

Report EurA1c 2020

*HbA1c Trial
EQA organisers*



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I Introduction and Overview of Results

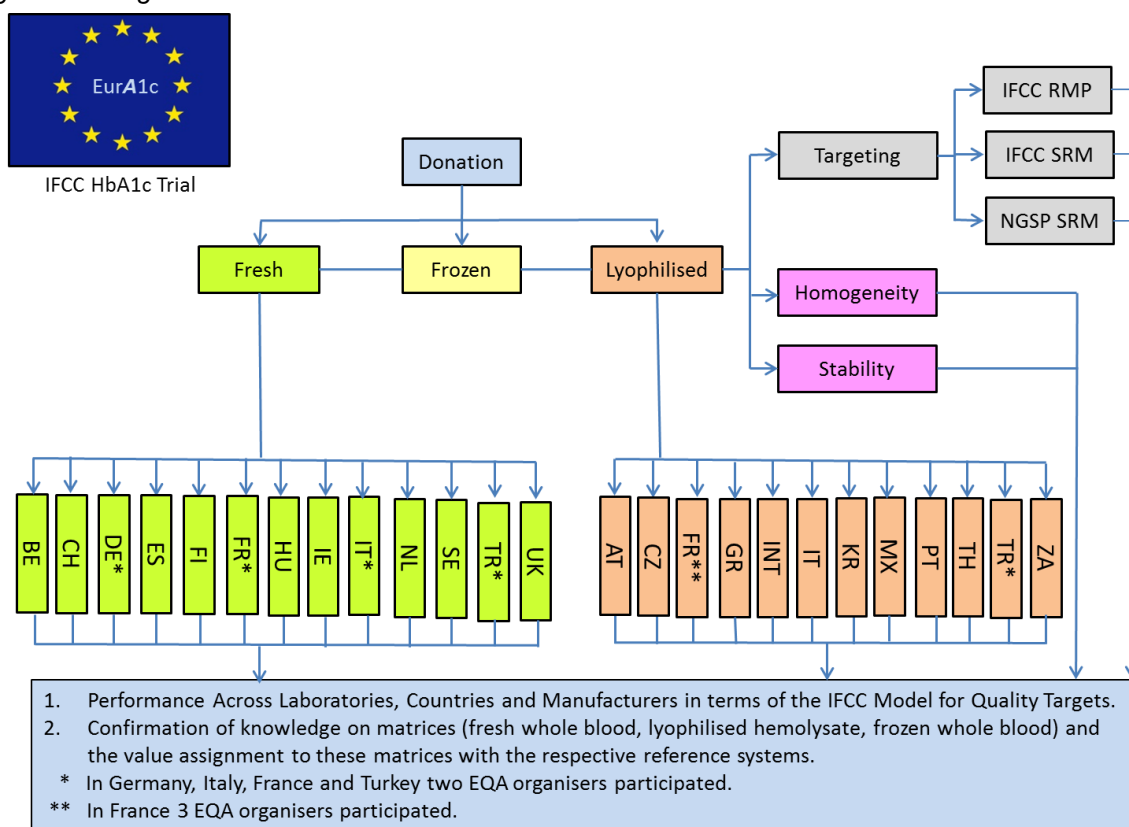
Introduction

27 EQA organisers of 22 countries agreed to participate in the fifth “EurA1c” project. The design is shown in figure 1. The project is renamed to EurA1c with the A in bold in the logo to acknowledge the participation of EQA organisers in Asia, America and Africa.

This year two identical samples in the normal range were distributed because COVID-19 made it impossible to get donations from diabetic persons. Obviously, we regret this fact, but at the same time this led to the advantage that CV could be calculated from the duplicate samples.

18 EQA organisers used fresh whole blood samples and 14 organisers used lyophilised hemolysate samples (4 organisations used both fresh and lyophilised samples). In October 2020 the fresh whole blood samples were sent to the participants. From November 2020 up to April 2021 the lyophilised samples were assayed by the participants.

Figure 1. Design EurA1c Trial 2020



Confidentiality and Ownership

The results of the EurA1c project are owned by all EQA organisers. As agreed the 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 2021: Draft report sent to all who are involved in EurA1c 2020. At the same time the invitation to participate in EurA1c 2021 is sent.
- 31 August 2021: Deadline for comments and remarks.
- 30 September 2021: Final report sent to all who are involved and published on the IFCC-HbA1c website (www.ifcchba1c.org). By then all who are involved are free to share results with third parties.

Value Assignment

Four Approved IFCC Network Laboratories performed the value assignment with the IFCC Reference Measurement Procedure. Because the EurA1c 2020-1 and 2 samples were identical one target value was assigned.

In the draft report the assigned value was reported to be 37.0 mmol/mol with an expanded uncertainty of 1.0 mmol/mol. One of the reference laboratories who assigned a value reconsidered its results and on basis of this the assigned value was modified to 36.5 mmol/mol with an uncertainty of 0.6 mmol/mol. This value is the target value for both fresh whole blood and lyophilised samples.

A discussion on the various options to assign a value was also raised: with the IFCC RMP or with the IFCC SRMs? And should it be the value in fresh whole blood only or should it be the mean of what was measured in whole blood, frozen whole blood and lyophilised hemolysate derived from whole blood? The table below shows the outcome of all these options.

Method Value Assignment	Mean (Expanded Uncertainty)	Range Expanded Uncertainty
IFCC RMP		
Fresh whole blood	36.6 (0.6)	36.0 – 37.2
Lyophilised hemolysate	36.1 (0.6)	35.5 – 36.7
Frozen whole blood	36.7 (0.6)	36.1 – 37.3
<i>Mean three matrixes</i>	36.5 (0.6)	35.9 – 37.1
IFCC SRMs		
Fresh whole blood	37.3 (0.6)	36.7 – 37.9
Lyophilised hemolysate	37.5 (0.7)	36.8 – 38.2
Frozen whole blood	37.2 (0.6)	36.6 – 37.8
<i>Mean three matrixes</i>	37.3 (0.6)	36.7 – 37.9
Mean all labs in EurA1c		
Fresh whole blood	37.1	
Lyophilised hemolysate	37.5	

It is very reassuring that differences for both the different methods and the respective matrixes are very small, in fact all expanded uncertainties have an overlap. The mean of all laboratories is in the same range.

For future EurA1c trials the definite assigned value will be based on the mean of the results measured with the IFCC RMP in the three matrixes.

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 33 results (0.5%) have been excluded from the database of fresh whole blood samples and 52 results (2.8%) from the database of lyophilised hemolysates.

Methods

This is a point of consideration. For fresh whole blood 213 and for lyophilised hemolysate 21 of the laboratories did not report their method at all. Also a number of labs did not specify their method/instrument: Siemens Advia/Atellica CH and Abbott ARCHITECT users did not specify whether they used the enzymatic or immunoassay; Abbott, Beckman Coulter, Bio-Rad, Menarini (ARKRAY), Roche, Sebia and Tosoh users did not specify the specific instrument used.

For details see table 3/4 (fresh whole blood) and table 8/9 (lyophilised).

