

MQ 2015-2 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 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	4.73 mmol/L	7.46 mmol/L
Glucose, iSTAT	4.63 mmol/L	7.47 mmol/L
Group 1	4.60 mmol/L	7.20 mmol/L
Group 2	4.65 mmol/L	7.38 mmol/L
Mean	5.9 kPa	3.9 kPa
PO ₂ , iSTAT (normal: 11.1-14.4 kPa)	4.73 mmol/L	7.46 mmol/L

Control samples

The manufacturer's control solutions were measured ten times.

MQ survey specimen K1 (2015-2)

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%.

At higher concentrations, the % CV of 18 from 19 devices were below 5%, at the lower concentration, 16 from 19 devices were below the 5% limit. 13 devices achieved the 3.3% limit with specimen A, and 16 units with specimen B.

In the manufacturer's control samples, 5 of 18 instruments were above the 3.3% limit, in the MQ specimen (plasma), 5 of 18 devices had a CV over 3.3%.

As seen in our last measurements, the precision of the instruments for lower glucose concentrations is worse than for higher glucose concentrations.

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 the higher concentration in Sample B, all instruments reached the specifications of the manufacturer where as in Sample A, 9 instruments showed a higher CV% than we expected.

Accuracy

To check the accuracy we used the following criteria:

- 3 measurements with iSTAT (GOx Elektrode)
- 3 measurements with Roche Cobas 8000 (Hexokinase)

We distinguish three groups of instruments:

- Group 1 is approved for the analysis of venous blood according to the manufacturer's specifications
- Group 2 may be used for fresh capillary blood only, but it shows no matrix effects in our measurements
- Group 3 may be used with fresh capillary blood only and exhibits a systematic error in our measurements, which cannot be observed with analysis of capillary blood.

Ideal deviations are <4%.

In the groups 1 and 2, for the lower concentration 6 out of 12 instruments and for the higher concentration 7 out of 12 instruments achieved a deviation of less than 4%.

IMPORTANT: Group 2 instruments cannot be used with venous blood from patients. In our measurements, we can measure venous blood only because we control the oxygen content of the specimen.

In Group 3, 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 values were within the limits.

	Gluc	Bias%	Gluc	Bias%	Gluc	Bias%
dynaValeo Liso	5.7	1.8	5.3	-3.6	5.6	5.7
GlucoMen Ready	5.8	3.6	5.9	7.3	5.5	3.8
Healthpro-X1	5.5	-1.8	5.5	0.0	5	-5.7
Glucosefino	5.5	-1.8	4.9	-10.9	5.1	-3.8
Accu-Chek Mobile	5.7	1.8	6	9.1	5.8	9.4
Breeze 2	5	-10.7	4.9	-10.9	4.7	-11.3
GlucoCard Xmini	6.1	8.9	5.7	3.6	4.8	-9.4
MyStar Extra	5.7	1.8	5.8	5.5	5.7	7.5
mean value	5.6		5.5		5.3	

Table 1: Comparison of glucometers of group 3 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 ± 0.83 mmol/l must be observed.

In Specimen A, this tolerance was 3.82 to 5.48 mmol/l, in Specimen B the tolerance was 6.27 to 8.49 mmol/l. All 12 instruments of group 1 and 2 conformed to the ISO 15197:2013 requirements.

With the measured values of Group 3 with fresh capillary blood, two instruments did not meet the Qualab-criteria, but all conformed to the ISO-requirements.

