



**IMPORTANT PRODUCT INFORMATION**

InteliQ Assayed Multiquel Control– Level 3

**Important information on** InteliQ Assayed Multiquel Control in Level 3, lot 45993T

**For the attention of:** Clinical Laboratory Director, Manager or Supervisor /Laboratory Professional Users /Channel Partner

**Please retain this letter for your records**

**Date:** January 10, 2025  
**Bio-Rad Reference:** FAR 2024-04C

Dear Valued Customer / Channel Partner,

The purpose of this letter is to inform you that you may observe lower calcium recovery in Level 3 of InteliQ Assayed Multiquel Control, Lot 45993T, when the product is initially thawed.

**Reason for the Action:**

Lower calcium recovery is observed when the product is initially thawed, followed with recovery increasing to the expected values within several hours after thaw.

**Affected Product Identification:**

Product Name		InteliQ Assayed Multiquel Control - Level 3		
Level	Catalog Number	Lot Number	Lot Number Expiration Date	UDI NUMBER
3	12008258	45993T	2026-08-31	03610522045839
MiniPak	12008259	45990T		03610522045846

**Action(s) to be taken by the Customer:**

For optimal performance and to minimize the impact of the initial low calcium recovery, the product requires an additional hold time of at least 24-48 hours in the refrigerator (2-8 °C) after the product is thawed and unopened, prior to use.

Bio-Rad is requesting that customers affected by this notice take the following action:

- Hold Lot 45993T (Level 3) for at least 24-48 hours in the refrigerator (2-8 °C) after the product is thawed and unopened prior to use.
- Ensure this notice is provided to all those who need to be aware within your organization or to any organization where the impacted devices have been transferred.
- Please complete and return the attached response form as soon as possible so that we are assured you have received this important communication.



**Bio-Rad  
Laboratories**

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**Resolution by Bio-Rad:**

We are working to resolve the issue and apologize for any inconvenience.

**Contact Information:**

Please contact your local Bio-Rad Technical Support if you have any questions regarding this communication. USA contact information is provided below.

- Technical Support Department (USA) at 1-800-854-6737, option #2, or by email at [qsd.techservice@bio-rad.com](mailto:qsd.techservice@bio-rad.com)

Bio-Rad is committed to ensuring the highest levels of safety and quality. We sincerely apologize for any inconvenience this issue may have caused

Mario Wijker  
Bio-Rad SVP, RAQA



**FIELD ACTION RESPONSE FORM**

**Bio-Rad Reference:** FAR 2024-04C

**Bio-Rad Product Segment:** Bio-Rad Laboratories Quality Systems (QS)

**Single Registration Number (SRN):** US-MF-000020712

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**CUSTOMER / CHANNEL PARTNER INFORMATION**

Account Name:	
Undersigning Manager Name:	
Address:	
Telephone Number / Fax:	
Account Number:	

**STATEMENT:**

- No affected product received
- I am aware of the information about the field action concerning the above reference product(s) and have proceeded according to the instructions issued by Bio-Rad.
- For completion by Channel Partners: All customers have been informed about this field action and have proceeded according to the instructions issued by Bio-Rad. Number of customers informed: \_\_\_\_\_

Number of affected products received:		Number of affected products corrected/ destroyed/ returned (as applicable to the Field Action instructions):	
If number of products corrected/ destroyed/ returned is different to the number received, please account for the difference:			

Date: \_\_\_\_\_

Customer / Channel Partner Signature (and Stamp if applicable):

Please return this form to: [qsd\\_far@bio-rad.com](mailto:qsd_far@bio-rad.com) or send it via fax to 949-598-1557 (Attention: Regulatory Affairs). We need this information to ensure that you have received the product notification.