



IMPORTANT PRODUCT INFORMATION
InteliQ Assayed Multiquel Control

Important information on InteliQ Assayed Multiquel Control: Lot numbers, 10300T, 10310T, 10320T, 10330T

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

Date: July 23, 2025
Bio-Rad Reference: FAR 2024-04E

Dear Valued Customer / Channel Partner,
cc Chairman Medical Board and/or relevant Head-of-Departments

The purpose of this letter is to inform you that you may observe lower calcium recovery in InteliQ Assayed Multiquel Control, Lot numbers, 10300T, 10310T, 10320T, 10330T, when the product is initially thawed.

This is a follow up letter to FAR 2024-04 dated: January 10, 2025

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	Catalog Number	Lot Number	Lot Number Expiration Date	UDI NUMBER
1	12008256	10301T	2026-11-30	03610522045815
		10311T	2027-01-31	03610522045815
		10321T	2027-06-30	03610522045815
		10331T	2027-08-31	03610522045815
2	12008257	10302T	2026-11-30	03610522045822
		10312T	2027-01-31	03610522045822
		10322T	2027-06-30	03610522045822
		10332T	2027-08-31	03610522045822
3	12008258	10303T	2026-11-30	03610522045839
		10313T	2027-01-31	03610522045839
		10323T	2027-06-30	03610522045839
		10331T	2027-08-31	03610522045839
MiniPak	12008259	10300T	2026-11-30	03610522045846
		10310T	2027-01-31	03610522045846
		10320T	2027-06-30	03610522045846
		10330T	2027-08-31	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 the impacted lot numbers at least 24-48 hours in the refrigerator (2-8 °C) after the product is thawed and unopened prior to use. Please refer to the product's Instructions for Use (IFU) for specific instructions regarding the stability and allowable usage period of the material once thawed.
- 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.

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

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

Elizabeth Platt
Bio-Rad SVP, RAQA



**Bio-Rad
Laboratories**

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FIELD ACTION RESPONSE FORM

Bio-Rad Reference: FAR 2024-04E

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

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

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		10320T	2027-06-30	03610522045846
		10330T	2027-08-31	03610522045846

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 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.