



**Bio-Rad  
Laboratories**

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## Important Product Quality Notice Notice of Correction

**Bio-Rad Laboratories Lyphocheck Specialty Immunoassay Control**  
**Catalog Numbers 27124, 27125, 27126 and 27125X**  
**Master Lot No. 25240, 25250, 25260, 25270 and Future Lots**

*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** March 29, 2019  
**To** Clinical Laboratory Supervisor, Manager or Director  
Cc Chairman Medical Board and relevant Head of Departments  
**From** Bio-Rad Laboratories QSD Regulatory Affairs  
**Product** **Lyphocheck Specialty Immunoassay Control**  
**Master Lot Numbers** 25240, 25250, 25260, 25270 and future lots  
**Levels** 1, 2, 3 and MiniPak  
**Catalog Nos.** 27124, 27125, 27126 and 27125X  
**Issue** We have observed that Intact PTH may not meet the reconstituted and refrigerated stability claim as printed in the package inserts. The claim for Intact PTH has been revised as indicated below by the highlighted text and bold font. All other claims for these lots of Lyphocheck Specialty Immunoassay Control remain unchanged.

### 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.



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

- All analytes: 30 days

Except:

- **PTH (Intact): 4 days**

- Procalcitonin: 3 days

**Aliquot-Frozen:** Once the control is reconstituted and stored in tightly capped aliquot vials at -20 to -70°C, this product will be stable as follows:

- All analytes: 30 days

Use content of each aliquot vial once. Discard the remaining material

### Revised lot specific inserts

The package inserts which now include the revised stability claim in the STORAGE AND STABILITY section are available through the Internet at <http://myeinserts.qcnet.com>.

### Actions Required

- Please obtain a revised copy of the Lyphocheck Specialty Immunoassay 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.