



Geneva, 23th November 2022
FSCA 5732

Please distribute to the Laboratory Manager

IMPORTANT : FIELD SAFETY CORRECTION 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 | TTOR impact | Customer Action |
|----------|------------|-------------|--|-----------------------|-----------------|
| 20070 | 1009427850 | 06.06.2024 | API NACL 0.85% MED 2ML 100AMP | No impact | Can be used |
| 20150 | 1009434300 | 12.06.2024 | API SUSP. MEDIUM (5ML) 100AMP | No impact | Can be used |
| 30126 | 1009534360 | 20.10.2023 | VIDAS UP LISTERIA 60T | No impact | Can be used |
| 30704 | 1009524100 | 21.07.2023 | VIDAS LMO 2 60 TESTS | No impact | Can be used |
| 42046 | 2119370 | 13.12.2022 | FRASER BROTH 6X225ML | Temperature sensitive | Discard |
| 42100 | 1009435750 | 07.12.2023 | Trypcase Soja Bouillon (TSB-T) 20 T | Temperature sensitive | Discard |
| 42633 | 1009258350 | 04.09.2023 | TSB CLEAN ROOMS BOTTLES 6x100ml | Temperature sensitive | Discard |
| 42634 | 1009455020 | 25.03.2023 | CLEAR TIO CLEAN ROOMS BOTTLES | Temperature sensitive | Discard |
| 43009 | 1009577700 | 29.11.2022 | TRYPCASE SOY AGAR + Sheep Blood 100 PLT | Temperature sensitive | Discard |
| 43011 | 1009554330 | 18.01.2023 | TRYPCASE SOY AGAR 20 PLT | Temperature sensitive | Discard |
| 43011 | 1009572850 | 30.01.2023 | TRYPCASE SOY AGAR 20 PLT | Temperature sensitive | Discard |
| 43041 | 1009543020 | 07.11.2022 | Columbia-Agar+5% Sheep Blood (COS) 20 PLT | Temperature sensitive | Discard |
| 43141 | 1009571850 | 01.12.2022 | MC CONKEY CRYST.VIOLET 20 PLT | Temperature sensitive | Discard |
| 43149 | 1009565150 | 29.11.2022 | Mac Conkey Agar (MCK) 100 PLT | Temperature sensitive | Discard |

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| Material | Batch | Expiry date | Description | TTOR impact | Customer Action |
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| 43151 | 1009545890 | 16.12.2022 | D-COCCOSEL 20PLT | Temperature sensitive | Discard |
| 43169 | 1009477050 | 07.07.2023 | TSA 3P IRR 100 PLT | No impact | Can be used |
| 43501 | 1009557440 | 18.11.2022 | COUNT-TACT 20PLT | No impact | Can be used |
| 43501 | 1009573500 | 28.11.2022 | COUNT-TACT 20PLT | No impact | Can be used |
| 43551 | 1009572670 | 14.12.2022 | R2A - GELOSE 20PLATES | No impact | Can be used |
| 43555 | 1009532580 | 29.11.2022 | SABOURAUD DEXTROSE AGAR | Temperature sensitive | Discard |
| 43555 | 1009563040 | 19.12.2022 | SABOURAUD DEXTROSE AGAR | Temperature sensitive | Discard |
| 43565 | 1009564850 | 15.11.2022 | CETRIMIDE AGAR | Temperature sensitive | Discard |
| 43580 | 1009569590 | 06.01.2023 | SABOURAUD DEXTROSE CONTACT | No impact | Can be used |
| 43691 | 1009522630 | 23.02.2023 | COUNT-TACT IRR 3P | No impact | Can be used |
| 43699 | 1009509440 | 14.02.2023 | COUNT-TACT IRR 3P X100 | No impact | Can be used |
| 43699 | 1009563430 | 21.03.2023 | COUNT-TACT IRR 3P X100 | No impact | Can be used |
| 43801 | 220604500 | 31.10.2023 | Quantiswab irradiated | Temperature sensitive | Discard |
| 43811 | 1009512560 | 29.07.2023 | Irradiated Trypcase Soy 3P agar with neutralizers, 20 PLT | No impact | Can be used |
| 43819 | 1009521360 | 02.08.2023 | Irradiated Trypcase Soy 3P agar with neutralizers, 100 PLT | No impact | Can be used |
| 51018 | 1009363200 | 10.03.2026 | THIOGLYCOLLATE BROTH RES.500G | No impact | Can be used |
| 51019 | 1009290820 | 06.01.2026 | TRYPCASE-SOY BROTH 500G | No impact | Can be used |
| 56001 | B7264 | 20.03.2024 | Aspergillus brasiliensis NCPF 2275 (PE) | Temperature sensitive | Discard |
| 56002 | B7190 | 16.02.2024 | Bacillus subtilis NCTC 10400 (PE) | Temperature sensitive | Discard |
| 56003 | B7277 | 27.03.2024 | Candida albicans NCPF 3179 (Pharmacopoeia) | Temperature sensitive | Discard |
| 56007 | B7179 | 10.02.2024 | Pseudomonas aeruginosa NCTC 12924 (PE) | Temperature sensitive | Discard |
| 56009 | B7232 | 03.03.2024 | Staphylococcus aureus NCTC 10788 (PE) | Temperature sensitive | Discard |

