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

Report
EurA1c 2022

HbA1c Trial
EQA organisers

FINAL Version
11 September 2023
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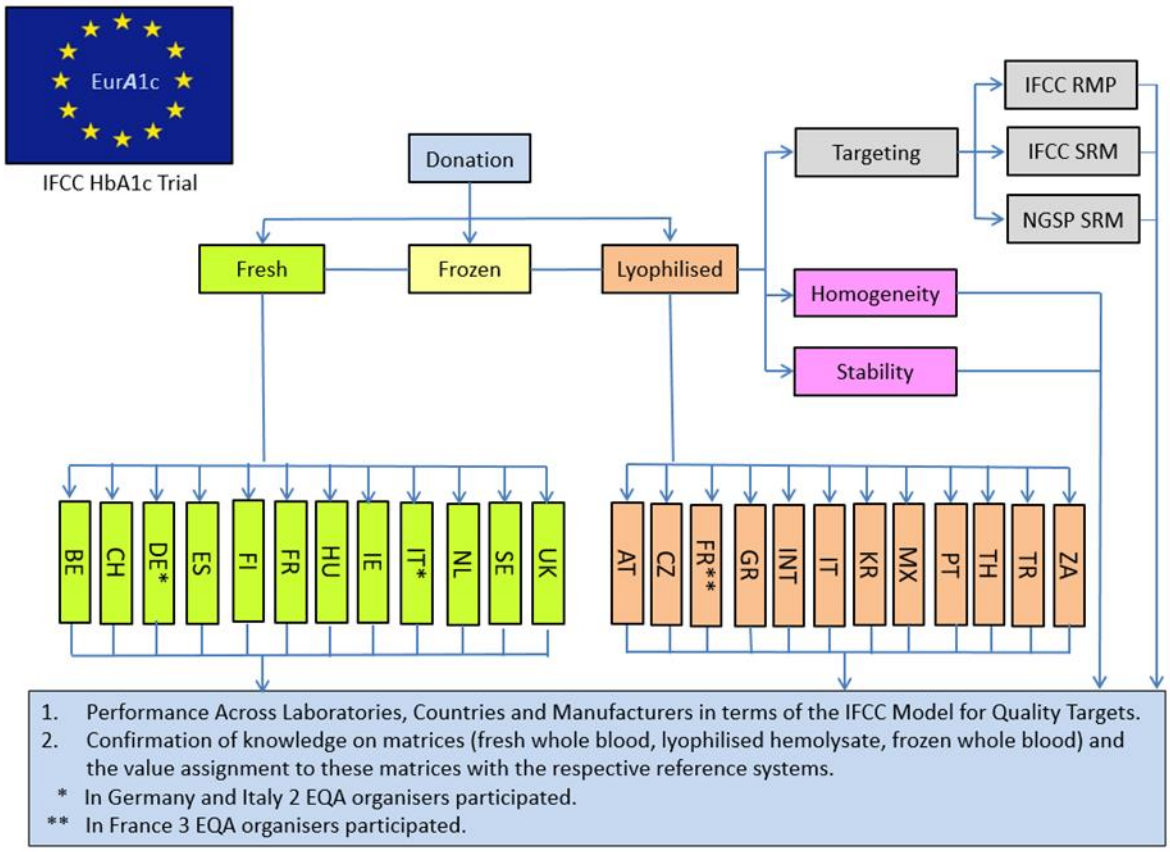
I Introduction and Overview of Results

Introduction
26 EQA organisers of 22 countries agreed to participate in the fifth “EurA1c” project. The design is shown in figure 1.

14 EQA organisers used fresh whole blood samples and 14 organisers used lyophilised hemolysate samples (2 organisations used both fresh and lyophilised samples). In October 2022 the fresh whole blood samples were sent to the participants. From November 2022 up to April 2023 the lyophilised samples were assayed by the participants.

Figure 1. Design EurA1c Trial 2022



Confidentiality and Ownership
The results of the EurA1c 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 2023:	Draft report sent to all who are involved in EurA1c 2022. At the same time the invitation to participate in EurA1c 2023 is sent.
31 August 2023:	Deadline for comments and remarks.
30 September 2023:	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
Five Approved IFCC Network Laboratories performed the value assignment with the IFCC Reference Measurement Procedure. For EurA1c 2022-1 the assigned value is 41.7 mmol/mol (expanded uncertainty 0.8 mmol/mol) and for EurA1c 2022-2 the assigned value is 58.2 mmol/mol (expanded uncertainty 1.2 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 18 results (0.6%) have been excluded from the database of the fresh whole blood samples and 12 results (0.8%) from the database of the lyophilised hemolysates.

Methods
This is still a point of consideration. For fresh whole blood 87 of the laboratories did not report their method at all and for lyophilised hemolysate 26 labs. Also a number of labs did not specify their method/instrument: For details see resp. table 3 and 7.