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 EurA1c 2020

Country	EQA Organiser	Fresh Whole Blood			Lyophilised Hemolysate		
		n*	Mean Bias in mmol/mol	Between Laboratory CV%	n*	Mean Bias in mmol/mol	Between Laboratory CV%
Austria	ÖQUASTA				117	+1.2	6.1
Belgium	Sciensano	122	+0.8	3.7			
Czech Republic	SEKK s.r.o				178	+1.0	5.1
Finland	Labquality	122	+0.7	4.4			
France	Asqualab				72	+1.4	7.6
France	CTCB	170	-0.1	5.1	163	+1.4	6.1
France	ProBioQual	465	+0.7	3.6	519	+0.5	7.0
Germany	INSTAND	638	+0.7	4.7			
Germany	RfB	797	+0.6	4.7			
Greece	ESEAP				85	+0.7	7.0
Hungary	QualiCont	62	+0.6	5.8			
International**	ERL				57	+1.1	4.0
Ireland	IEQAS	34	+0.5	4.9			
Italy	CRB	46	+1.1	6.3	44	+0.8	5.5
Italy	CRRVEQ	109	+0.9	5.7			
Korea	Korean Ass. EQAS				78	+0.9	3.2
Mexico	Labs Biom Panuco				30	+1.7	9.5
Netherlands	SKML	127	+0.9	3.8			
Portugal	PNAEQ-INSA				40	+1.2	6.3
South Africa	NHLS				5	+1.9	2.6
Spain	SEQC ^{ML}	104	+0.9	4.1			
Sweden	Equalis	127	-0.3	3.7			
Switzerland	CSCQ	62	+0.2	4.0			
Thailand	Nat. Inst. of Health				171	+0.4	8.8
Turkey	KBUDEK	98	+1.1	5.3	224	+2.3	6.4
Turkey	TUBITAK UME	47	-0.5	9.0	51	+1.7	8.6
United Kingdom	Weqas	156	+0.7	4.1			
Overall		3286	+0.6	4.7	1834	+1.0	6.9%

* n = the number of datasets.

** Individual laboratories of a number of countries

In total 5120 datasets were submitted (3286 in fresh whole blood and 1834 in lyophilised hemolysate). The results are encouraging. The mean bias of all countries in the fresh whole blood programme is +0.6 mmol/mol and the between laboratory CV of 4.7% is also quite satisfying. In the lyophilised hemolysate programme the mean bias of all countries is +1.0 mmol/mol and the between laboratory CV is 6.9%.

Differentiation of Results

Results are differentiated per sample and a) per country b) per manufacturer/method and c) per manufacturer/method 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 EQA organiser for each sample. Tables 3 and 4 show the results per manufacturer/method for manufacturers/methods with 5 or more participants (table 3) and those with 5 or less participants (table 4).

Table 2. Results per EQA organiser for Fresh Whole Blood

Country	EQA Organiser	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol				EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol				Mean 2 Samples	
		n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Belgium	Sciensano	122	37.2	+0.7	3.7	120	37.4	+0.9	3.6	+0.8	3.7
Finland	Labquality	122	37.2	+0.7	4.6	123	37.2	+0.7	4.3	+0.7	4.4
France	CTCB	170	36.4	-0.1	5.3	171	36.5	+0.0	4.9	-0.1	5.1
France	ProBioQual	465	37.3	+0.8	3.6	463	37.2	+0.7	3.6	+0.7	3.6
Germany	INSTAND	638	37.1	+0.6	4.7	639	37.2	+0.7	4.6	+0.7	4.7
Germany	RfB	797	37.1	+0.6	4.6	792	37.1	+0.6	4.7	+0.6	4.7
Hungary	QualiCont	62	37.1	+0.6	5.8	64	37.1	+0.6	5.9	+0.6	5.8
Ireland	IEQAS	34	37.0	+0.5	5.3	34	37.1	+0.6	4.6	+0.5	4.9
Italy	CRB	46	37.3	+0.8	6.0	46	37.8	+1.3	6.7	+1.1	6.3
Italy	CRRVEQ	109	37.3	+0.8	5.8	108	37.6	+1.1	5.5	+0.9	5.7
Netherlands	SKML	127	37.4	+0.9	4.1	126	37.5	+1.0	3.6	+0.9	3.8
Spain	SEQC ^{ML}	104	37.5	+1.0	3.9	105	37.4	+0.9	4.3	+0.9	4.1
Sweden	Equalis	127	36.2	-0.3	3.7	123	36.2	-0.3	3.7	-0.3	3.7
Switzerland	CSCQ	62	36.7	+0.2	4.4	62	36.7	+0.2	3.6	+0.2	4.0
Turkey	KBUDEK	98	37.6	+1.1	5.4	98	37.7	+1.2	5.3	+1.1	5.3
Turkey	TUBITAK	47	36.0	-0.5	8.4	48	36.0	-0.5	9.6	-0.5	9.0
United Kingdom	Weqas	156	37.2	+0.7	4.2	155	37.2	+0.7	4.0	+0.7	4.1
Overall		3286	37.1	+0.6	4.7	3277	37.1	+0.6	4.6	+0.6	4.7

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

Manufacturer/Method	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol				EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	12	36.1	-0.4	2.1	12	36.1	-0.4	1.9	-0.4	2.0
Abbott ARCHITECT (enzymatic)	6	36.8	+0.3	7.4	6	36.7	+0.2	7.1	+0.3	7.2
Abbott ARCHITECT (immunoassay)	21	38.1	+1.6	8.2	21	38.1	+1.6	8.1	+1.6	8.1
Abbott ARCHITECT not specified/other	39	36.9	+0.4	2.7	39	36.9	+0.4	2.9	+0.4	2.8
Abbott not specified/other	72	36.5	0.0	4.1	71	36.5	0.0	4.5	0.0	4.3
Abbott/Alere Afinion	150	35.6	-0.9	4.2	147	35.7	-0.8	4.5	-0.9	4.3
Beckman Coulter AU series	66	37.5	+1.0	6.0	66	37.9	+1.4	6.7	+1.2	6.3
Beckman Coulter Unicel DxC series	8	37.1	+0.6	3.8	8	36.8	+0.3	3.8	+0.5	3.8
Beckman Coulter not specified/other	14	37.8	+1.3	5.5	14	37.6	+1.1	6.5	+1.2	6.0
Bio-Rad D-10 series	72	36.7	+0.2	4.7	72	36.7	+0.2	4.4	+0.2	4.6
Bio-Rad D-100 series	78	36.5	0.0	3.1	77	36.5	0.0	2.7	0.0	2.9
Bio-Rad Variant series	121	36.5	0.0	6.5	120	36.3	-0.2	6.4	-0.1	6.5
Bio-Rad not specified/other	115	36.3	-0.2	4.5	114	36.3	-0.2	4.4	-0.2	4.5
EKF Diagnostics	18	37.7	+1.2	8.2	18	38.0	+1.5	6.2	+1.3	7.2
HemoCue HbA1c 501	13	35.7	-0.8	9.0	13	36.5	0.0	9.4	-0.4	9.2
Lifotronic	13	38.1	+1.6	8.5	12	39.2	+2.7	3.6	+2.2	6.0
Menarini (ARKRAY) HA-8160 series	51	36.8	+0.3	5.0	50	36.7	+0.2	4.9	+0.3	5.0
Menarini (ARKRAY) HA-8180 series	184	37.7	+1.2	3.1	185	37.8	+1.3	3.2	+1.3	3.2
Menarini (ARKRAY) not specified/other	12	37.1	+0.6	3.8	12	37.5	+1.0	3.1	+0.8	3.5
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	230	37.3	+0.8	4.1	232	37.3	+0.8	4.0	+0.8	4.0
Roche Diagnostics cobas c 513	38	37.2	+0.7	2.3	38	37.0	+0.5	2.1	+0.6	2.2
Roche Diagnostics cobas Integra	46	37.0	+0.5	4.2	46	37.3	+0.8	4.1	+0.7	4.2
Roche Diagnostics not specified/other	384	37.1	+0.6	3.7	382	37.1	+0.6	4.1	+0.6	3.9
Sebia CAPILLARYS 2	128	36.4	-0.1	3.9	129	36.6	+0.1	3.9	0.0	3.9
Sebia CAPILLARYS 3	141	36.4	-0.1	3.3	142	36.5	0.0	3.3	-0.1	3.3
Sebia MINICAP	25	35.9	-0.6	4.9	24	36.1	-0.4	4.8	-0.5	4.8
Sebia not specified/other	60	36.5	0.0	3.4	60	36.6	+0.1	3.6	+0.1	3.5
Siemens Advia not specified/other	11	37.4	+0.9	5.6	11	37.3	+0.8	6.0	+0.9	5.8
Siemens Atellica CH not specified/other	19	36.6	+0.1	5.6	19	36.5	0.0	4.3	+0.1	4.9
Siemens DCA 2000/Vantage	208	36.7	+0.2	3.8	207	36.9	+0.4	3.5	+0.3	3.6
Siemens Dimension series	109	39.0	+2.5	4.5	109	38.9	+2.4	4.8	+2.5	4.7
Thermo Fisher Scientific/Konelab	16	39.3	+2.8	5.5	16	38.8	+2.3	5.1	+2.5	5.3
Tosoh G7	15	37.0	+0.5	8.0	15	36.9	+0.4	7.6	+0.5	7.8
Tosoh G8	276	38.0	+1.5	2.7	274	38.1	+1.6	2.8	+1.6	2.8
Tosoh G11	124	37.5	+1.0	2.3	124	37.6	+1.1	2.4	+1.1	2.3
Tosoh GX	22	37.7	+1.2	3.4	22	37.9	+1.4	3.7	+1.3	3.5
Tosoh not specified/other	99	37.7	+1.2	3.1	98	37.8	+1.3	2.7	+1.3	2.9
Trinity Biotech Premier Hb9210	22	37.4	+0.9	4.2	23	37.5	+1.0	6.6	+0.9	5.4
Not specified/Other	213	36.9	+0.4	5.5	212	37.0	+0.5	4.9	+0.5	5.2