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| 56012 | B7190 | 16.02.2024 | Bacillus subtilis NCTC 10400 (PE) | Temperature sensitive | Discard |
| 56018 | B7266 | 21.03.2024 | Salmonella abony ACM 5080 (Pharmacopoeia) | Temperature sensitive | Discard |
| 56019 | B7243 | 09.03.2024 | Staphylococcus aureus NCTC 10788 (PE) | Temperature sensitive | Discard |
| 56024 | B7292 | 03.04.2024 | Bacillus subtilis NCTC 10400 (PE) | Temperature sensitive | Discard |
| 56026 | B7150 | 27.01.2024 | Candida albicans NCPF 3179 (Pharmacopoeia) | Temperature sensitive | Discard |
| 56147 | B7140 | 22.12.2023 | Pseudomonas aeruginosa NCTC 12924 (PE) | Temperature sensitive | Discard |
| 70402 | 1009471340 | 15.06.2023 | TDA 2 x 100 | No impact | Can be used |
| 70422 | 1009504980 | 01.04.2023 | VP 1 & VP 2 Kit 2 x 100 | No impact | Can be used |
| 70542 | 1009583340 | 16.08.2023 | James Reagenz Indolnachweis 2 x 100 | No impact | Can be used |
| 80002 | 1009482490 | 05.07.2023 | TEMPO STA 48T | No impact | Can be used |
| 80003 | 1009422450 | 27.02.2023 | TEMPO ENTEROBACTERIACEAE 48T | No impact | Can be used |
| 80004 | 1009489710 | 06.07.2023 | TEMPO E.COLI 48T | No impact | Can be used |
| 96124 | 1009507390 | 01.01.2024 | GENbox anaer 10 Generator | Temperature sensitive | Discard |
| 411113 | 1009478560 | 22.09.2023 | TEMPO AEROBIC COUNT 48T | No impact | Can be used |
| 417843 | NDK-162 | 18.04.2023 | Rehydratation Fluid | Temperature sensitive | Discard |
| 417843 | NE9-064 | 08.05.2023 | Rehydratation Fluid | Temperature sensitive | Discard |
| 417843 | NE9-065 | 08.05.2023 | Rehydratation Fluid | Temperature sensitive | Discard |
| 418427 | 2135860 | 28.07.2023 | CLEANING 3 (2X2,3L) | No impact | Can be used |
| 300-C2003-02 | 13507676A | 21.06.2026 | CHEMFILTER D17 (X10) | No impact | Can be used |
| 306-R3082-02 | 2144700 | 22.08.2023 | CHEMSOL A7 (6X300ML) | No impact | Can be used |
| AEB111499 | 2136610 | 04.08.2023 | PEPTONE SALT BROTH 100T9ML | No impact | Can be used |
| AEB120082 | 2147820 | 29.11.2022 | ALOA AGAR 10PLATES 140MM | Temperature sensitive | Discard |
| AEB520080 | 2149080 | 06.12.2022 | ALOA AGAR 20PLATES 90MM | Temperature sensitive | Discard |

| Material | Batch | Expiry date | Description | TTOR impact | Customer Action |
|-----------|---------|-------------|-----------------------------------|-----------------------|-----------------|
| AEB521970 | 2148910 | 05.12.2022 | NUTRITIVE ISO 6579 20 BT 90 | Temperature sensitive | Discard |
| AEB526760 | 2151710 | 12.12.2022 | SALSA (XLD/ASAP) 20BI-PLATES 90MM | Temperature sensitive | Discard |
| AEB620677 | 2143990 | 22.02.2023 | MSRV NOVOBIOCINE 6X200ML | Temperature sensitive | Discard |
| AEB620677 | 2150120 | 08.03.2023 | MSRV NOVOBIOCINE 6X200ML | Temperature sensitive | Discard |
| AEB623207 | 2132740 | 25.01.2023 | VRBG 6x200ML | Temperature sensitive | Discard |

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 you and either to inform you that products received can be used or to request you the scrap of the temperature sensitive product in your inventory as defined in table 1 above.

Impact to User:

The TTOR has been assessed for each product reference dedicated to industrial applications only, based on:

- The external temperatures in Geneva from 2022 Sept. 29th to Oct. 4th [5.4°C to 22.1°C], as effective TTOR
- The validated thermal shocks compared to the storage temperature
- The product hazard assessment towards customer and patient/consumer

Therefore, for the products having (i) thermal shocks sequences that are non-compatible with the TTOR and/or (ii) hazard assessment exceeding the low level of final risk towards customer and/or patient/consumer: mitigation action need to be taken on the field → the discard is required.

For all other products: the final risk is conform to usual and thus acceptable as low; no mitigation action to be taken → the use is confirmed.

Table 1 includes the impact of the Temperature Time Out of Range issue per products. Associated actions has to be done per the customer.

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 defined as to be discarded in Table 1 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



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).
6. You can continue to use the products defined as not impacted by the Temperature Time Out of Range issue.
7. 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", with a horizontal line underneath.

Hélène Rahon
Customer Supply Manager Switzerland

Attachment A: Acknowledgement Form



Attachment A: ACKNOWLEDGEMENT FORM

**FIELD SAFETY CORRECTION NOTICE
FSCA 5732 – Multiple Range - multiple Industry 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 field safety correction notice “**FSCA 5732 – Multiple Range - multiple Industry 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 field safety correction notice. You will further note the product references and number of units you have destroyed.

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.....