Units
In some cases results were reported in NGSP units. We converted them to SI (IFCC) units using the Master Equation (NGSP = 0.0915 IFCC + 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 2022

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				122	+3,7	5,8
Belgium	Sciensano	116	+0.7	3.2			
Czech Republic	SEKK s.r.o				166	+0,2	4,9
Finland	Labquality	235	-0.7	4.1			
France	Asqualab				23	-0,2	4,4
France	CTCB	135	+0.4	3.9	117	-0,3	3,9
France	ProBioQual				585	-0,7	5,4
Germany	INSTAND	633	+0.4	4.1			
Germany	RfB	796	+0.6	3.8			
Greece	ESEAP				94	-0,3	6,3
Hungary	QualiCont	82	+0.9	6.0			
International**	ERL				42	-0,6	3,0
Ireland	IEQAS	51	+0.8	3.0			
Italy	CRB	46	+0.2	6.0	36	0,0	4,5
Italy	CRRVEQ	149	+0.8	4.5			
Korea	Kor Ass. EQAS				74	-1,0	2,8
Mexico	Labs Biom Panuco				25	+0,9	3,7
Netherlands	SKML	133	+0.8	3.0			
Portugal	PNAEQ-INSA				26	+0,8	5,5
Spain	SEQC^{ML}	119	+0.8	3.3			
South Africa	NHLS				5	+1,6	4,1
Sweden	Equalis	84	+0.0	3.9			
Switzerland	CSCQ	59	+0.2	4.0			
Thailand	NIH				182	-0,1	8,0
Turkey	TUBITAK UME				43	+0,2	6,6
United Kingdom	Weqas	150	+0.7	4.2			
Overall		2788	+0.4	4.1	1537	0,0	6,1

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

In total 4325 datasets were submitted (2788 in fresh whole blood and 1537 in lyophilised hemolysate) for EurA1c 2022. The mean bias of all countries in the fresh whole blood programme is +0.4 mmol/mol and the between laboratory CV is 4.1%. In the lyophilised hemolysate programme the mean bias of all countries is +0.0 mmol/mol and the between laboratory CV is 6.1%.

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 2022-1 Target 41.7 mmol/mol				EurA1c 2022-2 Target 58.2 mmol/mol				Mean 2 Samples	
		n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Belgium	Sciensano	116	42.3	+0.6	3.3	116	59.0	+0.8	3.2	+0.7	3.2
Finland	Labquality	232	41.2	-0.5	4.4	235	57.2	-1.0	3.8	-0.7	4.1
France	CTCB	135	41.9	+0.2	4.3	134	58.9	+0.7	3.5	+0.4	3.9
Germany	INSTAND	632	42.0	+0.3	4.4	633	58.7	+0.5	3.7	+0.4	4.1
Germany	RfB	794	42.1	+0.4	4.0	796	59.1	+0.9	3.6	+0.6	3.8
Hungary	QualiCont	82	42.4	+0.7	6.6	80	59.3	+1.1	5.3	+0.9	6.0
Ireland	IEQAS	51	42.4	+0.7	3.1	51	59.1	+0.9	2.9	+0.8	3.0
Italy	CRB	45	42.2	+0.5	5.8	46	58.2	0.0	6.3	+0.2	6.0
Italy	CRRVEQ	149	42.2	+0.5	5.2	145	59.3	+1.1	3.8	+0.8	4.5
Netherlands	SKML	132	42.3	+0.6	3.4	133	59.2	+1.0	2.7	+0.8	3.0
Spain	SEQC^{ML}	119	42.2	+0.5	3.2	118	59.2	+1.0	3.4	+0.8	3.3
Sweden	Equalis	84	41.8	+0.1	4.8	81	58.0	-0.2	3.1	0.0	3.9
Switzerland	CSCQ	59	41.7	0.0	4.2	58	58.6	+0.4	3.7	+0.2	4.0
United Kingdom	Weqas	150	42.3	+0.6	4.0	147	59.0	+0.8	4.5	+0.7	4.2
Overall		2780	42.0	+0.3	4.3	2773	58.8	+0.6	3.9	+0.4	4.1