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

Manufacturer/Method	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol				EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott AxSym	3	36.4	-0.1	7.7	3	36.7	+0.2	3.1	+0.1	5.4
Hitado	3	37.2	+0.7	6.6	3	36.5	0.0	6.0	+0.3	6.3
Horiba Pentra	5	38.2	+1.7	4.3	5	38.1	+1.6	3.4	+1.6	3.8
Indiko plus	2	38.5	+2.0	5.5	2	39.5	+3.0	5.4	+2.5	5.5
ISE S.r.l. Hemo One ISE HbA1c					1	45.0	+8.5			
Medinor NycoCard	3	40.9	+4.4	13.8	4	39.4	+2.9	11.5	+3.6	12.7
Menarini (ARKRAY) HA-8140 series	1	38.8	+2.3		1	38.8	+2.3		+2.3	
Mindray bs series	1	36.6	+0.1		1	35.5	-1.0		-0.5	
Mindray not specified/other	1	38.0	+1.5		1	38.0	+1.5		+1.5	
Ortho Clinical Diagnostics Vitros series	1	38.0	+1.5		1	37.0	+0.5		+1.0	
Roche Diagnostics cobas b 101	4	35.9	-0.6	4.8	4	35.4	-1.1	1.9	-0.9	3.3
Roche Diagnostics cobas c 311	1	38.8	+2.3		1	39.9	+3.4		+2.9	
Roche Diagnostics cobas c 503 (cobas pro)	4	37.0	+0.5	4.7	4	36.9	+0.3	3.3	+0.4	4.0
Siemens Atellica CH (immunoassay)	1	42.9	+6.4		1	44.0	+7.5		+7.0	
Sysmex not specified/other	1	40.0	+3.5		1	40.0	+3.5		+3.5	
Thermo Fisher Scientific	4	35.9	-0.6	6.1	4	36.1	-0.4	5.9	-0.5	6.0

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

Table 5. Results per Manufacturer/Method and EQA organiser for Fresh Whole Blood (n>5)

Method	n	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol		EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol		Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
Abbott/Alere Afinion							
Overall	150	-0.9	4.2	-0.8	4.5	-0.9	4.3
CH-CSCQ	21	-0.5	4.2	-0.5	3.9	-0.5	4.0
DE-INSTAND	50	-0.8	3.0	-1.1	3.9	-1.0	3.5
IE-IEQAS	6	-1.7	8.4	-0.5	7.7	-1.1	8.1
NL-SKML	14	-0.4	5.9	+0.6	4.8	+0.1	5.3
SE-Equalis	47	-1.0	3.9	-1.1	4.1	-1.1	4.0
UK_Weqas	6	-2.2	3.5	-2.3	2.2	-2.3	2.8
Beckman Coulter AU series							
Overall	66	+1.0	6.0	+1.4	6.7	+1.2	6.3
DE-INSTAND	20	+0.2	5.5	+1.0	7.1	+0.6	6.3
DE-RfB	30	+1.3	5.9	+1.2	5.9	+1.3	5.9
TR-KBUDEK	6	+1.2	2.3	+1.7	2.6	+1.5	2.5
Bio-Rad D-10 series							
Overall	72	+0.2	4.7	+0.2	4.4	+0.2	4.6
DE-INSTAND	16	+0.7	3.3	+0.5	3.4	+0.6	3.3
FR-CTCB	14	-0.9	7.1	-1.1	5.7	-1.0	6.4
FR-ProBioQual	24	+0.7	2.3	+0.8	2.7	+0.7	2.5
Bio-Rad D-100 series							
Overall	78	0.0	3.1	0.0	2.7	0.0	2.9
DE-INSTAND	14	+0.4	3.2	+0.1	2.1	+0.3	2.7
FR-ProBioQual	28	-0.1	3.1	+0.1	3.1	0.0	3.1
ES-SEQC	13	+0.3	2.3	-0.1	2.6	+0.1	2.5
Bio-Rad Variant series							
Overall	121	0.0	6.5	-0.2	6.4	-0.1	6.5
DE-INSTAND	20	+0.9	3.3	+0.6	2.6	+0.7	3.0
FR-CTCB	12	-1.3	10.7	-0.8	9.2	-1.1	9.9
FR-ProBioQual	30	+0.7	4.0	+0.6	3.9	+0.7	4.0
HU-QualiCont	10	+0.6	7.6	-0.2	6.2	+0.2	6.9
IT-CRRVEQ	10	+1.2	3.5	+0.8	5.1	+1.0	4.3
TR-KBUDEK	13	-0.6	4.0	-0.5	5.6	-0.6	4.8
TR-TUBITAK	14	-3.0	7.3	-3.4	7.5	-3.2	7.4
HemoCue HbA1c 500							
Overall	13	-0.8	9.0	0.0	9.4	-0.4	9.2
DE-INSTAND	7	-1.0	7.4	+1.1	5.4	+0.1	6.4
DE-RfB	6	-0.6	11.3	-1.3	12.7	-1.0	12.0
Menarini (ARKRAY) HA-8160 series							
Overall	51	+0.3	5.0	+0.2	4.9	+0.3	5.0
BE-Sciensano	21	+0.6	3.3	+0.4	3.8	+0.5	3.5
HU-QualiCont	8	+0.5	2.9	+0.7	3.4	+0.6	3.1
Menarini (ARKRAY) HA-8180 series							
Overall	184	+1.2	3.1	+1.3	3.2	+1.3	3.2
BE-Sciensano	34	+1.2	3.4	+1.2	3.7	+1.2	3.5
DE-INSTAND	24	+1.0	2.8	+1.1	3.0	+1.1	2.9
ES-SEQC	46	+1.3	3.1	+1.4	3.1	+1.3	3.1
HU-QualiCont	16	+1.2	2.7	+1.3	2.5	+1.3	2.6
IE-IEQAS	11	+1.5	2.6	+1.7	2.6	+1.6	2.6
IT-CRRVEQ	14	+1.2	3.0	+1.2	3.5	+1.2	3.2
NL-SKML	21	+1.5	2.1	+1.4	2.1	+1.5	2.1

