Rev 1: 17.03.2022

FSN Ref: FSN_FA-2022-001 FSCA Ref: FSCA_FA-2022-001

Date: 24.MAR.2022

Urgent Field Safety Notice
E2-331-100
E2-331-020
Mueller-Hinton Broth, cation-adjusted

To whom it may concern

Legal Manufacturer
Bruker Daltonics GmbH & Co. KG **Michael Schubert – Person Responsible for Regulatory Compliance** **Fahrenheitstr. 4** **28359 Bremen, Germany** fieldactions.BDAL@bruker.com

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Urgent Field Safety Notice (FSN)
E2-331-100
E2-331-020
Mueller-Hinton Broth, cation-adjusted

1. Information on Affected Devices*

1. Device Type(s)*

E2-331-100, E2-331-020 Mueller-Hinton Broth, cation-adjusted.

2. Commercial name(s)

Mueller-Hinton Broth, cation-adjusted.

3. Unique Device Identifier(s) (UDI-DI)

E2-331-020: 04251204327127
E2-331-100: 04251204327134

4. Primary clinical purpose of device(s)*

Mueller-Hinton Broth, cation adjusted (CAMHB) intended for use in qualitative and quantitative diagnostic procedures for antimicrobial susceptibility testing of rapidly growing aerobic and facultatively anaerobic bacteria isolated from clinical specimens. CAMBH may be used in the cultivation of a wide variety of fastidious and non-fastidious microorganisms. For particular bacteria groups it is advisable to add supplement to the broth.CAMHB is for professional use only.

5. Device part number(s)*

E2-331-100; E2-331-020.

6. Software version

Not applicable.

7. Affected lots of products number range

List A

Ref#	Product Name	Lot#		
E1-331-020	Mueller-Hinton Broth, cation-adjusted	0530122	8931121	9171121
E1-331-100	Mueller-Hinton Broth, cation-adjusted	0330122	0530122	0540122
		6880921	7641021	8921121
		8941121	9181121	9381121

List B

Ref#	Product Name	Lot#		
E1-331-020	Mueller-Hinton Broth, cation-adjusted	1260221	6630821	7310921
		7480921	7581021	8061021
		8061021	8071021	8221021
		8371021	9571221	-
E1-331-100	Mueller-Hinton Broth, cation-adjusted	0320122	1260221	6430821
		6630821	6640821	6870921
		7320921	7480921	7490921
		7500921	8061021	8071021
		8221021	8371021	8381021

1. 8. Associated devices

Affected products are used in conjunction with MICRONAUT-S or MIC-Strip.

2 Reason for Field Safety Corrective Action (FSCA)*

2.1. 1. Description of the product problem*

A sediment is formed, which leads to turbidity of the medium when shaken. Microscopically, rod-shaped bacteria are visible. The bacterium that is causally responsible for the contamination has not yet been identified. Cultivation tests are still ongoing. A spore-forming bacterium is suspected, in the media tubes following autoclaving.

2.2. 2. Hazard giving rise to the FSCA*

The test results obtained may lead to a more effective antibiotic not being used for therapy, the is no risk that a patient would not receive a treatment. A delay to diagnosis may occur due to an invalid result, due to Implausible antibiograms, where the user would require to re-test.

2.3. 3. Probability of problem arising

Occurrence is estimated as 25% of the product currently in the field.

2.4. 4. Predicted risk to patient/users

The test results obtained may lead to a more effective antibiotic not being used for therapy.

2.5. 5. Further information to help characterise the problem

See point 2.3 – Probability of problem arising.

2.6. 6. Background on Issue

Source: Customer Complaints.
Root Cause: Nonconforming raw material.
For details refer to section 2.1.

2.	7. Other information relevant to FSCA
	None.

	3. Type of Action to mitigate the risk*
3.	**1. List A (Ref. Section 1.7) – 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
	2. List B (Ref. Section 1.7) – 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.	3. By when should the action(s) be completed? — **8.APR.2022**
3.	4. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No Refer to 2.4 - Predicted risk to patient/users.
3.	5. Is customer Reply Required? * (If yes, form attached specifying deadline for return) — Yes
3.	**6. Action Being Taken by the Manufacturer** ☒ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Affected product lots were removed from all points of Bruker Supply Chain.
3	7. By when should the action be completed? — **20.MAY.2022**

3.	8. Is the FSN required to be communicated to the patient /lay user?	No
3	9. 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	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable.
4.	**3.** For Updated FSN, key new information as follows:	
	Not applicable.	
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:	
	Not applicable.	
4	6. Anticipated timescale for follow-up FSN	Not planned yet.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Bruker Daltonics GmbH & Co. KG**
	b. Address	**Fahrenheitstr. 4, 28359 Bremen, Germany**
	c. Website address	**www.bruker.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	None.
4.	10. Name/Signature	**Francesco Capotorto** **Complaint Manager** 

	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.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Appendix 1 - Device inspection – Applicable to list B product lots

Please, inspect the product lots of list B (ref. section 1.7) as indicated below.

1. Before using the ready-to-use media tube, visually check for the presence of a sediment at the bottom of the tube.

2. If the tube is swivelled and sediment is present, turbidity will appear in the medium.
    a. If NO sediment or turbidity is present, the medium can be used.
    b. If sediment or turbidity is present, the product must be properly disposed.

For replacement, please contact your local supplier.

Appendix 2 – Acknowledgement Form – Applicable to list A and list B product lots

To be returned to Bruker Daltonics GmbH & Co. KG
By email (PDF format): fieldactions.BDAL@bruker.com

Please, send us this form **immediately** as acknowledgement of receipt and of completion.

Acknowledgement of Receipt (AOR) – Acknowledgement of Completion (AOC)	
☐ I/we acknowledge receipt of this customer information and forward this information to all concerned users. ☐ I/we confirm that **……** (number of) packaging units of the product have been properly destroyed. ☐ Please issue us a credit note for **……** (number of) packaging units. ☐ Please send us a replacement free of charge for **……** (number of) packaging units. ☐ We do not require a credit note or replacement.	
Lot Number(s) of destroyed products	
Company Name	
Print Name	
Signature	
E-Mail	
Date (DD.MM.YYYY)	