

MQ 2013-4 Comparison of Glucometers with Heparin 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. In Sample 1 we measured 5.2 kPa PO₂, in sample 2 4.9 kPa PO₂. Using iSTAT (GOD) glucose in the first sample was 4.9 mmol/l and in the second sample 9.8 mmol/l

After centrifugation of the samples, the glucose was determined using a Cobas 8000 (hexokinase method). The average of three measurements (at the beginning, in the middle and at the end of the series) was 5.1 mmol/l in the first and 17.10 mmol/l in the second sample.

Control samples

The manufacturer's control solutions were measured ten times.

MQ survey specimen K1

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. We assume that basically all instruments can measure heparin blood if the oxygen level is not too high.

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%.

23 of 24 devices had CV of <5% and 16 of 24 devices a CV <3.3% respectively.

In the manufacturer's control samples, scatter was within the same range. The plasma survey specimens showed even higher precision, although none of the devices are approved for the use with plasma.

Accuracy

To assess the accuracy of the devices, we use three criteria:

- Average of all devices
- Triple measurement heparin blood iSTAT (GOx electrode)
- Triple measurement heparin plasma Roche Cobas 8000 (hexokinase)

We used the average of all devices as target value in the last test.

Optimal deviations are <4%.

For sample A, 11 instruments had a deviation of less than 4%, for sample B 13 instruments.

Repeated measurement with fresh capillary blood showed no difference between the AccuChek Mobile, the AccuChek Inform2, and the Contour XT. We therefore suspect that the high values with the AccuChek Mobile are due to issues with venous blood. In contrast, we were able to confirm the deviations with the Contour 5s (-10%) and with the Healthpro (+10%).

Total error

Results within the QUALAB tolerance range of $\pm 10\%$ around the target value (average of all devices) are highlighted in green.

For blood glucose monitoring systems used by patients themselves, the new standard ISO 15197:2013 is applied as of May 2013. Now 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/ must be met.

In sample A, this tolerance was 4.17 to 5.83 mmol/l. The Hemocue 201RT and the Healthpro had problems.

In sample B, this tolerance was 8.49 to 11.49 mmol/l. There were problems with the Healthpro.

The deviations with AccuChek Mobile were due to problems with the specimen material. The other devices met the requirements of the new ISO 15197:2013.

For the professional measurement of glucose, QUALAB tolerance of 10% is applied in Switzerland. In terms of these tolerances, the results were encouraging as well.

Zürich, 4.12.2013

Dr. R. Fried

All Glucosevalues are in mmol/l, alle instruments are plasma calibrated. Values within the Qualab-tolerance of 10% are green colored.

