C-EUBD
Committee Education in the
Use of Biomarkers in Diabetes

Report
EurAAA1c 2019

HbA1c Trial
EQA organisers

Final Version
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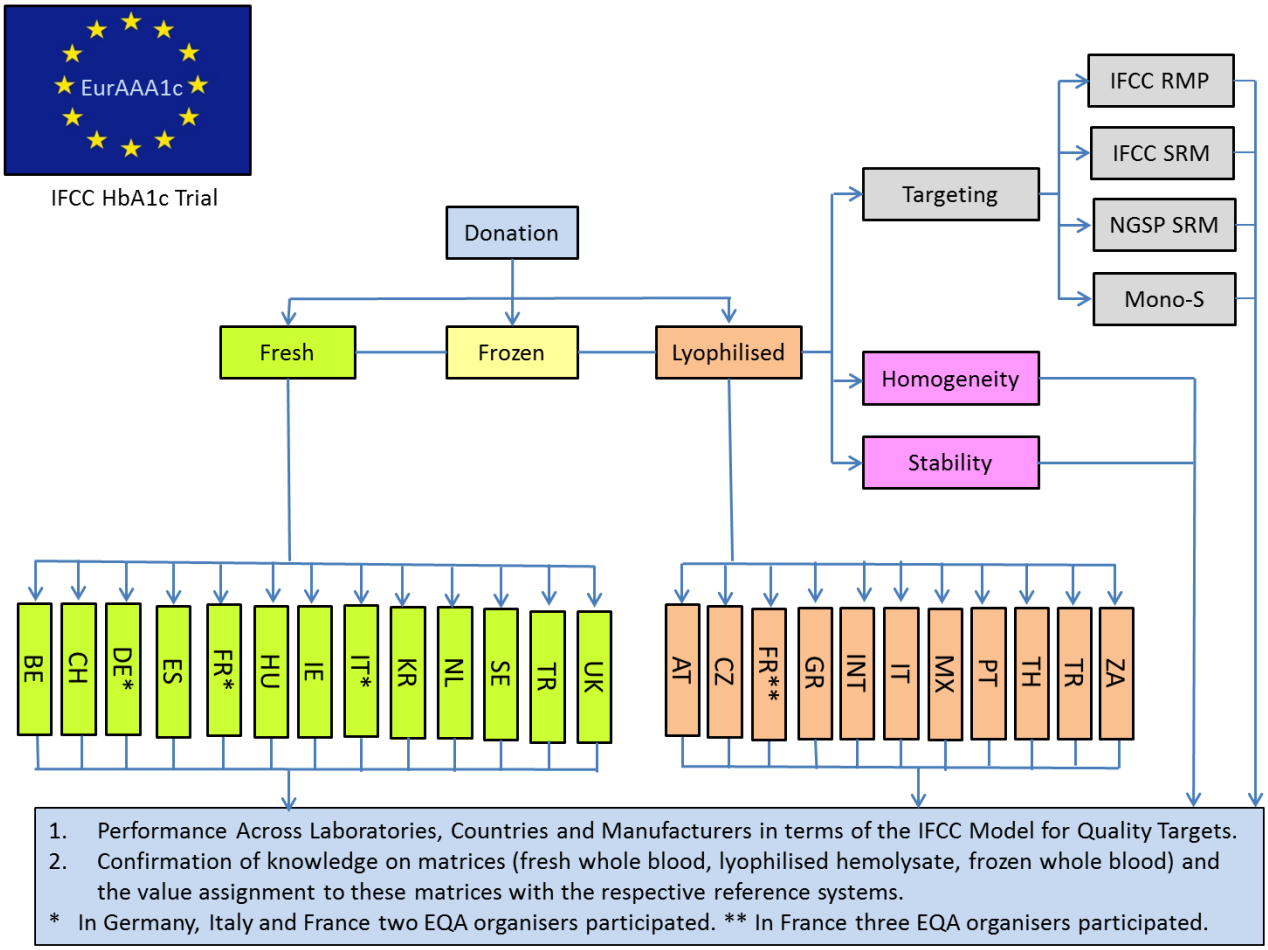
I Introduction and Overview of Results

Introduction

25 EQA organisers of 20 countries agreed to participate in the fourth “EurAAA1c” project. The design is shown in figure 1. The name and logo of the project have been changed to EurAAA1c to acknowledge the participation of EQA organisers in Asia, America and Africa.

16 EQA organisers used fresh whole blood samples and 13 organisers used lyophilised hemolysate samples (4 organisations used both fresh and lyophilised samples). In October 2019 the fresh whole blood samples were sent to the participants. From November 2019 up to April 2020 the lyophilised samples are assayed by the participants.

Figure 1. Design EurAAA1c Trial 2019



Confidentiality and Ownership

The results of the EurAAA1c project are owned by all EQA organisers. Previously we agreed that reports are confidential and will not be shared with participants and other third parties until the definite report is completed.

The time schedule is:

July 2020:	Draft report sent to all who are involved in EurAAA1c 2019. At the same time the invitation to participate in EurAAA1c 2020 is sent.
31 August 2020:	Deadline for comments and remarks
30 September 2020:	Final report sent to all who are involved. By then all who are involved are free to share results with third parties

Value Assignment
Five Approved IFCC Network Laboratories performed the value assignment with the IFCC Reference Measurement Procedure. For EurAAA1c 2019-1 the assigned value is 70.1 mmol/mol (expanded uncertainty 1.1 mmol/mol) and for EurAAA1c 2019-2 the assigned value is 38.2 mmol/mol (expanded uncertainty 0.6 mmol/mol). The values are the target values for both fresh whole blood and lyophilised samples.

Outliers
Outliers have been removed before calculation of the mean and between laboratory CV. Instead of using statistical criteria we only considered "blunders" as outliers. The criterion used was a difference exceeding 25% of the target values. In our opinion these results are a relevant picture of "real life". In this way 42 results (0.7%) have been excluded from the database of fresh whole blood samples and 35 results (2.5%) from the database of lyophilised hemolysates.

Methods
This is a point of consideration. 96 of the laboratories did not report their method at all. Also a number of labs did not specify their method (Siemens and Abbott users not specifying whether they used the enzymatic or immunoassay; Roche users who did not specify instruments). For details see table 3 (fresh whole blood) and table 7 (lyophilized).

Units
In some cases results were reported in NGSP units. We converted them to SI (IFCC) units using the Master Equation (NGSP = 0.0915IFCC + 2.15) prior to calculation of means, SDs and making comparisons. All results in the report are in SI units.

Summary of Results
Table 1 summarizes the results. The participating EQA organisers are ranked per country in alphabetical order. Results are given for the fresh whole blood and lyophilised hemolysate samples.

