



Geneva, 11<sup>th</sup> November 2022  
FSCA 5732

**Please distribute to the Laboratory Manager**

**IMPORTANT : URGENT FIELD SAFETY NOTICE**  
**Multiple product references – Temperature Out of Range issues (see Table 1)**  
**Reply required**

Dear Valued bioMérieux Customer,

our records indicate that your laboratory has received at least one of the following products listed in Table 1.

**Table 1: List of Affected Products**

Material	Batch	Expiry date	Description
20040	1009455270	26.06.2024	NaCl 0,85 % 100 Amp. 3 ml
21341	2412052103	10.07.2023	VITEK 2 GN 20 CARDS
21342	2422214503	19.12.2023	VITEK 2 GP 20 CARDS
30235	1009414600	16.05.2023	VIDAS EBV EBNA IgG 30 Tests
30236	1009552320	02.08.2023	VIDAS EBV VCA/EA IgG 30 Tests
30237	1009491890	03.06.2023	VIDAS EBV VCA IgM 30 Tests
30320	1009452780	07.06.2023	VIDAS LYME IGG 60 Tests
30400	1009557550	11.07.2023	VIDAS TSH 60 Tests
30403	1009474350	18.12.2023	VIDAS T3 60 Tests
30421	1009506720	03.06.2023	VIDAS CK-MB 30 Tests
30458	1009353740	11.04.2023	VIDAS NT-PROBNP 2 60 Tests
30459	1009578540	17.08.2023	VIDAS FT4 60 Tests
30706	1009540710	21.07.2023	VIDAS QCV (Quality Control VIDAS) 60 Tests
32400	1009245410	23.02.2023	ID 32 E, Gram-negative bacilli ID - 25 Strips.
33803	1009495430	20.07.2023	COEUR CERVELLE +0.1 % AGAR 20T PS
42038	1009422430	06.12.2023	Sab.Chloramph.2 Agar (SAB CHL 2-T) 20 T
42041	1009492380	17.01.2023	PORTAGERM pylori (PORT-PYL) 8 vials
43004	1009579010	04.12.2022	CHROMID VRE Agar (VRE) 20 PLT
43031	1009540320	16.11.2022	LEGIONELLA MEDIUM (GVPC) 20 PLT
43041	1009538800	07.11.2022	Columbia-Agar+5% Sheep Blood (COS) 20 PLT
43049	1009532630	30.10.2022	Columbia-Agar+5% Sheep Blood (COS) 100 PLT
43071	1009570130	10.11.2022	Columbia CNA Agar + 5% Sheep Blood 20 PLT
43101	1009588770	03.01.2023	CHOCOLAT AGAR POLYVITEX 20 PLT
43141	1009570240	02.12.2022	MC CONKEY CRYST.VIOLET 20 PLT
43149	1009565150	29.11.2022	Mac Conkey Agar (MCK) 100 PLT

**bioMérieux (Suisse) SA**

Material	Batch	Expiry date	Description
43279	1009537140	28.10.2022	Schaedler Agar + Sheep Blood (SCS) 100 PLT
43361	1009582440	04.11.2022	Campyloset Agar (CAM) 20 PLT
43401	1009554300	09.11.2022	Schaedler Agar + 5% Sheep Blood. (SCS) 20 PLT
43411	1009570120	02.12.2022	Gardnerella Agar (GAR) 20 PLT
43451	1009564870	15.11.2022	CHROMID MRSA 20 PLT
43481	1009565180	23.12.2022	CHROMID ESBL 20 PLT
43481	1009565190	23.12.2022	CHROMID ESBL 20 PLT
43631	1009559670	08.12.2022	CHROMID CANDIDA 20 PLT
43681	1009594800	23.12.2022	CHOCOLAT HAEMOPH. 2 MILIEU 20PLT
43901	1009545860	15.11.2022	MH + 5% hore blood + $\beta$ -NAD (MHF) 20 PLT
45534	1009507660	01.01.2024	GENbag anaer bags and Generators 20 Tests
55545	L91711	30.04.2023	R1 Oxalate Crystal violet (Hucker) 1x2 L
56508	1910501	11.02.2023	URILINE 100 LAMES
70491	1009243690	25.02.2023	Ninhydrin 2 x 100 T
70542	1009583340	16.08.2023	James Reagenz Indole detection 2 x 100 T.
96118	1009339550	30.09.2023	Anaerobic Indicator GENbox/GENbag x50
96124	1009507390	01.01.2024	GENbox anaer 10 Generator
96125	1009434220	01.12.2023	GENbox microaer 10 Generator
280131	Z013LG2EB	28.10.2023	NUCLISENS Extraction Buffer 2 (4x1L)
280132	Z013GF3EB	28.07.2023	NUCLISENS Extraction Buffer 3 (4x1L)
280135	CZ-Z103HN	28.08.2023	NUCLISENS easyMAG samples/tips 384 T
411968	1009582660	17.11.2022	BRUCELLA BLOOD AGAR 20 PLT
412108	1009594720	09.12.2022	CHROMID Salmon. Elite Agar (SALM) 20 PLT
413194	1009588690	29.11.2022	SCHAEDLER NEO.VANC.5%SB 20 PLT
413822	1009562720	21.11.2022	MUELLER HINTON E AGAR 90 20 PLT
413824	1009562790	21.11.2022	Mueller Hinton E Agar 90 mm $\varnothing$ 10x10 PLT
415058	7102197503	02.12.2023	AST-N290 TEST KIT 20 CARDS
416172	1009563330	25.12.2022	CHROMID CPS Elite Agar (CPSE+CPSO) 100 PLT
417011	1009516220	08.01.2024	VIDAS AMH
417951	7362217203	22.12.2023	AST-P636 TEST KIT 20 CARDS
421040	5422237203	11.01.2024	AST-ST03 TEST KIT 20 CARDS
421913	8052168103	03.11.2023	AST-P655 TEST KIT 20 CARDS
422231	1009567240	15.12.2022	LEGIONELLA BCYE with L-CYSTEINE 20B
423740	1298222	10.07.2023	RP2.1plus Panel, IVD 30 Tests
30451-30	1009535570	21.02.2023	VIDAS CORTISOL S 30 T
30455-02	1009270360	15.02.2023	VIDAS D-Dimer Exclusion II™ 60 Tests