1. Sample A (Heparine-blood, normal, postprandial)

	1	2	3	4	5	6	7	8	9	10	Mean	Bias	CV%
Hemocue 201+	5.3	5.3	5.2	5.3	5.0	5.2	5.0	5.0	5.0	4.6	5.1	1.20%	4.23
Hemocue 201RT	5.5	5.9	5.3	5.4	5.3	5.7	5.7	5.4	6.1	4.9	5.5	10.40%	6.21
AccuChek Aviva	4.8	4.8	4.8	4.8	4.8	4.6	4.7	4.8	4.6	4.6	4.73	-5.40%	2.01
AccuChek Mobile	5.9	5.7	5.6	5.8	5.5	5.5	5.7	5.5	5.6	5.6	5.64	12.80%	2.39
AccuChek Inform 2	4.9	4.7	4.8	4.7	4.8	4.8	4.7	4.6	4.6	4.7	4.73	-5.40%	2.01
Contour	4.3	4.6	4.7	4.5	4.2	4.3	4.5	4.3	4.6	4.2	4.42	-11.60%	4.10
Contour XT	5	5.1	5	4.9	4.8	4.7	4.9	4.9	4.8	4.8	4.89	-2.20%	2.45
Breeze 2	5.1	5.2	5.2	5.2	5.2	4.9	5.1	5	5.1	5.1	5.11	2.20%	1.95
Freestyle Freedom Lite	4.8	5.1	4.9	4.8	4.8	4.7	4.7	4.9	4.8	4.7	4.82	-3.60%	2.55
FreeStyle Precision	5.8	5.4	5.3	5.1	5.2	5.9	5.3	5.5	5.3	5.4	5.42	8.40%	4.67
OneTouch vita	5.1	5.1	5.1	5	4.9	4.9	4.8	4.7	4.8	4.9	4.93	-1.40%	2.88
OneTouch UltraEasy	5.2	5.1	5.2	5.2	5.1	5	4.8	5.1	4.8	4.9	5.04	0.80%	3.13
OneTouch Veriopro	5.4	5.1	5	5.1	5.2	5	4.9	4.9	4.9	4.8	5.03	0.60%	3.51
GlucoCard Xmini plus	5	4.6	4.6	4.8	4.6	5	4.5	4.6	4.7	4.5	4.69	-6.20%	3.95
dynaValeo Liso	5.5	5.3	5.4	5.4	5.3	5.3	5.3	5.2	5.2	5.2	5.31	6.20%	1.87
GlucoMen LX Plus	5.5	5.4	5.8	5.4	5.4	5.6	5.6	5.1	5.8	5.6	5.52	10.40%	3.80
GlucoMen Ready	5.8	5.6	5.6	5.5	5.78	5.6	5.5	5.5	5.4	5.3	5.558	11.16%	2.78
Pura	5.2	5.2	5.2	5.1	5.1	5.1	5.2	5.3	5.2	5.2	5.18	3.60%	1.22
Unio	5.4	5.4	5.3	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.18	3.60%	2.54
Healthpro	6.4	6.3	6.7	6.7	6.3	6.4	6.2	6.2	6.5	6.3	6.4	28.00%	2.85
BG-Star	5	5.1	4.9	4.9	4.9	4.8	4.9	4.9	5.1	5.2	4.97	-0.60%	2.52
Finetest	5.7	5.2	5.2	5.3	5.4	5.2	5	5.2	4.8	5.3	5.23	4.60%	4.51
FORA GD40a	4.8	4.8	4.8	4.8	4.9	4.7	4.8	4.7	4.6	4.7	4.76	-4.80%	1.77
FORA GD50	4.8	5.1	5	5	4.9	5.1	4.9	4.9	5.1	5	4.98	-0.40%	2.07

Mean value of all instruments: 5.00 mmol/l, mean USZ (Cobas 8000): 5.1 mmol/l, mean iSTAT 4.9 mmol/l (PO2 = 5.2 kPa), Hematocrit: 0.35 l/l