Table 1. Results of EurAAA1c 2019

Country	Fresh Whole Blood			Lyophilised Hemolysate		
	n*	Mean Bias in mmol/mol	Between Laboratory CV	n*	Mean Bias in mmol/mol	Between Laboratory CV
Austria				116	+1.0	5.6%
Belgium	133	+0.6	3.5%			
Czech Republic				195	+1.2	5.1%
France Asqualab				47	+1.4	5.2%
France CTCB	177	+0.4	3.8%	157	+1.4	4.9%
France Probioqual	361	+0.7	3.4%	548	+1.0	5.9%
Germany INSTAND	636	+0.1	5.2%			
Germany RfB	728	+0.5	4.6%			
Greece				78	+1.2	5.6%
Hungary	67	+0.4	6.1%			
International**				43	+0.9	3.9%
Ireland	37	-0.3	4.7%			
Italy CRB	56	+0.7	4.8%	43	+1.2	4.3%
Italy CRRVEQ	116	+0.9	4.9%			
Korea	74	+0.6	3.6%			
Mexico				27	+1.6	6.1%
Netherlands	119	+0.4	3.9%			
Portugal				43	+1.2	4.8%
South Africa				5	+2.2	3.5%
Spain	105	+0.8	3.7%			
Sweden	132	-0.9	4.0%			
Switzerland	67	-0.2	4.3%			
Thailand				185	+0.5	10.1%
Turkey	52	+1.0	5.8%	50	+2.3	7.2%
United Kingdom	178	+0.1	4.7%			
Overall	3038	+0.4	4.6%	1537	+1.1	6.2%

** n = the number of datasets.* *** Individual laboratories of a number of countries*

In total 4575 datasets were submitted (3038 in fresh whole blood and 1537 in lyophilised hemolysate). The results are encouraging. The mean bias of all countries in the fresh whole blood programme is +0.4 mmol/mol and the between laboratory CV of 4.6% is also quite satisfying. In lyophilised hemolysate the mean bias of all laboratories is +1.1 mmol/mol and the between laboratory CV is 6.2%.

Differentiation of Results

Results are differentiated per sample and a) per country. b) per manufacturer and c) per manufacturer per country in fresh whole blood (section II). and in lyophilised hemolysates (section III)

II Results EQA Fresh Whole Blood samples

Table 2 shows the results per country for each sample. Tables 3 and 4 show the results per manufacturer for manufacturers with 6 or more participants (table 3) and those with 5 or less participants (table 4).

Table 2. Results per Country for Fresh Whole Blood

Country	EurAAA1c 2019-1 Target 70.1 mmol/mol				EurAAA1c 2019-2 Target 38.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Belgium	133	71.3	+1.2	2.9	133	38.3	+0.1	4.0	+0.6	3.5
France CTCB	177	71.2	+1.1	3.3	174	37.9	-0.3	4.3	+0.4	3.8
France Probioqual	361	71.4	+1.3	3.1	358	38.3	+0.1	3.8	+0.7	3.4
Germany INSTAND	636	70.5	+0.4	4.8	632	38.0	-0.2	5.6	+0.1	5.2
Germany RfB	728	71.2	+1.1	4.1	727	38.2	0.0	5.1	+0.5	4.6
Hungary	67	71.0	+0.9	5.8	66	38.2	0.0	6.3	+0.4	6.1
Ireland	37	70.6	+0.5	4.1	36	37.1	-1.1	5.2	-0.3	4.7
Italy CRB	56	71.5	+1.4	4.1	54	38.3	+0.1	5.4	+0.7	4.8
Italy CRRVEQ	115	71.4	+1.3	4.5	116	38.6	+0.4	5.3	+0.9	4.9
Korea	74	71.3	+1.2	2.9	74	38.2	0.0	4.4	+0.6	3.6
Netherlands	119	71.0	+0.9	3.3	119	38.2	0.0	4.4	+0.4	3.9
Spain	104	71.6	+1.5	3.3	105	38.2	0.0	4.2	+0.8	3.7
Sweden	130	69.5	-0.6	3.7	132	37.0	-1.2	4.4	-0.9	4.0
Switzerland	67	70.3	+0.2	4.3	67	37.6	-0.6	4.4	-0.2	4.3
Turkey	51	71.9	+1.8	4.9	52	38.4	+0.2	6.7	+1.0	5.8
United Kingdom	176	70.9	+0.8	3.8	178	37.6	-0.6	5.7	+0.1	4.7
Overall	3031	71.0	+0.9	4.1	3023	38.1	-0.1	5.0	+0.4	4.6

Table 3. Results per Manufacturer for Fresh Whole Blood (n>5)

Manufacturer	EurAAA1c 2019-1 Target 70.1 mmol/mol				EurAAA1c 2019-2 Target 38.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott ARCHITECT (enzymatic)	24	71.9	+1.8	1.9	24	38.1	-0.1	3.1	+0.9	2.5
Abbott ARCHITECT not specified	24	71.2	+1.1	3.9	24	37.6	-0.6	4.0	+0.3	3.9
Abbott/Alere Afinion	142	68.4	-1.7	2.7	141	36.6	-1.6	5.1	-1.6	3.9
Beckman Coulter AU series	57	69.0	-1.1	6.3	57	38.3	+0.1	6.6	-0.5	6.5
Beckman Coulter Unicel DxC series	19	70.6	+0.5	3.3	19	37.7	-0.5	3.2	0.0	3.2
Bio-Rad D-10 series	91	73.7	+3.6	3.4	92	39.2	+1.0	4.3	+2.3	3.8
Bio-Rad D-100 series	124	69.0	-1.1	2.8	123	36.1	-2.1	3.6	-1.6	3.2
Bio-Rad Variant series	162	73.0	+2.9	2.8	163	38.4	+0.2	5.2	+1.6	4.0
EKF Diagnostics	11	71.4	+1.3	3.0	11	39.4	+1.2	5.4	+1.3	4.2
HemoCue HbA1c 501	14	68.4	-1.7	4.3	14	35.4	-2.8	8.9	-2.2	6.6
Menarini (ARKRAY) HA-8160 series	74	70.7	+0.6	3.2	73	37.6	-0.6	4.4	0.0	3.8
Menarini (ARKRAY) HA-8180 series	214	71.0	+0.9	2.8	213	38.1	-0.1	3.8	+0.4	3.3
Not known	96	69.3	-0.8	6.8	94	37.2	-1.0	7.0	-0.9	6.9
Roche Diagnostics cobas b 101	6	71.9	+1.8	3.8	6	40.3	+2.1	4.1	+2.0	3.9
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	387	71.6	+1.5	3.5	387	38.1	-0.1	4.0	+0.7	3.7
Roche Diagnostics cobas c 513	93	71.8	+1.7	2.7	93	38.5	+0.3	2.3	+1.0	2.5
Roche Diagnostics cobas c 311/c111	20	71.4	+1.3	3.6	20	37.7	-0.5	5.4	+0.4	4.5
Roche Diagnostics cobas Integra	98	71.7	+1.6	3.3	98	37.9	-0.3	3.5	+0.7	3.4
Roche Diagnostics not specified	33	71.2	+1.1	3.3	34	37.9	-0.3	3.1	+0.4	3.2
Sebia CAPILLARYS 2	193	71.2	+1.1	3.0	192	37.9	-0.3	3.7	+0.4	3.4
Sebia CAPILLARYS 3	112	70.8	+0.7	2.4	110	37.6	-0.6	3.3	+0.1	2.8
Sebia MINICAP	23	70.0	-0.1	2.8	23	37.3	-0.9	3.1	-0.5	3.0
Siemens Advia (immunoassay)	7	72.5	+2.4	6.7	7	39.2	+1.0	5.2	+1.7	5.9
Siemens Advia not specified	8	73.4	+3.3	6.1	8	39.3	+1.1	11.0	+2.2	8.6
Siemens DCA 2000/Vantage	262	68.8	-1.3	3.8	263	36.3	-1.9	3.8	-1.6	3.8
Siemens Dimension series	102	68.2	-1.9	2.9	102	39.3	+1.1	4.6	-0.4	3.8
Tosoh G11	148	72.3	+2.2	2.7	148	39.2	+1.0	3.4	+1.6	3.0
Tosoh G7	19	69.8	-0.3	6.6	19	38.2	0.0	7.1	-0.1	6.8
Tosoh G8	354	72.7	+2.6	2.4	351	39.6	+1.4	2.9	+2.0	2.6
Tosoh GX	22	72.8	+2.7	3.9	22	39.8	+1.6	2.6	+2.1	3.2
Trinity Biotech Premier Hb9210	29	71.1	+1.0	2.4	28	38.5	+0.3	5.4	+0.7	3.9

