

## MQ 2020-4 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.

	Sample A	Sample B
Glucose, Cobas 8000	4.78 mmol/L	8.67 mmol/L
Glucose, iSTAT	4.67 mmol/L	8.70 mmol/L
Group 1	4.45 mmol/L	7.92 mmol/L
Mean	4.63 mmol/L	8.43 mmol/L
PO <sub>2</sub> , iSTAT (normal: 11.1-14.4 kPa)	3.43 kPa	3.9 kPa

### Control samples

The manufacturer's control solutions were measured ten times.

### MQ survey specimen K1 (2020-4)

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 devices achieved CV values below 5% with specimen A and 17 with specimen B  
10 devices achieved the 3.3% limit with specimen A, and 15 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, 7 from 17 instruments reached the specifications of the manufacturer where as in Sample B, 9 from 17 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, with specimen A 5 out of 11 instruments and with specimen B 7 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.

	1	2	3
AC Mobile	4.4	4.6	4.9
Glucocard Xmini plus	3.8	4.4	4.5
Mylife Pura	4.9	4.7	4.8
Healthpro	5.0	4.9	4.9
My Star	4.6	4.4	5.1
Mean value	4.5	4.6	4.8

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

### Total error

Results within the QUALAB tolerance of  $\pm 10\%$  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  $\pm 15\%$  range. For glucose concentrations below <5.55 mmol/l an absolute tolerance of  $\pm 0.83$  mmol/l must be observed.

In Specimen A, this tolerance was 4.17 to 5.09 mmol/l, in Specimen B the tolerance was 7.17 to 9.69 mmol/l. Three devices of Group 1 did not meet to the ISO 15197:2013 requirements.

With the measured values of Group 2 with fresh capillary blood, 1 device meets the Qualab-requirements and all devices meet the ISO-requirements.

Zürich, 7.12.2020

Dr. R. Fried

Group 1	1	2	3	4	5	6	7	8	9	10	mean	Bias	VK%
Hemocue 201+	4.0	4.2	4.2	4.1	4.2	4.1	4.0	4.0	4.1	4.3	4.1	-11.06%	2.51
Hemocue 201RT	3.8	3.5	3.8	3.8	3.6	3.7	3.4	3.7	3.6	3.8	3.7	-20.77%	3.86
Accu-Chek Inform 2	4.3	4.2	4.3	4.2	4.2	4.1	4.2	4.1	4.2	4.3	4.21	-9.11%	1.75
Accu-Chek Aviva	4.3	4.3	4.3	4.2	4.1	4.1	4.2	4.1	4.2	4.2	4.2	-9.33%	1.94
Accu-Chek Guide	4.9	4.9	4.6	4.7	4.6	4.5	4.6	4.6	4.7	4.6	4.67	0.82%	2.86
Contour next one	4.7	4.8	4.3	4.3	4.5	4.4	4.7	4.4	4.3	4.4	4.48	-3.29%	4.18
Freestyle lite	4.7	4.6	4.6	4.5	4.4	4.4	4.4	4.4	4.4	4.4	4.48	-3.29%	2.53
Freestyle precision	5.2	4.7	4.9	4.9	4.9	5.1	5.2	5.1	5	5.1	5.01	8.16%	3.18
mylife Unio	4.6	4.7	4.4	4.4	4.5	4.6	4.8	4.6	4.6	4.2	4.54	-1.99%	3.77
FORA GD40a	4.4	4.4	4.4	4.1	4.3	4.6	4.3	4	4.4	4.2	4.31	-6.96%	4.01
FORA GD50	3.9	4.3	4	3.8	3.7	3.8	3.8	3.7	3.8	3.8	3.86	-16.67%	4.60
<b>Group 2 (venous blood not approved)</b>													
Accu-Chek Mobile	4.8	5	4.6	4.8	4.8	5	4.9	4.8	5	5			2.75
GlucoCard Xmini plus	4.3	4.3	4.1	4.7	4.3	4.3	4.4	4.1	4.6	4.5			4.48
mylife Pura	4.9	4.9	4.8	4.9	4.9	4.9	4.8	4.9	4.9	4.8	Accuracy		2.69
HealthproX1	7.1	7.3	7.3	7.2	7.1	7.1	7.5	7	6.8	7.1	see		3.23
MyStar	5.9	6.3	5.7	6.1	6.2	5.7	6.4	5.7	6.1	6.1	Table 1		2.98
OT Verio	4.7	4.8	4.8	4.7	4.7	4.6	4.6	4.7	4.5	4.6			2.03