Method	n	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol		EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol		Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)							
Overall	230	+0.8	4.1	+0.8	4.0	+0.8	4.0
CH-CSCQ	11	+1.2	2.3	+0.7	2.2	+0.9	2.2
DE-INSTAND	122	+0.8	4.1	+0.7	3.8	+0.7	3.9
ES-SEQC	8	+0.9	6.2	+0.1	7.3	+0.5	6.8
FI-Labquality	25	+0.9	3.9	+0.5	4.0	+0.7	4.0
IT-CRRVEQ	7	+0.1	3.8	+0.7	2.3	+0.4	3.0
NL-SKML	18	+0.6	4.1	+0.7	3.8	+0.7	3.9
TR-KBUDEK	11	+1.1	5.0	+1.3	5.4	+1.2	5.2
TR-TUBITAK	11	+0.5	4.9	+1.2	3.8	+0.9	4.3
Roche Diagnostics cobas Integra							
Overall	46	+0.5	4.2	+0.8	4.1	+0.7	4.2
DE-INSTAND	33	+0.8	3.7	+0.9	3.9	+0.9	3.8
TR-KBUDEK	6	+0.4	4.4	+0.8	4.5	+0.6	4.5
Sebia CAPILLARYS 2							
Overall	128	-0.1	3.9	+0.1	3.9	0.0	3.9
BE-Sciensano	9	-0.3	4.9	+0.1	3.4	-0.1	4.2
FR-CTCB	26	-0.8	4.4	-0.3	4.2	-0.6	4.3
FR-ProBioQual	69	+0.2	3.6	+0.3	3.7	+0.3	3.7
IT-CRRVEQ	7	-0.4	2.5	+0.6	5.0	+0.1	3.8
Sebia CAPILLARYS 3							
Overall	141	-0.1	3.3	0.0	3.3	-0.1	3.3
DE-INSTAND	9	-0.5	3.2	+0.1	2.2	-0.2	2.7
FR-CTCB	33	-0.6	3.3	-0.5	3.6	-0.6	3.5
FR-ProBioQual	62	+0.2	3.0	+0.2	3.3	+0.2	3.1
IT-CRRVEQ	7	+0.4	2.4	+0.4	3.6	+0.4	3.0
SE-Equalis	10	-0.5	2.3	-0.4	2.0	-0.5	2.1
Siemens DCA 2000/Vantage							
Overall	208	+0.2	3.8	+0.4	3.5	+0.3	3.6
DE-INSTAND	58	+0.1	4.5	+0.4	4.2	+0.3	4.3
FI-Labquality	13	0.0	4.1	+0.3	4.1	+0.1	4.1
FR-ProBioQual	34	+0.2	3.9	+0.5	3.0	+0.3	3.5
IE-IEQAS	9	+0.1	4.6	-0.2	3.4	-0.1	4.0
NL-SKML	13	-0.1	2.4	+0.2	3.8	+0.1	3.1
SE-Equalis	44	+0.2	3.2	+0.3	2.6	+0.3	2.9
UK-Wegas	28	+0.6	3.7	+0.5	3.7	+0.5	3.7
Siemens Dimension series							
Overall	109	+2.5	4.5	+2.4	4.8	+2.5	4.7
DE-INSTAND	37	+2.5	5.1	+2.5	4.9	+2.5	5.0
DE-RfB	47	+2.7	3.7	+2.7	4.5	+2.7	4.1
FR-ProBioQual	14	+1.6	6.3	+1.6	6.6	+1.6	6.4
Tosoh G8							
Overall	276	+1.5	2.7	+1.6	2.8	+1.6	2.8
BE-Sciensano	28	+1.5	2.2	+1.7	2.2	+1.6	2.2
DE-INSTAND	24	+1.4	1.8	+1.6	2.5	+1.5	2.1
ES-SEQC	10	+1.9	2.3	+1.9	2.6	+1.9	2.5
FI-Finland	22	+1.3	2.2	+1.6	1.9	+1.5	2.0
FR-CTCB	23	+1.4	3.4	+1.5	3.2	+1.5	3.3
FR-ProBioQual	66	+1.5	2.1	+1.6	2.1	+1.6	2.1
IT-CRB	8	+2.7	3.0	+3.0	4.5	+2.9	3.8
IT-CRRVEQ	17	+1.9	2.9	+2.0	3.1	+1.9	3.0
NL-SKML	26	+2.0	3.4	+2.0	2.6	+2.0	3.0
SE-Equalis	9	+0.8	1.7	+0.8	1.9	+0.8	1.8
TR-KBUDEK	11	+1.0	2.2	+0.8	2.4	+0.9	2.3
TR-TUBITAK	7	+0.4	5.0	+0.4	6.2	+0.4	5.6
UK-Wegas	21	+1.5	1.7	+1.6	2.0	+1.6	1.8

Method	n	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol		EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol		Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
Tosoh G11							
Overall	124	+1.0	2.3	+1.1	2.4	+1.1	2.3
DE-INSTAND	18	+1.1	2.5	+1.4	1.9	+1.3	2.2
FI-Labquality	13	+0.3	2.5	+0.7	3.1	+0.5	2.8
FR-CTCB	13	+0.9	2.0	+0.9	2.9	+0.9	2.5
FR-ProBioQual	45	+1.5	1.6	+1.2	2.4	+1.3	2.0
IT-CRRVEQ	12	+0.5	2.0	+0.7	1.7	+0.6	1.8
NL-SKML	7	+0.8	2.3	+0.9	2.4	+0.9	2.3
UK-Wegas	6	+1.7	1.1	+1.5	0.0	+1.6	0.6
Tosoh GX							
Overall	22	+1.2	3.4	+1.4	3.7	+1.3	3.5
FR-CTCB	8	+1.0	3.7	+1.0	4.0	+1.0	3.8
FR-ProBioQual	10	+1.5	2.5	+1.9	2.5	+1.7	2.5
Trinity Biotech Premier Hb9210							
Overall	22	+0.9	4.2	+1.0	6.6	+0.9	5.4
IT-CRB	6	+2.3	3.0	+2.8	3.1	+2.5	3.0
TR-KBUDEK	7	+0.3	3.2	+0.6	1.3	+0.5	2.2

From the two identical (duplicate) samples the within run precision was calculated. In total 3142 results for both EurA1c 2020-1 and 2 were submitted. Table 6 shows the mean CV for each manufacturer. The overall mean within run CV is 1.3%. As it can be expected that participating laboratories measure both samples in the same run, this CV probably reflects within-run CV.