2. Sample B (Heparine-blood, normal with additional glucose)

	1	2	3	4	5	6	7	8	9	10	Mean	Bias	CV%
Hemocue 201+	10.2	10.0	10.5	10.1	10.7	10.1	10.6	10.9	10.5	10.2	10.4	3.85%	2.69
Hemocue 201RT	10.0	10.2	10.0	10.3	10.3	10.0	10.7	11.0	10.2	10.3	10.3	3.11%	3.14
AccuChek Aviva	10.2	9.4	9.4	9.5	9.2	9.1	9.6	9.8	9.3	9.1	9.46	-5.29%	3.60
AccuChek Mobile	11.2	11.1	11.4	11	11.9	11.2	12.2	11	11.4	11.7	11.41	14.23%	3.54
AccuChek Inform 2	9.3	9.6	9.4	9.3	9.1	9.4	9.3	9.2	9.2	9.1	9.29	-7.00%	1.64
Contour	9.1	8.8	9.2	8.9	8.9	9.2	8.8	8.6	8.8	8.7	8.9	-10.90%	2.31
Contour XT	10	10.2	9.9	9.8	9.4	10.3	9.4	9.6	9.3	9.1	9.7	-2.89%	4.15
Breeze 2	10.6	10.4	9.9	10.7	10.5	10.7	10.2	10.6	10.4	10.1	10.41	4.22%	2.58
Freestyle Freedom Lite	10.2	9.9	9.6	9.7	9.8	9.9	9.2	9.7	9.6	9.4	9.7	-2.89%	2.88
FreeStyle Precision	11.7	10.6	9.9	10.9	10.7	10.6	10.7	10.8	10.7	10.3	10.69	7.02%	4.26
OneTouch vita	10.1	10.2	10	10.3	9.7	9.9	10.4	9.9	9.9	10	10.04	0.51%	2.11
OneTouch UltraEasy	10.2	10.2	10.2	10.1	10.2	9.9	9.9	9.8	9.9	9.8	10.02	0.31%	1.75
OneTouch Veriopro	9.7	9.6	9.6	9.6	9.5	9.7	9.8	9.2	9.4	9.4	9.55	-4.39%	1.86
GlucoCard Xmini plus	10.1	9.5	9.5	9.4	9.5	9.5	9.7	9.9	9.6	9.2	9.59	-3.99%	2.67
dynaValeo Liso	10.6	9.5	9.5	9.4	9.3	9.5	9.7	9.9	9.6	9.2	9.62	-3.69%	4.12
GlucoMen LX Plus	10.2	10.5	9.7	10.6	9.8	9.3	9.3	10	9.4	9.6	9.84	-1.49%	4.82
GlucoMen Ready	10.5	10.1	10.4	10.2	9.8	10	10.1	10.3	10	9.8	10.12	1.31%	2.32
Pura	9.6	9.7	9.7	9.5	9.6	9.4	9.6	9.3	9.5	9.4	9.53	-4.59%	1.40
Unio	10.2	9.8	10.1	9.8	10	9.8	9.7	10.1	10.1	10	9.96	-0.29%	1.72
Healthpro	12.2	11.3	11.4	11.9	11	11.3	11.4	10.8	10.8	11.2	11.33	13.43%	3.93
BG-Star	10.1	10.3	10.2	9.8	9.9	10.1	9.9	10.2	10	9.7	10.02	0.31%	1.93
Finetest	10.4	9.7	9.8	10	10	9.7	9.9	9.5	10	9.8	9.88	-1.09%	2.47
FORA GD40a	9.7	10.1	9.6	9.6	8.3	9.5	9.4	9.2	8.8	9.1	9.33	-6.60%	5.44
FORA GD50	10.6	10.4	10.9	10.7	10.7	11	10.8	10.4	10.7	10.5	10.67	6.82%	1.88

Mean of all instruments: 9.99 mmol/l, mean USZ (Cobas 8000): 10.17 mmol/l, mean iSTAT 9.77 mmol/l (PO2 = 4.9 kPa), Hematocrit: 0.35 l/l

3. Control solution of manufacturer

	from	to	target	1	2	3	4	5	6	7	8	9	10	mean	bias	cv%
Hemocue 201+	5	6.8	5.9	5.6	5.7	5.6	5.7	5.6	5.8	5.8	5.8	5.3	5.6	5.65	-4.24	2.67
	8.7	11.1	9.9	9.7	9.3	9.9	9.6	9.4	9.8	9.7	9.6	9.8	9.4	9.62	-2.83	2.07
Hemocue 201RT	5.2	7	6.1	5.9	5.9	5.8	5.9	5.9	6	5.8	5.9	5.9	5.9	5.89	-3.44	0.96
	9.3	11.7	10.5	10.1	10.2	10.1	10.2	10.1	10	10.2	9.9	10.1	10.2	10.11	-3.71	0.98
AccuChek Aviva	1.7	3.3	2.5	2.4	2.4	2.3	2.4	2.4	2.4	2.4	2.3	2.4	2.3	2.37	-5.20	2.04
	14.1	19.1	16.6	16.4	16.2	16.3	16	16.1	15.9	16.3	16.3	16.1	16.1	16.17	-2.59	0.97
AccuChek Mobile	2.9	4.6	3.75	3.6	3.5	3.6	3.4	3.4	3.6	3.8	3.6	3.8	3.7	3.60	-4.00	3.93
	8.4	11.4	9.9	9.7	10	10.3	10	9.9	10	9.9	9.9	10.1	10.3	10.01	1.11	1.85
AccuChek Inform 2	1.7	3.3	2.5	2.4	2.5	2.6	2.5	2.5	2.5	2.6	2.5	2.6	2.5	2.52	0.80	2.51
	14.5	19.6	17.05	17.1	16.9	17	17.2	17.1	17	17.4	17.3	16.9	17	17.09	0.23	0.97
Contour	5.9	8.2	7.05	7.1	6.9	6.7	6.9	6.9	6.9	6.7	6.9	6.9	7.1	6.90	-2.13	1.93
Contour XT	6.5	8.2	7.35	7.1	7.1	7.3	7.2	7.1	6.9	7.1	6.9	7.1	6.9	7.07	-3.81	1.89
Breeze 2	5.2	7.1	6.15	6	6.1	6	6.1	6.3	6.3	6.2	6.2	5.9	6.1	6.12	-0.49	2.15
Freestyle Freedom Lite	1.7	3.3	2.5	2.6	2.6	2.7	2.7	2.6	2.7	2.6	2.7	2.8	2.7	2.67	6.80	2.53
	13.8	20.7	17.25	17.2	17.2	17.3	16.8	17.4	16.7	16.4	16.6	16.4	16.8	16.88	-2.14	2.20
FreeStyle Precision	3.8	6.9	5.35	4.9	5.2	4.8	5.2	4.9	5.1	5.4	4.9	4.7	5.2	5.03	-5.98	4.40
	1.7	3.4	2.55	2.5	2.6	2.5	2.4	2.6	2.6	2.6	2.6	2.6	2.5	2.55	0.00	2.77
	12	20.3	16.15	16.1	15.4	16.5	17.6	16.7	16.9	17.2	16.2	16.1	16.2	16.49	2.11	3.84
OneTouch vita	6.4	8.6	7.5	7.2	7.2	7.2	7.2	7.2	7.1	7.3	7.1	7.2	7.3	7.20	-4.00	0.93
OneTouch UltraEasy	6.4	8.6	7.5	7.2	7.2	7.1	7.2	7	7.2	7.2	7.1	7.2	7	7.14	-4.80	1.18
OneTouch Veriopro	5.7	7.7	6.7	6.8	7.1	7	7	7.2	7	6.9	7.2	6.9	7	7.01	4.63	1.84
GlucoCard mini	4.9	6.3	5.6	5.6	5.6	5.7	5.3	5.2	5.2	5.5	5	4.9	5.3	5.33	-4.82	5.01