Table 4. Results per Manufacturer for Fresh Whole Blood (n<6)

Manufacturer	EurAAA1c 2019-1 Target 70.1 mmol/mol				EurAAA1c 2019-2 Target 38.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	4	72.2	+2.1	5.0	4	38.3	0.0	4.6	+1.1	4.8
Abbott ARCHITECT (immunoassay)	3	66.8	-3.3	12.2	3	36.9	-1.3	0.7	-2.3	6.5
Abbott AxSym	3	70.0	-0.1	5.7	3	37.0	-1.2	8.1	-0.6	6.9
Beckman Coulter not specified	2	69.2	-0.9	5.8	2	37.4	-0.8	6.1	-0.9	6.0
Bio-Rad not specified	5	74.7	+4.6	5.5	5	39.5	+1.3	5.1	+3.0	5.3
Diasys InnovaStar	1	80.8	+10.7		1	46.5	+8.3		+9.5	
Eurolyser	2	68.0	-2.2		2	34.4	-3.7		-2.9	
Hitado	2	64.2	-5.9	0.5	2	34.6	-3.6	10.7	-4.7	5.6
Horiba Pentra	5	72.6	+2.5	5.3	5	37.3	-0.9	4.1	+0.8	4.7
ISE S.r.l. Hemo One ISE HbA1c	1	59.2	-10.9		1	31.0	-7.2		-9.1	
Lifotronic	1	70.4	+0.3		1	38.7	+0.5		+0.4	
Medinor NycoCard	5	67.0	-3.1	9.9	6	38.3	+0.1	11.3	-1.5	10.6
Menarini (ARKRAY) HA-8140 series	2	71.3	+1.2	1.5	2	39.0	+0.8	0.0	+1.0	0.7
Menarini (ARKRAY) not specified	3	70.2	+0.1	3.3	3	38.7	+0.5	5.4	+0.3	4.3
MTD Diagnostics	1	68.7	-1.4		1	32.9	-5.3		-3.4	
Ortho Clinical Diagnostics Vitros series	1	70.0	-0.1		1	35.0	-3.2		-1.7	
Randox RX series	1	64.7	-5.4		1	42.1	+3.9		-0.7	
Roche Diagnostics cobas c 503 (cobas pro)	4	70.3	+0.2	3.7	4	38.6	+0.3	2.7	+0.3	3.2
Siemens Advia (enzymatic)	3	71.8	+1.7	3.7	3	39.2	+1.0	4.3	+1.4	4.0
Siemens Atellica CH (immunoassay)	2	68.7	-1.4	3.6	2	38.9	+0.7	0.4	-0.3	2.0
Siemens Atellica CH not specified	2	75.0	+4.9	0.0	2	41.5	+3.3	1.7	+4.1	0.9
Siemens not specified	1	68.0	-2.1		1	37.0	-1.2		-1.7	
Siemens Other	1	66.0	-4.1		1	35.0	-3.2		-3.7	
Thermo Scientific	5	67.0	-3.1	5.1	5	39.5	+1.3	4.6	-0.9	4.8
Tosoh not specified	3	75.7	+5.6	2.9	3	41.2	+3.0	4.0	+4.3	3.5

Table 5 shows the performance per manufacturer per country. Included are only manufacturers meeting 2 criteria: at least 6 participants per country and at least two countries with at least 6 participants each. We marked high biases (>2 mmol/mol) and high between laboratory CVs (>6%).

Table 5. Fresh Whole Blood Results per Manufacturer and Country (n>5)

