

# HbA1c **neefs**

## The Future of Diabetes Management



**Accuracy. Efficiency. Comfort.**  
**The New Enzymatic Method**  
**for Determination of HbA1c.**

**DiaSys**

Diagnostic Systems

**CHOOSING QUALITY.**

# The Gold Standard of Tomorrow Exceeding Your Expectations Today

The worldwide rapid rise in diabetes is a challenge for treatment as well as for diagnosis and monitoring. Diagnostic technologies providing precise, reliable and quick results are crucial. With HbA1c net FS, DiaSys offers an enzymatic test with high specificity and precision, setting new standards for accuracy.

## Innovative and Easy: A Modern Method for More Efficiency

DiaSys' HbA1c net FS test is based on an enzymatic method that provides a number of advantages in addition to high quality results. It simplifies operations and increases throughput because it requires less steps than other methods.

- This ready-to-use 2-component reagent ensures convenient and easy handling.
- With onboard hemolysis workflow of HbA1c testing will be optimized.
- Excellent precision – exceeding international requirements – guarantees safe patient monitoring.
- High onboard and calibration stability of up to 6 weeks ensures economic reagent usage.
- With the enzymatic HbA1c test, cuvettes do not get contaminated by latex; therefore, less cleaning effort is required, saving costs and time.

### High Specificity for Highly Accurate Results

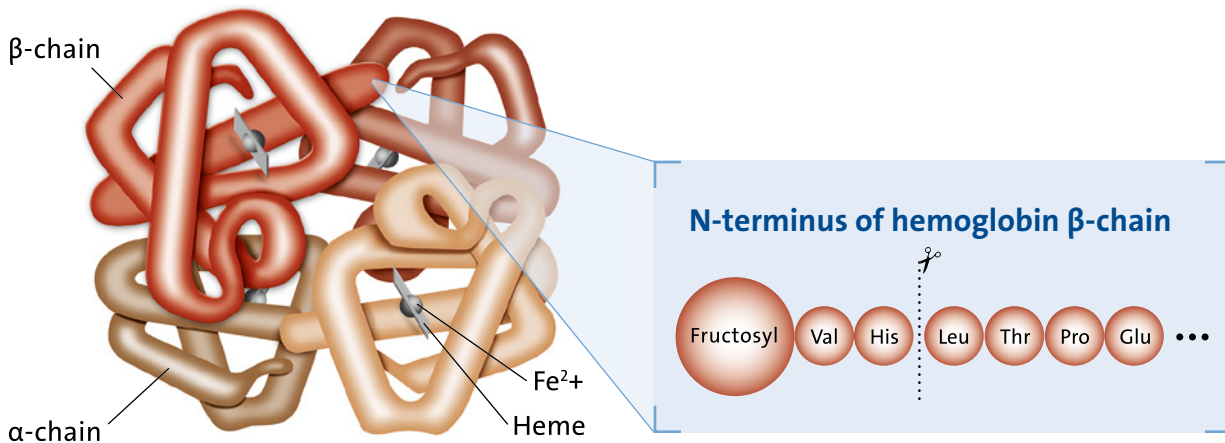
HbA1c net FS mainly owes its accuracy to the high specificity of the method, because it determines fructosyl dipeptides at the N-terminus of the hemoglobin  $\beta$ -chain. The specificity is comparable to the IFCC HbA1c reference method, which determines the N-terminal hexapeptide of the hemoglobin  $\beta$ -chain.

An extensive variety of hemoglobin variants (HbS, HbC, HbD, HbE, HbF etc.), acetylated hemoglobin, carbamylated hemoglobin and other interfering substances such as ascorbate, bilirubin, triglycerides and urea do not show significant interference.



# Clinical Significance of HbA1c Assessment

The HbA1c value correlates with the average blood glucose level over the past 8–12 weeks and is used for long-term glycemic control in diabetic individuals. Besides monitoring, HbA1c is also recommended by international organizations as WHO and ADA for reliable diabetes diagnosis. Clinical studies demonstrate that lowering the HbA1c level may help to delay or prevent the incidence of late diabetic complications.