Control solution of manufacturer

	from	to	target	1	2	3	4	5	6	7	8	9	10	mean	bias	cv%
GlucoMen LX Plus	5.7	7.2	6.45	7.1	6.5	6.4	6.8	6.7	6.9	6.5	6.6	6.5	6.7	6.67	3.41	3.24
	14.7	19.8	17.25	16.9	16.5	16.2	16.4	17.5	17.2	17.4	17.3	18	17	17.04	-1.22	3.26
GlucoMen Ready	7.2	9	8.1	8.1	8.1	8	8.2	8.3	8.1	8.3	8.3	8.1	8.4	8.19	1.11	1.57
	13	16.2	14.6	13.8	13.9	14.3	14.5	14.1	14.2	14.3	13.9	13.9	14.1	14.10	-3.42	1.60
Pura	2.5	3.7	3.1	3.1	3	3.1	3.1	3.1	3	3.1	3	2.9	3	3.04	-1.94	2.30
	4.8	6.5	5.65	5.3	5.3	5.3	5.2	5.3	5.4	5.3	5.6	5.7	5.4	5.38	-4.78	2.88
	13	17.6	15.3	14.6	14.8	14.7	14.7	14.5	14.4	14.8	14.3	13.9	14.4	14.51	-5.16	1.91
Unio	5.3	7.2	6.25	6.3	6.3	6.5	6.3	6.6	6.3	6.3	6.3	6.2	6.3	6.34	1.44	1.85
	13.7	18.5	16.1	17.3	17.7	16.6	17.5	17.9	17.3	17.9	16.7	17.2	16.6	17.27	7.27	2.90
Healthpro	4.21	6.3	5.255	5.5	5.2	5.4	5.8	5.4	5.9	5.5	5.5	5.5	5.3	5.50	4.66	3.83
BG-Star	5.7	8.6	7.15	6.4	6.2	6.6	6.7	6.4	6.6	6.8	6.5	7	6.7	6.59	-7.83	3.46
Finetest	4.3	5.4	4.85	4.6	4.7	4.8	4.8	4.7	4.7	4.7	4.7	4.6	4.6	4.69	-3.30	1.57
	12.2	15.2	13.7	12.9	12.7	13.1	13.3	13.4	13.2	13	12.7	12.2	12.7	12.92	-5.69	2.77

