MQ 2019-4 Comparison of glucometers using whole blood

Note:
The instrument comparison is structured as a survey. This is a sample test, not a complete evaluation.

Introduction
Glucose self-testing devices are intended for patient’s analysis of fresh capillary blood. Some of the devices are also suitable for the analysis of anticoagulated venous whole blood. Hemocue, StatStrip and AccuChek Inform 2 are intended exclusively for professional use.

As part of our inter-laboratory comparisons (surveys) for external quality control, plasma-based control samples (sample K1: Clinical Chemistry) are sent to our participating laboratories. Because of the occurring matrix effects, an individual target value for each glucose meter must be determined. Unfortunately, these target values do not compare well, since the properties of plasma are different than those of fresh capillary blood.

To nevertheless provide our participants with a target value that can be compared between instruments, we conduct additional comparative measurements with fresh blood in our laboratory.

Approach
The manufacturers provide equipment and test strips. All devices were tested using the manufacturer’s control solutions and passed.
We used heparin venous blood from the same donor for both samples. Sample A was used as is. In sample B, the glucose concentration was increased by addition of a 1 mol/l glucose solution. Both samples were taken approx. one hour prior to the measurements.

Additional readings
The oxygen content of both samples was monitored using iSTAT from Axonlab. The glucose was measured with the iSTAT, using a Glucoseoxidase (GOD) electrode. For measuring the samples with Cobas 8000, we used the plasma after centrifugation of the sample. The Cobas 8000 Glucose-reagent works according to the hexokinase method. The measurements with iSTAT and Cobas 8000 are traceable to NIST 965 standard solution for glucose in plasma.

<table>
<thead>
<tr>
<th></th>
<th>Sample A</th>
<th>Sample B</th>
</tr>
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<tbody>
<tr>
<td>Glucose, Cobas 8000</td>
<td>4.80 mmol/L</td>
<td>8.80 mmol/L</td>
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<tr>
<td>Glucose, iSTAT</td>
<td>4.67 mmol/L</td>
<td>8.60 mmol/L</td>
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<tr>
<td>Group 1</td>
<td>4.78 mmol/L</td>
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<tr>
<td>Mean</td>
<td>4.75 mmol/L</td>
<td>8.71 mmol/L</td>
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<tr>
<td>PO₂, iSTAT (normal: 11.1-14.4 kPa)</td>
<td>5.10 kPa</td>
<td>5.33 kPa</td>
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</table>

Control samples
The manufacturer's control solutions were measured ten times.

MQ survey specimen K1 (2019-4)
The plasma sample for the current survey was measured with instruments that were available to participants of the survey.

Manufacturer information
Not all devices are certified for analysis of venous blood. Please consult the list at the end of this report.

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**Precision**  
To stay within the QUALAB tolerance range of 10%, the % CV for glucose concentration may not exceed 5%, and is ideally lower than 3.3%.

17 from 19 devices achieved CV values below 5% with both samples.  
13 devices achieved the 3.3% limit with specimen A, and 16 units with specimen B.

You can find the expected CV% - values according to the manufacturers in Table 6, in the columns "precision". Sample A corresponds to the concentration 2, Sample B corresponds to the concentration 4. With Sample A, 8 from 19 instruments reached the specifications of the manufacturer where as in Sample B, 11 from 19 instruments reached the specifications.

**Accuracy**  
To check the accuracy we used the following criteria:

- 3 measurements with iSTAT (GOx Elektrode)  
- 3 measurements with Roche Cobas 8000 (Hexokinase)  
- Mean of all devices where measuring venous blood is part of their intended use (group 1).

We distinguish two groups of instruments:
- Group 1 is approved for the analysis of venous blood according to the manufacturer's specifications  
- Group 2 may be used with fresh capillary blood only.

Ideal deviations are <4%.

In the group 1, for the lower concentration 6 out of 11 instruments and for the higher concentration 5 out of 11 instruments achieved a deviation of less than 4%.
In Group 2, we did not assess the accuracy of measurements with venous blood.

In addition, we compared the devices using fresh capillary blood. Green marked are the deviations (Dev%) of the measured values <10% of the mean value. With reference to ISO15197:2013, all devices were within the limits.

<table>
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<td>4.9</td>
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</table>

*Table 1: Comparison of glucometers of group 2 with fresh capillary blood*

**Total error**
Results within the QUALAB tolerance of ± 10% around the target value were highlighted in green.

For blood glucose monitoring systems that are used by patients themselves, the ISO 15197:2013 standard applies as of May 2013. New is that 95% of the test results must be within the ± 15% range. For glucose concentrations below <5.55 mmol/l an absolute tolerance of ± 0.83 mmol/l must be observed.

In Specimen A, this tolerance was 3.92 to 5.58 mmol/l, in Specimen B the tolerance was 7.40 to 10.02 mmol/l. All devices of Group 1 conformed to the ISO 15197:2013 requirements.

With the measured values of Group 2 with fresh capillary blood, 2 devices meet the Qualab-requirements and all the ISO-requirements.

Zürich, 27.12.2019

Dr. R. Fried
### Table 1: Sample A wholeblood, normal, postprandial.

All Glucose values are in mmol/l, all instruments are plasma calibrated. Values of group 1 within the Qualab-tolerance of 10% are green colored.

**Target value:** 4.75 mmol/l, mean USZ (Cobas 8000): 4.8 mmol/l, mean iSTAT 4.67 mmol/l (PO2 = 5.1 kPa), Hematocrit: 0.36 l/l

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### Group 1

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<th>9</th>
<th>10</th>
<th>mean</th>
<th>Bias</th>
<th>VK%</th>
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### Group 2 (venous blood not approved)

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<th>VK%</th>
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**Table 3: Sample B, venous whole blood, normal with additional glucose.**

Target value: 8.7 mmol/l, mean USZ (Cobas 8000): 8.8 mmol/l, mean iSTAT 8.6 mmol/l (PO2 = 5.3 kPa), hematocrit: 0.35 l/l
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Table 4a: Control solution of manufacturer

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**Table 5: Survey Sample MQ 2019-4 K1 (Plasma-sample).** The target value for the hexokinase method on Cobas instruments was 10.2 mmol/l. None of the listed instruments is approved for the analysis of plasma glucose. The systems respond quite differently to plasma, depending on the type of electrode and hematocrit compensation. Therefore, a separate target value is calculated in the survey for each system.

* Not enough participants at the MQ-surveys for this instrument. It was not possible to calculate a consensus value as target.
### Table 6: Manufacturer informations on the instruments

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<th>Instrument</th>
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</table>

**Sample:** K=capillary blood, V=venous blood, A=arteriel blood, N=neonatal blood  
**Anticoagulans (Ac):** H=Heparin, E=EDTA, C=Citrate, F=Fluoride  
**Enzyme:** GDH=Glukosedehydrogenase, GOx=Glukoseoxidase  
**Method:** A=Amperometry, C=Coulometry, RF=Reflection-photometry, AF=Absorption-photometry  
**Calibration:** HK=wet chemistry, with Hexokinase-Method, YSI=instrument with Glucoseoxidase-Electrode  
**HK: Hämaturie-range**  
**Precision after ISO15197** (concentrations: 1: 1.7-2.8 mmol/L; 2: 2.9-6.1 mmol/L; 3: 6.2-8.3 mmol/L; 4: 8.4-13.9 mmol/L; 5: 14.0-22.2 mmol/L)  
Alle data in table 5 are from the package inserts of the teststrips or from additional documents of the manufactures.

Version 1.0 vom 26.12.2019