

Sampling at home for HbA1c monitoring in diabetes

The *Capitainer*® sampling solution enables accurate and precise at-home sampling of blood for postal shipment to the central laboratory

✓ At home blood collection

> 95% successful samples with first-time users of *Capitainer*®B demonstrated in diagnostic settings

✓ Accurate and precise

HbA1c results on par with liquid samples when analysed on routine clinical chemistry platform

✓ Ship by regular post

Shipment of qDBS samples by regular post removes the need for cold chain transport and allows postage in regular postal envelope

✓ Stability of dried format

Excellent stability at room temperature. HbA1c in qDBS remains stable after 4 weeks, which is longer than liquid samples



qDBS - a solution for the central lab

Capitainer® cards are developed with quantitative Dried Blood Spot (qDBS) technology for at-home sampling followed by analysis at the central lab. A successful sampling indicator, metered sample volume with superb accuracy and precision, pre-cut DBS sample discs, sample protection and lab automation solutions together provide an ideal solution for at-home sampling for HbA1c testing.

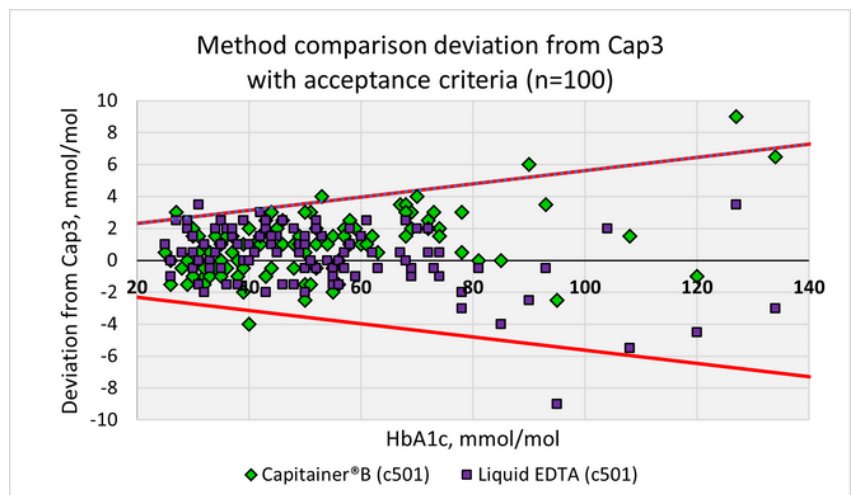
Tina-quant Hemoglobin A1c Gen.3 with Capitainer®B

Researchers at Uppsala University Hospital Sweden developed a pre-analytical protocol to create a haemolysate from qDBS samples for use on the standard cobas® 6000 analyzer (Roche) comparing the results with liquid samples on cobas® and CAPILLARYS 3 TERA. Sample reconstitution was performed with PBS and kit reagents only. The process is performed directly from the pre-cut sample discs after transfer from the card to a sample well/tube.

Analytical performance specifications using qDBS cards compared to standard laboratory methods showed an agreement up to 75 mmol/mol.

The Swedish Medicines Agency's treatment recommendation for glucose control in type 2 diabetes specifies a target value of 42–52 mmol/mol. Importantly, all samples in this interval were inside the national accuracy goal for HbA1c for Hospital laboratory equipment in Sweden.

Finally, the study shows that qDBS samples can be stored at room temperature for a month without any decrease in HbA1c values.



Method comparison using cobas 6000, with liquid EDTA and qDBS samples, to assigned values from CAPILLARYS 3 TERA, in mmol/mol. Based on data kindly provided by Rollborn et al.

Pre-analytical protocol for Roche Tina-quant HbA1c (A1C-3 #05336163190)

- Place one Capitainer®B sample disc in a 5 mL tube
- Add 100µL PBS (+4°C or RT)
- Incubate for 30 minutes at 300rpm on an orbital shaker at RT.
- Add 900µL Hemolysing Reagent for Tina-quant HbA1c (#11488457122)
- Incubate for 30 minutes at 300rpm on an orbital shaker at RT.
- Use the eluate on the Roche Tina-quant hemolysate application*.

*With this application, all samples need to be haemolysed outside of the cobas instrument prior to analysis. The lysis step in the above protocol is integrated in the elution step from Capitainer®B.

Reference:

Rollborn N, Larsson A, Kultima K. Analysis of HbA1c using microfluidic card (Capitainer qDBS card) as a pre-step before determination of the HbA1c value with an immunological method, Scandinavian Journal of Clinical and Laboratory Investigation, 2024.

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