4. Suvey sample MQ 2013-4 K1 (Plasma-sample)

	target MQ	1	2	3	4	5	6	7	8	9	10	mean	CV%	bias %
Hemocue 201+ PI	14.6	14.9	14.9	15.2	15.3	13.8	15.1	15.1	14.0	15.1	14.21	14.75	3.76	1.0
Hemocue 201RT	14.7	14.3	14.3	14.3	14.3	14.3	14.5	14.3	14.3	14.4	14.7	14.37	0.93	-2.2
AccuChek Aviva	13.3	13.7	13.4	13.2	13.6	13.3	13.2	13.7	13.7	13.4	13.5	13.47	1.49	1.3
AccuChek Mobile	14.5	15.1	15.4	15.6	15.2	15.4	15.7	15	15.3	15	15.6	15.33	1.66	5.7
AccuChek Inform 2	13.6	13.6	13.6	13.5	13.6	13.5	13.6	13.4	13.3	13.7	13.4	13.52	0.91	-0.6
Contour	10.8	10.8	10.6	10.7	10.9	10.7	10.9	10.8	10.9	10.8	10.9	10.80	0.98	0.0
Contour XT	13.2	13.2	12.8	13.9	13.3	13.6	12.8	13.4	13.1	13.1	13.7	13.29	2.76	0.7
Breeze 2	23.3	24.3	22.7	23.9	23.7	23.6	23.3	24.2	24.3	24.4	24	23.84	2.24	2.3
Freestyle Freedom Lite	14.7	15	14.7	14.9	15.2	14.9	14.6	14.9	15.3	15.2	15.2	14.99	1.56	2.0
OneTouch UltraEasy	19.4	19.6	20.2	19.6	20.3	20.4	20.2	19.8	20.5	19.8	20.1	20.05	1.63	3.4
OneTouch Veriopro	13.4	13.5	13.5	13.5	13.5	13.7	13.5	13.5	13.7	13.4	13.7	13.55	0.76	1.1
GlucoCard Xmini plus	21.5	19.9	20.4	19.4	18.9	19.6	19.3	18.9	18.9	17.7	18.9	19.19	3.59	-10.7
Pura	16.3	15.7	16.8	15.9	15.7	15.7	15.8	16.2	16.2	15.4	16	15.94	2.32	-2.2
Healthpro	23.5	23.3	24	23	23.2	24	24.4	23.2	23.4	22.8	24.3	23.56	2.28	0.3
BG-Star	20.1	17.7	18.2	17.8	18.3	17.7	18.8	18.3	18.3	18.3	18	18.14	1.80	-9.8

5. Manufacturer informations on the instruments

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
AccuChek Mobile	Roche	K		mGDH-PQQ	RF	HK	25-55	6.5	2.6	2.4	2.0	1.9
AccuChek Inform 2	Roche	KVAN	HEF	mGDH-PQQ	A	HK	10-65	4.0	4.1	3.3	3.3	3.2
AccuChek Aviva	Roche	KVAN	HE	mGDH-PQQ	A	HK	20-70	3.6	3.3	3.3	3.4	3.4
Contour	Bayer	K		GDH-FAD	A	YSI	0-70	4.8	5.1	3.7	3.3	3.6
Contour XT	Bayer	KVN	H	GDH-FAD	A	YSI	0-70	1.8	1.9	1.3	1.2	1.7
Breeze	Bayer	K		GOx	A	YSI	20-55		4.1	2.3	2.1	1.9
Freestyle Freedom Lite	Abbott	KV	H	GDH	C	YSI	15-65	3.3	2.4	2.2	2.3	2.4
Freestyle Precision	Abbott	KVAN	HE	GDH-NAD	A	YSI	30-60		4	3	2.7	3.2
OneTouch vita	Lifescan	K	H	GOx	A	YSI	30-55	3.5	1.7	1.9	1.3	1.5
OneTouch UltraEasy	Lifescan	K	H	GOx	A	YSI	30-55	3.2	2.0	2.1	1.8	1.6
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	GO-FAD	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
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	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
Finetest	Belonga	K		GOx	A	HK	20-60	3.5	2.5	2.2	2.9	3.7
FORA GD40a	FORA	KV	H	GDH-FAD	A	YSI	0-70	8.4	3.4	3.1	4.3	2.4
FORA GD50	FORA	KV	H	GDH-FAD	A	YSI	20-60	4.6	3.9	3.4	2.9	2.8

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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