Method	**n**	**EurAAA1c 2019-1** Target 70.1 mmol/mol		**EurAAA1c 2019-2** Target 38.2 mmol/mol		**Mean**	
		Bias	**CV%**	**Bias**	**CV%**	**Bias**	**CV%**
Abbott/Alere AFINION							
Overall	142	-1.7	2.7	-1.6	5.1	-1.6	3.9
CH	19	-2.1	2.1	-1.5	2.4	-1.8	2.2
DE-INSTAND	47	-1.6	2.6	-1.0	4.4	-1.3	3.5
DE-RfB	7	-1.8	4.3	-0.9	8.2	-1.4	6.2
IE	6	+0.2	1.5	-1.7	3.8	-0.7	2.6
NL	11	-1.1	3.3	-1.5	4.9	-1.3	4.1
SE	37	-1.9	2.0	-1.8	3.7	-1.9	2.9
UK	14	-2.6	2.8	-3.7	4.7	-3.1	3.7
Beckman Coulter AU series							
Overall	57	-1.1	6.3	+0.1	6.6	-0.5	6.5
DE-INSTAND	22	-0.2	6.0	+0.6	8.2	+0.2	7.1
DE-RfB	25	-1.0	6.3	-0.3	4.1	-0.6	5.2
Bio-Rad D-10 series							
Overall	91	+3.6	3.4	+1.0	4.3	+2.3	3.8
DE-INSTAND	22	+3.6	3.5	+1.0	3.9	+2.3	3.7
DE-RfB	31	+3.7	3.1	+0.8	4.4	+2.2	3.8
FR-CTCB	9	+3.1	3.8	+0.8	6.1	+2.0	4.9
FR-Probioqual	14	+3.9	3.1	+1.6	2.7	+2.8	2.9
Bio-Rad D-100 series							
Overall	124	-1.1	2.8	-2.1	3.6	-1.6	3.2
BE	6	-1.5	2.1	-3.2	1.6	-2.3	1.8
DE-INSTAND	13	-1.2	6.6	-1.0	5.6	-1.1	6.1
DE-RfB	30	-1.2	1.5	-2.5	3.7	-1.8	2.6
ES	12	-1.0	3.1	-2.1	3.4	-1.6	3.2
FR-Probioqual	19	-1.4	2.5	-2.3	2.6	-1.8	2.6
KR	27	-0.7	1.9	-1.7	2.8	-1.2	2.3
Bio-Rad Variant series							
Overall	162	+2.9	2.8	+0.2	5.2	+1.6	4.0
DE-INSTAND	21	+2.0	3.8	0.0	6.1	+1.0	4.9
DE-RfB	43	+2.6	2.4	-0.3	5.8	+1.2	4.1
FR-CTCB	16	+3.3	2.6	-0.3	5.7	+1.5	4.2
FR-Probioqual	31	+3.3	2.0	+0.5	3.6	+1.9	2.8
HU	8	+2.8	4.0	+1.1	4.5	+1.9	4.3
IT-CRRVEQ	9	+4.1	2.6	+0.2	2.3	+2.2	2.4
SE	8	+1.7	1.7	+0.1	3.3	+0.9	2.5
TR	13	+4.5	2.2	+1.5	5.2	+3.0	3.7
HemoCue HbA1c 501							
Overall	14	-1.7	4.3	-2.8	8.9	-2.2	6.6
DE-INSTAND	7	-1.1	5.7	-3.2	8.9	-2.2	7.3
DE-RfB	7	-2.3	2.4	-2.4	9.5	-2.3	6.0
Menarini (ARKRAY) HA-8160 series							
Overall	74	+0.6	3.2	-0.6	4.4	0.0	3.8
BE	21	+0.7	2.5	-0.7	2.7	0.0	2.6
HU	21	-0.2	4.3	-0.7	5.4	-0.5	4.9
IT-CRB	12	+1.9	2.4	-0.1	6.2	+0.9	4.3
NL	9	+1.1	2.0	-0.2	3.9	+0.5	3.0
Menarini (ARKRAY) HA-8180 series							
Overall	214	+0.9	2.8	-0.1	3.8	+0.4	3.3
BE	39	+0.6	2.6	-0.2	3.1	+0.2	2.8
CH	2	-0.7	4.5	-0.5	8.2	-0.6	6.3
DE-INSTAND	20	+1.3	2.3	+0.4	3.2	+0.8	2.7
DE-RfB	26	+0.4	4.2	-0.7	6.4	-0.2	5.3
ES	47	+1.4	2.9	0.0	3.3	+0.7	3.1
HU	6	+1.2	2.7	+0.6	3.8	+0.9	3.2
IE	7	+1.8	2.6	+0.4	2.9	+1.1	2.8
IT-CRB	8	+1.8	1.7	+0.4	2.4	+1.1	2.1
IT-CRRVEQ	11	+0.9	1.8	-0.1	2.5	+0.4	2.1
KR	8	+1.2	1.6	+0.1	2.2	+0.6	1.9
NL	20	+0.4	2.1	-0.1	2.7	+0.2	2.4
TR	6	+0.7	3.9	-0.8	7.0	-0.1	5.4
UK	14	+0.8	2.4	-0.3	2.7	+0.2	2.5

Method	n	EurAAA1c 2019-1 Target 70.1 mmol/mol		EurAAA1c 2019-2 Target 38.2 mmol/mol		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)							
Overall	387	+1.5	3.5	-0.1	4.0	+0.7	3.7
CH	13	+2.6	3.3	+0.2	2.9	+1.4	3.1
DE-INSTAND	127	+1.5	3.3	-0.1	3.7	+0.7	3.5
DE-RfB	163	+1.4	3.4	-0.2	4.6	+0.6	4.0
ES	6	+3.4	2.1	-0.1	3.8	+1.7	3.0
FR-Probioqual	27	+1.7	4.0	-0.1	3.7	+0.8	3.9
NL	15	+1.2	2.1	+0.1	2.9	+0.7	2.5
SE	9	+0.5	4.1	-0.7	2.1	-0.1	3.1
TR	11	+1.4	4.3	0.0	4.1	+0.7	4.2
Roche Diagnostics cobas c 513							
Overall	93	+1.7	2.7	+0.3	2.3	+1.0	2.5
DE-INSTAND	28	+1.4	2.9	+0.3	1.9	+0.8	2.4
DE-RfB	54	+1.4	1.9	+0.1	1.8	+0.8	1.9
Roche Diagnostics cobas Integra							
Overall	98	+1.6	3.3	-0.3	3.5	+0.7	3.4
DE-INSTAND	45	+1.4	3.4	-0.7	3.5	+0.4	3.4
DE-RfB	46	+1.6	3.4	+0.2	3.1	+0.9	3.3
Roche Diagnostics not specified							
Overall	33	+1.1	3.3	-0.3	3.1	+0.4	3.2
FR-CTCB	20	+1.0	3.4	-0.4	3.1	+0.3	3.2
KR	9	+1.7	2.1	+0.4	2.4	+1.0	2.2
Sebia CAPILLARYS 2							
Overall	193	+1.1	3.0	-0.3	3.7	+0.4	3.4
BE	9	+0.7	4.3	+0.5	3.2	+0.6	3.7
DE-INSTAND	9	+0.8	3.0	+0.4	1.9	+0.6	2.5
DE-RfB	42	+1.7	3.1	-0.1	4.7	+0.8	3.9
FR-CTCB	34	-0.1	3.9	-1.0	3.8	-0.5	3.9
FR-Probioqual	69	+1.2	2.3	-0.2	2.9	+0.5	2.6
IT-CRB	6	+0.7	2.3	0.0	2.6	+0.3	2.4
IT-CRRVEQ	8	+2.3	2.9	+0.2	4.2	+1.2	3.5
UK	7	+1.0	1.0	-1.5	3.4	-0.2	2.2
Sebia CAPILLARYS 3							
Overall	112	+0.7	2.4	-0.6	3.3	+0.1	2.8
DE-RfB	6	+0.7	2.7	-0.4	3.9	+0.2	3.3
FR-CTCB	30	+0.4	2.8	-1.1	3.3	-0.4	3.1
FR-Probioqual	46	+0.9	2.1	-0.3	3.1	+0.3	2.6
IT-CRRVEQ	8	+0.9	2.6	-0.7	2.9	+0.1	2.7
SE	6	+0.4	1.2	-1.2	3.4	-0.4	2.3
UK	6	+1.3	3.2	-0.8	1.5	+0.3	2.3
Sebia MINICAP							
Overall	23	-0.1	2.8	-0.9	3.1	-0.5	3.0
BE	6	-0.1	3.6	-1.0	4.6	-0.6	4.1
FR-Probioqual	8	0.0	2.1	-0.6	2.4	-0.3	2.3
Siemens DCA 2000/Vantage							
Overall	262	-1.3	3.8	-1.9	3.8	-1.6	3.8
CH	10	-1.1	5.6	-1.8	4.9	-1.5	5.2
DE-INSTAND	49	-2.1	3.0	-2.3	4.3	-2.2	3.7
DE-RfB	32	-1.8	3.5	-1.9	3.6	-1.9	3.6
FR-Probioqual	26	-1.0	3.5	-1.5	2.7	-1.3	3.1
IE	18	-0.7	5.0	-2.2	3.9	-1.5	4.4
NL	14	-1.5	3.8	-1.8	2.6	-1.7	3.2
SE	52	-1.2	3.8	-1.6	4.2	-1.4	4.0
UK	58	-0.6	3.5	-1.9	3.7	-1.3	3.6
Siemens Dimension series							
Overall	102	-1.9	2.9	+1.1	4.6	-0.4	3.8
DE-INSTAND	37	-2.0	2.5	+1.0	3.9	-0.5	3.2
DE-RfB	47	-1.8	3.5	+1.0	5.0	-0.4	4.3
FR-Probioqual	9	-2.4	0.8	+1.2	4.4	-0.6	2.6