Table 6. Fresh Whole Blood mean CV per manufacturer/method from the duplicate samples

Manufacturer/Method	Fresh Whole Blood	
	n	Mean Within run CV%
Abbott Alinity	6	0.2
Abbott ARCHITECT (enzymatic)	6	0.3
Abbott ARCHITECT (immunoassay)	21	0.9
Abbott ARCHITECT not specified/other	36	0.5
Abbott AxSym	3	2.2
Abbott not specified/other	71	1.6
Abbott/Alere Afinion	142	1.9
Beckman Coulter AU series	65	1.6
Beckman Coulter not specified/other	14	2.1
Beckman Coulter Unicel DxC series	8	1.2
Bio-Rad D-10 series	70	1.1
Bio-Rad D-100 series	77	1.3
Bio-Rad not specified/other	114	1.1
Bio-Rad Variant series	120	1.0
EKF Diagnostics	18	2.5
HemoCue HbA1c 501	13	3.8
Hitado	3	1.4
Horiba Pentra	5	0.9
Lifotronic	12	1.2
Medinor NycoCard	3	3.4
Menarini (ARKRAY) HA-8140 series	1	0.0
Menarini (ARKRAY) HA-8160 series	50	0.8
Menarini (ARKRAY) HA-8180 series	184	0.5
Menarini (ARKRAY) not specified/other	12	1.3
Mindray bs series	1	2.1
Mindray not specified/other	1	0.0
Not specified/Other	211	1.5
Ortho Clinical Diagnostics Vitros series	1	1.9
Roche Diagnostics cobas b 101	4	2.1
Roche Diagnostics cobas c 311	1	2.0
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	205	1.8
Roche Diagnostics cobas c 503 (cobas pro)	2	0.7
Roche Diagnostics cobas c 513	36	0.9
Roche Diagnostics cobas Integra	46	1.4
Roche Diagnostics not specified/other	382	1.5
Sebia CAPILLARYS 2	128	1.8
Sebia CAPILLARYS 3	138	1.5
Sebia MINICAP	24	1.3
Sebia not specified/other	60	1.9
Siemens Advia not specified/other	10	1.1
Siemens Atellica CH (immunoassay)	1	1.8
Siemens Atellica CH not specified/other	6	0.6
Siemens DCA 2000/Vantage	194	1.9
Siemens Dimension series	109	1.4
Sysmex not specified/other	1	0.0
Thermo Fisher Scientific	4	1.4
Thermo Fisher Scientific/Konelab	4	1.3
Tosoh G11	110	0.8
Tosoh G7	15	1.2
Tosoh G8	252	0.7
Tosoh GX	22	0.8
Tosoh not specified/other	98	0.8
Trinity Biotech Premier Hb9210	22	1.3
Total	3142	1.3

III Results EQA Lyophilised Hemolysate samples

Table 7 shows the results per EQA organiser for each sample. Tables 8 and 9 show the results per manufacturer for manufacturers with 6 or more participants (table 8) and 5 or less participants (table 9).

Table 7. Results per EQA organiser for Lyophilised Hemolysate

Country	EQA Organiser	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol				EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol				Mean 2 Samples	
		n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Austria	ÖQUASTA	117	37.8	+1.3	6.4	117	37.6	+1.1	5.9	+1.2	6.1
Czech Republic	SEKK s.r.o	178	37.6	+1.1	5.3	176	37.5	+1.0	5.0	+1.0	5.1
France	Asqualab	72	37.9	+1.4	7.6					+1.4	7.6
France	CTCB	163	37.8	+1.3	6.2	163	38.0	+1.5	6.1	+1.4	6.1
France	ProBioQual	519	37.0	+0.5	7.1	519	37.0	+0.5	6.9	+0.5	7.0
Greece	ESEAP	85	36.9	+0.4	7.5	85	37.4	+0.9	6.6	+0.7	7.0
International*	ERL	57	37.7	+1.2	4.3	60	37.6	+1.1	3.7	+1.1	4.0
Italy	CRB	44	37.5	+1.0	5.6	44	37.2	+0.7	5.5	+0.8	5.5
Korea	Kor Ass. EQAS	78	37.5	+1.0	3.2	78	37.4	+0.9	3.1	+0.9	3.2
Mexico	Labs Biom Panuco	30	38.5	+2.0	8.9	30	38.0	+1.5	10.2	+1.7	9.5
Portugal	PNAEQ-INSA	40	37.8	+1.3	6.2	40	37.6	+1.1	6.4	+1.2	6.3
South Africa	NHLS	5	38.4	+1.9	2.3	5	38.4	+1.9	3.0	+1.9	2.6
Thailand	NIH	171	36.9	+0.4	8.9	169	36.9	+0.4	8.8	+0.4	8.8
Turkey	KBUDEK	224	38.8	+2.3	6.7	223	38.8	+2.3	6.1	+2.3	6.4
Turkey	TUBITAK	51	38.1	+1.6	8.5	50	38.2	+1.7	8.7	+1.7	8.6
Overall		1834	37.5	+1.0	7.0	1759	37.5	+1.0	6.7	+1.0	6.9

Table 8. Results per Manufacturer/Method for Lyophilised Hemolysate (n>5)

Manufacturer	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol				EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	17	34.0	-2.5	8.2	15	34.2	-2.3	8.2	-2.4	8.2
Abbott ARCHITECT (enzymatic)	28	34.1	-2.4	9.3	22	34.9	-1.6	8.0	-2.0	8.7
Abbott ARCHITECT (immunoassay)	31	39.4	+2.9	9.8	31	39.0	+2.5	8.8	+2.7	9.3
Abbott ARCHITECT not specified/other	29	33.0	-3.5	6.9	29	33.2	-3.3	6.4	-3.4	6.6
Beckman Coulter AU series	46	39.3	+2.8	8.0	46	39.1	+2.6	7.9	+2.7	8.0
Bio-Rad D-10 series	98	37.8	+1.3	7.2	94	37.6	+1.1	6.4	+1.2	6.8
Bio-Rad D-100 series	78	37.8	+1.3	2.9	74	37.6	+1.1	3.1	+1.2	3.0
Bio-Rad Variant series	89	37.0	+0.5	8.1	85	36.9	+0.4	8.3	+0.5	8.2
Lifotronic	21	37.2	+0.7	8.8	21	36.7	+0.2	9.9	+0.4	9.3
Menarini (ARKRAY) HA-8160 series	49	37.1	+0.6	4.9	50	36.8	+0.3	5.1	+0.5	5.0
Menarini (ARKRAY) HA-8180 series	99	37.0	+0.5	4.2	104	37.0	+0.5	4.2	+0.5	4.2
Menarini (ARKRAY) not specified/other	15	36.4	-0.1	4.8	15	36.3	-0.2	5.0	-0.2	4.9
Mindray bs series	8	37.8	+1.3	12.4	8	38.3	+1.8	11.8	+1.5	12.1
Roche Diagnostics cobas c 111	11	40.2	+3.7	6.1	11	39.8	+3.3	4.3	+3.5	5.2
Roche Diagnostics cobas c 311	8	37.6	+1.1	9.3	8	38.0	+1.5	8.4	+1.3	8.8
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	214	38.7	+2.2	6.2	213	38.6	+2.1	6.3	+2.1	6.3
Roche Diagnostics cobas c 503 (cobas pro)	7	39.1	+2.6	4.5	7	39.6	+3.1	4.6	+2.8	4.6
Roche Diagnostics cobas c 513	16	38.6	+2.1	2.8	16	38.3	+1.8	2.8	+2.0	2.8
Roche Diagnostics cobas Integra	51	38.3	+1.8	4.5	50	38.7	+2.2	4.6	+2.0	4.5
Roche Diagnostics not specified/other	93	36.6	+0.1	8.5	87	36.2	-0.3	9.2	-0.1	8.9
Sebia CAPILLARYS 2	122	36.2	-0.3	3.7	120	36.2	-0.3	4.2	-0.3	4.0
Sebia CAPILLARYS 3	127	36.9	+0.4	3.3	122	36.9	+0.4	2.9	+0.4	3.1
Sebia MINICAP	25	36.2	-0.3	6.5	23	37.1	+0.6	4.9	+0.1	5.7
Sebia not specified/other	7	36.6	+0.1	2.7	7	37.3	+0.8	3.7	+0.4	3.2
Siemens DCA 2000/Vantage	38	42.4	+5.9	5.5	27	42.3	+5.8	4.5	+5.8	5.0
Siemens Dimension series	33	39.9	+3.4	5.2	32	39.5	+3.0	5.6	+3.2	5.4
Tosoh G7	39	38.2	+1.7	4.4	39	38.1	+1.6	4.5	+1.6	4.5
Tosoh G8	199	37.7	+1.2	3.5	182	37.8	+1.3	3.7	+1.2	3.6
Tosoh G11	112	38.1	+1.6	5.1	102	38.3	+1.8	5.1	+1.7	5.1
Tosoh GX	20	37.6	+1.1	4.8	20	37.7	+1.2	5.2	+1.2	5.0
Trinity Biotech Premier Hb9210	27	37.0	+0.5	5.1	26	37.0	+0.5	4.4	+0.5	4.7
Not specified/Other	21	36.9	+0.4	12.0	21	37.7	+1.2	8.9	+0.8	10.4

For Siemens DCA/Vantage it is known that there is a positive matrix effect for lyophilised samples. And for Abbott enzymatic a negative matrix effect is likely. For other methods this can not be excluded.

