



Diabetes Controls and Lyphochek Hemoglobin A1C Linearity Set



Monitor Hemoglobin A1C Testing with Independent Quality Controls from Bio-Rad

HbA1C Values for More than 30 Methods – Including HPLC, Immunoassay and Point-of-Care Instruments

Hemoglobin A1C (HbA1c) levels correlate with average blood sugar levels but don't have the extent of variation seen in random blood sugar measurements. Glucose levels that have not been controlled well are reflected in elevated HbA1c levels. While normal levels vary slightly by laboratory, typically HbA1c levels less than 7.0% indicate good glucose control; in poorly controlled diabetes, levels are generally 8.0% or above. The higher the HbA1c, the higher the risks may be of developing other health complications related to diabetes. Using quality controls from Bio-Rad can assist your laboratory in delivering quality HbA1c results.

Multilevel Diabetes controls are available in a variety of formats and are designed to monitor HbA1c and Total Hemoglobin test procedures. These controls have value assignment listings for over 30 methods – including HPLC, Immunoassay and point-of-care methodologies.

Based on CLIA regulations (42 CFR 493.1255) and CAP requirements, the linearity of HbA1C assays needs to be verified at least once every 6 months. Our 6-level Lyphochek Hemoglobin A1C Linearity Set provides an easy-to-use solution for labs to perform the verification.

Liquichek Diabetes Control

A liquid, human whole blood based control designed to monitor the precision of hemoglobin test procedures associated with diabetes monitoring. Available in three levels and two configurations.



Standard vials (1 mL fill size)

- 3 year shelf life at -20°C to -70°C
- 45 day open-vial stability at 2–8°C
- Higher third level to monitor your assay range



Compact vials (2 mL fill size)

- Compatible with applicable automated platforms such as Siemens Dimension Vista and Abbott Alinity
- 2D barcode for quick and easy QC set-up
- 3 year shelf life at -20°C to -50°C
- 30 day open-vial stability at 2–8°C

Analyte

Hemoglobin A1C



InteliQ Diabetes Control



Trilevel HbA1c control designed to monitor the precision of test procedures associated with diabetes monitoring for Hemoglobin A1C.

- Liquid, human whole blood based
- 3 year shelf life at -20°C to -70°C
- 45 day on-board stability at 2-8°C*
- 10 day open-vial stability at 2-8°C

Analyte

Hemoglobin A1C

Lyphochek Diabetes Control



A human whole blood based product intended to monitor the precision of hemoglobin tests procedures used in diabetes monitoring, including Hemoglobins A1, A1C, F and Total Glycated Hemoglobin.

- Lyophilized control available in two levels
- Human whole blood based control
- Extensive value assignment listings
- Convenient 0.5 mL fill size
- 3 year shelf life at 2-8°C
- 7 day reconstituted stability at 2-8°C

Analytes

Hemoglobin (Total Glycated)**
 Hemoglobin (Total)
 Hemoglobin A1**
 Hemoglobin A1C
 Hemoglobin F

POCT Methods Listed

Lyphochek Hemoglobin A1C Linearity Set



A human whole blood based product intended to verify linearity throughout the patient reportable range of Hemoglobin A1C assays.

- Intended to verify linearity throughout the reportable range of Hemoglobin A1C assays
- Human whole blood based
- 3 year shelf life at 2-8°C
- 7 day reconstituted stability at 2-8°C

Analyte

Hemoglobin A1C

Linearity Web software available on QCNet.com

Assayed values available for common analyzers:

Bio-Rad Analyzers

- D-10
- VARIANT
- VARIANT II Turbo

Other Analyzers

- Beckman Coulter SYNCHRON Systems
- Siemens ADVIA
- Siemens Dimension Series
- Roche COBAS INTEGRA & Hitachi Systems
- Tosoh G7 & G8

Expected Values for Hemoglobin A1C (%NGSP)¹

Level 1	2.7 - 3.8%
Level 2	4.1 - 5.1%
Level 3	5.5 - 6.5%
Level 4	8.4 - 10%
Level 5	12 - 15%
Level 6	16 - 22%

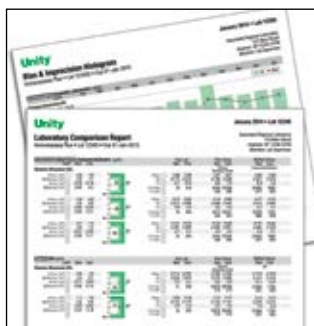
¹Ranges reflect typical recovery values for this product. Exact values may vary depending on test/assay methodology, instruments, reagent, system calibrators or laboratory technique.

*Please refer to the package insert for platform-specific stability and performance claims.

**No claims are made regarding performance or stability.

Refer to myInserts.com or the package insert of currently available lots for specific analyte and stability claims.

Unity QC Data Management Solutions



Bio-Rad Diabetes 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 50,000 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 using simple tools to review rule violations and document corrective actions
- Define your own quality requirements and track key quality performance indicators

You can consolidate your entire laboratory into one QC system through our Unity Program. This sophisticated software includes best-in-class tools to support releasing results, benchmarking laboratory performance, and designing your QC system.

Ordering Information

Cat #	Description	Cat #	Description
Liquichek Diabetes Control*		InteliQ Diabetes Control	
Standard Vials		12008309	Level 16 x 2 mL
12011343	Level 16 x 1 mL	12008310	Level 26 x 2 mL
12011344	Level 26 x 1 mL	12008311	Level 36 x 2 mL
12011345	Level 36 x 1 mL	12008312	Trilevel MiniPak (1 of each level)3 x 2 mL
12011334	Trilevel MiniPak (1 of each level)3 x 1 mL		
Compact Vials		Lyphocheck Diabetes Control	
12011308	Level 16 x 2 mL	740	Bilevel (3 of each level)6 x 0.5 mL
12011309	Level 26 x 2 mL	740X	Bilevel MiniPak (1 of each level)2 x 0.5 mL
12011310	Level 36 x 2 mL		
12011331	Trilevel MiniPak (1 of each level)3 x 2 mL	Lyphocheck Hemoglobin A1C Linearity Set	
		12000070	Set (1 of each level)6 x 0.5 mL

*Not all products may be available in all countries.

EQAS	Independent QC	Unity
An independent, external assessment of performance in comparison to your peers.	Ongoing, proactive, unbiased daily QC that helps identify errors as they occur or begin to trend.	QC Data Management tools that help you create a strategy to reduce risk and streamline QC workflow.
QCNet.com/eqas	QCNet.com/independentqc	QCNet.com/datamanagement



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

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