Method	n	EurAAA1c 2019-1 Target 70.1 mmol/mol		EurAAA1c 2019-2 Target 38.2 mmol/mol		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Tosoh G8							
Overall	354	+2.6	2.4	+1.4	2.9	+2.0	2.6
BE	35	+2.3	2.1	+1.6	2.4	+1.9	2.2
DE-INSTAND	23	+2.8	2.7	+1.6	3.2	+2.2	3.0
DE-RfB	59	+2.9	2.2	+1.6	2.6	+2.2	2.4
ES	13	+2.9	2.4	+1.6	3.2	+2.3	2.8
FR-CTCB	39	+1.3	1.7	+0.5	2.0	+0.9	1.9
FR-Probioqual	56	+2.4	1.7	+1.2	2.1	+1.8	1.9
IT-CRB	6	+4.2	2.2	+2.1	3.0	+3.2	2.6
IT-CRRVEQ	28	+2.4	3.4	+1.3	3.1	+1.8	3.3
KR	11	+3.2	1.7	+1.9	2.4	+2.5	2.0
NL	26	+2.5	2.6	+1.5	3.2	+2.0	2.9
SE	11	+2.1	2.5	+0.7	3.6	+1.4	3.1
TR	7	+2.9	3.3	+0.6	5.7	+1.8	4.5
UK	37	+3.7	1.9	+1.9	2.5	+2.8	2.2
Tosoh G11							
Overall	148	+2.2	2.7	+1.0	3.4	+1.6	3.0
DE-INSTAND	19	+2.8	3.2	+1.4	3.5	+2.1	3.4
DE-RfB	40	+2.9	3.7	+1.1	5.1	+2.0	4.4
FR-Probioqual	37	+1.4	1.2	+0.9	1.6	+1.1	1.4
IT-CRRVEQ	9	+1.7	1.9	+0.9	2.9	+1.3	2.4
KR	18	+2.6	1.8	+1.1	1.7	+1.8	1.7
UK	8	+1.7	1.2	+0.7	2.1	+1.2	1.7

III Results EQA Lyophilised Hemolysate samples

Table 6 shows the results per country for each sample. Tables 7 and 8 show the results per manufacturer for manufacturers with 6 or more participants (table 7) and 5 or less participants (table 8).

Table 6. Results per Country for Lyophilised Hemolysate

Country	EurA1c 2019-1 Target 70.1 mmol/mol				EurA1c 2019-2 Target 38.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Austria	116	72.0	+1.9	5.4	117	38.3	+0.1	5.8	+1.0	5.6
Czech Republic	195	72.3	+2.2	5.1	197	38.5	+0.3	5.2	+1.2	5.1
France Asqualab	47	71.9	+1.8	4.6	46	39.1	+0.9	5.8	+1.4	5.2
France CTCB	157	72.4	+2.3	4.8	157	38.7	+0.5	5.0	+1.4	4.9
France Probioqual	548	71.8	+1.7	5.1	539	38.5	+0.3	6.7	+1.0	5.9
Greece	78	72.1	+2.0	4.7	86	38.6	+0.4	6.4	+1.2	5.6
International*	43	71.5	+1.4	4.4	56	38.5	+0.3	3.5	+0.9	3.9
Italy CRB	43	72.1	+2.0	3.2	42	38.7	+0.5	5.3	+1.2	4.3
Mexico	27	72.4	+2.3	5.8	27	39.1	+0.9	6.5	+1.6	6.1
Portugal	43	72.2	+2.1	4.5	43	38.6	+0.4	5.2	+1.2	4.8
South Africa	5	73.6	+3.5	3.9	5	39.0	+0.8	3.1	+2.2	3.5
Thailand	185	71.1	+1.0	9.5	184	38.1	-0.1	10.6	+0.5	10.1
Turkey	50	73.4	+3.3	7.0	50	39.4	+1.2	7.4	+2.3	7.2
Overall	1537	71.9	+1.8	5.8	1549	38.5	+0.3	6.7	+1.1	6.2

** Individual laboratories of a number of countries*

Table 7. Results per Manufacturer for Lyophilised Hemolysate (n>5)

Manufacturer	EurA1c 2019-1 Target 70.1 mmol/mol				EurA1c 2019-2 Target 38.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott ARCHITECT (enzymatic)	39	69.3	-0.8	4.0	39	36.7	-1.5	6.2	-1.2	5.1
Abbott ARCHITECT not specified	17	64.1	-6.0	7.3	17	32.8	-5.4	10.4	-5.7	8.9
Beckman Coulter AU series	13	76.6	+6.5	5.6	14	41.7	+3.5	6.6	+5.0	6.1
BioMajesty JCA-BM6010	7	64.1	-6.0	6.9	6	35.1	-3.1	7.6	-4.5	7.3
Bio-Rad D-10 series	106	73.4	+3.3	5.2	107	38.4	+0.2	6.6	+1.8	5.9
Bio-Rad D-100 series	49	71.4	+1.3	2.3	49	37.8	-0.4	3.6	+0.4	2.9
Bio-Rad Variant series	66	73.1	+3.0	5.3	67	38.6	+0.4	8.9	+1.7	7.1
Menarini (ARKRAY) HA-8160 series	59	70.8	+0.7	3.6	62	37.8	-0.4	5.1	+0.2	4.4
Menarini (ARKRAY) HA-8180 series	99	68.0	-2.1	5.7	102	37.2	-1.0	5.4	-1.5	5.5
Menarini (ARKRAY) not specified	24	69.7	-0.4	4.6	24	37.1	-1.1	3.9	-0.7	4.3
Not known	11	71.5	+1.4	4.6	13	37.5	-0.7	8.7	+0.4	6.7
Ortho Clinical Diagnostics Vitros series	7	74.6	+4.5	4.8	7	40.6	+2.4	5.0	+3.5	4.9
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	203	75.2	+5.1	3.7	199	39.3	+1.1	6.1	+3.1	4.9
Roche Diagnostics cobas c 513	10	74.0	+3.9	2.7	10	40.6	+2.4	4.6	+3.2	3.7
Roche Diagnostics cobas c311/c111	12	74.5	+4.4	6.3	13	38.1	-0.1	10.3	+2.1	8.3
Roche Diagnostics cobas Integra	39	74.5	+4.4	3.3	39	39.3	+1.1	7.0	+2.7	5.2
Roche Diagnostics not specified	22	74.3	+4.2	3.9	23	39.9	+1.7	4.0	+3.0	4.0
Sebia CAPILLARYS 2	131	70.1	0.0	2.4	135	37.9	-0.3	3.8	-0.2	3.1
Sebia CAPILLARYS 3	101	70.8	+0.7	2.6	104	38.4	+0.2	2.9	+0.5	2.8
Sebia MINICAP	23	70.2	+0.1	3.2	20	38.0	-0.2	3.8	0.0	3.5
Sebia not specified	10	71.2	+1.1	2.9	10	38.0	-0.2	4.1	+0.5	3.5
Siemens DCA 2000/Vantage	61	75.9	+5.8	4.4	58	42.6	+4.4	5.2	+5.1	4.8
Siemens Dimension series	32	75.3	+5.2	8.5	33	41.4	+3.2	7.1	+4.2	7.8
Sysmex bx-3010	8	63.2	-6.9	10.8	8	34.0	-4.2	13.0	-5.6	11.9

