Convenient Use

- Only one channel and one reagent position needed
- Direct determination of HbA1c in one measurement
- Liquid-stable reagents in dedicated vials
- Human based, ready-to-use calibrators and controls
- Applicable to a variety of clinical chemistry analyzers

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 on-board stability as well as traceability to international references
- Perfectly matched fluid-stable reagents, calibrators and controls
- High grade raw materials from traceable origin
- Processes and resources certified according to ISO 13485, ISO 9001, fulfilling highest quality standards
- Sustainable processes and products preserve the environment

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CHOOSING QUALITY.

one HbA1c FS

Exceeding Expectations

Direct. Precise. Accurate.

DiaSys
Diagnostic Systems

CHOOSING QUALITY.

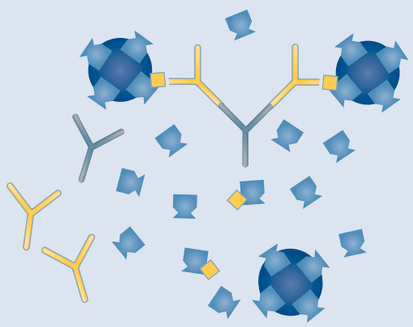
Clinical Relevance

Hemoglobin A1c (HbA1c) is a glycated hemoglobin formed by non-enzymatic reaction of glucose with native hemoglobin. This process runs at a slow but constant rate during life span of erythrocytes. The glycation rate is directly proportional to the glucose level in blood. Hence, the HbA1c value represents the average blood glucose level over the past three months, and is an ideal marker for long-term glycemic control and therapeutic monitoring.

Diagnosis of Diabetes

Since 2011 international organizations as WHO and ADA recommend HbA1c also for the diagnosis of diabetes. Common methodologies as fasting plasma glucose (FPG) and oral glucose tolerance test (oGTT) are associated with numerous drawbacks for diabetes diagnosis. Both methods are time-consuming, inconvenient and expensive. HbA1c determination however, is a fast, convenient, fully automated, flexible and standardized methodology.

Reaction Principle



Total Hb and HbA1c bind with similar affinity to latex particles in R1. The amount of binding is proportional to their relative concentration in blood. Anti-HbA1c antibodies (R2) specifically bind to HbA1c, interact with polyclonal antibodies after addition of R3 and cause agglutination. The measured absorbance is directly proportional to the HbA1c concentration in the sample.

Hemoglobin · HbA1c · Latex particles · anti-HbA1c monoclonal antibody · anti-mouse polyclonal antibody

oneHbA1c FS Exceeds IFCC Precision Requirements

To achieve HbA1c results for reliable diabetes monitoring excellent precision is required. IFCC stated an analytical CV of 3% to delineate a change in patients' HbA1c value of 0.5% and a CV of 2% to delineate a difference of 0.3%. In fact, many other immunoassays do not achieve IFCC precision claims due to multiple measurement steps for hemoglobin and HbA1c. Since each measurement represents a source of error precision is adversely affected.

Immunoinhibition (Competitor)	Hb in g/dL	HbA1c in g/dL	HbA1c calculation in %
Particle-enhanced immunoturbidimetry (DiaSys)	Direct HbA1c determination in % or mmol/mol		

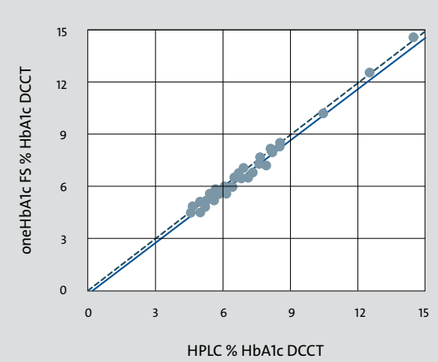
DiaSys' oneHbA1c FS assay **directly** determines HbA1c concentration in a single measurement, thereby exceeding international requirements with an excellent precision of a CV < 2% over the entire measuring range.

Precision

Intra-assay n = 20	Mean (mmol / mol)	SD (mmol / mol)	CV (%)
Sample 1	35.0	0.48	1.37
Sample 2	80.7	1.09	1.36
Sample 3	114	2.04	1.80

Inter-assay n = 20	Mean (mmol / mol)	SD (mmol / mol)	CV (%)
Sample 1	36.5	0.66	1.82
Sample 2	83.3	1.39	1.67
Sample 3	116	1.83	1.58

Method Comparison vs HPLC



n = 109; Passing/Bablok Regression:
Y = 0.968 x + 0.199%; r = 0.995

Test Characteristics of oneHbA1c FS

- Particle-enhanced immunoturbidimetric test
- Measuring range: 15 – 150 mmol/mol (IFCC); in a wide hemoglobin range of 6 – 26 g/dL
- 3- or 2-component use
- Direct HbA1 determination: No extra determination of hemoglobin or calculation of % HbA1c
- Superior precision
- 4-level calibration
- No interference from major hemoglobin variants
- Standardized and certified according to IFCC and NGSP/DCCT