Zürich, 1.7.2015

Dr. R. Fried

Group 1	1	2	3	4	5	6	7	8	9	10	mean	Bias	VK%
Hemocue 201+	4.9	5.0	4.5	4.5	4.8	4.6	4.7	5.0	4.7	4.0	4.7	0.43%	6.39
Hemocue 201RT	5.7	5.2	5.2	4.5	4.6	4.9	4.9	5.4	4.6	4.7	5.0	6.88%	7.94
Accu-Chek Inform 2	4.3	4.4	4.2	4.4	4.4	4.3	4.3	4.4	4.4	4.3	4.34	-6.67%	1.61
Accu-Chek Aviva	4.4	4.4	4.5	4.4	4.5	4.6	4.4	4.4	4.4	4.5	4.45	-4.30%	1.59
Contour XT	4.5	4.5	4.4	4.5	4.4	4.6	4.3	4.6	4.6	4.6	4.5	-3.23%	2.34
OneTouch Veriopro	4.9	4.8	4.7	4.7	4.6	4.7	4.6	4.7	4.4	4.3	4.64	-0.22%	3.83
Unio	4.6	4.7	4.5	4.6	4.4	4.5	4.6	4.6	4.2	4.6	4.53	-2.58%	3.13
FORA GD40a	5	5	5	5.3	5	4.7	5	5.1	4.9	4.8	4.98	7.10%	3.25
Group 2 (venous blood not approved, in the experiment only small matrix effects observed)													
GlucoCard Xmini plus	4.6	4.3	4.5	4.3	4.3	4.6	4.3	4.6	4.7	4.7	4.49	-3.44%	3.85
GlucoMen LX Plus	5.4	5.4	5.2	5.2	5.4	5.3	5.4	5.2	5	5.2	5.27	13.33%	2.54
Glucomen areo	5.4	5.1	5.1	5.4	5.1	5.1	5.2	5	5.1	5.2	5.17	11.18%	2.59
PuraX	4.9	4.8	4.8	4.8	4.8	4.7	4.7	4.9	4.7	4.7	4.78	2.80%	1.65
Group 3 (venous blood not approved, significant matrix effects)													
dynaValeo Liso	5	5.5	5.5	5.5	4.7	5.4	5.4	5.5	5.4	5.4			5.01
GlucoMen Ready	5.2	5	5.2	5.3	5.1	5.1	5.4	5.4	5.1	5.1	Accuracy		2.64
Healthpro-X1	5.6	5.5	5.7	5.5	5.6	5.4	5.5	5.4	5.4	5.6	see		1.87
Glucofine	5.3	5.3	5.3	5.2	5.5	5.3	5.3	5.2	5.4	5.2	Table 1		1.78
Accu-Chek Mobile	4.8	4.9	4.8	4.9	4.8	4.8	4.8	4.8	4.8	4.9			1.00
Breeze 2	4.8	4.9	4.8	4.6	4.7	4.6	4.5	4.4	4.6	4.8			3.36
MyStar Extra	5.2	5.2	5.1	6.2	5.3	5.3	5.1	5.3	5.4	5.3			5.94

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

Target value: 4.65 mmol/l, mean USZ (Cobas 8000): 4.73 mmol/l, mean iSTAT 4.63 mmol/l (PO2 = 5.9 kPa), Hematocrit: 0.43 l/l