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

Manufacturer/Method	EurA1c 2022-1 Target 41.7 mmol/mol				EurA1c 2022-2 Target 58.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	39	40.7	-1.0	2.2	39	57.9	-0.3	1.7	-0.6	1.9
Abbott ARCHITECT (enzymatic)	45	40.8	-0.9	4.9	46	58.0	-0.2	4.7	-0.6	4.8
Abbott not specified/other	31	40.4	-1.3	6.7	31	56.9	-1.3	3.3	-1.3	5.0
Abbott/Alere Afinion	229	40.6	-1.1	4.0	228	57.1	-1.1	3.0	-1.1	3.5
Aidian QuickRead go HbA1c	13	41.7	0.0	5.8	10	59.1	+0.9	6.0	+0.4	5.9
ARKRAY ADAMS HA-8160 series	7	41.9	+0.2	4.7	7	58.0	-0.2	4.7	0.0	4.7
ARKRAY ADAMS HA-8180 series	179	42.3	+0.6	3.0	178	58.8	+0.6	3.1	+0.6	3.1
Beckman Coulter AU series	56	41.8	+0.1	5.5	55	57.7	-0.5	4.4	-0.2	5.0
Bio-Rad D-10 series	55	42.7	+1.0	5.4	56	59.7	+1.5	4.5	+1.2	5.0
Bio-Rad D-100 series	71	40.9	-0.8	3.0	71	57.5	-0.7	2.5	-0.8	2.7
Bio-Rad Variant series	52	42.6	+0.9	5.4	50	60.2	+2.0	3.2	+1.4	4.3
Bio-Rad not specified/other	76	42.0	+0.3	3.8	76	59.2	+1.0	3.8	+0.6	3.8
EKF Diagnostics	15	43.1	+1.4	4.7	15	59.5	+1.3	4.2	+1.3	4.4
HemoCue HbA1c 501	25	40.8	-0.9	9.7	28	56.5	-1.7	7.8	-1.3	8.7
Menarini HA-8160 series (Lifotronic reagent)	6	41.8	+0.1	4.4	7	55.6	-2.6	10.5	-1.2	7.4
Menarini HA-8180 series (Lifotronic reagent)	25	42.3	+0.6	2.1	25	58.8	+0.6	2.1	+0.6	2.1
Menarini Hb NEXT	7	42.9	+1.2	4.0	7	61.5	+3.3	4.6	+2.3	4.3
Roche Diagnostics cobas b 101	17	41.2	-0.5	3.2	17	58.8	+0.6	3.6	0.0	3.4
Roche Diagnostics cobas c 111/311	9	40.8	-0.9	6.0	9	58.4	+0.2	5.6	-0.4	5.8
Roche Diagnostics cobas c 303/503	53	42.8	+1.1	2.9	54	59.9	+1.7	2.5	+1.4	2.7
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	236	42.2	+0.5	3.7	235	59.3	+1.1	3.5	+0.8	3.6
Roche Diagnostics cobas c 513	70	42.3	+0.6	2.3	70	59.4	+1.2	2.2	+0.9	2.2
Roche Diagnostics cobas Integra	49	42.2	+0.5	3.1	49	60.6	+2.4	2.9	+1.4	3.0
Roche Diagnostics not specified/other	180	42.2	+0.5	3.5	179	59.5	+1.3	3.4	+0.9	3.5
Sebia CAPILLARYS 2	54	41.2	-0.5	3.3	54	58.5	+0.3	2.6	-0.1	3.0
Sebia CAPILLARYS 3	128	41.5	-0.2	3.0	128	58.3	+0.1	2.6	-0.1	2.8
Sebia MINICAP	10	41.8	+0.1	4.5	10	59.8	+1.6	5.6	+0.9	5.0
Sebia not specified/other	36	41.4	-0.3	2.2	36	57.7	-0.5	1.7	-0.4	1.9
Siemens Advia (enzymatic)	7	41.7	0.0	7.9	7	59.2	+1.0	7.2	+0.5	7.6
Siemens Advia not specified/other	22	42.4	+0.7	5.3	22	59.2	+1.0	4.8	+0.9	5.1
Siemens Atellica CH (enzymatic)	38	42.0	+0.3	3.4	38	59.6	+1.4	3.4	+0.9	3.4
Siemens Atellica CH not specified/other	16	41.4	-0.3	5.9	16	59.1	+0.9	3.5	+0.3	4.7
Siemens DCA 2000/Vantage	208	42.3	+0.6	4.1	209	58.9	+0.7	3.8	+0.7	3.9
Siemens Dimension EXL series	70	42.0	+0.3	4.3	69	57.5	-0.7	3.1	-0.2	3.7
Thermo Fisher Scientific/Konelab	20	43.2	+1.5	4.5	20	58.4	+0.2	4.6	+0.8	4.6
Tosoh G7	13	42.7	+1.0	3.8	13	59.1	+0.9	5.7	+1.0	4.8
Tosoh G8	193	42.8	+1.1	2.3	192	59.9	+1.7	2.2	+1.4	2.2
Tosoh G11	182	42.8	+1.1	3.0	182	59.7	+1.5	2.3	+1.3	2.7
Tosoh GX	14	43.2	+1.5	5.3	14	60.4	+2.2	3.4	+1.9	4.3
Tosoh not specified/other	66	43.0	+1.3	2.0	65	59.9	+1.7	1.6	+1.5	1.8
Trinity Biotech Premier Hb9210	27	42.7	+1.0	2.7	25	58.9	+0.7	5.8	+0.8	4.3
Not specified/other	87	42.0	+0.3	6.7	87	58.3	+0.1	5.6	+0.2	6.1

