REMOTE SAMPLING FOR GLYCATED HEMOGLOBIN

DIABETES TESTING – HBA1C

With Capitainer

Capitainer®

HbA1c as a Biomarker in Diabetes

Definition and Function

- HbA1c measures glucose bound to hemoglobin, reflecting average blood sugar over 2-3 months.
- HbA1c helps diagnose diabetes and monitor treatment effectiveness over time.
- According to the American Diabetes Association (ADA) Standards of Care 2026, diabetes is diagnosed at: HbA1c ≥ 6.5%
- High HbA1c levels increase risk of microvascular and macrovascular diabetes complications.

HbA1c can be expressed in two units

Percentage (%)

Traditional unit used in the US and many other countries
Based on the DCCT/NGSP standard
Example: 6.5%

Millimoles per mole (mmol/mol)

International standardized unit (IFCC)
Reports the amount of glycated hemoglobin (HbA1c) per 1 mole of hemoglobin
Example: 48 mmol/mol

6.5% = 48 mmol/mol

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CGM vs HbA1c – Understanding the Difference

CGM

CGM (Continuous Glucose Monitoring): Provides real-time glucose readings every few minutes, showing daily patterns, spikes, and variability.

CGM helps identify immediate risks such as hypoglycemia and post-meal hyperglycemia, enabling rapid adjustments.

CGM exists as a home-use system, allowing patients to measure glucose continuously without laboratory visits.

HbA1c

HbA1c: Reflects average blood glucose over the past 2–3 months by measuring glycated hemoglobin.

HbA1c must be analyzed in a certified laboratory and does not capture short-term fluctuations.

Together, CGM and HbA1c give a comprehensive view: real-time control + long-term metabolic status.

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Capitainer enables HbA1c sampling at home

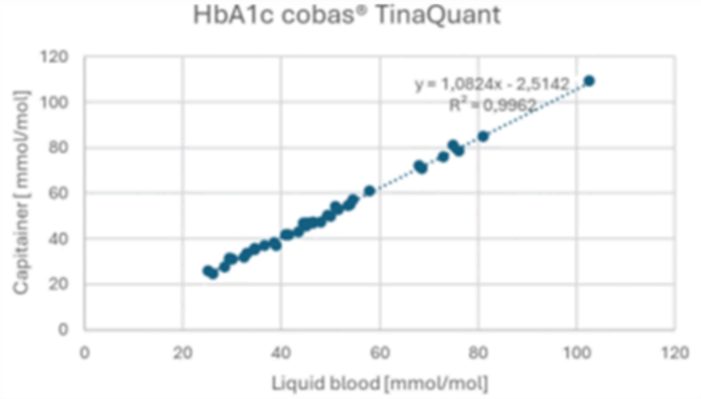
→ without compromising analytical performance

HbA1c from volumetric dried blood samples with Capitainer® shows strong agreement with liquid blood using standard analyzers.

External evaluation confirms high usability and strong ratings from patients and lab staff.

Samples works well with multiple platforms.

Excellent agreement between liquid samples and Capitainer samples on the Roche Tina-quant HbA1c test.



Correlation of venous blood samples analyzed from EDTA tubes versus as eluate one day post application to Capitainer®B10. The eluates were analyzed with the hemolysate application and the liquid blood with the whole blood application. On Roche cobas© TinaQuant assay 6.5% HbA1c ≈ 48 mmol/mol

Mean value HbA1c (mmol/mol) / [%]	CV% (90% CI)	n*
36,2 / [5,46%]	1,3 (1,0-2,1)	11
46,0 / [6,36%]	0,8 (0,6-0,9)	39
69,6 / [8,52%]	1,0 (0,7-1,7)	8

Repeatability results based on a cohort of lay persons performing self-sampling with Capitainer®B10 for HbA1c measurement. CV% calculated based on the difference between sample disc one and two in the Capitainer card, representing two individual blood drops.

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