



**Bio-Rad
Laboratories**

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Important Product Quality Notice Notice of Correction

Bio-Rad Laboratories Liquichek Diabetes Control
Catalog Numbers 171, 172, 173, 172X and 291, 292, 293, 292X
Master Lots No. 38530, 38540, 38550 and 38530V, 38540V, 38550V

***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 February 14, 2017
To Clinical Laboratory Supervisor, Manager, Director or Chairman Medical Board
and/or relevant Head of Department
Product Liquichek Diabetes Control
Master Lot Numbers 38530, 38540, 38550 and 38530V, 38540V, 38550V
Levels 1, 2, 3 and MiniPak
Catalog Nos. 171, 172, 173 and 172X
291, 292, 293, and 292X

Issue We have observed that the values for Hemoglobin A1C may gradually decrease over the shelf life of these product lots. A LIMITATION for Hemoglobin A1C has been added to the package insert with highlighted text and bold font, as indicated below:

Revised Claims

 Significant changes are highlighted!

LIMITATIONS



Values may gradually decrease over the product shelf life for the following analyte: **Hemoglobin A1C.**

All other claims for these lots of Liquichek Diabetes Control remain unchanged.

Revised lot specific inserts

The package inserts which now include the new LIMITATION are available through the Internet at <http://myeinserts.qcnet.com>.

Actions Required

- Laboratory means and acceptable ranges may need to be re-established for HbA1C during the shelf life of the product.
- Please obtain a revised copy of the Liquichek Diabetes 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.