CAPILLARY BLOOD SAMPLING KIT FOR HBA1C VERSUS VENOUS PUNCTURE ON CAPILLARYS 2 FLEX PERCING

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ABSTRACT

BACKGROUND AIM

Capillary blood sample collected from finger prick presents many advantages over venous puncture: low volume, less invasive for the patient, better patient’s compliance with monitoring recommendations. The present study was designed to compare the measurement of capillary blood hemoglobin A1c levels with venous blood hemoglobin A1c levels using the Capillaries 2 Flex Percing system (C2FP) (Sebia, France) on a large range of HbA1c values and with different storage conditions.

METHODS

Data was collected from samples of 60 volunteer patients and covering a wide range of HbA1c values (4.7% – 14% NGSP). Both venous and capillary blood samples obtained simultaneously from each subject were tested using the C2FP system. After an initial assessment of venous HbA1c at 30°C and capillary and venous samples were stored at room temperature (30°C) and 4°C respectively, away from light, and re-analyzed together at J5 on the same C2FP system in duplicates. To test stability, 5 different samples were simultaneously taken from venous puncture and finger prick, and stored at different °C: 20°C, 8 days; 26°C, 8 days; Room T°, 8 days; 30°C, 3 days. Respective duplicates values were compared to capillary and venous reference result at J5.

RESULTS

The equation of Y values using mmol/mol IPCC units (Y y = 0.9396 + 0.046; R2=0.9971) or %NGSP units (Y = 0.9388 + 0.046; R2=0.9973) showed a good correlation. Bland Altman plots showed a 0.4mmol/mol IPCC and 0% NGSP mean differences. All values were included in the recommended ±6% bias on the bias plot. Room T° storage during 3 days resulted in a small additional peak of degradation but HbA1c value was still accurate. Reproducibility was assessed using the mean biases between the NGSP duplicates and showed this same 0% for venous and capillary results. Stability study on low, medium and high HbA1c levels showed that ideal conservation was 4°C. Room T° and 20°C gave rise to degradation without alteration of HbA1c result. After 8 days at 30°C only one sample result was slightly out of uncertainty of measurement.

CONCLUSION

The Sebia capillary sampling kit offers full automation and full positive ID. We have demonstrated a good correlation with venous sample results. Storage study showed a sufficient robustness for usual sample delivery to central laboratory.

Diabetic children are used to self check with finger prick and receive insulin. One should think they are over used to blood puncture ... Kids, parents and above all, adolescents dislike to come for venous sampling at their diabetology control visit

Strong demand from pediatric consultations to keep the kids and adolescents coming to diabetes clinic. Venous puncture is just the additional puncture they don’t want in their life. It’s part of the good therapeutic observance we need.

Now Young diabetic adults ask to keep this sampling method for them in their routine control.

Correlation capillary blood vs venous blood (%NGSP)

Bland-Altman plot of differences (%NGSP)

Stability : qualitative profiles comparison

Stability : quantitative comparison %

Reproducibility

<table>
<thead>
<tr>
<th>Venous blood (n=60)</th>
<th>Capillary blood (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean absolute difference</td>
<td>0.0%</td>
</tr>
<tr>
<td>Min absolute difference</td>
<td>-0.3%</td>
</tr>
<tr>
<td>Max absolute difference</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

All venous blood sample and capillary blood samples were run in duplicate. Reproducibility assessed on the absolute difference between 2 replications.

Precision on the capillary blood samples appears to be as good as with venous blood samples.

Sample heterozygous A/S

<table>
<thead>
<tr>
<th>Venous blood</th>
<th>Capillary blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis n°1</td>
<td>Analysis n°1</td>
</tr>
<tr>
<td>Analysis n°2</td>
<td>Analysis n°2</td>
</tr>
<tr>
<td>4.9%</td>
<td>5.1%</td>
</tr>
<tr>
<td>5.0%</td>
<td>5.0%</td>
</tr>
</tbody>
</table>

Mean of differences ± 0.5%