Manufacturer	EurA1c 2019-1 Target 70.1 mmol/mol				EurA1c 2019-2 Target 38.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Tosoh G11	64	73.6	+3.5	4.8	64	38.6	+0.4	3.7	+2.0	4.2
Tosoh G7	41	72.1	+2.0	2.7	42	39.4	+1.2	3.6	+1.6	3.2
Tosoh G8	180	70.9	+0.8	3.8	182	38.8	+0.6	3.4	+0.7	3.6
Tosoh GX	18	70.3	+0.2	5.0	18	38.0	-0.2	4.3	0.0	4.7
Tosoh not specified	9	70.8	+0.7	4.5	11	38.8	+0.6	6.0	+0.7	5.2
Trinity Biotech Premier Hb9210	16	70.7	+0.6	4.3	16	38.8	+0.6	5.9	+0.6	5.1

For Siemens DCA/Vantage it is known that there is a positive matrix effect for lyophilised samples. For the Abbott enzymatic test we investigated the negative bias in relation to stability. Fresh whole blood and lyophilised hemolysates were assayed on our Abbott instrument after manufacture of the samples and we did not find a difference in results. However, on storage in the refrigerator for 6, 18 and 24 months we found a decrease in measured HbA1c which we did not see in the same samples stored in the freezer (see section on stability on page 13). As samples have not been stored in the freezer the negative bias of Abbott might be contributed to instability of the samples for this method.

Table 8. Results per Manufacturer for Lyophilised Hemolysate (n < 6)

Manufacturer	EurA1c 2019-1 Target 70.1 mmol/mol				EurA1c 2019-2 Target 38.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	4	62.9	-7.2	7.4	4	31.7	-6.5	10.7	-6.9	9.0
Abbott ARCHITECT (immunoassay)	3	73.6	+3.5	8.2	2	36.3	-1.9	5.2	+0.8	6.7
Abbott not specified	2	76.4	+6.3	4.0	2	40.5	+2.3	0.5	+4.3	2.2
Abbott Other	2	72.5	+2.4	6.8	1	39.0	+0.8		+1.6	
Beckman Coulter AU series	2	80.0	+9.9	7.1	2	39.5	+1.3	1.6	+5.6	4.3
Beckman Coulter P/ACE MDQ	1	68.0	-2.1		1	37.0	-1.2		-1.7	
Beckman Coulter Unicel DxC series	1	76.0	+5.9		1	42.0	+3.8		+4.9	
BioHermes A1c Check Pro	1	68.3	-1.8		1	37.7	-0.5		-1.2	
Bio-Rad not specified	5	76.0	+5.9	4.8	4	39.2	+1.0	3.2	+3.5	4.0
Bio-Rad Other	1	73.0	+2.9		1	39.0	+0.8		+1.9	
BioSystems BA400					1	37.7	-0.5		-0.5	
Ceragem LabonaCheck A1c	1	69.0	-1.1		1	37.0	-1.2		-1.2	
Ceragem Medisys CERA-STAT 4000	1	70.5	+0.4							
Furuno CA-800	1	73.8	+3.7		1	43.2	+5.0		+4.4	
ISE S.r.l. Hemo One ISE HbA1c	1	69.1	-1.0		1	36.8	-1.4		-1.2	
Lifotronic	2	68.5	-1.6	9.3	2	38.5	+0.3	9.2	-0.6	9.2
Medconn MQ-2000PT	2	68.9	-1.3	1.1	2	38.8	+0.5	7.8	-0.4	4.5
Menarini (ARKRAY) HA-8140 series	3	74.3	+4.2	1.6	3	38.3	+0.1	3.0	+2.2	2.3
Mindray bs series	3	62.8	-7.3	6.9	2	31.7	-6.5	12.0	-6.9	9.5
Other	2	65.4	-4.7	22.2	2	34.1	-4.1	10.3	-4.4	16.3
Randox RX series	4	63.0	-7.1	9.6	5	37.7	-0.5	11.5	-3.8	10.5
Roche Diagnostics cobas b 101	2	62.9	-7.2	2.5	2	32.6	-5.6	1.7	-6.4	2.1
Roche Diagnostics cobas c 503 (cobas pro)	4	77.1	+7.0	4.9	4	41.7	+3.5	4.4	+5.3	4.7
Sekisui CS T240	1	69.0	-1.1		1	37.0	-1.2		-1.2	
Siemens Advia not specified	1	67.0	-3.1		1	36.0	-2.2		-2.7	
Siemens Atellica CH not specified	3	68.4	-1.7	11.1	3	35.7	-2.5	15.6	-2.1	13.3
Spinreact Spinlab 200E	2	76.0	+5.9	5.6	2	40.0	+1.8	3.5	+3.9	4.6
Sysmex not specified	2	68.3	-1.8	8.7	2	36.5	-1.8	11.4	-1.8	10.1
Wondfo Finecare™ FIA Meter	2	64.5	-5.6	10.7	2	42.6	+4.4	9.3	-0.6	10.0
Zepnurhealth Audicom AC6600	1	70.6	+0.5		1	30.1	-8.1		-3.8	

Table 9 shows results per manufacturer per country. Included are only manufacturers with 6 or more participants in at least 2 countries.
High biases (>2 mmol/mol) and high between laboratory CVs (>6%) are marked.