Table 9. Results per Manufacturer/Method for Lyophilised Hemolysate (n < 6)

Manufacturer	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol				EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Aeroset multigent	3	37.0	+0.5	14.0	2	38.0	+1.5	18.6	+1.0	16.3
Beckman Coulter P / ACE MDQ	1	29.0	-7.5		1	29.0	-7.5		-7.5	
BioMajesty JCA-BM6010	5	34.8	-1.7	8.2	5	33.7	-2.8	5.2	-2.2	6.7
Bio-Rad not specified/other	5	37.4	+0.9	5.9	5	37.6	+1.1	4.5	+1.0	5.2
Ceragem	1	37.0	+0.5		1	39.0	+2.5		+1.5	
Erba XL series	3	38.1	+1.6	7.2	3	37.7	+1.2	7.7	+1.4	7.4
Horiba Pentra	1	39.0	+2.5		1	39.0	+2.5		+2.5	
ISE S.r.l. Hemo One ISE HbA1c	1	40.4	+3.9		1	39.6	+3.1		+3.5	
Medconn MQ-2000PT	1	37.7	+1.2		1	37.7	+1.2		+1.2	
Menarini (ARKRAY) HA-8140 series	1	34.0	-2.5		1	34.0	-2.5		-2.5	
Menarini (ARKRAY) HA-8190 series	1	35.5	-1.0		1	35.5	-1.0		-1.0	
Ortho Clinical Diagnostics Vitros series	5	37.3	+0.8	5.3	5	38.6	+2.1	1.4	+1.5	3.4
Osang Clover A1c	3	38.5	+2.0	7.2	3	37.9	+1.4	4.3	+1.7	5.7
Randox RX series	3	38.3	+1.8	12.3	3	38.4	+1.9	10.7	+1.9	11.5
Siemens Advia (enzymatic)	4	34.4	-2.1	3.7	4	36.3	-0.2	4.5	-1.1	4.1
Siemens Advia not specified/other	1	37.0	+0.5							
Siemens Atellica CH (enzymatic)	1	39.0	+2.5							
Siemens Atellica CH (immunoassay)	2	38.9	+2.4	4.2	3	37.2	+0.7	6.6	+1.5	5.4
Siemens Atellica CH not specified/other	1	34.0	-2.5		1	34.0	-2.5		-2.5	
Siemens not specified/other	3	38.0	+1.5	7.0	1	34.0	-2.5		-0.5	
Spinreact Spinlab 200 E	1	39.0	+2.5		1	37.0	+0.5		+1.5	
Sysmex bx series	4	34.6	-2.0	13.2	4	35.3	-1.3	15.4	-1.6	14.3
Tosoh not specified/other	4	36.9	+0.4	3.6	4	36.4	-0.1	4.2	+0.1	3.9
Wondfo Finecare™ FIA Meter	1	38.8	+2.3		1	37.7	+1.2		+1.8	

Table 10 shows results per manufacturer/method per EQA organiser. Included are only manufacturers/methods meeting 2 criteria: at least 6 participants per EQA organiser and at least two EQA organisers with at least 6 participants each.

High biases (>2 mmol/mol) and high between laboratory CVs (>6%) are marked.

Table 10. Lyophilised Hemolysate Results per Manufacturer and Country (n>5)

Method	n	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol		EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol		Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
Abbott ARCHITECT (enzymatic)							
Overall	28	-2.4	9.3	-1.6	8.0	-2.0	8.7
AT-ÖQUASTA	9	-4.1	6.0	-3.6	4.1	-3.8	5.1
FR-Asqualab	6	-4.5	2.8				
GR-ESEAP	6	-0.7	5.7	+0.2	4.4	-0.2	5.0
Bio-Rad D-10 series							
Overall	98	+1.3	7.2	+1.1	6.4	+1.2	6.8
CZ-SEKK	34	+1.2	5.8	+1.3	4.5	+1.3	5.1
FR-CTBC	9	+2.2	6.5	+2.3	5.1	+2.2	5.8
FR-Probioqual	29	+0.5	7.8	+0.4	7.0	+0.4	7.4
MX-Labs Biom. Panuco	7	+3.4	2.7	+1.5	7.7	+2.4	5.2
TR-KBUDEK	6	+1.8	6.9	+3.0	7.4	+2.4	7.1
Bio-Rad D-100 series							
Overall	78	+1.3	2.9	+1.1	3.1	+1.2	3.0
AT- ÖQUASTA	11	+1.4	3.0	+1.1	2.5	+1.3	2.7
FR-Probioqual	27	+1.5	3.4	+1.4	3.4	+1.4	3.4
KR-Kor Ass. of EQAS	26	+1.0	2.4	+0.8	2.0	+0.9	2.2
Bio-Rad Variant series							
Overall	89	+0.5	8.1	+0.4	8.3	+0.5	8.2
CZ-SEKK	7	+1.3	3.0	+1.2	2.7	+1.3	2.9
FR-CTBC	9	+1.9	5.5	+1.9	5.6	+1.9	5.5
FR-Probioqual	33	-0.3	11.1	-0.5	10.5	-0.4	10.8
TR-KBUDEK	14	+1.4	3.8	+1.5	3.6	+1.5	3.7
TR-TUBITAK	12	+1.1	6.7	+0.5	8.6	+0.8	7.6
Lifotronic							
Overall	21	+0.7	8.8	+0.2	9.9	+0.4	9.3
TH-NIH	7	-1.8	11.3	-2.4	11.9	-2.1	11.6
TR-KBUDEK	13	+2.5	2.5	+2.1	2.3	+2.3	2.4
Menarini (ARKRAY) HA-8160 series							
Overall	49	+0.6	4.9	+0.3	5.1	+0.5	5.0
GR-ESEAP	15	+1.0	4.6	+0.7	5.0	+0.8	4.8
IT-CRB	6	-0.5	8.7	-0.7	8.3	-0.6	8.5
PT-PNAEQ-INSA	15	+0.5	4.8	0.0	5.4	+0.2	5.1
TR-KBUDEK	7	+0.6	1.6	+0.3	2.1	+0.4	1.8
Menarini (ARKRAY) HA-8180 series							
Overall	99	+0.5	4.2	+0.5	4.2	+0.5	4.2
AT-ÖQUASTA	22	+1.3	3.4	+1.2	3.2	+1.3	3.3
CZ-SEKK	27	-0.6	3.7	-0.7	3.5	-0.6	3.6
International*	17	+1.9	1.8	+1.5	2.9	+1.7	2.4
KR- Kor Ass. of EQAS	10	-0.2	2.0	-0.3	1.6	-0.3	1.8
TR-KBUDEK	6	-0.2	4.5	+0.1	4.6	-0.1	4.6
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)							
Overall	214	+2.2	6.2	+2.1	6.3	+2.1	6.3
AT-ÖQUASTA	36	+1.9	4.4	+1.6	5.0	+1.8	4.7
CZ-SEKK	7	+2.2	5.7	+2.2	6.0	+2.2	5.9
GR-ESEAP	11	+0.3	6.6	+1.0	7.2	+0.6	6.9
TH-NIH	79	+1.7	6.2	+1.6	6.1	+1.7	6.1
TR-KBUDEK	60	+3.0	6.5	+3.3	5.8	+3.2	6.2
TR-TUBITAK	11	+3.1	6.6	+3.2	7.6	+3.1	7.1
Roche Diagnostics cobas Integra							
Overall	51	+1.8	4.5	+2.2	4.6	+2.0	4.5
CZ-SEKK	6	+1.6	2.6	+1.4	3.8	+1.5	3.2
TH-NIH	14	+1.3	2.6	+1.9	3.2	+1.6	2.9
TR-KBUDEK	20	+2.1	5.1	+2.3	5.4	+2.2	5.3

