



Important Product Quality Notice Notice of Correction

Bio-Rad Laboratories InteliQ Assayed Multiquel Control

Level Kit Description	Catalog Number	Lot Number	Expiration Date
Level 1	12008256	45821T	2021-07-31
Level 2	12008257	45822T	
Level 3	12008258	45823T	
MiniPak	12008259	45820T	

*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 October 4, 2019
To Clinical Laboratory Director, Manager or Supervisor cc Chairman Medical Board and relevant
From Bio-Rad Laboratories QSD Regulatory Affairs Head of Departments
Product InteliQ Assayed Multiquel Control
Master Lot Numbers 45820T
Issue

We have observed that some analytes may not meet the Thawed-Opened stability when the product is stored open in the instrument. The claims for these analytes have been revised as indicated below by the highlighted text and bold font. In addition, the Aliquot-Frozen claims have been removed.

All other claims for this lot of InteliQ Assayed Multiquel Control remain unchanged.

Important Information for Atellica® Solution Users: Please refer to the Atellica Operator's Guide to manually update the revised open vial stability values.

Revised Claims



Significant changes are highlighted!

STORAGE AND STABILITY



Thawed-Opened: Once thawed and opened, this product may be stored open in the instrument or tightly capped in the refrigerator at 2 to 8°C. This product will be stable as follows:

– All analytes: 14 days

Except:

- Alkaline Phosphatase, AST/SGOT, Bilirubin (Neonatal) and Bilirubin (Total): 9 days
- Bilirubin (Direct), Cholesterol (HDL), Cholinesterase, Creatine Kinase (CK), Phosphorus and Triglycerides: 7 days
- Calcium (Ionized), Ethanol and LAP Arylamidase: **1 day**
- Carbon Dioxide (CO₂): **8 hours**

Aliquot-Frozen: No frozen stability provided.

Revised lot specific inserts

The package insert which now includes the revised stability claims 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 InteliQ Assayed Multiquel Control package insert (Rev. 1) through the Internet at <http://myeinserts.qcnet.com>. Discard all previous versions of the package insert for this lot of product that you may have at your location and substitute with the revised package insert.
- 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 back the completed form via email to QSD_FAR@bio-rad.com or fax to 949-598-1557.
- Contact Bio-Rad Laboratories Technical Support Department (USA) at 1-800-854-6737, option #2, or by email at qsd.techservice@bio-rad.com if you have technical questions regarding this notice.

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