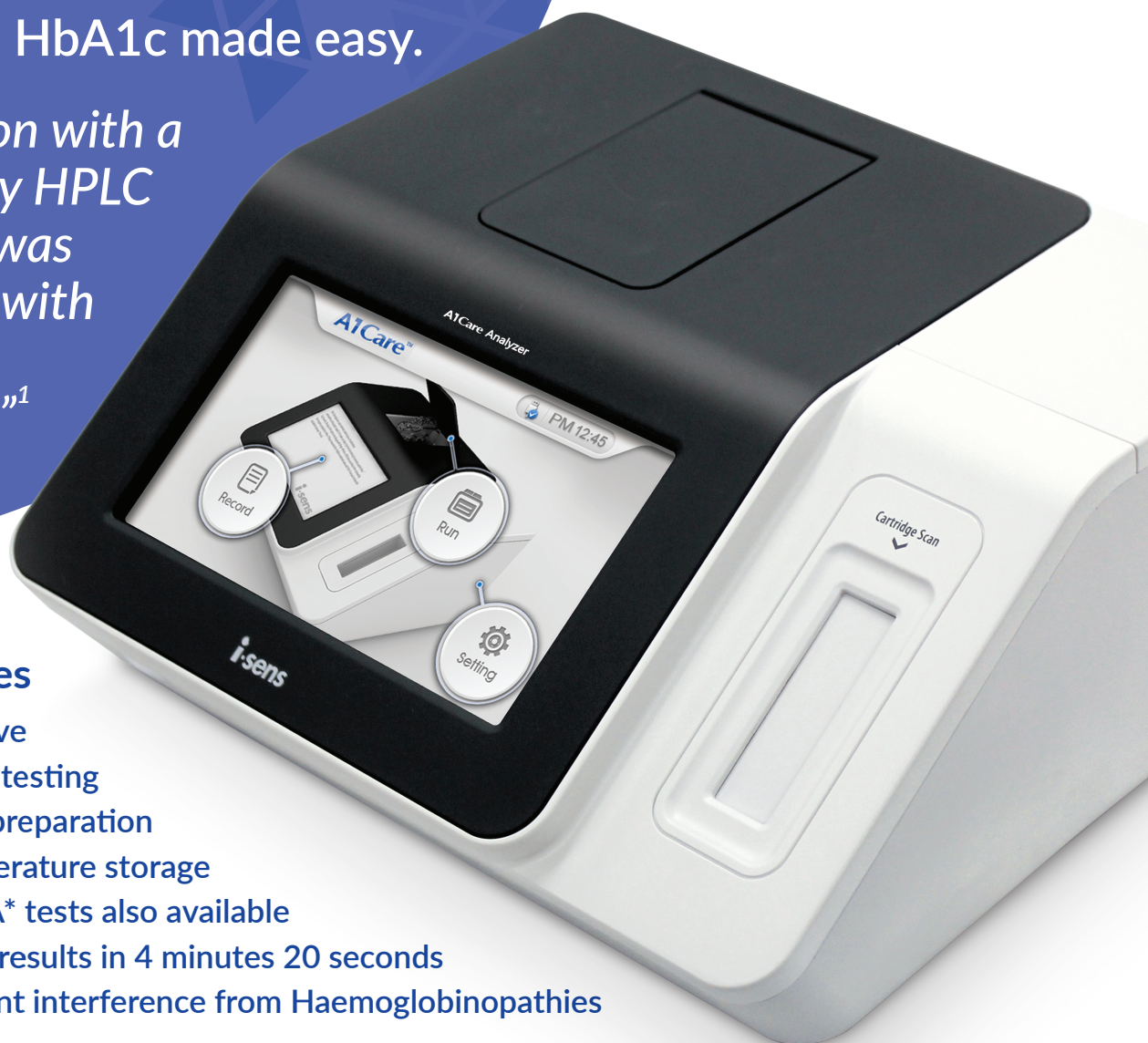


A1Care™

HbA1c Analyser

Accurate HbA1c made easy.

*"Correlation with a laboratory HPLC analyser was excellent with little bias in results."*¹