**Table 2: Sample A wholeblood, normal, postprandial.** All Glucose values are in mmol/l, alle instruments are plasma calibrated. Values of group 1 within the Qualab-tolerance of 10% are green colored.

Target value: 4.63 mmol/l, mean USZ (Cobas 8000): 4.78 mmol/l, mean iSTAT 4.67 mmol/l (PO<sub>2</sub> = 3.43 kPa), Hematocrit: 0.41 l/l

Group 1	1	2	3	4	5	6	7	8	9	10	mean	Bias	VK%
Hemocue 201+	7.9	7.9	8.0	7.4	7.3	7.7	7.6	7.8	7.9	7.7	7.7	-8.43%	2.98
Hemocue 201RT	7.2	7.6	7.3	7.2	7.3	7.4	7.0	7.3	7.1	7.4	7.3	-13.65%	2.32
Accu-Chek Inform 2	7.7	7.8	7.5	7.5	7.7	7.7	7.8	7.6	7.5	7.5	7.63	-9.50%	1.64
Accu-Chek Aviva	7.8	7.5	7.5	7.5	7.5	7.6	7.5	7.4	7.5	7.8	7.56	-10.33%	1.79
Accu-Chek Guide	8.3	8.2	8.5	8.8	8.8	8.5	8.3	8.3	8	8.6	8.43	-0.01%	3.07
Contour XT	8	7.9	8.4	8.4	7.9	7.8	8.2	8	8.1	8.1	8.08	-4.16%	2.53
Freestyle lite	8.4	8.2	8.5	8.1	8	8.2	8.4	8.5	8.4	8.2	8.29	-1.67%	2.09
Freestyle precision	8.5	8.5	8.5	8.3	8.5	8.4	8.4	8.3	8.4	8.5	8.43	-0.01%	0.98
mylife Unio	8.2	7.9	8.1	8.1	8.3	8.4	7.9	8.2	8.2	8.2	8.15	-3.33%	1.94
FORA GD40a	7.6	7.7	7.9	7.6	7.7	7.7	7.8	7.8	7.3	7.5	7.66	-9.14%	2.24
FORA GD 50	6.7	6.6	6.8	7	6.6	6.8	6.8	6.6	6.9	6.6	6.74	-20.06%	2.12
<b>Group 2 (venous blood not approved)</b>													
Accu-Chek Mobile	8.5	8.9	8.7	8.6	8.3	8.5	8.7	8.7	8.5	8.5			1.94
GlucoCard Xmini plus	8.3	7.9	8.3	8	7.8	7.5	7.2	7.9	7.7	8.2			4.47
mylife Pura	8.3	8.4	8.4	8.4	8.3	8.3	8.4	9.4	8.4	8.2	Accuracy		1.30
Healthpro XI	10.5	10.4	10	9.9	10.1	10	9.9	10	10.6	10.5	see		3.85
My Star	10.6	10.3	9.8	10.9	10.5	10.8	10.4	10.4	10.5	10.6	Table 1		2.80
OT Verio	8.4	8.4	8.2	8.3	8.4	8.4	8.4	8.3	8.4	8.2			1.01