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

Manufacturer/Method	EurA1c 2022-1 Target 41.7 mmol/mol				EurA1c 2022-2 Target 58.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott AxSym	1	42.0	+0.3		1	58.0	-0.2		0.0	
ARKRAY ADAMS HA-8380 series	2	41.5	-0.2	5.1	2	58.5	+0.3	3.6	0.0	4.4
ARKRAY ADAMS not specified/other	4	42.9	+1.2	5.6	4	59.3	+1.1	5.5	+1.1	5.5
Beckman Coulter Unicel DxC series	5	42.1	+0.4	4.3	5	58.8	+0.5	3.3	+0.5	3.8
Beckman Coulter not specified/other	3	40.2	-1.5	7.5	3	56.4	-1.8	5.4	-1.7	6.5
Eurolyser	1	34.0	-7.7		1	45.0	-13.2		-10.5	
Hitado	4	42.5	+0.8	9.7	4	61.5	+3.3	6.8	+2.0	8.2
Horiba Pentra	3	43.1	+1.4	6.3	3	62.0	+3.8	4.3	+2.6	5.3
Lifotronic	1	47.5	+5.8		1	60.6	+2.4		+4.1	
Menarini not specified/other	1	43.3	+1.6		1	58.5	+0.3		+0.9	
Mindray bs series	1	42.0	+0.3		1	58.0	-0.2		0.0	
Sebia CAPILLARYS not specified/other	5	41.6	-0.1	2.2	5	58.8	+0.6	1.4	+0.2	1.8
Siemens Atellica not specified/other	1	40.3	-1.4		1	57.6	-0.6		-1.0	
Siemens not specified/other	3	44.6	+2.9	8.5	3	61.2	+3.0	4.5	+3.0	6.5
Sysmex not specified/other	1	34.0	-7.7		1	46.0	-12.2		-10.0	
Thermo Fisher Scientific	2	42.2	+0.5	1.0	2	59.9	+1.7	1.7	+1.1	1.3

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 2022-1** Target 41.7 mmol/mol		**EurA1c 2022-2** Target 58.2 mmol/mol		**Mean**	
		Bias	**CV%**	**Bias**	**CV%**	**Bias**	**CV%**
Abbott Alinity							
Overall	39	-1.0	2.2	-0.3	1.7	-0.6	1.9
BE-Sciensano	6	-0.9	4.0	-0.2	3.1	-0.6	3.5
DE-INSTAND	8	-1.1	1.5	-0.3	1.9	-0.7	1.7
DE-RfB	6	-0.7	1.3	-0.1	1.7	-0.4	1.5
FI-Labquality	6	-1.1	0.5	-0.3	0.6	-0.7	0.6
Abbott ARCHITECT (enzymatic)							
Overall	45	-0.9	4.9	-0.2	4.7	-0.6	4.8
DE-INSTAND	20	-0.6	2.5	+0.2	3.3	-0.2	2.9
DE-RfB	6	-1.3	1.6	-0.7	1.3	-1.0	1.4
Abbott/Alere Afinion							
Overall	229	-1.1	4.0	-1.1	3.0	-1.1	3.5
CH-CSCQ	19	-0.5	3.9	-0.8	2.5	-0.7	3.2
DE-INSTAND	63	-1.1	3.1	-0.9	2.3	-1.0	2.7
DE-RfB	9	-1.1	2.2	-1.9	4.2	-1.5	3.2
FI-Labquality	85	-1.4	3.8	-1.5	3.1	-1.4	3.4
NL-SKML	15	-0.6	3.4	-0.3	2.7	-0.5	3.1
SE-Equalis	18	-1.5	3.1	-1.9	2.5	-1.7	2.8
UK-Weqas	13	-0.9	4.6	-0.6	3.8	-0.7	4.2
ARKRAY ADAMS HA-8180 series							
Overall	179	+0.6	3.0	+0.6	3.1	+0.6	3.1
BE-Sciensano	26	+0.5	3.8	+0.2	3.2	+0.4	3.5
DE-INSTAND	29	+0.7	2.4	+0.5	2.7	+0.6	2.5
DE-RfB	13	+1.4	2.0	+2.0	2.0	+1.7	2.0
ES-SEQC^{ML}	42	+0.6	2.6	+1.0	2.5	+0.8	2.6
HU-QualiCont	28	+0.5	3.9	+0.5	3.5	+0.5	3.7
IE-IEQAS	12	+1.0	2.7	+1.2	2.7	+1.1	2.7
NL-SKML	16	+0.7	1.5	+0.4	1.4	+0.5	1.4
UK-Weqas	10	-0.6	3.5	-1.3	3.8	-1.0	3.7
Beckman Coulter AU series							
Overall	56	+0.1	5.5	-0.5	4.4	-0.2	5.0
DE-INSTAND	21	+0.2	3.3	-0.8	3.5	-0.3	3.4
DE-RfB	27	-0.1	4.4	-0.6	3.2	-0.3	3.8
Bio-Rad D-10 series							
Overall	55	+1.0	5.4	+1.5	4.5	+1.2	5.0
DE-INSTAND	21	+1.2	5.0	+1.4	3.5	+1.3	4.2
DE-RfB	14	+1.4	2.8	+2.1	2.6	+1.7	2.7
FR-CTCB	8	-0.9	7.1	-0.5	7.1	-0.7	7.1
Bio-Rad D-100 series							
Overall	71	-0.8	3.0	-0.7	2.5	-0.8	2.7
BE-Sciensano	7	-0.6	0.9	-0.1	1.9	-0.3	1.4
DE-INSTAND	17	-0.6	1.9	-0.8	1.9	-0.7	1.9
DE-RfB	14	-1.1	2.5	-0.9	2.2	-1.0	2.3
ES-SEQC^{ML}	14	-0.5	1.8	-0.3	1.7	-0.4	1.7
Bio-Rad Variant series							
Overall	52	+0.9	5.4	+2.0	3.2	+1.4	4.3
DE-INSTAND	15	+1.4	4.7	+2.0	3.8	+1.7	4.2
DE-RfB	11	+0.5	5.2	+1.2	3.6	+0.8	4.4
HU-QualiCont	8	+1.3	8.2	+3.2	3.5	+2.3	5.8
IT-CRRVEQ	10	-0.1	5.1	+2.1	1.5	+1.0	3.3
HemoCue HbA1c 501							
Overall	28	-0.9	9.7	-1.7	7.8	-1.3	8.7
DE-INSTAND	7	-0.4	11.8	-2.2	7.2	-1.3	9.5
FI-Labquality	18	-1.8	7.3	-1.4	8.7	-1.6	8.0

