

# HbA1c quantification in qDBS samples using cobas and Alinity fulfill analytical performance targets set for Sweden

## Background

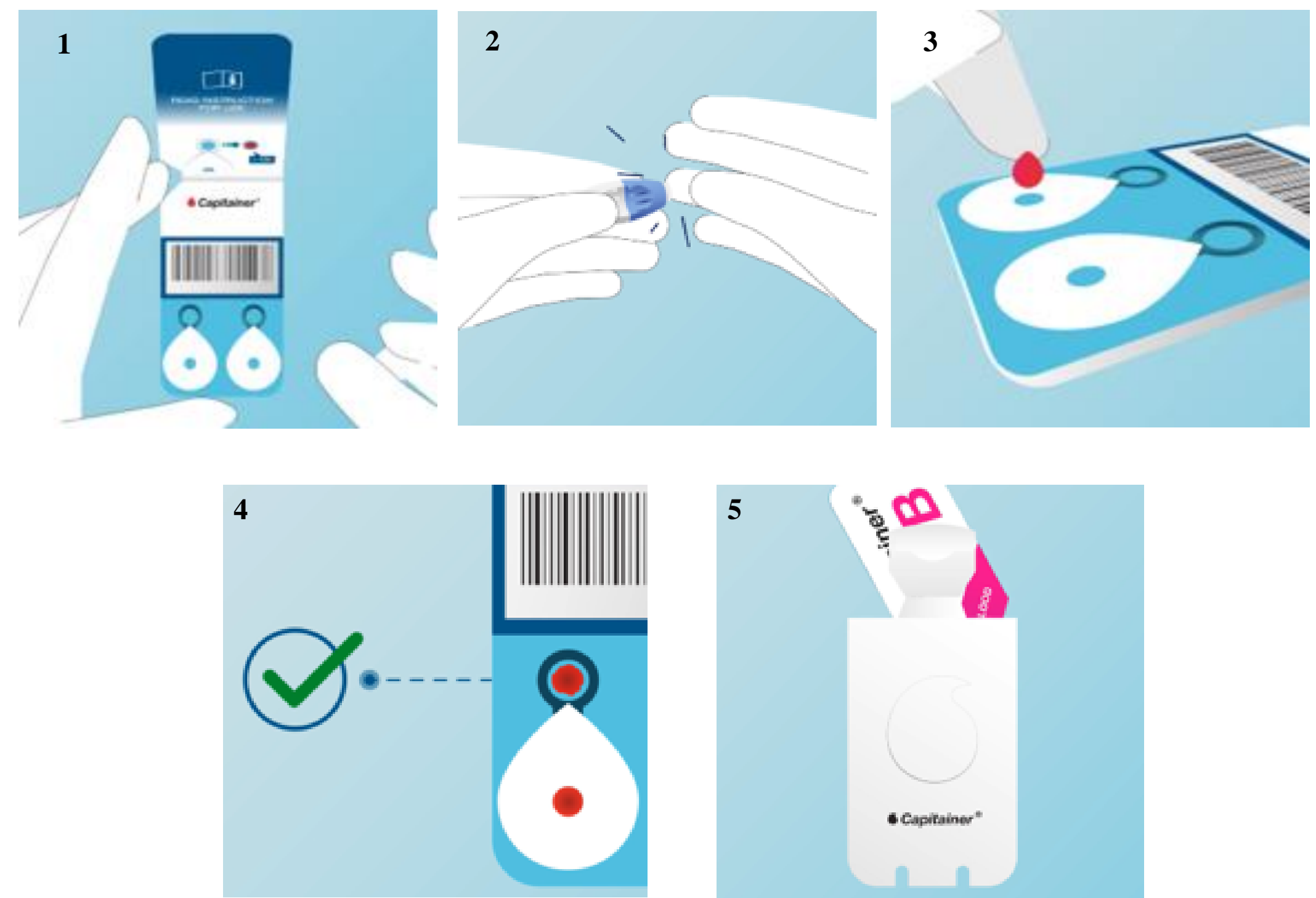
As the Swedish healthcare system continues to adopt a patient-centred care approach, it aims to implement routine testing outside of the hospital setting whenever possible. In addition to increasing patient convenience, this will also reduce the staffing pressure on the healthcare system, so that it can provide care for the 40% of Sweden's population who live with one or more chronic diseases. Self-sampling solutions that can be used by patients at home, and then followed up in hospital laboratories with validated instruments, knowledge and quality control are preferable to ensure reliable results. In addition, test results obtained in the hospital setting can be directly added to patient records. For individuals with diabetes, home sampling to monitor HbA1c levels could make everyday life easier.