**Table 3: Sample B, venous whole blood, normal with additional glucose.**

Target value: 8.43 mmol/l, mean USZ (Cobas 8000): 8.67 mmol/l, mean iSTAT 8.70 mmol/l ( $PO_2 = 3.9$  kPa), hematocrit: 0.43 l/l

	low	high	target	1	2	3	4	5	6	7	8	9	10	mean	Bias	CV%
Hemocue 201+	<b>5.5</b>	<b>6.7</b>	<b>6.10</b>	6.30	6.10	6.70	6.20	6.60	6.30	6.50	6.30	6.30	6.40	6.37	4.43	2.87
Hemocue 201+	<b>8.9</b>	<b>10.9</b>	<b>9.90</b>	11.00	11.00	10.90	10.90	11.10	11.00	10.80	11.00	10.70	11.10	10.95	10.61	1.16
Hemocue 201RT	<b>5.3</b>	<b>6.5</b>	<b>5.90</b>	6.20	6.20	6.00	6.10	6.10	5.90	6.00	6.10	6.10	6.10	6.08	3.05	1.51
Hemocue 201RT	<b>8.7</b>	<b>10.7</b>	<b>9.70</b>	10.60	10.70	10.60	10.80	10.70	9.80	10.80	10.60	10.60	10.60	10.58	9.07	2.70
AccuChek Inform 2	<b>2.3</b>	<b>2.8</b>	<b>2.50</b>	2.50	2.50	2.40	2.50	2.50	2.40	2.40	2.40	2.50	2.40	2.45	-2.00	2.15
AccuChek Inform 2	<b>15.3</b>	<b>18.8</b>	<b>17.05</b>	17.10	17.20	16.80	17.50	17.30	16.90	16.80	17.40	17.20	17.00	17.12	0.41	1.43
AccuCheck Aviva	<b>2.3</b>	<b>2.8</b>	<b>2.50</b>	2.70	2.80	2.70	2.70	2.70	2.70	2.70	2.70	2.70	2.70	2.71	8.40	1.17
AccuCheck Aviva	<b>14.9</b>	<b>18.3</b>	<b>16.60</b>	18.80	17.80	18.40	18.10	18.40	18.40	17.90	17.70	17.90	18.50	18.19	9.58	1.98
AccuChek Guide	<b>2.3</b>	<b>2.8</b>	<b>2.5</b>	2.70	2.60	2.70	2.80	2.70	2.70	2.70	2.70	2.60	2.60	2.68	7.20	2.36
AccuChek Guide	<b>14.9</b>	<b>18.2</b>	<b>16.5</b>	17.60	17.20	17.20	17.60	17.00	17.00	17.40	17.30	17.00	17.20	17.25	4.55	1.32
AccuCheck Mobile	<b>2.9</b>	<b>3.6</b>	<b>3.25</b>	3.30	3.10	3.20	3.20	2.90	3.20	3.10	3.30	3.30	3.30	3.19	-1.85	4.03
AccuCheck Mobile	<b>8.1</b>	<b>10.0</b>	<b>9.05</b>	9.20	9.70	9.00	9.80	9.50	9.80	9.50	9.30	10.00	9.50	9.53	5.30	3.21
Contour next one	<b>6.1</b>	<b>7.4</b>	<b>6.75</b>	6.90	6.90	6.80	6.70	7.00	6.80	6.90	7.00	7.30	6.70	6.90	2.22	2.56
Freestyle lite	<b>2.3</b>	<b>2.8</b>	<b>2.50</b>	2.70	2.80	2.80	2.80	2.80	2.60	2.80	2.70	2.80	2.80	2.76	10.40	2.53
Freestyle lite	<b>15.5</b>	<b>19.0</b>	<b>17.25</b>	18.40	17.80	16.30	18.10	17.90	18.10	17.80	18.30	18.30	17.90	17.89	3.71	3.35
Freestyle precision	<b>2.3</b>	<b>2.8</b>	<b>2.55</b>	2.40	2.60	2.40	2.40	2.20	2.20	2.40	2.40	2.40	2.10	2.35	-7.84	6.10
Freestyle precision	<b>14.5</b>	<b>17.7</b>	<b>16.10</b>	16.80	15.90	16.80	16.40	13.20	13.80	16.70	17.20	13.80	16.30	15.69	-2.55	9.51
ML Pura	<b>2.2</b>	<b>2.6</b>	<b>2.40</b>	2.30	2.30	2.30	2.20	2.30	2.20	2.20	2.30	2.20	2.10	2.24	-6.67	3.12
ML Pura	<b>13.2</b>	<b>16.2</b>	<b>14.70</b>	13.30	13.20	13.60	13.40	13.40	13.60	13.90	13.50	13.70	13.60	13.52	-8.03	1.51
ML Unio	<b>6.3</b>	<b>7.8</b>	<b>7.05</b>	6.70	6.50	6.60	6.50	6.40	6.50	6.40	6.50	6.30	6.40	6.48	-8.09	1.75
ML Unio	<b>14.3</b>	<b>17.4</b>	<b>15.85</b>	16.10	15.80	16.20	16.30	14.70	14.70	14.70	16.10	15.20	14.60	15.44	-2.59	4.69
FORA GD40a	<b>6.8</b>	<b>8.3</b>	<b>7.50</b>	7.60	7.30	7.50	7.40	7.50	7.30	7.30	7.30	7.40	7.30	7.39	-1.47	1.49

