



## Important Product Field Action Notification Notice of Correction

This letter contains important information. Please ensure all impacted users in your facility are made aware of this letter and the recommended actions.

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

**Please retain this letter for your records**

**Date:** November 4, 2024

**Bio-Rad Reference:** FAR 2024-01B

**Legal Manufacturer:** Bio-Rad Laboratories Inc.


Dear Valued Customer / Channel Partner,  
Cc Chairman Medical board and relevant Head of Departments

The purpose of this letter is to advise you that Bio-Rad is conducting a field action for InteliQ Immunology Control to revise the in-use stability claim for anti-cyclic Citrullinated Peptide (anti-CCP) for the batches listed below.

### Reason for the Correction

We have observed that anti-CCP may not meet the Thawed Unopened, and Instrument On-Board storage stability claim as printed in the package insert. The claim for anti-CCP has been revised for the Thawed Unopened and Instrument Storage to 10 days, as indicated below by the highlighted text and bold font. All other claims for these lots of InteliQ Immunology Control remain unchanged including claims for Refrigerator Storage (All Instruments, Off-Board, 2 to 8°C).

### Revised Claims - Significant changes are highlighted!

<p> <b>STORAGE AND STABILITY</b></p> <p><b><u>Thawed Unopened:</u></b> When thawed and stored unopened at 2 to 8°C, this product will be stable as follows: - All Analytes: 45 days Except: - Beta-2-Microglobulin: 24 days - Apolipoprotein A-I: 22 days - <b>Anti-cyclic Citrullinated Peptide (Anti-CCP)</b> and Rheumatoid Factor: <b>10 days</b></p> <p><b><u>Instrument Storage (Siemens Atellica, On-Board, 2 to 8°C):</u></b> This product will be stable as follows: - All analytes: 30 days Except: - Beta-2-Microglobulin: 21 days - Apolipoprotein A-I: 14 days - <b>Anti-cyclic Citrullinated Peptide (Anti-CCP)</b> and Rheumatoid Factor: <b>10 days</b> Do not refreeze this product after opening the tubes.</p>
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### Risk to Health:

- There is no expected risk to health due to the reduction of the in-use stability claim for anti-CCP. InteliQ Immunology Control is intended for use as a precision quality control



and not for use as an accuracy control. Laboratories must adhere to stringent QC protocols. This issue should be detectable, making the likelihood of false QC acceptance and potentially affecting patient test results minimally to none.

- The issue was uncovered internally during stability monitoring studies. There have been no customer complaints related to anti-CCP stability.

**Affected Product Identification:**

<b>Product Name</b>	<b>InteliQ Immunology Control</b>
<b>INTENDED USE</b>	InteliQ Immunology Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

Product Name		InteliQ Immunology Control				
Level	Catalog Number	Lot Number Expiration Date 2025-01-31	Lot Number Expiration Date 2025-03-31	Lot Number Expiration Date 2025-06-30	Lot Number Expiration Date 2026-02-28	UDI NUMBER
Level 1	12009941	85711T	85721T	85731T	85751T	03610522113842
Level 2	12009942	85712T	85722T	85732T	85752T	03610522113859
Level 3	12009943	85713T	85723T	85733T	85753T	03610522113866
MiniPak	12009944	85710T	85720T	85730T	85750T	03610522113873

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

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

- Obtain the revised (Rev. 1) package insert through the Internet at <http://myeinserts.qcnet.com>. Discard all previous versions of the insert that you may have at your location.

The package insert's STORAGE AND STABILITY section has been revised to indicate the new in-use stability claim for anti-CCP.

- 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:**

The Thawed Unopened and Instrument Storage claim change for anti-CCP will be a permanent change, impacting all current and future lots.

**Contact Information:**

Please contact Bio-Rad Technical Support if you have any questions regarding this communication.

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) if you have technical questions regarding this notice.

Bio-Rad would like to assure you that our highest priority is maintaining a high level of safety and quality. We regret any inconvenience caused by this issue.

Mario Wijker  
Bio-Rad SVP, RAQA



**FIELD ACTION RESPONSE FORM**

**Bio-Rad Reference:** FAR 2024-01B

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

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

Product Name		InteliQ Immunology Control				
Level	Catalog Number	Lot Number Expiration Date 2025-01-31	Lot Number Expiration Date 2025-03-31	Lot Number Expiration Date 2025-06-30	Lot Number Expiration Date 2026-02-28	UDI NUMBER
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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: [ctssingapore@bio-rad.com](mailto:ctssingapore@bio-rad.com)

We need this information to ensure that you have received the product notification.

Thank you for your time and cooperation.