

Tina-quant[®] HbA1c Gen. 3

Turbidimetric inhibition immunoassay (TINIA)

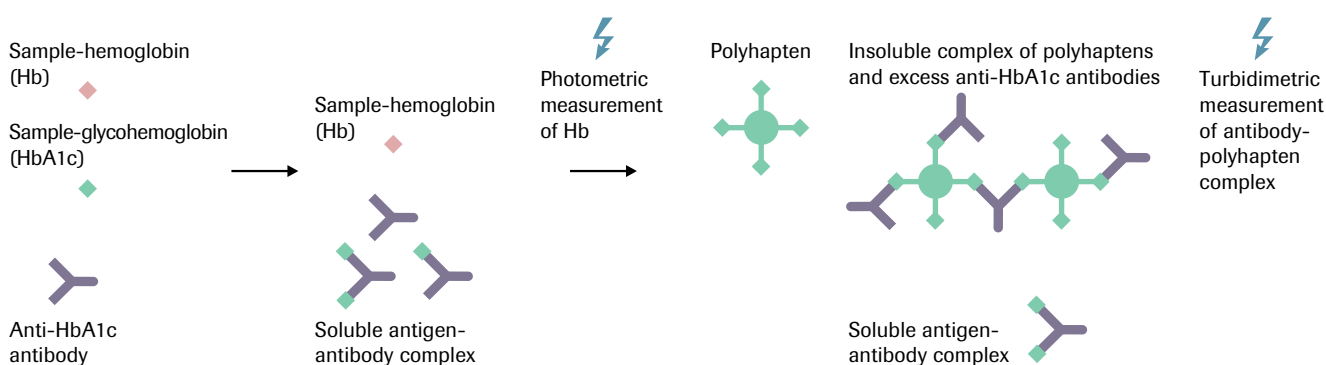
for the in vitro determination of hemoglobin A1c in whole blood or hemolysate

Indication

Hemoglobin, the red blood dye, is a defined chromoprotein located within the erythrocytes with the main function to transport oxygen and carbon dioxide in blood. Amongst the existing subfractions and derivatives of hemoglobin molecules, HbA1c belongs to the glycated hemoglobins, a sub fraction formed by the attachment of various sugars to the Hb molecule. The formation of HbA1c is performed by the non-enzymatic reaction of glucose with the N-terminal amino group of the hemoglobin β -chain. The relative amount of HbA converted to HbA1c increases with the concentration of glucose in the blood and is limited by the erythrocyte lifespan of approximately 100 to 120 days. As a result, HbA1c reflects the blood glucose level during the preceding 2 to 3 months.

The Tina-quant HbA1c Gen. 3 test is intended for the quantitative measurement of HbA1c in hemolysate or whole blood samples to aid monitoring of long-term glycemic control in individuals with diabetes mellitus. In addition, it can be used for diagnosis of diabetes and identifying persons at risk of developing diabetes.

Test principle: competitive turbidimetric inhibition immunoassay (TINIA) for hemolyzed whole blood



Hemolysate preparation

The whole blood sample is hemolyzed using a detergent-containing reagent. The hemolyzing step can either be performed automatically on the instrument or manually using hemolyzing reagent.

Preincubation phase – Photometric measurement of total Hb

The liberated hemoglobin in the hemolyzed sample is converted to a stable derivative which is measured photometrically during the preincubation phase of the immunological reaction. Glycohemoglobin (HbA1c) in the sample reacts with the anti-HbA1c antibody to form soluble antigen-antibody complexes.

Start of turbidimetric reaction – Measurement of HbA1c

The polyhapten in the reagent reacts with excess anti-HbA1c antibodies and form an insoluble antibody-polyhapten complex. This complex can be measured turbidimetrically: the higher the HbA1c concentration, the lower the turbidity.