Group 1	1	2	3	4	5	6	7	8	9	10	mean	Bias	VK%
Hemocue 201+	7.3	7.4	7.4	7.1	7.5	7.2	7.3	7.3	7.2	7.1	7.3	-1.36%	1.81
Hemocue 201RT	7.6	7.0	7.2	7.4	7.2	7.0	7.0	7.9	7.5	7.4	7.3	-0.81%	4.06
Accu-Chek Inform 2	6.9	6.7	6.9	6.9	6.7	6.7	6.7	6.7	6.6	6.7	6.75	-8.54%	1.60
Accu-Chek Aviva	6.7	6.8	7.3	6.9	6.8	6.7	6.8	6.9	6.8	6.8	6.85	-7.18%	2.51
Contour XT	7.1	7.2	7.3	7.4	7.3	7.6	7.3	7.4	7.5	7.4	7.35	-0.41%	1.95
OneTouch Veriopro	7.9	7.4	7.7	7.7	7.6	7.4	7.4	7.4	7.8	7.3	7.56	2.44%	2.73
Unio	6.9	6.9	6.9	6.9	6.8	6.9	6.7	7	6.7	7.1	6.88	-6.78%	1.79
FORA GD40a	7.5	7.6	7.7	7.7	7.4	7.3	7.4	7.5	7.8	7.1	7.5	1.63%	2.81
Group 2 (venous blood not approved, in the experiment only small matrix effects observed)													
GlucoCard Xmini plus	7.2	7.4	7.4	7.8	7.8	7.5	7.2	7.4	6.9	7.7	7.43	0.68%	3.86
GlucoMen LX Plus	7.7	7.7	8	7.9	7.8	7.5	8	7.7	7.6	7.4	7.73	4.74%	2.59
Glucomen areo	8.3	8.4	8.4	8.4	8.3	8.2	8.3	8.3	7.9	8.1	8.26	11.92%	1.91
Pura	7.1	7.2	7.3	7.2	7.2	7.2	7.3	7.3	7.2	7.2	7.22	-2.17%	0.88
Group 3 (venous blood not approved, significant matrix effects)													
dynaValeo Liso	8.3	8	8.3	8.2	7.8	7.8	7.7	8.3	8	7.8			2.99
GlucoMen Ready	8.8	8.1	8	8.7	8.5	8.3	8.5	8.5	8.1	8.1	Accuracy		3.35
Healthpro-X1	8.8	9.3	8.8	9.2	8.7	8.9	8.8	8.9	8.7	8.5	see		2.67
Glucosefine	8.4	8.9	8.8	8.2	8.2	8.5	8.4	8.5	8.4	8.4	Table 1		2.67
Accu-Chek Mobile	7.6	7.7	7.7	7.7	7.8	7.5	8	7.4	7.5	7.8			2.30
Breeze 2	7.6	7.5	7.7	7.3	7.4	7.1	7.1	7.4	7.1	7.3			2.89
MyStar Extra	8.6	9.3	9.8	8.7	8.9	9.5	9.9	9	9.6	9.9			5.30

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

Target value: 7.38 mmol/l, mean USZ (Cobas 8000): 7.46 mmol/l, mean iSTAT 7.47 mmol/l ($PO_2 = 3.9$ kPa), hematocrit: 0.42 l/l

	low	high	Target	1	2	3	4	5	6	7	8	9	10	MW	Bias	VK%
Hemocue 201+	5.8	7.0	6.4	6.6	6.8	6.7	6.3	6.8	6.7	6.7	6.6	6.6	6.7	6.65	3.91	2.16
	9.9	12.1	11	10.8	10.9	10.9	10.4	10.9	10.7	10.5	10.8	10.6	10.5	10.70	-2.73	1.76
Hemocue 201RT	5.7	6.9	6.3	6.3	6.3	6.2	6.3	6.2	6.3	6.3	6.3	6.3	6.3	6.28	-0.32	0.67
	9.5	11.6	10.5	9.7	10	10.5	10.5	10.1	10.4	9.9	10.1	10.1	10.1	10.14	-3.43	2.55
Accu-Chek Aviva	2.3	2.8	2.5	2.4	2.4	2.5	2.4	2.4	2.4	2.4	2.5	2.5	2.5	2.44	-2.40	2.12
	14.9	18.3	16.6	16.5	16.6	16.9	16.3	16.5	16.7	16.4	16.4	16.6	16.5	16.54	-0.36	1.04
Accu-Chek Mobile	3.4	4.1	3.75	3.3	3.9	3.8	3.7	3.8	3.8	3.8	3.9	3.7	3.9	3.76	0.27	4.72
	8.7	10.6	9.65	9.3	9.8	10.3	10.2	10	10					9.93	2.94	3.58
Accu-Chek Inform 2	2.3	2.8	2.5	2.5	2.4	2.4	2.5	2.6	2.4	2.4	2.5	2.4	2.5	2.46	-1.60	2.84
	15.3	18.8	17.05	17.2	16.9	16.8	17	17.8	16.7	16.8	16.9	17	17.5	17.06	0.06	2.03
Contour XT	7.0	8.5	7.75	7.1	7.2	7.1	7.2	7.2	7.3	7.3	7.2	7.3	7.2	7.21	-6.97	1.02
Breeze 2	5.6	6.9	6.25	6	6	6.2	7.3	6.1	5.8	5.9	5.9	6.1	6	6.13	-1.92	6.97
OneTouch Veriopro	6.0	7.4	6.7	6.8	6.9	6.7	6.6	6.7	6.8	6.8	6.6	6.8	6.8	6.75	0.75	1.44
Glucocard Xmini plus	5.0	6.2	5.6	5.8	5.6	5.9	5.7	6	5.8	5.8	5.9	5.8	5.8	5.81	3.75	1.89
	10.2	12.4	11.3	11.3	11.4	12.1	10.9	11.8	11.6	11.3	11.8	11.9	11.4	11.55	2.21	3.09
dynaValeo Liso	5.6	6.8	6.2	6.3	6.2	7	6.7	6.7	7	6.7	7.2	7	6.4	6.72	8.39	5.00
Glucomen LX Plus	14.7	19.8	17.25	16.7	17.8	18	17.3	15.7	16.7	18	16.5	16.9	17.3	17.09	-0.93	4.30

