Rev 1: September 2018
FSN Ref: FSN-2026-003
Date: 31 March 2026

Urgent Field Safety Notice

YEASTONE BROTH, 11ML, 10/BOX (YY3462)

For Attention of*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
Confidential business information

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YEASTONE BROTH, 11ML, 10/BOX (YY3462)

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	IVD
1.	2. Commercial name(s)
	Yeastone Broth, 11ml, 10/Box
1.	3. Unique Device Identifier(s) (UDI-DI)
	848838018817
1.	4. Primary clinical purpose of device(s)*
	Yeastone Broth, 11ml, 10/Box (YY3462) is an antibiotic susceptibility testing of mycological clinical specimens.
1.	5. Device Model/Catalogue/part number(s)*
	YY3462
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range

Kit Lot Number
321046
329835
330316
327069
330317
336325
338314
341161
303851
311723

1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Remel Inc., part of Thermo Fisher Scientific, received ten customers' complaints reporting performance issues of Yeastone Broth, 11ml, 10/Box, YY3462, lots 321046, 329835, 330316, 327069, 330317, 336325, 338314, 341161, 303851, 311723. There were no reports of illness/injury resulting of this issue. An internal technical investigation confirmed that the products below may report incorrect AST results during quality control.
2.	2. Hazard giving rise to the FSCA*
	Incorrect AST results during quality control.
2.	3. Probability of problem arising
	High
2.	4. Predicted risk to patient/users
	There should be moderate health consequences for patients when laboratories ignore Quality Control test results. From a clinical perspective, antifungal susceptibility testing should be considered only a guide. The likelihood of antifungal agents being associated with serious life-threatening consequences should be considered relatively low, possibly associated with delayed response or the need to change to another agent.

2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Nine customers reported performance issues of Yeastone Broth, 11ml, 10/Box, YY3462, lots 321046, 329835, 330316, 327069, 330317, 336325, 338314, 341161, 303851, 311723.
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?	Immediately
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes Review results.	
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 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	Thermo Fisher Scientific
	b. Address	Confidential business information
	c. Website address	www.thermofisher.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. **Yes**	
4.	9. List of attachments/appendices:	Customer response form
4.	10. Name	Personal data
	Signature	Personal data

	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*	2026-003
FSN Date*	31 March 2026
Product/ Device name*	Yeastone Broth 11ML, 10/Box
Product Code(s)	YY3462
Batch/Serial Number (s)	321046; 329835; 330316; 327069; 330317; 336325; 338314; 341161; 303851; 311723

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.	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	Confidential business information
Deadline for returning the reply form*	**28 April 2026**

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.