

# QC Communication




**Product:** Liquichek Cardiac Markers Plus Control LT; Liquichek Cardiac Markers Plus Control LT Low and Liquichek Cardiac Markers Plus Control

**Subject:** Reduction of NT-proBNP Thawed Open vial stability claims



May 17, 2016

Dear Valued Customer,

This is to inform you that the Thawed Open vial stability claim for **NT-proBNP** in our Liquichek Cardiac Markers Plus Controls have been reduced from the previous 15 days open claim at 2 to 8°C as indicated in the table below. All other claims remain unchanged.

Product Name	Catalog numbers	NT-ProBNP open vial claim 12 days at 2 to 8°C	NT-ProBNP open vial claim 8 days at 2 to 8°C
Cardiac Markers Plus Control LT	146, 147, 148, 27104, 27105, 27106, 146X, 147X, 148X, 27104X, 27105X, and 27106X.	Lot 23620	Lot 23630 and future lots
Cardiac Markers Plus Control LT Low	149 and 149X.	Lot 23850	Lot 23860 and future lots
Cardiac Markers Plus Control	180, 181, 182, 183, and 180X.	Lot 29840	Lot 29850 and future lots

The Thawed Open vial insert claims revised in the IFU as indicated in the below highlighted text depending on the Lot Number:

The insert for <b>Lot 23620, 23850 and 29840</b> reflect the following claims	The insert for <b>Lots 23630, 23860 and 29850 and future lots</b> reflect the following claims
<p><b>STORAGE AND STABILITY</b> This product will be stable until the expiration date when stored unopened at -20 to -70°C. Do not store this product in a frost-free freezer.</p> <p> <b>Thawed Opened:</b> Once thawed, opened, and stored tightly capped at 2 to 8°C, this product will be stable as follows: - All analytes: 20 days Except: - <b>N-terminal pro-Brain Natriuretic Peptide (NT-proBNP): 12 days</b> - Troponin I: 10 days - B-type Natriuretic Peptide (BNP): 8 days - Troponin T: 4 days</p>	<p><b>STORAGE AND STABILITY</b> This product will be stable until the expiration date when stored unopened at -20 to -70°C. Do not store this product in a frost-free freezer.</p> <p> <b>Thawed Opened:</b> Once thawed, opened, and stored tightly capped at 2 to 8°C, this product will be stable as follows: - All analytes: 20 days Except: - Troponin I: 10 days - <b>N-terminal pro-Brain Natriuretic Peptide (NT-proBNP)</b> and B-type Natriuretic Peptide (BNP): <b>8 days</b> - Troponin T: 4 days</p>

## Actions Required

- 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.

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

For questions, please contact us. In the United States, Bio-Rad representatives are available at 800-2-BIORAD. Outside the United States, please contact your local Bio-Rad Sales Office.



**Bio-Rad  
Laboratories**

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

## Customer Acknowledgement

Product Name	Catalog numbers	NT-ProBNP open vial claim 12 days at 2 to 8°C	NT-ProBNP open vial claim 8 days at 2 to 8°C
Cardiac Markers Plus Control LT	146, 147, 148, 27104, 27105, 27106, 146X, 147X, 148X, 27104X, 27105X, and 27106X.	Lot 23620	Lot 23630 and future lots
Cardiac Markers Plus Control LT Low	149 and 149X.	Lot 23850	Lot 23860 and future lots
Cardiac Markers Plus Control	180, 181, 182, 183, and 180X.	Lot 29840	Lot 29850 and future lots

Dear Clinical Laboratory Manager/ Director,

Please complete the information below and email this form to [techsupport.SEACDG@Bio-Rad.com](mailto:techsupport.SEACDG@Bio-Rad.com). We need this information to ensure that you have received the product notification.

Thank you for your time and cooperation.

☐ I am aware of information in the QC Communication

☐ This message does not apply because:

☐ Discontinued using Lot(s) \_\_\_\_\_

☐ Other (please specify) \_\_\_\_\_

Account Name: \_\_\_\_\_

Undersigning Manager Name/Signature: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone Number / Fax: \_\_\_\_\_

Customer Account Number: \_\_\_\_\_