### **Description of Issue:**

Due to a logistic issue, it has been identified by bioMérieux Swiss Subsidiary that some products were potentially exposed to uncontrolled temperature during shipment because of missing temperature data. The impacted products have been precisely identified and are listed in the table above.

This customer letter is provided to inform the customer and to request the scrap of the impacted product linked to these shipments.

### **Impact to User:**

As the temperature data are missing, product performances cannot be guaranteed and therefore, worst case risk is consider for patient; discrepant/incorrect results.

### **Required Actions:**

Please take the following actions at this time:

1. Confirm this letter has been distributed to and reviewed by all appropriate personnel within your organization.
2. Check your inventory for any of the impacted products (reference Table 1 of the acknowledgement form attached as Appendix A) associated with local shipments.
- 3. Stop using and scrap any remaining impacted products in your inventory.**
4. Complete the attached Acknowledgement Form which specifically details the products impacted for your deliveries and return it by email to [ch\\_support@biomerieux.com](mailto:ch_support@biomerieux.com)
5. Please also enter the number of kits received and destroyed in the table in order to receive a corresponding credit for the destroyed packages. If you need a replacement for the product, please order it in the usual way ([ch.order@biomerieux.com](mailto:ch.order@biomerieux.com) ).
6. Please store this letter with your bioMérieux documentation.

If the products have already been used, the issue could have led to potential incorrect results. We recommend that you identify any possible incorrect results to analyze the related risks and to determine appropriate actions, if relevant.

bioMérieux is committed to providing our customers with the highest quality product possible.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact our Scientific Customer Service at +41 22 906 57 96.

Yours faithfully,

bioMérieux (Suisse) SA

A handwritten signature in blue ink, appearing to read "Rahon".

Hélène Rahon  
Customer Supply Manager Switzerland

Attachment A: Acknowledgement Form



**Attachment A: ACKNOWLEDGEMENT FORM**

**URGENT FIELD SAFETY NOTICE  
FSCA 5732 – Multiple Range - multiple Clinical reference – Temperatures Out of Range  
issues**

**Reply required**

In accordance with traceability legislation, we thank you for completing this form, even if you do not have the product any more.

**Please return this form to your customer service:  
ch\_support@biomerieux.com**

---

**Name of the laboratory:** \_\_\_\_\_

**Contact person:** \_\_\_\_\_

**City:** \_\_\_\_\_

**Customer No. :** \_\_\_\_\_

---

By signing this document, you acknowledge that you have received the urgent field safety notice “**FSCA 5732 – Multiple Range - multiple Clinical reference – Temperatures Out of Range issues**” from bioMérieux regarding the above mentioned issue.

You further confirm that you will follow the instructions and implement the actions as indicated in the urgent field safety notice. You will further note the product references and number of units you have destroyed.

Have you received reports of illness or injury related to the described issue?

**No**                       **Yes**

If YES, please provide your contact phone number: \_\_\_\_\_

Table 1 which specifically details the products impacted for your deliveries

bioMérieux information	Customer Order Number	Customer	Material & Description	Batch & Shelf life Expiry date	Quantity received	Customer Action	Destroyed quantity
------------------------	-----------------------	----------	------------------------	--------------------------------	-------------------	-----------------	--------------------

**DATE .....**

**SIGNATURE.....**