



Cardiac Assessment Controls

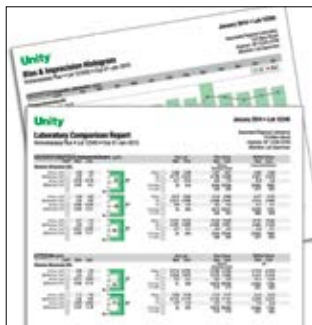
Value Assigned for Clinical Laboratory and Point of Care Test Systems





Solving the Challenges of Troponin I Testing for the Central Laboratory and POCT Systems

Quality control of Troponin I (TnI) at low levels is critical. At least one value above the 99th percentile upper reference limit (URL) designates myocardial infarction.¹ Yet TnI test methods vary. The FDA has stated, “different troponin assays have wide variations in lower detection limits, upper reference limits, diagnostic points, assay imprecision (CV), and specimen matrices.”² But physicians rely greatly on TnI results due to their critical significance which means it is best if the control materials you use reflect precision at diagnostic levels.



Unity QC Data Management Solutions

Bio-Rad Cardiac Assessment Controls are part of the Unity QC program with its industry-leading features for benchmarking laboratory performance.

- Benefit from peer data generated from more than 45,000 instruments worldwide
- Utilize real-time access to peer group comparisons to help troubleshooting
- Consolidate your entire laboratory into one system
- Facilitate run-time decisions with optimized Westgard rules
- Ease compliance with ISO 15189 and regulatory requirements using simple tools to review rule violations and document corrective actions

1. Joint ESC/AACF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction. Third universal definition of myocardial Infarction. European Heart Journal 2012; 33: 2551-2567. Available online at: www.escardio.org/guidelines.

2. "Troponin: What Laboratorians Should Know to Manage Elevated Results," accessed May 16, 2012, <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109362.htm>



The Right Quality Controls – at the Level of Assessment You Need – for Your Cardiac Testing

Packaged how you need it – with our new 2.5 mL fill size for the Dimension Vista®

Liquichek Cardiac Markers Plus Control LT

A comprehensive cardiac assessment control designed to monitor assay precision across the range of clinically significant values such as lower levels of Troponin.

3 mL Fill Size

- Liquid, human serum based
- 3 year shelf life at -20°C to -70°C
- 20 day open-vial stability at 2–8°C for most analytes
- Choice of four low Troponin I levels (1, 1A, 1B and 1C)
- Includes values for Troponin T (GEN 4 and hs) and hs-CRP
- Offers both BNP and NT-proBNP
- Level Low offers lower target values for all analytes

2.5 mL Fill Size

- Offers 7 analytes to match the Dimension Vista® test menu
- Shared lot numbers and Unity peer groups with existing 3mL fill size
- Compatible with on-board refrigerated storage on the Dimension Vista®
- 2D barcode for quick and easy product insert and vial label scanning
- 10 day open-vial (punctured) stability for all analytes when stored at 2-8°C

Analytes

BNP**
CK (Total)

CK-MB Isoenzyme
CRP

Digitoxin
Homocysteine*

Myoglobin
NT-proBNP

Troponin I
Troponin T**



With Bio-Rad Quality Controls, you choose the products best suited for your cardiac assessment needs.

Correct diagnosis regarding the source of chest pain is a pivotal decision that can rely on accurate assessment of specific cardiac markers. So many variables—markers, platforms, sites—affect cardiac marker results that carry sizeable outcomes for both patients and providers. It is best

if laboratories choose QC product at decision levels that are appropriate for the cardiac markers they test. So much is at stake! Does that one-size-fits-all control actually indicate performance where the laboratory needs it most? If not, it's time to look at Bio-Rad for a QC solution.

*No claim is made for expected values or stability.

**Not claimed under 2.5 mL fill size.

For specific analyte, open-vial stability, methods, mean values and ranges, refer to the package inserts of currently available lots at myeinserts.com.



There is no one-size-fits-all Quality Control in a State-of-the-Art Cardiac Program

Because no single marker provides the complete picture of a cardiac patient's clinical status.

Liquichek D-dimer Control

Provides the laboratory with a four level control for monitoring the precision of D-dimer testing on most automated coagulation, chemistry and immunoassay analyzers.

- Liquid, human plasma based
- 3 year shelf life at -20°C to -70°C which allows for fewer crossover studies
- 15 day open-vial stability at 2–8°C

	Target Value
	D-dimer ng/mL (FEU)*
Level Low	250
Level 1	550
Level 2	1600
Level 3	3200

*Fibrinogen Equivalent Units (FEU) = twice the mass of the D-DU (D-dimer units).

The values listed are approximate targets. The actual observed values will vary depending upon lot number, analyzer, reagent, method, and calibrator.

Liquichek Homocysteine Control

A single analyte control designed to monitor Homocysteine precision across a wide range of target values.

- Liquid, human serum based
- 3 year shelf life at -20°C to -70°C
- Includes values on all three levels for HPLC and automated immunoassays (Abbott, Beckman Coulter®, Roche and Siemens)

	Target Value		
	Level 1	Level 2	Level 3
Homocysteine (µmol/L)	6.5	12.0	28

Recovered values may vary with methodology.



Complete the clinical picture using Liquichek D-dimer and Liquichek Homocysteine Controls.