Life needs answers

Tina-quant® HbA1c Gen. 3 test characteristics

Analyzer compatibility	cobas c 311 analyzer, cobas c 501 module, cobas c 502 module
Reaction time	10 min
Throughput	10 min to first result, subsequently 1 result every 24 seconds
Calibration	Hb: linear; HbA1c: 6-point spline; standardized against IFCC reference method
Sample material	Anticoagulated venous or capillary blood or hemolysate Acceptable anticoagulants: Li-, Na-heparin, K ₂ -EDTA, K ₃ -EDTA, Fluoride/Na ₂ -EDTA, and Fluoride/K-oxalate
Sample volume	2 µL (whole blood)
Intermediate precision	Whole blood application: 2.0 % [5.6% HbA1c] Hemolysate application: 1.6 % [5.6% HbA1c] Whole blood application: 1.4 % [8.0% HbA1c] Hemolysate application: 1.9 % [8.2% HbA1c]
Repeatability	Whole blood application: 1.6% [5.6% HbA1c] Hemolysate application: 1.2% [5.6% HbA1c] Whole blood application: 1.0% [8.0% HbA1c] Hemolysate application: 1.0% [8.2% HbA1c]
Expected values	According to IFCC: 29 – 42 mmol/mol HbA1c According to DCCT/NGSP: 4.8 – 5.9 % HbA1c
Measuring range	Hemoglobin: 2.48 – 24.8 mmol/L (4 – 40 g/dL); HbA1c: typically 0.186 – 1.61 mmol/L (0.3 – 2.6 g/dL) Correct and reproducible recovery of fast settling whole blood samples is ensured by 70% immersion depth into the primary tube and the high dynamic test range for Hb and HbA1c.
Analytical specificity (whole blood and hemolysate)	Hb derivatives: Labile HbA1c (pre-HbA1c), acetylated Hb, and carbamylated Hb do not affect the assay results Hb variants: Specimens containing high amounts of HbF (> 10%) may yield lower than expected HbA1c results The assay is not affected by HbAS, HbAC, HbAE and HbAD traits
On-board stability	28 days

Twin Test technology

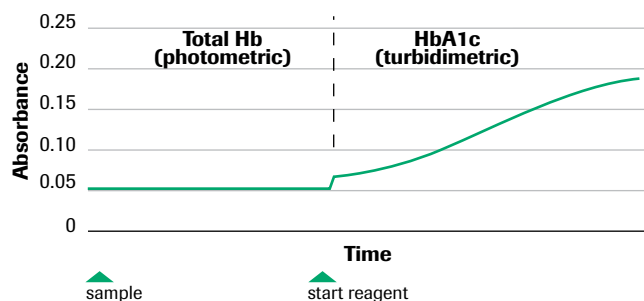
The Twin Test reaction mode allows sequential measurement of the Hb and HbA1c in a single cuvette. Thus only one sample pipetting step is required with the positive effect of minimizing errors, improved precision and faster sample turnaround time. The final result is expressed as mmol/mol HbA1c according to IFCC or % HbA1c according to DCCT/NGSP and is calculated from the HbA1c/Hb ratio as follows:

$$\text{IFCC: HbA1c (mmol/mol)} = (\text{HbA1c/Hb}) \times 1,000$$

$$\text{NGSP/DCCT: HbA1c (\%)} = (\text{HbA1c/Hb}) \times 91.5 + 2.15$$

Result interpretation

HbA1c levels above the established range for expected values are an indication of hyperglycemia during the preceding 2 to 3 months or longer. Diabetes patients with HbA1c levels below 53 mmol/mol HbA1c (IFCC) or 7% HbA1c (DCCT/ NGSP) meet the goal of the American Diabetes Association. HbA1c levels below the established reference range may indicate the presence of Hb variants, or shortened lifetime of erythrocytes. Stand-alone HbA1c levels greater than 48 mmol/mol (IFCC) or 6.5% (DCCT) meet the ADA criteria for the diagnosis of diabetes.



Order information

Tina-quant® Hemoglobin A1c Gen. 3	150 tests	05336163 190
C.f.a.s. HbA1c	3 x 2 mL	04528417 190
HbA1c Control P	4 x 0.5 mL	20764841 322
HbA1c Control N	4 x 0.5 mL	20764833 322
PreciControl HbA1c norm	4 x 1 mL	05479207 190
PreciControl HbA1c path	4 x 1 mL	05912504 190
Hemolyzing Reagent Gen. 2	51 mL	04528182 190
HbA1c Hemolyzing Reagent for Tina-quant® HbA1c	1,000 mL	11488457 122 for Hemolysate Application only

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