Hemoglobin A1c (HbA1c) is metabolically produced by reaction of glucose with the N-terminal Valine residue of each  $\beta$ -chain of hemoglobin A and the subsequent formation of a stable ketoamine.

## Test Characteristics

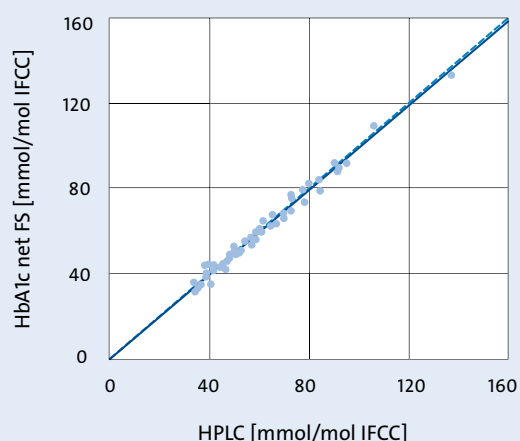
- Liquid-stable, ready-to-use 2-component reagent
- 1-level calibrator (auto-dilution) and 2-level controls
- Onboard and calibration stability of up to 6 weeks
- Wide measuring range from 20 to 150 mmol/mol IFCC (4 – 16% DCCT/NGSP) within a hemoglobin concentration range from 6 to 30 g/dL
- Excellent precision
- Latex free reagent: No contamination of cuvettes
- Standardized against IFCC<sup>1</sup> reference method and traceable according to the DCCT/NGSP<sup>2</sup> network

<sup>1</sup> International Federation of Clinical Chemistry

<sup>2</sup> Diabetes Control and Complications Trial/National Glycohemoglobin Standardization Program



## Excellent Correlation to HPLC\*



n = 100

Passing / Bablok:  
 $y = 0.996x - 0.015$  mmol/mol

r = 0.9931

## No Significant Interferences by Hemoglobin Variants\*

	Hb variant (≤)	Value range HbA1c (% DCCT)	Recovery HbA1c (%)
Hb variant AS	40% S	5.2 – 8.8	94.7
Hb variant AC	36% C	5.0 – 7.4	97.1
Hb variant AD	41% D	5.6 – 7.0	93.9
Hb variant AE	26% E	5.9 – 7.6	99.1
Hb variant AJ	50%	5.2 – 8.4	100.1
Hb variant AG	20% G	6.1 – 6.6	97.4
Hb variant SC	52% S, 44% C	4.5 – 7.0	91.6
Hb variant SE	65% S, 27% E	7.4	95.4
Hb variant EE	94% E	5.1 – 8.9	98.0
Hb variant elevated F	4.6% F	6.5 – 8.1	93.6

## Outstanding Precision Over the Entire Measuring Range\*

Intra-assay n = 20	Mean (mmol/mol)	SD (mmol/mol)	CV (%)	Total n = 20	Mean (mmol/mol)	SD (mmol/mol)	CV (%)
Sample 1	32.7	0.31	0.95	Sample 1	32.1	0.52	1.63
Sample 2	33.2	0.21	0.62	Sample 2	33.6	0.43	1.29
Sample 3	63.7	0.31	0.48	Sample 3	67.6	0.82	1.22