Markers signify different health conditions at different concentrations. Running two concentrations of a control material may meet minimum regulatory requirements but may not adequately address the need to provide control across the Analytical Measurement Range (AMR). Having more than two levels of D-dimer and Homocysteine

control is particularly useful for monitoring test precision over a wide assay range. These single analyte controls for D-dimer and Homocysteine also spare consumption of multi-analyte controls where these two markers are measured on separate platforms.



Simple – Effective – Comprehensive QC Covering a Wide Range of Values

Liquichek Cardiac Markers Plus Control LT and Cardiac Markers Plus Control Target Value Comparison Chart

	Plus LT, Level Low	Plus LT, Level 1	Plus, Level 1	Plus LT, Level 2	Plus, Level 2	Plus LT, Level 3	Plus, Level 3
Catalog Number	149	146	181	147	182	148	183
BNP (pg/mL) ^o	42	105	105	410	410	1,550	1,550
Total CK (U/L)	132	265	265	567	567	1,060	1,060
CK-MB (ng/mL)	2.3	3.3	4.3	21	21	92	92
hs-CRP (mg/dL)	0.03	0.07	0.05	0.20	0.20	0.60	0.60
Digitoxin (ng/mL)	5.0	10.0	8.0	17.5	17.5	40	40
Myoglobin (ng/mL)	50	80	52	155	155	410	410
NT-proBNP (pg/mL) ^o	56	90	105	278	305	3,150	3,485
Troponin I (ng/mL)	0.050	0.045	0.25	1.1	6.4	4.4	26
Troponin T (ng/mL)	0.02	0.07	0.2	0.3	1.0	2.0	5.0
D-dimer	Use Liquichek D-dimer Control						
Homocysteine	Use Liquichek Homocysteine Control						

^oEither BNP or NT-proBNP can be used to help detect, diagnose, and evaluate the severity of heart failure so values are provided for both analytes. Recovered values may vary with methodology. For specific analyte, open-vial stability, methods, mean values and ranges, refer to the package inserts of currently available lots at myinserts.com



Take advantage of our unique options to build an effective cardiac marker QC Plan in your laboratory.

The need for immediate patient results in cardiac diagnosis means tests may be performed at different sites—hospital, clinical laboratory or point of care—that have different test platforms. Bio-Rad is your partner with a corresponding solution; we offer a choice of controls suitable for QC on most platforms.

Our cardiac assessment control users submit their data to the Unity Interlaboratory Program. Data from the large peer group of participants will help you be confident in the reliability and precision of your lab's test systems.

Ordering Information

Cat #	Product Name	Quantity
Liquichek Cardiac Markers Plus Control LT		
146	Level 1	6 x 3 mL
147	Level 2	6 x 3 mL
148	Level 3	6 x 3 mL
149	Level Low	6 x 3 mL
146X	Level 1 MiniPak	1 x 3 mL
147X	Level 2 MiniPak	1 x 3 mL
148X	Level 3 MiniPak	1 x 3 mL
149X	Level Low MiniPak	1 x 3 mL
27104	Level 1A	6 x 3 mL
27105	Level 1B	6 x 3 mL
27106	Level 1C	6 x 3 mL
27104X	Level 1A MiniPak	1 x 3 mL
27105X	Level 1B MiniPak	1 x 3 mL
27106X	Level 1C MiniPak	1 x 3 mL
297	Level 1C	6 x 2.5 mL
298	Level 2	6 x 2.5 mL
299	Level 3	6 x 2.5 mL
298X	Trilevel MiniPak (1 of each level)	3 x 2.5 mL
Liquichek D-dimer Control		
27100	Level Low	6 x 1 mL
27101	Level 1	6 x 1 mL
27102	Level 2	6 x 1 mL
27103	Level 3	6 x 1 mL
27102X	Four Level MiniPak (1 of each level)	4 x 1 mL

Cat #	Product Name	Quantity
Liquichek™ Homocysteine Control		
287	Level 1	6 x 1 mL
288	Level 2	6 x 1 mL
289	Level 3	6 x 1 mL
288X	Trilevel MiniPak (1 of each level)	3 x 1 mL

Additional Controls Available

Cat #	Product Name	Quantity
Liquichek™ CK/LD Isoenzyme Control		
671	Level 1	6 x 1 mL
672	Level 2	6 x 1 mL
670X	Bilevel MiniPak (1 of each level)	2 x 1 mL

Liquichek Cardiac Markers Plus Control

180	Trilevel (2 of each level)	6 x 3 mL
181	Level 1	6 x 3 mL
182	Level 2	6 x 3 mL
183	Level 3	6 x 3 mL
180X	Trilevel MiniPak (1 of each level)	3 x 3 mL

Liquichek Cardiac Markers Control LT

645	Trilevel (2 of each level)	6 x 3 mL
646	Level 1	6 x 3 mL
647	Level 2	6 x 3 mL
648	Level 3	6 x 3 mL
645X	Trilevel MiniPak (1 of each level)	3 x 3 mL

Liquichek Cardiac Markers Control LT, Level Low

649	Level Low	6 x 3 mL
649X	Level Low MiniPak	1 x 3 mL



**Bio-Rad
Laboratories**

For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/cardiaccontrols

*Clinical
Diagnostics Group*

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