



**Important Product Field Action Notification  
Notice of Correction**

**Product Name: Lyphochek Hemoglobin A<sub>2</sub> Control**

Level	Catalog Number	Lot Number	Lot Number	UDI Number
		Expiration Date: 2025-02-28	Expiration Date: 2024-03-31	
Bilevel	553	54820	54810	00847661000884
MiniPak	553X	54820	54810	00847661002093

*This Notice is intended for the end-users of this product.  
If you are not the end-user, please forward this Notice to the appropriate laboratory personnel.*

**Date** September 8, 2023


**To** Clinical Laboratory Director, Manager or Supervisors  
Cc Chairman Medical Board and/or relevant Head-of-Departments

**From** Bio-Rad Laboratories QSD Regulatory Affairs

**Product** Lyphochek Hemoglobin A<sub>2</sub> Control


**Issue** We have observed that Hemoglobin F may not meet the reconstituted refrigerated (2 to 8°C) storage stability claims as printed in the package insert. The stability claims for **Hemoglobin F** have been revised as indicated below by the highlighted text and bold font.

**Revised Claims**

 **Significant changes are highlighted!**

**STORAGE AND STABILITY**

Once the control is reconstituted and stored tightly capped at 2 to 8°C this product will be stable as follows when used on:

-  • **Gel Electrophoresis: 14 days**  
Except - **Hemoglobin F: 7 days**
- **Other Methods: 21 days**  
Except - **Hemoglobin F: 7 days**

All other claims for Lyphochek Hemoglobin A<sub>2</sub> Control remain unchanged.

**Actions Required**

- The package insert's STORAGE AND STABILITY section has been revised to indicate the new stability claims for Hemoglobin F. Please obtain the revised (Rev. 1) insert through the Internet at <http://myeinserts.qcnet.com>. Discard all previous versions of the insert that you may have at your location.
- Contact Bio-Rad Laboratories 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.

We appreciate your patience and apologize for any inconvenience this may have caused.