Field Safety Corrective Action (FSCA)*		
2.	1.	Description of the product problem*
		An internal technical investigation confirmed that the products below may contain fungal contamination.
2.	2.	Hazard giving rise to the FSCA*
		There should be no immediate or long-term health consequences for patients.
2.	3.	Probability of problem arising
		High
2.	4.	Predicted risk to patient/users
		There should be no immediate or long-term health consequences for patients.
2.	5.	Further information to help characterise the problem
		Contamination may result in a darker or brown media colour. Visible precipitate may also be visible in the bottom of impacted tubes.
2.	6.	Background on Issue
		N/A
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 Clinical tests 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?	
	No Not appended to this FSN	

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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	Remel Inc.
	b. Address	12076 Santa Fe Trail Drive Lenexa, KS 66215
	c. Website address	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/appendices:	Customer Response Form
4.	10. Name	[redacted]
	Signature	[redacted]

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 Response Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2025 - 002
FSN Date*	21 November 2025
Product/ Device name*	CAMHB W/LHB, MANUAL, 11ML, 10/BOX BRUCELLA BROTH
Product Code(s)	YCP112-10 YT3450
Batch/Serial Number (s)	305529, 311228, 316019, 320993 317287
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 Completed (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*	**19 December 2025**

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.