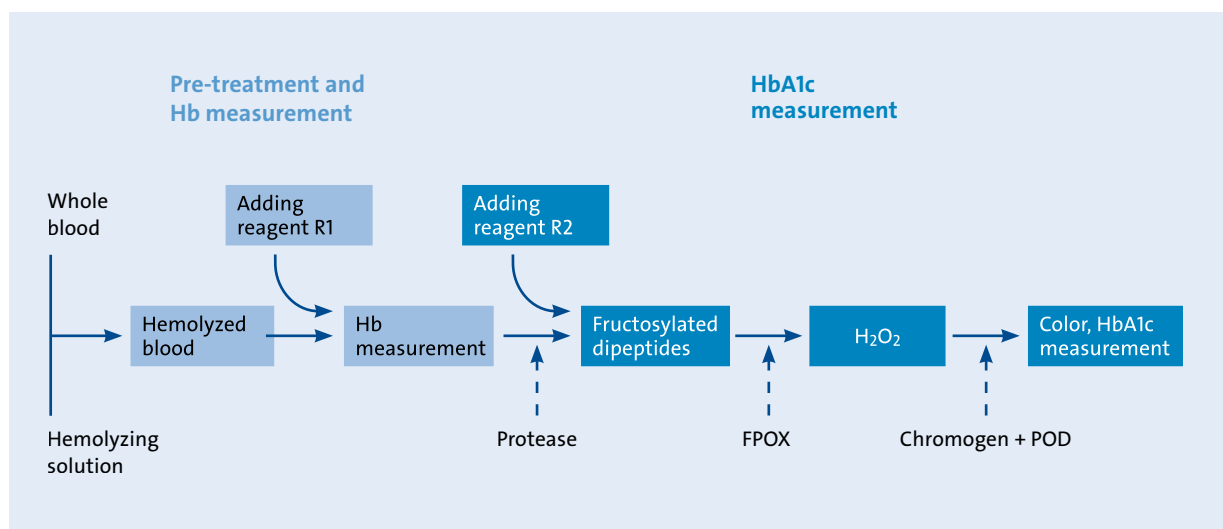
\* Determined on BioMajesty® JCA-BM6010/C

# The Crucial Advantage: Unsurpassed Accuracy

Common HbA1c assays based on HPLC or immunoturbidimetry may be affected by hemoglobinopathies which are frequent in certain patient groups. The extraordinary specificity of DiaSys' enzymatic HbA1c test ensures reliable results, qualifying HbA1c net FS as the new standard in HbA1c determination.

## Specific and Precise: The Enzymatic Principle

The test is based on a colorimetric, enzymatic method. The concentrations of HbA1c and total hemoglobin are determined separately. The instrument automatically performs the calculation of HbA1c ratio in % or mmol/mol from total hemoglobin.



## Consistently Precise Results: The Assay Procedure

### Pre-treatment and hemoglobin measurement

Whole blood samples are lysed with hemolyzing solution. Hemoglobin is released from erythrocytes. The absorbance of hemoglobin is determined at 570 nm after addition of R1 and is proportional to the total hemoglobin concentration in the sample.

### HbA1c measurement

After addition of R2, fructosylated dipeptides from the N-terminal hemoglobin  $\beta$ -chain are released by protease. Hydrogen peroxide ( $H_2O_2$ ) is produced by oxidative cleavage of fructosylated dipeptides by FPOX (fructosyl-peptide oxidase). The generated  $H_2O_2$  is determined colorimetrically by reaction with a chromogen in presence of peroxidase at 660 nm. The absorbance increase is proportional to the HbA1c concentration.

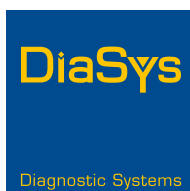
## Leading Technology in Fluid-stable Reagents from DiaSys

- Over 25 years of experience in development and production of clinical chemistry tests
- Premium service supply in technics, applications and after sales
- Quality products made in Germany
- High performance, ready-to-use reagents with minimized interferences, long shelf life and onboard stability as well as traceability to international references
- Perfectly matched reagents, calibrators and controls
- High grade raw materials from traceable origin
- Processes and resources certified according to ISO 13485, fulfilling highest quality standards
- Sustainable processes and products preserve the environment

Handed over by:



Climate neutral print  
(Carbon neutral)  
ID: DE 626-352867  
Printed on FSC certified paper



**DiaSys**  
**Diagnostic Systems GmbH**  
Alte Strasse 9  
65558 Holzheim  
Germany

Phone: +49 6432 9146-0  
Fax: +49 6432 9146-32  
E-Mail: [reagents@diasys.de](mailto:reagents@diasys.de)  
[www.diasys-diagnostics.com](http://www.diasys-diagnostics.com)



**CHOOSING QUALITY.**