Method	n	EurA1c 2022-1 Target 41.7 mmol/mol		EurA1c 2022-2 Target 58.2 mmol/mol		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Menarini HA-8180 series (Lifotronic reagent)							
Overall	25	+0.6	2.1	+0.6	2.1	+0.6	2.1
ES-SEQC^{ML}	9	+0.4	2.2	+0.9	1.8	+0.7	2.0
IT-CRRVEQ	14	+0.6	2.2	+0.3	2.1	+0.4	2.1
Roche Diagnostics cobas c 303/503							
Overall	54	+1.1	2.9	+1.7	2.5	+1.4	2.7
DE-INSTAND	18	+0.7	3.6	+1.2	2.3	+1.0	3.0
DE-RfB	20	+1.1	2.7	+1.6	2.9	+1.3	2.8
NL-SKML	7	+1.6	1.9	+2.8	1.2	+2.2	1.6
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)							
Overall	236	+0.5	3.7	+1.1	3.5	+0.8	3.6
CH-CSCQ	8	+1.3	2.8	+1.6	3.2	+1.5	3.0
DE-INSTAND	113	+0.5	3.5	+1.1	3.0	+0.8	3.2
DE-RfB	57	+0.7	2.8	+1.5	3.0	+1.1	2.9
ES-SEQC^{ML}	8	+1.5	5.5	+2.2	8.6	+1.9	7.0
FI-Labquality	14	0.0	3.2	-0.3	4.1	-0.2	3.6
IT-CRRVEQ	12	+0.2	4.5	+1.0	3.3	+0.6	3.9
NL-SKML	13	+0.6	6.5	+0.6	3.3	+0.6	4.9
Roche Diagnostics cobas c 513							
Overall	70	+0.6	2.3	+1.2	2.2	+0.9	2.2
DE-INSTAND	25	+0.5	2.7	+0.7	2.0	+0.6	2.3
DE-RfB	33	+0.8	1.9	+1.7	1.8	+1.3	1.9
Roche Diagnostics cobas Integra							
Overall	49	+0.5	3.1	+2.4	2.9	+1.4	3.0
DE-INSTAND	29	+0.4	2.6	+2.0	2.4	+1.2	2.5
DE-RfB	16	+0.8	3.9	+3.2	3.6	+2.0	3.7
Sebia CAPILLARYS 2							
Overall	54	-0.5	3.3	+0.3	2.6	-0.1	3.0
BE-Sciensano	6	+1.1	2.3	+1.3	3.3	+1.2	2.8
DE-RfB	10	-0.4	3.1	+0.8	2.0	+0.2	2.5
FR-CTCB	13	-1.2	3.2	+0.2	2.2	-0.5	2.7
IT-CRRVEQ	11	-0.6	3.0	-0.6	3.1	-0.6	3.1
Sebia CAPILLARYS 3							
Overall	128	-0.2	3.0	+0.1	2.6	-0.1	2.8
BE-Sciensano	16	+0.3	2.1	+0.2	1.7	+0.3	1.9
DE-INSTAND	10	-0.7	2.8	-0.8	2.0	-0.7	2.4
DE-RfB	11	-0.7	3.1	0.0	3.0	-0.3	3.0
ES-SEQC^{ML}	8	-0.7	1.4	-0.2	3.0	-0.5	2.2
FR-CTCB	38	-0.1	2.8	+0.1	2.3	0.0	2.5
IT-CRRVEQ	12	+0.2	4.4	+0.9	4.6	+0.5	4.5
NL-SKML	6	+0.6	2.7	+0.6	1.7	+0.6	2.2
SE-Equalis	13	-0.1	3.2	0.0	2.1	-0.1	2.6
UK-Weqas	7	-0.3	1.3	+0.5	1.9	+0.1	1.6
Siemens Atellica CH (enzymatic)							
Overall	38	+0.3	3.4	+1.4	3.4	+0.9	3.4
DE-INSTAND	13	+1.1	4.6	+1.4	2.6	+1.3	3.6
FI-Labquality	11	-0.1	1.4	+2.2	4.7	+1.1	3.1
Siemens DCA 2000/Vantage							
Overall	208	+0.6	4.1	+0.7	3.8	+0.7	3.9
DE-INSTAND	48	+0.2	3.1	+0.6	3.9	+0.4	3.5
DE-RfB	13	+0.8	4.4	+1.3	4.4	+1.1	4.4
FI-Labquality	28	+0.6	4.1	+0.5	4.4	+0.6	4.3
IE-IEQAS	28	+0.8	3.2	+0.7	3.3	+0.7	3.3
NL-SKML	16	+0.5	3.3	+1.1	3.7	+0.8	3.5
SE-Equalis	22	+1.2	5.4	+0.8	2.8	+1.0	4.1
UK-Weqas	47	+0.7	3.9	+0.6	3.8	+0.6	3.9
Siemens Dimension EXL series							
Overall	70	+0.3	4.3	-0.7	3.1	-0.2	3.7
DE-INSTAND	30	+0.1	4.7	-1.1	3.7	-0.5	4.2
DE-RfB	39	+0.4	4.0	-0.5	2.4	0.0	3.2