**Table 4a: Control solution of manufacturer**

	<b>low</b>	<b>high</b>	<b>target</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>mean</b>	<b>Bias</b>	<b>CV%</b>
Healthpro-X1	<b>4.6</b>	<b>5.6</b>	<b>5.10</b>	5.30	5.10	4.90	5.20	5.10	5.20	5.20	5.30	5.20	5.30	5.18	1.57	2.37
MyStar	<b>7.2</b>	<b>8.7</b>	<b>7.95</b>	8.20	8.40	7.60	8.30	8.10	8.00	7.70	8.70	8.20	8.00	8.12	2.14	3.97
OT Verio	<b>6.0</b>	<b>7.4</b>	<b>6.70</b>	6.60	6.60	8.00	6.90	5.10	6.70	6.50	5.90	6.30	6.50	6.51	-2.84	11.25

**Table 4b: Control solution of manufacturer**

	target	1	2	3	4	5	6	7	8	9	10	mean	CV%	Bias %
Hemocue 201+	9.3	9.7	9.7	9.5	9.4	9.6	9.6	9.6	9.6	9.5	9.7	9.56	0.96	2.82
Hemocue 201RT	9.3	9.3	9.6	9.3	9.4	9.2	9.3	9.4	9.2	9.4	9.4	9.33	0.95	0.27
AccuChek Inform 2	8.9	8.9	8.9	9	8.8	8.9	8.8	8.8	8.9	8.8	8.8	8.85	0.85	-0.56
AccuChek Aviva	8.7	8.5	8.5	8.7	8.7	8.6	8.7	8.9	8.6	8.6	8.5	8.66	1.37	-0.43
AC Guide	7.2	7	7	7.2	7.1	6.9	7.2	7.3	7.1	7.1	7	7.11	1.64	-1.22
Contour next one	7.4	7.5	7.3	7.2	7.3	7.4	7.3	7.3	7.3	7.2	7.1	7.26	1.26	-1.86
Freestyle lite	8.4	8.7	8.8	8.8	8.3	8.7	9.1	8.7	8.8	8.4	8.8	8.70	2.88	3.57
Freestyle precision	*	7.8	8.3	8.2	8.9	8.4	8.2	8.1	8	7.9	8.1	8.23	3.78	
mylife Unio	9.6	9.4	9.7	9.5	9.6	9.6	9.7	9.4	9.7	9.6	9.6	9.59	1.03	-0.13
FORA GD40a	*	6.1	6.4	6.4	5.9	6.3	6.1	6.2	6.3	6.1	6.2	6.19	2.35	
FORA GD50	*	10.6	11.1	10.8	11.1	10.7	10.6	10.5	10.7	10.8	10.5	10.71	1.71	
AccuChek Mobile	*	7.8	8.3	8.3	8	7.8	8.4	7.8	8.1	8.1	8	8.06	2.48	
GlucocardX	10.6	10.8	10.4	10.7	11.3	10.9	11.1	10.9	10.9	10.6	11.2	10.95	2.04	3.30
mylife Pura	8.5	8.4	8.4	8.6	8.6	8.4	8.4	8.4	8.4	8.4	8.6	8.48	1.14	-0.29
Healthpro XI	14.2	13.9	14.1	13.9	14.6	14	18.5	14.5	13.9	14	14.2	14.70	9.92	3.52
MY Star	9.9	11.1	11.6	10.7	11.1	11.5	12.1	12.1	11.4	11.6	11	11.44	4.10	
OT Verio	7.5	7.7	7.7	7.6	7.7	7.5	7.8	7.5	7.5	7.7	7.7	7.63	1.53	1.67