Table 4a: Control solution of manufacturer

	low	high	target	1	2	3	4	5	6	7	8	9	10	mean	Bias	VK%
PuraX	5.1	6.2	5.65	5.5	5.4	5.4	5.5	5.5	5.4	5.4	5.6	5.6	5.4	5.47	-3.19	1.51
Unio	5.6	6.9	6.25	5.9	6.1	5.7	5.8	5.7	5.9	5.8	5.9	5.7	5.9	5.84	-6.56	2.17
	14.4	17.6	16	16.2	15.7	16.2	15.9	15.4	15.1	15.6	16	15.6	16.6	15.83	-1.06	2.78
GlucMen areo	6.0	7.4	6.7	6.9	6.6	6.8	6.8	6.5	6.9	6.7	6.8	6.7	6.8	6.75	0.75	1.88
	11.8	14.4	13.1	13.6	13.4	12.9	12.9	12.7	13.1	13.1	13.2	13.2	13.2	13.13	0.23	1.97
FORA GD40a	7.2	8.7	7.95	8.6	8.5	8.1	7.9	8.3	8.2	8.3	8.2	8.4	8.2	8.27	4.03	2.42
Healthpro X1	4.3	5.3	4.8	5.1	5.4	5.3	5	5.2	5.2	5.4	5.1	5.5	5	5.22	8.75	3.35
BG-Star	6.6	8.0	7.3	7.8	7.9	7.6	7.2	8.2	7.4	7.9	7.2	8	7.9	7.71	5.62	4.47
Glucosefine	5.0	6.2	5.6	5	4.7	5	5.1	4.8	5	5	4.9	4.8	5	4.93	-11.96	2.54
	13.1	16.1	14.6	14.1	14.4	13.2	13.8	14.1	14.4	14.2	13	13.7	13.7	13.86	-5.07	3.44
GlucMen Ready	7.2	8.7	7.95	8.5	8.5	8.8	8.3	8.5	8.7	8.9	8	8.5	8.5	8.52	7.17	2.97
	13.0	15.8	14.4	14.3	14.5	14.4	14	13.9	13.9	14.4	14.8	14.7	15.5	14.44	0.28	3.36