Table 9. Lyophilised Hemolysate Results per Manufacturer and Country (n>5)

Method	n	HbA1c High (2019-1)		HbA1c Low (2019-2)		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Abbott ARCHITECT (enzymatic)							
Overall	39	-0.8	4.0	-1.5	6.2	-1.2	5.1
AT	11	-2.8	1.9	-3.2	2.9	-3.0	2.4
FR-Probioqual	13	-0.6	3.0	-1.5	5.7	-1.1	4.3
GR	8	+0.2	3.8	-0.3	2.2	-0.1	3.0
Bio-Rad D-10 series							
Overall	106	+3.3	5.2	+0.2	6.6	+1.8	5.9
CZ	36	+4.7	3.3	+0.4	4.6	+2.6	4.0
FR-CTCB	12	+3.8	6.3	+0.3	5.6	+2.0	5.9
FR-Probioqual	32	+1.6	5.5	-0.3	7.7	+0.6	6.6
MX	7	+2.3	4.9	+0.8	6.5	+1.6	5.7
Bio-Rad D-100 series							
Overall	49	+1.3	2.3	-0.4	3.6	+0.4	2.9
AT	10	+1.5	2.3	-0.5	3.8	+0.5	3.0
FR-Probioqual	28	+1.5	2.0	-0.3	3.3	+0.6	2.7
Bio-Rad Variant series							
Overall	66	+3.0	5.3	+0.4	8.9	+1.7	7.1
FR-CTCB	12	+4.3	3.7	+1.6	6.7	+2.9	5.2
FR-Probioqual	36	+2.0	5.5	-0.5	10.0	+0.7	7.8
Menarini (ARKRAY) HA-8160 series							
Overall	59	+0.7	3.6	-0.4	5.1	+0.2	4.4
CZ	8	+0.3	6.1	-1.3	7.7	-0.5	6.9
GR	13	+1.7	3.6	+0.1	4.8	+0.9	4.2
IT	8	+1.1	1.9	-1.0	6.9	0.0	4.4
PT	24	+0.6	3.3	-0.5	3.9	+0.1	3.6
Menarini (ARKRAY) HA-8180 series							
Overall	99	-2.1	5.7	-1.0	5.4	-1.5	5.5
AT	23	-0.8	2.6	+0.1	3.2	-0.3	2.9
CZ	29	-1.1	2.3	-1.1	2.5	-1.1	2.4
IT	7	+2.0	2.5	+1.2	3.5	+1.6	3.0
International*	9	+0.3	3.0	+0.2	1.7	+0.3	2.4
TH	20	-8.6	2.8	-4.1	3.2	-6.4	3.0
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)							
Overall	203	+5.1	3.7	+1.1	6.1	+3.1	4.9
AT	34	+4.8	3.3	+1.5	5.0	+3.1	4.2
FR-Probioqual	52	+4.1	3.9	-1.1	6.0	+1.5	4.9
GR	10	+3.5	4.8	+1.0	6.5	+2.3	5.6
TH	77	+6.0	3.2	+1.8	4.9	+3.9	4.0
TR	12	+6.5	3.6	+2.0	5.1	+4.3	4.3
Roche Diagnostics cobas Integra							
Overall	39	+4.4	3.3	+1.1	7.0	+2.7	5.2
CZ	6	+5.4	2.0	+0.8	12.0	+3.1	7.0
GR	6	+4.4	2.8	+1.5	4.7	+2.9	3.7
TH	16	+4.3	4.0	+1.5	6.5	+2.9	5.3
Sebia CAPILLARYS 2							
Overall	**131**	**0.0**	**2.4**	**-0.3**	**3.8**	**-0.2**	**3.1**
FR-CTCB	25	+1.4	2.3	0.0	2.8	+0.7	2.5
FR-Probioqual	90	-0.4	2.1	-0.5	4.2	-0.5	3.2
International*	6	+0.2	1.5	+0.3	2.8	+0.3	2.1
Sebia CAPILLARYS 3							
Overall	101	+0.7	2.6	+0.2	2.9	+0.5	2.8
FR-CTCB	29	+1.4	2.6	+0.3	2.3	+0.9	2.5
FR-Probioqual	66	+0.3	2.5	+0.2	3.3	+0.2	2.9
Siemens DCA 2000/Vantage							
Overall	61	+5.8	4.4	+4.4	5.2	+5.1	4.8
FR-Asqualab	6	+6.1	6.2	+3.4	4.7	+4.7	5.5
FR-Probioqual	46	+5.3	3.9	+4.9	4.9	+5.1	4.4
Siemens Dimension series							
Overall	32	+5.2	8.5	+3.2	7.1	+4.2	7.8
FR-Probioqual	14	+11.2	5.3	+3.0	8.8	+7.1	7.1
GR	6	-0.1	2.4	+3.7	6.1	+1.8	4.2
Tosoh G11							
Overall	64	+3.5	4.8	+0.4	3.7	+2.0	4.2
FR-CTCB	8	+4.6	5.0	+1.6	4.7	+3.1	4.8
FR-Probioqual	45	+3.1	4.2	+0.2	2.7	+1.7	3.5

Method	n	HbA1c High (2019-1)		HbA1c Low (2019-2)		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Tosoh G8							
Overall	180	+0.8	3.8	+0.6	3.4	+0.7	3.6
AT	8	+1.4	5.3	-0.5	2.7	+0.5	4.0
CZ	19	+2.1	1.6	+1.2	2.5	+1.6	2.0
FR-Asqualab	13	+0.7	2.2	+0.8	3.0	+0.8	2.6
FR-CTCB	30	+2.6	4.9	+0.1	4.1	+1.4	4.5
FR-Probioqual	83	-0.6	3.0	+0.4	2.9	-0.1	2.9
IT	6	+3.6	2.2	+2.0	2.7	+2.8	2.5
TR	9	+1.8	3.5	+1.2	4.9	+1.5	4.2

** Group of Individual laboratories of a number of countries*

IV. Value Assignment (Targeting)

The samples in their respective matrices have been measured with the IFCC RMP, the IFCC SRLs, the US NGSP SRLs and the Swedish Mono S. Table 10 shows the results. The assigned values are the values assigned with the IFCC RMP. Values of the SRLs are for comparison and information.

Table 10. Results of Reference Measurement Procedures

Matrix	**Low HbA1c (range 37.6 – 38.8 mmol/mol)**				**High HbA1c (range 69.0 – 71.2 mmol/mol)**			
	IFCC RMP	IFCC SRLs	US NGSP SRLs	Sweden Mono S	IFCC RMP	IFCC SRLs	US NGSP SRLs	Sweden Mono S
	n = 5	n = 8	n = 3	n = 1	n = 5	n = 8	n = 3	n = 1
Fresh Whole Blood	38.2	38.6	5.63	4.48	70.1	70.7	8.58	7.37
Lyophilised Hemolysate	38.2	38.2	5.67	4.55	70.3	69.9	8.55	7.44
Frozen Whole Blood	37.9	39.1	5.70	4.64	70.3	71.7	8.68	7.57

1) US-NGSP and Sweden Mono-S results in % are converted to SI (IFCC) units with the respective Master Equations
2) Expanded Uncertainty (k=2) of the IFCC RMP in fresh whole blood is 0.6 mmol/mol in the low and 1.1 in the high sample.

V. Homogeneity

Homogeneity testing of the samples EurAAA1c-2019-2. 4 and 6 is performed according to ISO 13528:2005 (Annex B) with the Menarini (ARKRAY) HA- 8180V. The results in table 11 show that the samples are homogeneous.