**Table 5: Survey Sample MQ 2020-4 K1 (Plasma-sample).** The target value for the hexokinase method on Cobas instruments was 7.9 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.



Instrument	Company	Samp.	Ac	Enzyme	Meas	Cal.	Hc%	Precision				
								1	2	3	4	5
Hemocue 201+	Hemocue	KVAN	HEF	GDH-NAD	AF	ID-GCMS			3.5	2.6	1.9	1.6
Hemocue 201RT	Hemocue	KVAN	HEF	GDH-NAD	AF	ID-GCMS	2.4			1.3		1.3
Accu-Chek Inform 2	Roche	KVAN	HEF	mGDH-PQQ	A	HK	10-65	4.0	4.1	3.3	3.3	3.2
Accu-Chek Aviva	Roche	KVAN	HE	mGDH-PQQ	A	HK	20-70	3.6	3.3	3.3	3.4	3.4
Accu-Chek Guide	Roche	KVAN	HE	GDH-FAD	A	HK	10-65	4.3	2.2	2.1	2.6	2.6
Contour next one	Ascensia	KVN	H	GDH-FAD	A	YSI	0-70	1.8	1.9	1.3	1.2	1.7
Freestyle Precision	Abbott	KVAN	HE	GDH-NAD	A	YSI	30-60		4	3	2.7	3.2
Freestyle Freedom Lite	Abbott	KV	H	GDH	C	YSI	15-65	3.3	2.4	2.2	2.3	2.4
mylife Unio	Ypsomed	KV	HE	GDH-FAD	A	HK	10-70	3.8	1.8	1.7	1.6	1.7
FORA GD40a	FORA	KV	H	GDH-FAD	A	YSI	0-70	8.4	3.4	3.1	4.3	2.4
Accu-Chek Mobile	Roche	K		mGDH-PQQ	RF	HK	25-55	6.5	2.6	2.4	2.0	1.9
GlucoCard Xmini plus	Axonlab	K		GDH	A	YSI	30-52	2.8	2.8	2.9	3.0	2.6
mylife Pura	Ypsomed	K		GOx	A	HK	30-60	1.8	1.1	1.1	1.7	1.7
Healthpro-X1	Axapharm	K	E	GOx	A	HK	20-60	3.6	2.9	2.5	3.2	2.5
MyStar Extra	Sanofi	K		GOx	A	YSI	20-60	4.3	3.6	3.4	3.1	3.8
OneTouch Verio pro	Lifescan	KV	HEC	FAD-GDH	A	YSI	20-60	2.2	2.0	1.9	1.9	1.9

**Table 6: Manufacturer informations on the instruments**

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: Hämatocrit-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.

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