Table 4b: Control solution of manufacturer

	target	1	2	3	4	5	6	7	8	9	10	mean	CV%	Bias %
Hemocue 201+	8.2	8.5	8	8.2	8.3	8.7	8.5	8.8	8.5	8.4	8.3	8.41	2.94	2.57
Hemocue 201RT	8.1	8	8.1	8.1	8.1	8.2	8.1	7.8	8	7.8	8.1	8.03	1.76	-0.82
Accu-Chek Inform 2	7.3	7	7	6.9	6.9	6.4	7	7.1	7.1	6.9	7.4	6.97	3.80	-4.57
Accu-Chek Aviva	7.3	7.2	6.9	6.8	6.8	6.9	7.1	7	6.9	7	7.2	6.96	1.92	-4.72
Contour XT	7.2	6.9	7	6.9	6.9	6.8	6.8	6.8	6.9	6.7	6.8	6.84	1.29	-4.94
OneTouch Veriopro	7	7	6.9	7	6.9	6.9	7	6.9	6.9	6.9	7.1	6.94	1.05	-0.79
Unio	7.6	7.2	7.1	7.1	7.3	7.2	7.2	7.5	7.4	7.3	7.3	7.27	1.82	-4.39
GlucoMen areo	*	9	8.6	8.8	8.8	9.3	8.5	8.4	8.2	8.5	8.2	8.59	4.01	
FORA GD40a	*	6.5	6.1	6.2	6.2	6.5	6.4	6.1	6	6.2	6.1	6.20	2.40	
GlucoCard Xmini plus	9.4	8.9	9	8.9	8.9	8.6	8.9	8.7	8.9	8.9	8.4	8.80	2.07	-6.38
MyStar Extra	9.1	8.6	8.3	8.7	8.8	8.4	9	8.9	9.1	9.9	9.4	8.94	5.19	-1.71
PuraX	8.7	8.1	8.4	8.4	8.1	8	8.1	8.3	8.1	8.2	8.4	8.22	1.79	-5.49
dynaValeo Liso	*	11.4	11.4	11	11.6	11.3	10.8	10.8	11.4	11.8	11.2	11.26	2.87	
GlucoMen Ready	*	11.3	11.2	11.8	11.6	10.6	11.2	10.7	10.5	11.2	11.6	11.16	3.97	
Healthpro-X1	12	10.5	11.1	10.7	10.4	10.8	10.5	10.3	10.3	10.5	10.1	10.52	2.72	-12.31
Glucofine	*	11.2	10.8	10.7	10.5	10.7	10.8	10.5	10.5	10.5	10.4	10.60	1.33	
Accu-Chek Mobile	7.3	7.2	6.9	6.8	6.8	6.9	7.1	7	6.9	7	7.2	6.96	1.81	-4.72
Breeze 2	11.1	11.1	10.9	11.3	10.8	11.1	11.2	11	10.9	10.9	10.8	10.99	1.51	-1.00

Table 5: Survey Sample MQ 2015-2 K1 (Plasma-sample). The target value for the hexokinase method on Cobas instruments was 7.0 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 Mobile	Roche	K		mGDH-PQQ	RF	HK	25-55	6.5	2.6	2.4	2.0	1.9
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
Contour XT	Bayer	KVN	H	GDH-FAD	A	YSI	0-70	1.8	1.9	1.3	1.2	1.7
Breeze 2	Bayer	K		GOx	A	YSI	20-55		4.1	2.3	2.1	1.9
OneTouch Verio pro	Lifescan	KV	HEC	FAD-GDH	A	YSI	20-60	2.2	2.0	1.9	1.9	1.9
GlucoCard Xmini plus	Axonlab	K		GDH	A	YSI	30-52	2.8	2.8	2.9	3.0	2.6
DynaValeo Liso	dynamicare	K		GOx	A	YSI	35-55	4.7	3.2	3.3	2.4	2.1
GlucoMen LX Plus	Menarini	K	H	GOx	A	YSI	25-60	2.6	3.6	1.9	1.7	3.0
GlucoMen Ready	Menarini	K		GOx	A	YSI	20-60	5.5	3.3	3.4	3.4	3.2
GlucoMen areo	Menarini	K		GOx	A	YSI	10-70	3.5	2.4	2.3	2.3	1.7
PuraX	Ypsomed	K		GOx	A	HK	30-60	1.8	1.1	1.1	1.7	1.7
Unio	Ypsomed	KV	HE	GDH-FAD	A	HK	10-70	3.8	1.8	1.7	1.6	1.7
Healthpro X1	Axapharm	K	E	GOx	A	HK	20-60	3.6	2.9	2.5	3.2	2.5
BG-Star	Sanofi	K		GOx	A	YSI	20-60	4.3	3.6	3.4	3.1	3.8
Glucosefine	Belonga	K		GOx	A	HK	20-60	4.0	2.8	2.2	2.8	2.7
FORA GD40a	FORA	KV	H	GDH-FAD	A	YSI	0-70	8.4	3.4	3.1	4.3	2.4

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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