Method	n	EurA1c 2022-1 Target 41.7 mmol/mol		EurA1c 2022-2 Target 58.2 mmol/mol		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Tosoh G8							
Overall	193	+1.1	2.3	+1.7	2.2	+1.4	2.2
BE-Sciensano	27	+1.1	1.7	+2.1	2.7	+1.6	2.2
DE-INSTAND	24	+1.0	1.9	+1.3	1.2	+1.2	1.6
DE-RfB	13	+1.2	1.4	+1.7	1.3	+1.4	1.4
ES-SEQC^{ML}	12	+1.2	1.8	+1.5	2.0	+1.4	1.9
FI-Labquality	14	+0.9	2.0	+1.2	1.9	+1.0	2.0
FR-CTCB	16	+1.2	1.9	+1.8	2.5	+1.5	2.2
IT-CRRVEQ	32	+1.0	3.2	+1.9	2.1	+1.4	2.6
NL-SKML	21	+1.2	2.5	+1.6	1.8	+1.4	2.1
SE-Equalis	8	+1.1	1.8	+1.4	1.5	+1.2	1.6
UK-Weqas	22	+1.1	2.1	+1.8	2.0	+1.4	2.1
Tosoh G11							
Overall	182	+1.1	3.0	+1.5	2.3	+1.3	2.7
BE-Sciensano	10	+1.0	1.3	+1.0	1.0	+1.0	1.1
DE-INSTAND	27	+1.4	1.9	+1.7	1.5	+1.5	1.7
DE-RfB	20	+1.2	2.0	+1.9	1.7	+1.6	1.9
ES-SEQC^{ML}	9	+2.0	2.7	+2.1	1.3	+2.0	2.0
FI-Labquality	20	+0.4	1.6	+0.6	1.5	+0.5	1.6
FR-CTCB	23	+1.1	1.8	+1.5	1.4	+1.3	1.6
HU-QualiCont	9	+2.6	6.3	+3.2	7.2	+2.9	6.8
IT-CRB	8	+1.2	4.9	+0.8	1.5	+1.0	3.2
IT-CRRVEQ	18	+0.4	5.0	+1.1	2.1	+0.7	3.6
NL-SKML	12	+1.2	1.0	+1.4	0.9	+1.3	0.9
UK-Weqas	21	+0.9	1.8	+1.7	1.6	+1.3	1.7
Trinity Biotech Premier Hb9210							
Overall	27	+1.0	2.7	+0.7	5.8	+0.8	4.3
IT-CRB	10	+0.4	2.6	+0.3	2.3	+0.3	2.5
UK-Weqas	10	+1.8	2.2	+0.3	10.3	+1.1	6.2

III Results EQA Lyophilised Hemolysate samples

Table 6 shows the results per EQA organiser 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 EQA organiser for Lyophilised Hemolysate

