



IMPORTANT PRODUCT INFORMATION
Lyphocek Assayed Chemistry Control

Important information on Lyphocek Assayed Chemistry Control – The reconstituted and refrigerated storage stability claim for Bilirubin (Direct) has been reduced to 4 days.

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

Please retain this letter for your records

Date: 17 January 2025
Bio-Rad Reference: FAR 2024-05

Dear Valued Customer / Channel Partner,

The purpose of this letter is to inform you that we have revised the Reconstituted and Refrigerated storage stability for Bilirubin (Direct) from 7 to 4 days in Lyphocek Assayed Chemistry Control for the lot listed below.

All other claims for this lot of Lyphocek Assayed Chemistry Control remain unchanged.

Reason for the Action:

We observed that for this lot of Lyphocek Assayed Chemistry Control, Bilirubin (Direct) may not meet the Reconstituted and Refrigerated 7-days storage stability claims as printed in the package insert.

Affected Product Identification:

Product Name		Lyphocek Assayed Chemistry Control		
Level	Catalog Number	Lot Number	Expiration Date	UDI NUMBER
Level 1	C-310-5	89761	2027-04-30	00847661000754
Level 2	C-315-5	89762	2027-04-30	00847661000761
MiniPak	313X	89760	2027-04-30	00847661001973

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 inserts through the Internet at <http://myeinserts.qcnet.com>. Discard all previous versions that you may have at your location.

The STORAGE AND STABILITY section has been revised to indicate the new stability claims for Bilirubin (Direct).

- 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 Bilirubin (Direct) Reconstituted and Refrigerated storage stability claim in the package insert has been revised to 4 days, as indicated below.

Revised Claims - Significant changes are highlighted!



STORAGE AND STABILITY

Reconstituted and Refrigerated: After reconstituting and storing tightly capped at 2 to 8°C, this product will be stable as follows:

- All analytes: 7 days

Except:

- **Bilirubin (Direct): 4 days**

- T3 (Free), Acid Phosphatase (Total) and Prostatic Acid Phosphatase (PAP): 3 days

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 if you have technical questions regarding this notice.

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 2024-05

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

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

Product Name		Lyphochek Assayed Chemistry Control		
Level	Catalog Number	Lot Number	Expiration Date	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: 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.