



**Bio-Rad
Laboratories**

Clinical Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017
Tel: (949) 598-1200
www.bio-rad.com/qualitycontrol

Important Product Quality Notice Notice of Correction

qUAntify Control -- Catalog Numbers 975, 975X

Master Lot No. 78770, 78780

qUAntify Plus Control --- Catalog Numbers 995, 995X (12 mL)

Master Lot No. 80510, 80520, 80530, 80540, 80550, 80560

qUAntify Plus Control --- Catalog Numbers # 962, 963, 964, 962X (120 mL)

Master Lot No. 79610, 79620, 79630, 79640, 79650, 79660

*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 June 5, 2018

To Clinical Laboratory Supervisor, Manager or Director
Cc Chairman Medical Board and relevant Head of Departments

Product qUAntify Control and qUAntify Plus Control

Master Lot Numbers Listed above

Catalog Nos. Listed above

Issue We have observed that the values for Blood and Ketones may gradually decrease and values for pH may gradually increase over the shelf life of these product lots. This information has been added to the Storage and Stability section in the package insert (**Rev.1**) with highlighted text and bold font.
The package inserts which now include the new information in the STORAGE AND STABILITY Section and **updated** values are available through the Internet at <http://myeinserts.qcnet.com>.

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. Once opened, this product will be stable for 31 days when stored tightly capped at 2 to 25°C with the following exception: Ketones will be stable for 31 days at 2 to 8°C or 10 days at room temperature (18 to 25°C).



For optimum performance store the product at 2 to 8°C
Values may gradually **decrease** over the product shelf life for the following analytes: **Blood and Ketones**
Values may gradually **increase** over the product shelf life for the following analyte: **pH**

All other claims for these lots of qUAntify Control and qUAntify Control Plus remain unchanged.



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Important Product Quality Notice Notice of Correction (continued)

Actions Required

- Laboratory means and acceptable ranges may need to be re-established for Blood, Ketones and pH during the shelf life of the product.
- Please obtain a revised copy of the qUAntify Control and qUAntify Plus Control package inserts through the Internet at <http://myeinserts.qcnet.com>. Discard all previous versions of the package inserts for these lots of product that you may have at your location and substitute with the revised package inserts.
- Have the appropriate laboratory personnel complete the enclosed acknowledgment form to document that you have received this notice and are aware of this product quality notification. Please send the completed form back via email to QSD_FAR@Bio-Rad.com or by fax to 949-598-1557 (Attention: Regulatory Affairs).
- 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.