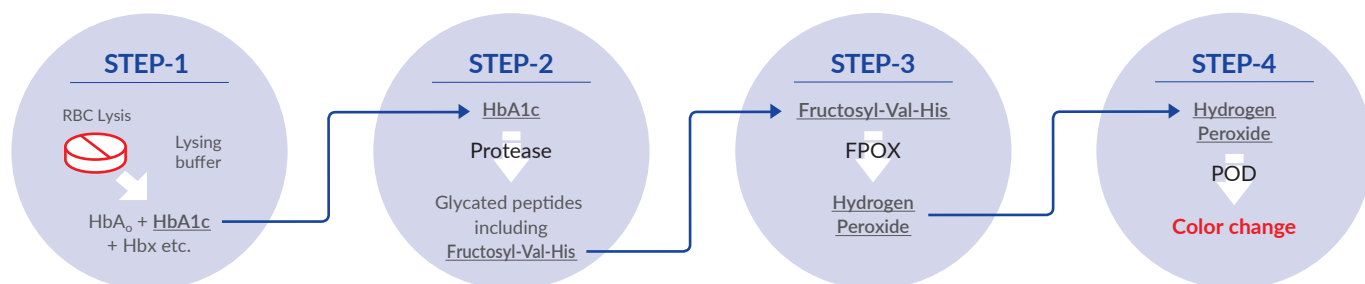


Key features

- ▶ Cost effective
- ▶ Simple, fast testing
- ▶ No sample preparation
- ▶ Room temperature storage
- ▶ ACR and GA* tests also available
- ▶ HbA1c test results in 4 minutes 20 seconds
- ▶ No significant interference from Haemoglobinopathies

First POCT Enzymatic HbA1c Assay in the World

A1Care's IFCC & NGSP certified enzymatic HbA1c assay provides unique performance advantages over conventional immunoassay, boronate affinity and chromatography methods



PRODUCT PERFORMANCE

The A1Care™ analyser, manufactured by i-SENS, is a small, CE marked, whole blood, point of care HbA1c analyser. The device is also NGSP and IFCC certified.

An independent study was performed by the Diabetes Research Group at Swansea University to:

- ▶ Compare the performance of the A1Care POCT HbA1c analyser with a reference HPLC laboratory method (Tosoh GX).
- ▶ Compare whole blood venous and capillary HbA1c concentrations measured using the A1Care POCT HbA1c analyser.

Whole blood venous EDTA samples (n=100) from subjects across a wide glycaemic range were assayed using the Tosoh GX HPLC analyser as the laboratory reference method and the A1Care HbA1c POC analyser (i-SENS). Two HbA1c POC analysers were used, and all 100 samples were measured on each analyser.

Figure 1 shows the comparison of 100 EDTA samples measured on two A1Care analysers and the Tosoh GX HPLC analyser.

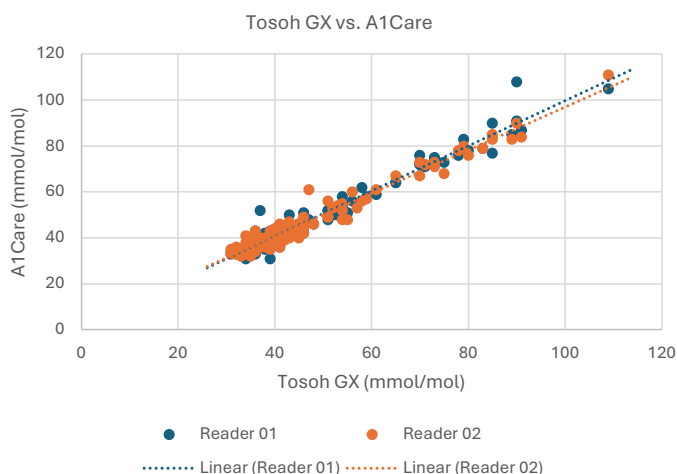


Fig. 1: Comparison of Tosoh GX vs. A1Care Analysers 1 and 2

The bias (\pm SD) of the individual A1Care analysers compared to the Tosoh GX reference method was 0.54 (3.63) and 0.14 (3.28) mmol/mol for A1Care analysers 1 and 2, respectively.

In addition, in 30 subjects, a 4ml venous blood (EDTA) sample was taken. These samples were measured using the A1Care analyser and a laboratory analyser (Tosoh GX). At the same time, a finger prick sample was also taken and measured on the A1Care analyser. Comparison of results are shown in Fig. 2.

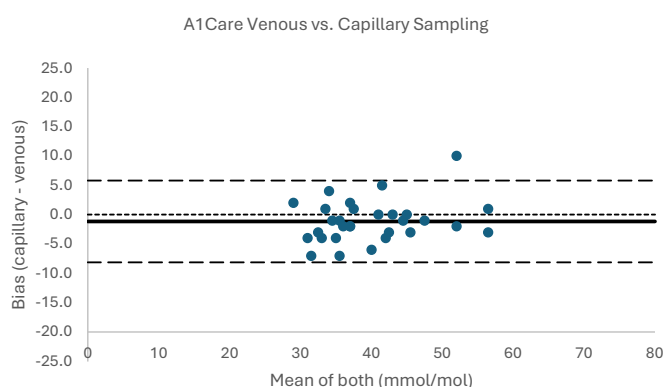


Fig. 2: Comparison of venous and capillary sampling of the A1Care analyser

Summary

The analysis shows that the A1Care analyser correlation with a laboratory HPLC analyser was excellent with little bias in results. Results showed that there was no difference in results obtained from venous or capillary samples, and venous samples could be stored for up to one week at room temperature without affecting the results. If stored at 4°C sample results were not affected for up to 14 days.