## Aim

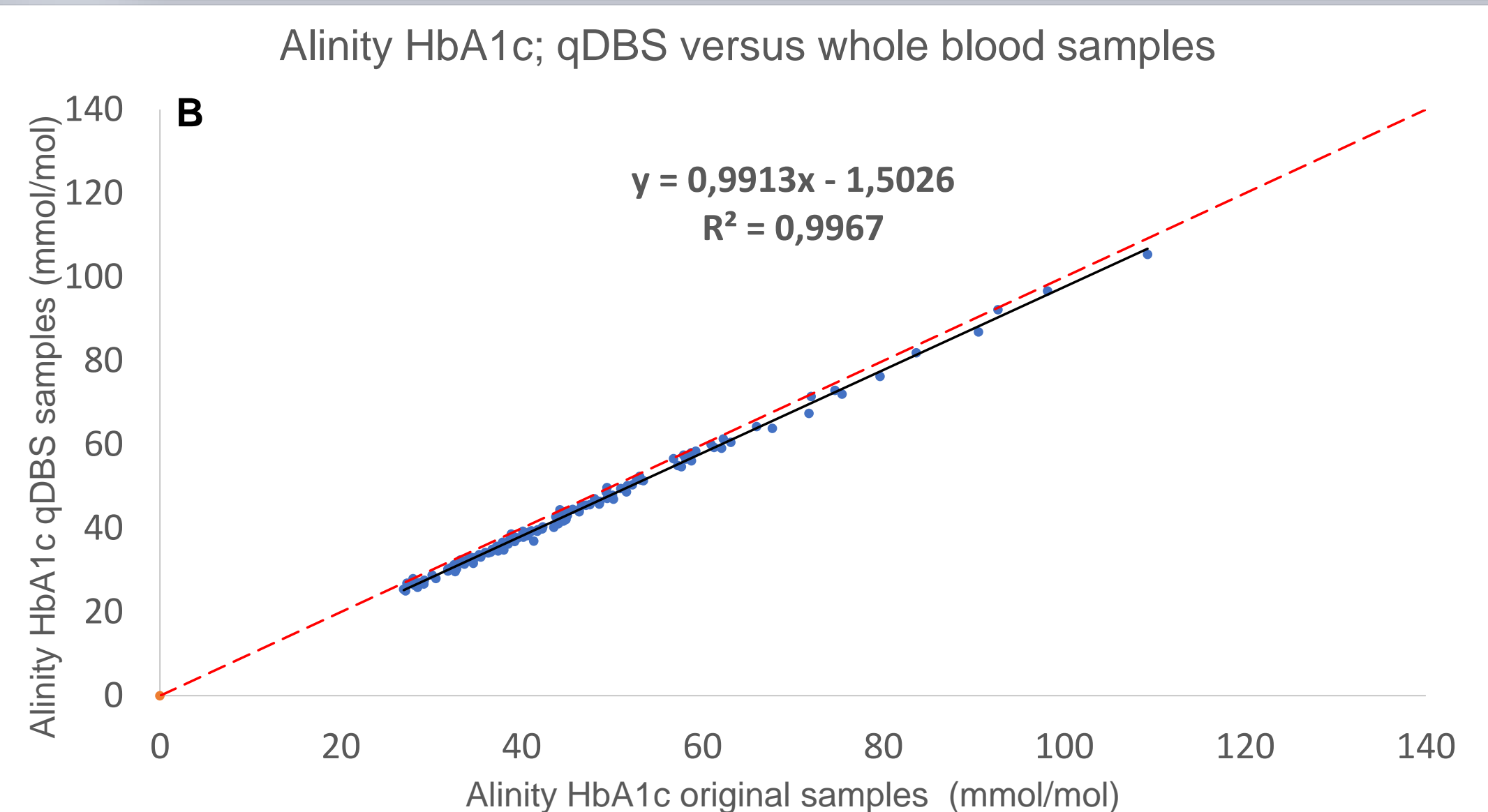
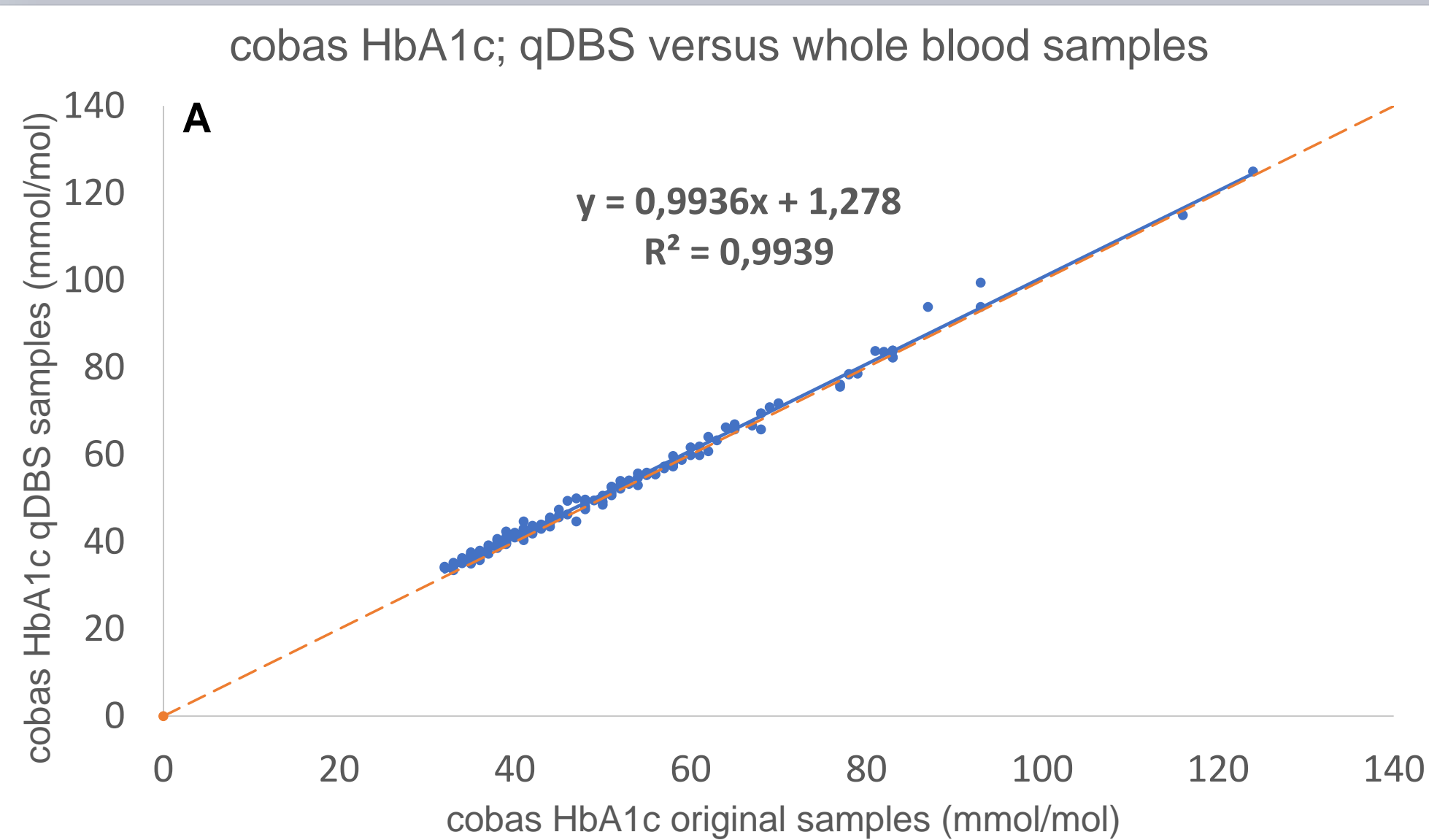
The aim of this study was to evaluate the analytical performance of HbA1c testing on cobas c503 (Roche) and Alinity c (Abbott), using qDBS samples collected with the *Capitainer®B10* self-sampling device. *Capitainer®B10* allows safe and user-friendly capillary blood sampling conducted by the individual at own home. The device is developed with qDBS technology and each device contains two sample wells designed to deliver exactly 10 µL of whole blood through a microfluidic channel on a removable filter disc present in the device.

