



Diabetes Controls and Lyphocheck® Hemoglobin A1C Linearity Set

BIO-RAD

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 Liquichek™ and Lyphochek® Diabetes Controls monitor HbA1C and Total Hemoglobin test procedures, and 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 critical levels.

1 mL Fill Size

- 3 year shelf life at -10°C to -70°C
- 6 month shelf life at 2–8°C
- 14 day open-vial stability at 2–8°C
- Higher third level to monitor your assay range
- Value assignment listings for over 30 methods

2 mL Fill Size

- Dimension Vista® vials offer ready-to-use convenience for on-board refrigerated storage
- Shared lot numbers and Unity™ peer groups with 1 mL fill size
- 3 year shelf life at -10°C to -50°C
- 6 month shelf life at 2–8°C
- 14 day open-vial stability at 2–8°C

Analytes

Hemoglobin (Total)*
Hemoglobin A1C

*Not available in 2 mL fill size



Lyphochek® Diabetes Control

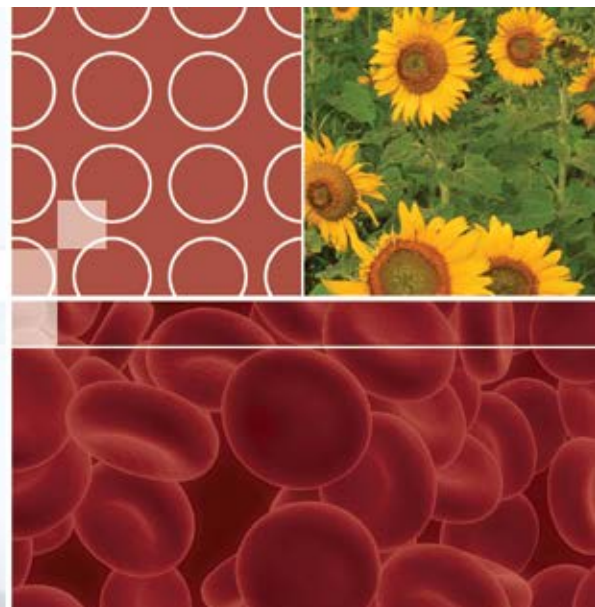
A human whole blood based product intended to monitor the precision of hemoglobin tests procedures used in diabetes monitoring, including Hemoglobins A1, A1C, F and Total Glycated Hemoglobin.

- Human whole blood based control
- 2 significant levels
- Convenient 0.5 mL fill size
- 3 year shelf life at 2–8°C
- 7 day open-vial stability at 2–8°C
- Extensive value assignment listings

Analytes

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

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



Lyphochek® Hemoglobin A1C Linearity Set

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

- Human whole blood based control
- 6 significant levels
- 3 year shelf life at 2–8°C
- 7 day open-vial stability at 2–8°C

Linearity Web™ software tool is available online at QCNet.com for immediate documentation of the testing result.

Analyte

Hemoglobin A1C

Expected Values for Hemoglobin A1C (%NGSP)*

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%

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

Assayed Values Typically Available for Common Analyzers

Bio-Rad Analyzers

- D-10™
- in2it™
- VARIANT™
- VARIANT™ II/TURBO

Other Analyzers

- Beckman Coulter® Synchron® and AU Systems
- Abbott Architect™ Series
- Roche COBAS® and Hitachi
- Siemens ADVIA®, DCA and Dimension® Series
- TOSOH G7 and G8
- Trinity Biotech Series
- Ortho VITROS® Series
- Pointe Scientific

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

Ordering Information

Cat #	Product Name	Quantity
Liquichek™ Diabetes Control*		
171	Level 1	6 x 1 mL
172	Level 2	6 x 1 mL
173	Level 3	6 x 1 mL
172X	Trilevel MiniPak (1 of each level)	3 x 1 mL
291	Level 1	6 x 2 mL
292	Level 2	6 x 2 mL
293	Level 3	6 x 2 mL
292X	Trilevel MiniPak (1 of each level)	3 x 2 mL

Cat #	Product Name	Quantity
Lyphocek® Diabetes Control		
740	Bilevel (3 of each level)	6 x 0.5 mL
740X	Bilevel MiniPak (1 of each level)	2 x 0.5 mL
Lyphocek® Hemoglobin A1C Linearity Set		
12000070	Set (1 of each level)	6 x 0.5 mL

*Not all products may be available in all countries.

Bio-Rad is Dedicated to Advancing QC Solutions Worldwide

Quality Controls

Broad portfolio of independent controls provides an unbiased assessment of methods and system performance.

QC Data Management Solutions

Manage and interpret your QC results using the industry-leading Unity™ Interlaboratory Program and benefit from data generated by users worldwide.

Customer Support

Receive the backing of full-service technical and customer support trained to handle your inquiries in a prompt, knowledgeable manner.

Education

We offer the educational tools and resources to help improve your ability to produce reliable test results.



**Bio-Rad
Laboratories**

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

**Clinical
Diagnostics Group**

Website www.bio-rad.com/qualitycontrol **Australia** 61-2-9914-2800 **Austria** 43-1-877-8901 **Belgium** 32-9-385-5511 **Brazil** +55 (31)3689-6600 **Canada** 1-514-334-4372 **China** 86-21-61698500 **Czech Republic** 420-241-430-532 **Denmark** +45-4452-1000 **Finland** 358-9-804-22-00 **France** 33-1-47-95-60-00 **Germany** +49 (0)89-318-840 **Greece** 30-210-7774396 **Hong Kong** 852-2789-3300 **Hungary** +36-1-459-6100 **India** 1800-180-1224 **Israel** 972-3-9636050 **Italy** +39-02-216091 **Japan** 81-3-6361-7070 **Korea** 82-2-3473-4460 **Mexico** +52 (55)5488-7670 **The Netherlands** +31-318-540666 **New Zealand** 64-9-415-2280 **Norway** +47-23-38-41-30 **Poland** 48-22-3319999 **Portugal** 351-21-472-7700 **Russia** 7-495-721-14-04 **Singapore** 65-6415-3170 **South Africa** 27-11-442-85-08 **Spain** 34-91-590-5200 **Sweden** +46-8-555-127-00 **Switzerland** +41 (0)26-674-55-05/06 **Taiwan** 886-2-2578-7189 **Thailand** 662-651-8311 **United Kingdom** +44 (0)20-8328-2000

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