Method	n	EurA1c 2020-1 36.5 (35.9-37.1) mmol/mol		EurA1c 2020-2 36.5 (35.9-37.1) mmol/mol		Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
Sebia CAPILLARYS 2							
Overall	122	-0.3	3.7	-0.3	4.2	-0.3	4.0
FR-CTBC	21	0.0	3.1	0.0	2.9	0.0	3.0
FR-Probioqual	84	-0.5	3.9	-0.4	4.6	-0.4	4.2
Overall	122	-0.3	3.7	-0.3	4.2	-0.3	4.0
Sebia CAPILLARYS 3							
Overall	127	+0.4	3.3	+0.4	2.9	+0.4	3.1
FR-CTBC	35	+0.9	3.7	+1.1	2.6	+1.0	3.2
FR-Probioqual	76	+0.1	3.1	+0.1	2.8	+0.1	3.0
International*	8	+0.8	2.4	+0.4	1.9	+0.6	2.1
Siemens DCA 2000/Vantage							
Overall	38	+5.9	5.5	+5.8	4.5	+5.8	5.0
FR-Asqualab	8	+4.9	3.6				
FR-Probioqual	21	+6.7	5.9	+6.2	4.9	+6.5	5.4
Siemens Dimension series							
Overall	33	+3.4	5.2	+3.0	5.6	+3.2	5.4
FR-Probioqual	13	+3.3	5.4	+3.2	6.5	+3.3	6.0
GR-ESEAP	5	+3.9	7.3	+3.1	6.3	+3.5	6.8
Tosoh G8							
Overall	198	+1.2	3.5	+1.3	3.7	+1.2	3.6
AT-OQUASTA	10	+1.7	3.7	+1.6	3.4	+1.7	3.5
CZ-SEKK	20	+1.8	4.0	+1.9	3.7	+1.8	3.8
FR-Asqualab	18	+1.7	3.5				
FR-CTBC	26	+0.6	3.4	+1.2	4.7	+0.9	4.1
FR-Probioqual	78	+0.8	3.1	+1.0	3.2	+0.9	3.1
International*	5	+1.7	2.2	+1.5	2.9	+1.6	2.5
KR- Kor Ass. of EQAS	8	+1.6	3.0	+1.5	2.0	+1.5	2.5
TR-KBUDEK	12	+1.5	2.2	+1.6	1.9	+1.5	2.0
TR-TUBITAK	9	+0.3	4.3	+0.3	4.7	+0.3	4.5
Tosoh G11							
Overall	112	+1.6	5.1	+1.8	5.1	+1.7	5.1
FR-Asqualab	8	+1.3	2.7				
FR-CTBC	28	+3.3	6.8	+3.3	6.5	+3.3	6.6
FR-Probioqual	43	+1.2	3.7	+1.6	3.8	+1.4	3.7
KR- Kor Ass. of EQAS	21	+0.9	1.8	+0.7	2.0	+0.8	1.9
Tosoh GX							
Overall	20	+1.1	4.8	+1.2	5.2	+1.2	5.0
FR-CTBC	6	+1.0	6.8	+1.2	7.3	+1.1	7.0
FR-Probioqual	12	+1.2	4.3	+1.2	4.8	+1.2	4.6

* Group of Individual laboratories of a number of countries

From the two identical (duplicate) samples the within run precision was calculated. In total 1689 results for both EurA1c 2020-1 and 2 were submitted. Table 6 shows the mean CV for each manufacturer. The overall mean within run CV is 1.7%. As it can be expected that participating laboratories measure both samples in the same run, this CV probably reflects within-run CV.

Table 11. Lyophilised Hemolysate mean CV per manufacturer/method from the duplicate samples

Manufacturer/Method	Fresh Whole Blood	
	n	Mean Within run CV%
Abbott Aeroset multigent	2	0.9
Abbott Alinity	15	0.5
Abbott ARCHITECT (enzymatic)	21	1.7
Abbott ARCHITECT (immunoassay)	30	1.7
Abbott ARCHITECT not specified/other	28	1.4
Beckman Coulter AU series	45	1.7
Beckman Coulter P / ACE MDQ	1	0.0
BioMajesty JCA-BM6010	5	2.2
Bio-Rad D-10 series	93	2.2
Bio-Rad D-100 series	70	1.2
Bio-Rad not specified/other	5	1.1
Bio-Rad Variant series	82	1.1
Ceragem	1	3.7
Erba XL series	3	2.0
Horiba Pentra	1	0.0
Lifotronic	21	1.5
Medconn MQ-2000PT	1	0.0
Menarini (ARKRAY) HA-8140 series	1	0.0
Menarini (ARKRAY) HA-8160 series	43	1.4
Menarini (ARKRAY) HA-8180 series	95	0.6
Menarini (ARKRAY) HA-8190 series	1	0.0
Menarini (ARKRAY) not specified/other	15	0.3
Mindray bs series	8	1.7
Not specified/Other	18	2.5
Ortho Clinical Diagnostics Vitros series	5	2.3
Osang Clover A1c	3	5.2
Randox RX series	3	0.7
Roche Diagnostics cobas c 111	11	1.5
Roche Diagnostics cobas c 311	8	1.0
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	209	1.9
Roche Diagnostics cobas c 503 (cobas pro)	7	2.0
Roche Diagnostics cobas c 513	16	0.6
Roche Diagnostics cobas Integra	50	1.5
Roche Diagnostics not specified/other	87	3.4
Sebia CAPILLARYS 2	115	2.3
Sebia CAPILLARYS 3	119	1.7
Sebia MINICAP	23	3.5
Sebia not specified/other	7	1.9
Siemens Advia (enzymatic)	4	3.8
Siemens Atellica CH (immunoassay)	2	2.0
Siemens Atellica CH not specified/other	1	0.0
Siemens DCA 2000/Vantage	22	2.1
Siemens Dimension series	29	2.3
Siemens not specified/other	1	2.0
Spinreact Spinlab 200 E	1	3.7
Sysmex bx series	4	4.0
Tosoh G7	37	1.2
Tosoh G8	175	1.2
Tosoh G11	98	1.4
Tosoh GX	19	1.0
Tosoh not specified/other	4	1.0
Trinity Biotech Premier Hb9210	23	1.1
Wondfo Finecare™ FIA Meter	1	2.0
Total	1689	1.7

IV. Value Assignment (Targeting)

The samples in their respective matrixes have been measured with the IFCC RMP, the IFCC SRLs, and the US NGSP SRLs. Table 12 shows the results. The assigned values are the values assigned with the IFCC RMP. Values of the SRLs are for comparison and information.