Country	EQA Organiser	EurA1c 2022-1 Target 41.7 mmol/mol				EurA1c 2022-2 Target 58.2 mmol/mol				Mean 2 Samples	
		n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Austria	ÖQUASTA	122	45.2	+3.5	6.7	122	62.0	+3.8	5.0	+3.7	5.8
Czech Republic	SEKK s.r.o	166	41.9	+0.2	5.2	166	58.5	+0.3	4.6	+0.2	4.9
France	Asqualab	22	41.5	-0.2	3.8	23	58.0	-0.2	4.9	-0.2	4.4
France	CTCB	117	41.5	-0.2	4.2	117	57.9	-0.3	3.7	-0.3	3.9
France	ProBioQual	581	41.1	-0.6	6.2	585	57.5	-0.7	4.6	-0.7	5.4
Greece	ESEAP	92	41.2	-0.5	6.6	94	58.1	-0.1	6.1	-0.3	6.3
International*	ERL	40	41.2	-0.5	3.4	42	57.5	-0.7	2.6	-0.6	3.0
Italy	CRB	36	41.9	+0.2	4.8	35	58.1	-0.1	4.2	0.0	4.5
Korea	Kor Ass. EQAS	74	40.8	-0.9	3.0	74	57.1	-1.1	2.5	-1.0	2.8
Mexico	Labs Biom Panuco	25	42.7	+1.0	4.1	25	59.0	+0.8	3.4	+0.9	3.7
Portugal	PNAEQ-INSA	26	42.4	+0.7	5.5	26	59.0	+0.8	5.5	+0.8	5.5
South Africa	NHLS	5	43.2	+1.5	3.0	5	59.8	+1.6	5.2	+1.6	4.1
Thailand	NIH	182	41.3	-0.4	8.2	180	58.3	+0.1	7.9	-0.1	8.0
Turkey	TUBITAK UME	43	41.7	0.0	7.4	43	58.6	+0.4	5.8	+0.2	6.6
Overall		1531	41.6	-0.1	6.6	1537	58.2	0.0	5.5	0.0	6.1

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

Manufacturer	EurA1c 2022-1 Target 41.7 mmol/mol				EurA1c 2022-2 Target 58.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	29	38.9	-2.8	4.9	30	55.3	-2.9	5.2	-2.8	5.0
Abbott ARCHITECT (enzymatic)	51	38.5	-3.2	6.6	50	54.6	-3.6	6.2	-3.4	6.4
ARKRAY ADAMS HA-8160 series	7	43.0	+1.3	6.2	7	59.3	+1.1	3.6	+1.2	4.9
ARKRAY ADAMS HA-8180 series	75	41.6	-0.1	6.3	76	57.6	-0.6	5.0	-0.3	5.7
ARKRAY ADAMS HA-8190 series	6	39.5	-2.2	1.4	6	55.9	-2.3	1.6	-2.2	1.5
ARKRAY ADAMS not specified/other	9	40.1	-1.6	5.8	9	56.6	-1.6	5.5	-1.6	5.6
Beckman Coulter AU series	16	42.9	+1.2	8.0	18	60.1	+1.9	6.7	+1.5	7.3
BioMajesty JCA-BM6010	6	39.7	-2.0	3.2	5	55.0	-3.2	2.5	-2.6	2.8
Bio-Rad D-10 series	75	41.6	-0.1	6.2	74	58.5	+0.3	4.3	+0.1	5.2
Bio-Rad D-100 series	75	41.5	-0.2	6.5	76	57.6	-0.6	3.9	-0.4	5.2
Bio-Rad not specified/other	19	42.9	+1.2	5.0	19	59.7	+1.5	4.7	+1.3	4.8
Bio-Rad Variant series	55	40.3	-1.4	7.0	54	56.7	-1.5	4.9	-1.4	6.0
Lifotronic	12	42.6	+0.9	9.1	11	58.2	0.0	6.5	+0.5	7.8
Menarini Hb NEXT	18	41.3	-0.4	3.7	19	57.5	-0.7	3.1	-0.6	3.4
Ortho Clinical Diagnostics Vitros series	6	40.8	-0.9	9.6	6	58.1	-0.1	9.3	-0.5	9.4
Roche Diagnostics cobas c 111/311	11	44.0	+2.3	4.8	11	61.0	+2.8	6.6	+2.6	5.7
Roche Diagnostics cobas c 303/503	33	45.2	+3.5	5.2	35	61.9	+3.7	4.2	+3.6	4.7
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	148	43.5	+1.8	5.5	150	61.3	+3.1	4.5	+2.5	5.0
Roche Diagnostics cobas c 513	22	43.6	+1.9	3.8	22	60.7	+2.5	3.0	+2.2	3.4
Roche Diagnostics cobas Integra	26	42.5	+0.8	5.8	25	61.0	+2.8	5.2	+1.8	5.5
Roche Diagnostics not specified/other	64	40.6	-1.1	9.5	65	59.4	+1.2	5.7	+0.1	7.6
Sebia CAPILLARYS 2	94	40.4	-1.3	3.7	93	56.9	-1.3	2.8	-1.3	3.2
Sebia CAPILLARYS 3	183	40.9	-0.8	2.7	183	56.9	-1.3	2.1	-1.1	2.4
Sebia MINICAP	15	40.1	-1.6	2.9	16	55.9	-2.3	2.7	-2.0	2.8
Siemens Atellica CH (enzymatic)	16	38.8	-2.9	4.3	16	55.1	-3.1	3.1	-3.0	3.7
Siemens DCA 2000/Vantage	38	46.2	+4.5	7.0	40	63.0	+4.8	4.9	+4.6	5.9
Siemens Dimension EXL series	13	43.8	+2.1	3.7	14	59.4	+1.2	4.1	+1.6	3.9
Tosoh G7	10	43.0	+1.3	6.7	11	58.9	+0.7	5.6	+1.0	6.1
Tosoh G8	144	42.1	+0.4	4.7	143	58.0	-0.2	3.4	+0.1	4.1
Tosoh G11	131	41.3	-0.4	2.2	130	57.3	-0.9	1.6	-0.7	1.9
Tosoh GX	17	41.6	-0.1	3.1	17	57.2	-1.0	2.6	-0.5	2.9
Tosoh not specified/other	19	42.3	+0.6	2.6	19	59.0	+0.8	2.4	+0.7	2.5
Trinity Biotech Premier Hb9210	18	41.9	+0.2	5.6	20	58.2	0.0	4.2	+0.1	4.9
Not specified/other	26	42.0	+0.3	9.9	23	60.6	+2.4	8.8	+1.3	9.4