## Method

We determined HbA1c levels in dried blood spots by applying whole blood aliquots to *Capitainer®B10*. We tested a total of 269 routinely collected clinical samples for HbA1c testing, of which 140 has been collected for the cobas workflow and 129 were collected for the Alinity workflow. To each sample well on a *Capitainer®B10* card, 25 µL of EDTA blood was pipetted. Exactly 10 µL of this was automatically delivered to a filter disc through a microfluidic channel within the home sampling card. The cards were dried overnight before elution was performed with PBS followed by the assay method's hemolysis buffer. The eluates were then used to measure HbA1c on cobas c503 (immunological method) and Alinity c (enzymatic method).



**Figure 1.** *Capitainer®B10* is a next-generation quantitative dried blood spot (qDBS) microsampling card that collects an exact volume of 10 µL of capillary blood. The images depict the five simple steps in the self-sampling procedure. 1. Open and unfold the *Capitainer®B10* card, 2. Prick the finger with the attached lancet, 3. Place a hanging drop of blood per microfluidic channel on the card, 4. Check that the test was successful using the inbuilt visual indicator, 5. Send the card by post to the laboratory in a prepaid envelope.



**Figure 2.** Comparison between qDBS samples and regular whole blood samples (original samples) for HbA1c quantification on cobas (Roche), 140 samples (Figure A) and Alinity (Abbott), 129 samples (Figure B). The results show very good agreement between the sample materials when analysis is performed on these instruments, which proves the possibility of using *Capitainer®* self-sampling cards for monitoring HbA1c with high analytical quality.

## Result

The analytical performance of HbA1c testing on both analytical platforms was satisfactory, with intra-assay and total imprecision meeting the Swedish quality targets with a total imprecision score of <3.0%.

## Discussion/conclusion

The study shows that qDBS sampling with *Capitainer®B10* for HbA1c testing can be performed with equally good results as whole blood samples. From a patient-centred perspective, qDBS sampling for HbA1c testing can make life easier for individuals with diabetes who find it inconvenient and time-consuming to attend the hospital for regular routine venous sampling, as well as for those living far out in rural areas. For these individuals, self-sampling with *Capitainer®B10* in the home environment offers a clear improvement on current approaches.



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