

Hemoglobin A1c (Ver.2) Assay for Chemistry Analyzers

Introducing the **new** K-ASSAY® HbA1c (Ver.2) assay, a highly accurate, quantitative assay for measuring Hemoglobin A1c in patient whole blood.

Features and Advantages:

- **Direct measurement of HbA1c:** Quantitative latex immunoassay method directly measures HbA1c in the sample. No additional total Hb measurements and no errors associated with additional formula calculations.
- **No dedicated analyzer:** Adaptable to most chemistry analyzer models
- **Low cost:** No expensive column replacements or consumables
- **Superior thermal reagent stability** compared to enzymatic methods
- **Fully automatic method:** high-throughput testing is possible
- **Wide assay range:** 2.5% to 16.5% (NGSP) - wider than HPLC
- **Excellent correlation** to HPLC and enzymatic methods
- NGSP-certified on multiple chemistry analyzers
- CE mark registered, FDA-clearance pending
- Available in **K-ASSAY®** brand kits, unlabeled bottles, and bulk

The K-ASSAY® HbA1c (Ver.2) Assay is the assay you can trust!

CALL US
1-800-526-4925 x111
1-206-575-8068 x111

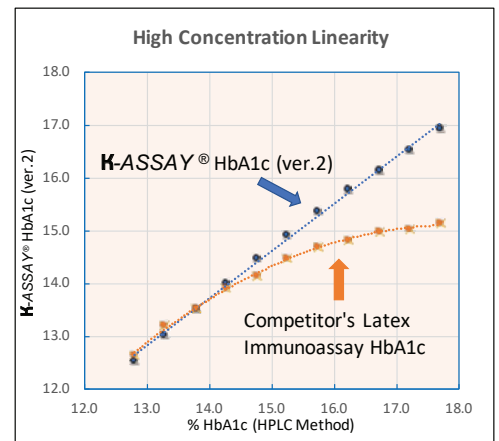
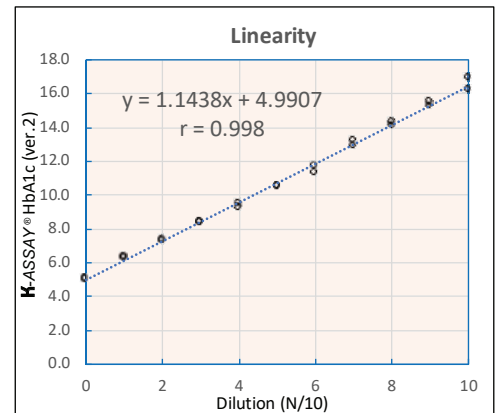
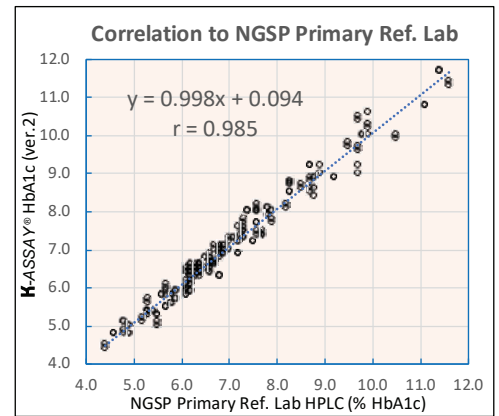
OR EMAIL US
diagnostics@k-assay.com

IVD FDA 510(k) pending
CE registered for EU

KAMIYA BIOMEDICAL COMPANY
www.k-assay.com

Assay Characteristics:

Assay Format	Latex-enhanced immunoturbidimetric assay. 2 reagent system for chemistry analyzers. Direct measurement of HbA1c.	
Sample Material	Whole blood. Acceptable anticoagulants: citric acid, EDTA, lithium heparin	
Calibration	5-point	
Standardization	Primary standard is JCCRM 411 which is IFCC/NGSP certified. Results are traceable to NGSP, IFCC, and DCCT.	
Sample Volume	6.0 µL (may vary by analyzer)	
Expected Values	4.0 – 6.0% (NGSP) 20 – 42 mmol/mol (IFCC)	
Measuring Range	2.5 - 16.5% HbA1c (NGSP) 3.8 - 156.8 mmol/mol (IFCC)	
Precision	<u>Specimen A</u>	<u>Specimen B</u>
	N	20
	Ave.	4.43
	SD	0.03
	CV	0.59%
On-Board Stability	30 days	
Analyzers	Applications available for most chemistry analyzers. Contact us for details.	
Regulatory	FDA 510(k) pending (U.S.) CE Mark (EU) NGSP certified method on multiple chemistry analyzers	



Thermal Stability - severe conditions (37°C storage for 2 weeks)

K-ASSAY® HbA1c (Ver.2) vs. Another Company's Enzymatic HbA1c


Sample	K-ASSAY® HbA1c (Ver.2)				Competitor's Enzymatic HbA1c			
	0 day	3 day	1 week	2 week	0 day	3 day	1 week	2 week
Control 1	100%	100%	100%	100%	100%	100%	65%	58%
Control 2	100%	99%	99%	98%	100%	100%	82%	79%

Product Information:

	Cat. No.	Product Name	Kit Size
REAGENT	KAI-310	HbA1c (Ver.2) Reagent Set	R1: 1 x 30 mL, R2: 1 x 10 mL (liquid)
CALIBRATOR	KAI-311C	HbA1c (Ver.2) Calibrator Set	5 levels x 0.5 mL (lyophilized)
CONTROL	K312C-4M	HbA1c (Ver.2) Control Set	2 levels, 2 x 0.5 mL each level (lyophilized)

Ordering: 800-526-4925 x100
206-575-8068 x100
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Technical Support: 800-526-4925 x111
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