Table 12. Results of Reference Measurement Procedures

Matrix	EurA1c 2020-1 (range 35.9-37.1 mmol/mol)			EurA1c 2020-2 (range 35.9-37.1 mmol/mol)		
	IFCC RMP	IFCC SRLs	US NGSP SRLs	IFCC RMP	IFCC SRLs	US NGSP SRLs
	n = 4	n = 8	n = 3	n = 4	n = 8	n = 3
Fresh Whole Blood	36.5	37.3	37.0	36.5	37.2	37.2
Lyophilised Hemolysate	36.1	37.5	37.1	36.1	37.5	36.9
Frozen Whole Blood	36.7	37.3	37.0	36.7	37.1	36.8

- 1) US-NGSP 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 for EurA1c 2020-1 and 2.

V. Homogeneity

Homogeneity testing of the samples EurA1c 2020-2, 4 and 6 is performed according to ISO 13528:2015 (Annex B) with the Menarini (ARKRAY) HA- 8180V. The results in table 13 show that the samples are homogeneous.

Table 13. Homogeneity test of EurA1c 2020

Vial	Fresh Whole Blood				Lyophilised Hemolysate				Frozen Whole Blood			
	EurA1c 2020-2				EurA1c 2020-4				EurA1c 2020-6			
	1	2	mean	Δ	1	2	mean	Δ	1	2	mean	Δ
1	37.2	36.8	37.00	0.4	36.8	36.7	36.75	0.1	36.5	36.3	36.40	0.2
2	37.1	37.1	37.10	0.0	36.7	36.7	36.70	0.0	36.4	36.3	36.35	0.1
3	37.1	36.9	37.00	0.2	36.7	36.8	36.75	0.1	36.4	36.2	36.30	0.2
4	37.2	36.8	37.00	0.4	36.7	36.5	36.60	0.2	36.5	36.2	36.35	0.3
5	37.2	36.9	37.05	0.3	36.7	36.7	36.70	0.0	36.4	36.3	36.35	0.1
6	36.9	37.2	37.05	0.3	36.7	38.0	37.35	1.3	36.4	36.2	36.30	0.2
7	36.9	36.9	36.90	0.0	36.7	36.8	36.75	0.1	36.7	36.3	36.50	0.4
8	36.9	36.8	36.85	0.1	36.8	36.5	36.65	0.3	36.5	36.4	36.45	0.1
9	36.8	36.9	36.85	0.1	36.7	36.5	36.60	0.2	36.7	36.4	36.55	0.3
10	36.9	36.9	36.90	0.0	36.8	36.7	36.75	0.1	36.5	36.5	36.50	0.0
11	36.9	36.9	36.90	0.0	36.5	36.7	36.60	0.2	36.3	36.2	36.25	0.1
12	36.9	36.9	36.90	0.0	36.7	36.7	36.70	0.0	36.3	36.4	36.35	0.1
average			37.0				36.7				36.4	
SD	0.000	0.085	0.153		0.000	0.201	0.284		0.000	0.093	0.146	
0.3 x SD _{RL}		0.262				0.260				0.258		
Criterion		-0.262				-0.260				-0.258		
Homogeneity:		Pass				Pass				Pass		

VI. Stability

Fresh Whole Blood

Fresh whole blood samples EurA1c 2020-2 (HbA1c 36.5 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 14). 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 14. 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	1	-1	-1	-2	-3
Roche cobas c 513	0	0	0	0	0	0
Abbot Enzymatic Alignity	0	0	0	0	+1	0
Tosoh G8	0	0	0	0	-1	0
Trinity Biotech Premier Hb9210	0	0	0	-1	-1	-2
Storage Refrigerator						
Menarini/ARKRAY HA-8180V	0	0	0	0	0	0
Sebia CAPILLARYS 3 Octa	0	0	0	0	+1	0
Roche cobas c 513	0	0	0	0	0	-1
Abbott enzymatic Alinity	0	1	0	0	+1	0
Tosoh G8	0	0	0	0	0	0
Trinity Biotech Premier Hb9210	0	0	0	0	0	0

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

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, 25 and 37 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 15. 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 15. Stability* of Frozen Whole Blood in Freezer -20°C and Freezer -70°C

Method	0 month	6 months	13 months	18 months	25 months	37 months
Storage Freeze -20°C						
Menarini/ARKRAY HA-8180V	0	0	-5	n.m.***	n.m.***	-1
Sebia CAPILLARYS 3 Octa**	0	+2	+3	n.m.***	n.m.***	n.m.***
Roche Cobas c 513	0	+1	0	+1	+1	+3
Abbott enzymatic Alinity****	0	+1	+2	+2	+2	+4
Tosoh G8	0	-3	-2	-1	-1	-3
Trinity Biotech Premier Hb9210	0	-5	-11	-3	-3	+8
Storage Freezer <-70°C						
Menarini/ARKRAY HA-8180V	0	0	0	-1	-1	0
Sebia CAPILLARYS 3 Octa**	0	0	+1	+2	+2	+2
Roche Cobas c 513	0	1	-1	0	0	+2
Abbott enzymatic Alinity****	0	1	1	0	0	+1
Tosoh G8	0	1	1	1	1	0
Trinity Biotech Premier Hb9210	0	0	+2	0	0	+1

* difference between Month X and Month 0 in mmol/mol

** initial measurement (0 month) on Sebia CAPILLARYS 2 FP)

*** not measurable

**** until 18 months on Abbott ARCHITECT C4000

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 / <-70°C and measured after 6, 13, 18, 25 and 37 months. Results are shown in table 16. It can be seen that the results of the Abbott enzymatic assay start to show differences after 6 months.

Table 16. Stability* of Lyophilised Hemolysate in Refrigerator and Freezer -20°C and Freezer -70°C

Method	0 month	6 months	13 months	18 months	25 months	37 months
Storage Refrigerator						
Menarini/ARKRAY HA-8180V	0	0	-1	0	-1	-1
Sebia CAPILLARYS 3 Octa**	0	-2	+1	0	-1	0
Roche Cobas c 513	0	0	0	+1	+1	+2
Abbott enzymatic Alinity***	0	-3	-5	-5	-8	-7
Tosoh G8	0	-1	+1	-2	-2	+4
Trinity Biotech Premier Hb9210	0	0	0	-1	0	+1
Storage Freezer -20°C						
Menarini/ARKRAY HA-8180V	0	+1	0	0	+1	+1
Sebia CAPILLARYS 3 Octa**	0	-1	+1	+1	-1	0
Roche Cobas c 513	0	+1	0	0	+1	+2
Abbott enzymatic Alinity***	0	+2	+2	+2	0	+3
Tosoh G8	0	+1	+1	+1	+1	+1
Trinity Biotech Premier Hb9210	0	+1	+1	+1	+2	+2
Storage Freezer <-70°C						
Menarini/ARKRAY HA-8180V	0	+1	0	0	+1	+1
Sebia CAPILLARYS 3 Octa**	0	-1	+1	0	-1	0
Roche Cobas c 513	0	+1	0	0	+2	+1
Abbott enzymatic Alinity***	0	+2	+3	+3	+1	+2
Tosoh G8	0	+1	+1	+1	+1	+1
Trinity Biotech Premier Hb9210	0	+1	+1	+1	+2	+2

* Difference between Month X and Month 0 in mmol/mol

**Initial measurement (0 month) on Sebia CAPILLARYS 2 FP)

*** until 18 months on Abbott ARCHITECT C4000

VII Organisations and Persons Involved

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FR	Asqualab	Anne Vassault
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NL	Coordination	Carla Siebelder
NL	Quality Assurance	Liesbeth Schröer
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