



**Bio-Rad
Laboratories**

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Important Product Quality Notice Notice of Correction

Bio-Rad Laboratories Lyphocheck Coagulation Control
Catalog Numbers 744, 745X
Master Lot No. 78420

*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 August 8, 2016
To Clinical Laboratory Supervisor, Manager or Director
Product Lyphocheck Coagulation Control
Master Lot Numbers 78420
Levels 1 and MiniPak
Catalog Nos. 744, 745X
Issue We have observed that Lyphocheck Coagulation Control **Level 1** may not meet the open vial claims at 2- 25°C as printed in the package insert. The claims for open vial in Level 1 have been revised as indicated below by the highlighted text and bold font:

Revised Claims



Significant changes are highlighted!

STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at 2 to 8°C.



After reconstituting and storing tightly capped, this product will be stable as follows:

Level 1 - All analytes:

48 hours at 2 to 8°C

or 30 days at -20 to -70°C

or three freeze-thaw cycles within 7 days at -20 to -70°C

Level 2 and 3 - All analytes:

48 hours at 2 to 25°C

or 30 days at -20 to -70°C

or three freeze-thaw cycles within 7 days at -20 to -70°C

All other claims for this lot of Lyphocheck Coagulation Control remain unchanged.

Revised lot specific inserts

The package inserts which now include the revised Storage and Stability claims are available through the Internet at <http://myeinserts.qcnet.com>.

Actions Required

- We recommend that one you reconstitute the product, you do not store Lyphocheck Coagulation Control Level 1 at a temperature above 8°C for all analytes.
- The stability claims for Levels 2 and 3 have not changed.
- Please obtain a revised copy of the Lyphocheck Coagulation Control package insert through the Internet at <http://myeinserts.qcnet.com>. Discard all previous versions of the package insert for these lots of product that you may have at your location and substitute with the revised package insert.
- Have the appropriate laboratory personnel complete and send back to us via fax the enclosed acknowledgment form to document that you have received this notice and are aware of the stability changes.
- Contact Bio-Rad Laboratories Technical Support Department at 1-800-854-6737 if you have technical questions regarding this notice. Alternate methods for receiving the package insert or Instructions for Use (IFU) are available by contacting your local Bio-Rad Laboratories Office.

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