Table 11. Homogeneity test of EurAAA1c 2019

Vial	**Fresh Whole Blood**				**Lyophilised Hemolysate**				**Frozen Whole Blood**			
	EurAAA1c 2019-2				**EurAAA1c 2019-4**				**EurAAA1c 2019-6**			
	1	2	mean	Δ	1	2	mean	Δ	1	2	mean	Δ
1	38.8	38.7	38.75	0.1	38.6	38.8	38.70	0.2	38.2	38.1	38.15	0.1
2	38.8	38.7	38.75	0.1	38.9	38.9	38.90	0.0	38.2	38.1	38.15	0.1
3	38.8	38.7	38.75	0.1	38.6	38.8	38.70	0.2	38.2	38.1	38.15	0.1
4	38.8	38.7	38.75	0.1	38.8	38.8	38.80	0.0	38.1	38.1	38.10	0.0
5	38.7	38.7	38.70	0.0	38.8	38.9	38.85	0.1	38.1	38.2	38.15	0.1
6	38.7	38.7	38.70	0.0	38.8	38.9	38.85	0.1	38.1	38.1	38.10	0.0
7	38.8	38.7	38.75	0.1	38.9	38.9	38.90	0.0	38.1	38.1	38.10	0.0
8	38.8	38.8	38.80	0.0	38.8	38.9	38.85	0.1	38.1	38.1	38.10	0.0
9	38.7	38.7	38.70	0.0	38.6	38.8	38.70	0.2	38.1	38.0	38.05	0.1
10	38.7	38.7	38.70	0.0	38.9	38.8	38.85	0.1	38.1	38.1	38.10	0.0
11	38.7	38.7	38.70	0.0	38.6	38.8	38.70	0.2	38.2	38.1	38.15	0.1
12	39.0	38.7	38.85	0.3	38.8	38.9	38.85	0.1	38.1	38.1	38.10	0.0
average			38.7				38.8				38.1	
SD		0.000	0.047	0.076		0.047	0.081	0.094		0.000	0.033	0.050
0.3 x SD_{RL}			0.306				0.306				0.306	
Criterion			-0.306				-0.259				-0.306	
Homogeneity:			**Pass**				**Pass**				**Pass**	

VI. Stability

Fresh Whole Blood
Fresh whole blood samples EurAAA1c 2019-2 (HbA1c 38.2 mmol/mol) were stored at room temperature and in the refrigerator at 2-8°C and measured after 1,2,3,4,5 and 8 days after storage. Results are expressed as the difference in measured HbA1c on day X and day 1 (table 12). Differences of 2 mmol/mol and higher are flagged amber. It can be seen that on storage at room temperature results of three methods start to show differences on day 8. It can be concluded that at room temperature samples are stable for 5 and in the refrigerator for at least 8 days.

Table 12. Stability of Fresh Whole Blood at Room Temperature and in the Refrigerator*

Method	Day 1	Day 2	Day 3	Day 4	Day 5	Day 8
Storage at Room Temperature						
Menarini/ARKRAY HA-8180V	0	0	0	0	-1	-2
Sebia CAPILLARYS 3 Octa	0	-2	-1	0	0	+2
Roche Cobas c 513	0	0	0	0	0	0
Abbott ARCHITECT C4000	0	+1	+1	+1	+1	0
Tosoh G8	0	0	0	0	0	-1
Trinity Biotech Premier Hb9210	0	0	0	+1	+1	+2
Storage Refrigerator						
Menarini/ARKRAY HA-8180V	0	-1	0	0	0	0
Sebia CAPILLARYS 3 Octa	0	0	0	0	0	0
Roche Cobas c 513	0	0	0	0	0	0
Abbott ARCHITECT C4000	0	1	0	0	0	0
Tosoh G8	0	0	0	0	0	0
Trinity Biotech Premier Hb9210	0	-1	-1	-1	0	0

** Difference between Day X and Day 1 in mmol/mol*

Lyophilised Hemolysate
Lyophilised hemolysate samples EurA1c 2017-2 (HbA1c 58.0 mmol/mol) were stored in the refrigerator at 2-8°C and in the freezer at -20°C and measured after 6, 13, 18 and 25 months. Results are shown in table 13. It can be seen that the results of the Abbott ARCHITECT enzymatic assay start to show differences after 6 months in the refrigerator. This is a remarkable and unexpected result of this new test. This may explain why a negative bias is observed in the EurA1c trial in some countries.

Table 13. Stability of Lyophilised Hemolysate in Refrigerator and Freezer -20°C*

Method	0 month	6 months	13 months	18 months	25 months
Storage Refrigerator					
Menarini/ARKRAY HA-8180V	0	0	-1	0	-1
Sebia CAPILLARYS 3 Octa**	0	-2	+1	0	-1
Roche Cobas c513	0	0	0	+1	+1
Abbott ARCHITECT C4000	0	-3	-5	-5	-8
Tosoh G8	0	-1	+1	-2	-2
Trinity Biotech Premier Hb9210	0	0	0	-1	0
Storage Freezer -20°C					
Menarini/ARKRAY HA-8180V	0	+1	0	0	+1
Sebia CAPILLARYS 3 Octa**	0	-1	+1	+1	-1
Roche Cobas c 513	0	+1	0	0	+1
Abbott ARCHITECT C4000	0	+2	+2	+2	0
Tosoh G8	0	+1	+1	+1	+1
Trinity Biotech Premier Hb9210	0	+1	+1	+1	+2

** Difference between Month X and Month 0 in mmol/mol*
***Initial measurement (0 month) on Sebia Capillarys 2 FP)*

Frozen Whole Blood

Frozen whole blood is used only for RMP measurements. Frozen whole blood samples EurA1c 2017-2 (HbA1c 58.0 mmol/mol) were stored in freezers at -20°C and -70°C and measured after 6, 13, 18 and 25 months (results of EurA1c 2017 samples are chosen to show stability because of these samples long-term results are available).

Results are shown in table 14. It can be seen that on storage at -20°C results start to differ from the originally measured HbA1c concentration, starting from 6 months.

Table 14. Stability of Frozen Whole Blood in Freezer -20°C and Freezer -70°C*

Method	**0 month**	**6 months**	**13 months**	**18 months**	**25 months**
Storage Freeze -20°C					
Menarini/ARKRAY HA-8180V	0	0	-5	n.m***	n.m***
Sebia CAPILLARYS 3 Octa**	0	+2	+3	n.m***	n.m***
Roche Cobas c513	0	+1	0	+1	+1
Abbott ARCHITECT C4000	0	+1	+2	+2	+2
Tosoh G8	0	-3	-2	-1	-1
Trinity Biotech Premier Hb9210	0	-5	-11	-3	-3
Storage Freezer <-70°C					
Menarini/ARKRAY HA-8180V	0	0	0	-1	-1
Sebia CAPILLARYS 3 Octa**	0	0	+1	+2	+2
Roche Cobas c513	0	1	-1	0	0
Abbott ARCHITECT C4000	0	1	1	0	0
Tosoh G8	0	1	1	1	1
Trinity Biotech Premier Hb9210	0	0	+2	0	0

** difference between Month X and Month 0 in mmol/mol*
*** initial measurement (0 month) on Sebia Capillarys 2 FP)*
**** not measurable*

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