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

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

Manufacturer	EurA1c 2022-1 Target 41.7 mmol/mol				EurA1c 2022-2 Target 58.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Aeroset multigent	1	39.0	-2.7		2	60.5	+2.3	10.5	-0.2	10.5
Abbott not specified/other	5	41.3	-0.4	11.9	5	55.4	-2.8	3.6	-1.6	7.8
ARKRAY ADAMS HA-8380 series	5	39.2	-2.5	10.8	4	54.3	-3.9	12.7	-3.2	11.7
Beckman Coulter not specified/other	2	47.9	+6.2	12.0	2	62.4	+4.2	8.5	+5.2	10.3
Beckman Coulter P/ACE MDQ					1	58.0	-0.2		-0.2	
Beckman Coulter Unicel DxC series	2	38.1	-3.6	14.7	1	57.0	-1.2		-2.4	14.7
Erba XL series	3	44.3	+2.6	6.5	3	65.9	+7.7	8.1	+5.1	7.3
Medconn MQ-2000PT	2	43.7	+2.0	12.4	2	58.5	+0.3	7.9	+1.1	10.2
Menarini HA-8160 series (Lifotronic reagent)	1	43.0	+1.3		1	59.0	+0.8		+1.1	
Menarini HA-8180 series (Lifotronic reagent)	1	39.0	-2.7		1	55.0	-3.2		-3.0	
Mindray bs series	5	38.1	-3.6	3.7	5	52.5	-5.7	6.3	-4.6	5.0
Osang Clover A1c	3	41.7	0.0	16.8	3	54.5	-3.7	11.4	-1.9	14.1
Randox RX series	1	38.0	-3.7		1	57.5	-0.7		-2.2	
Roche Diagnostics cobas b 101	2	35.5	-6.2	6.0	2	50.0	-8.2	2.8	-7.2	4.4
Sebia not specified/other	5	42.6	+0.9	6.0	5	59.2	+1.0	3.4	+0.9	4.7
Siemens Dimension Vista series	2	42.5	+0.8	5.0	2	57.7	-0.5	0.7	+0.1	2.9
Sysmex bx series	2	38.7	-3.0	2.2	2	56.9	-1.3	4.1	-2.1	3.1
Thermo Fisher Scientific	2	42.1	+0.4	7.3	2	59.6	+1.4	5.2	+0.9	6.3

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

Method	**n**	**EurA1c 2022-1** Target 41.7 mmol/mol		**EurA1c 2022-2** Target 58.2 mmol/mol		**Mean 2 Samples**	
		Bias	**CV%**	**Bias**	**CV%**	**Bias**	**CV%**
Abbott Alinity							
Overall	30	-2.8	4.9	-2.9	5.2	-2.8	5.0
GR-ESEAP	8	-2.7	3.6	-2.3	2.4	-2.5	3.0
TH-NIH	7	-5.1	5.4	-7.2	4.3	-6.1	4.8
Abbott ARCHITECT (enzymatic)							
Overall	51	-3.2	6.6	-3.6	6.2	-3.4	6.4
AT-ÖQUASTA	9	-1.8	4.1	-0.3	2.3	-1.1	3.2
FR- Probioqual	8	-1.0	3.6	-0.7	2.3	-0.8	2.9
GR-ESEAP	12	-2.5	5.9	-3.3	4.0	-2.9	4.9
TH-NIH	16	-6.0	3.8	-7.6	3.6	-6.8	3.7
ARKRAY ADAMS HA-8180 series							
Overall	76	-0.1	6.3	-0.6	5.0	-0.3	5.7
AT-ÖQUASTA	22	+3.0	4.6	+2.3	2.8	+2.7	3.7
CZ-SEKK	32	-1.1	3.5	-1.6	3.9	-1.3	3.7
International*	10	-1.1	1.8	-0.5	1.2	-0.8	1.5
Bio-Rad D-10 series							
Overall	75	-0.1	6.2	+0.3	4.3	+0.1	5.2
CZ-SEKK	18	+0.2	5.6	+0.8	2.9	+0.5	4.2
FR-CTBC	6	+0.9	5.1	+0.8	4.2	+0.9	4.6
FR-Probioqual	26	-1.5	6.9	-0.4	4.9	-0.9	5.9
MX-Labs Biom. Panuco	13	+1.0	2.8	+0.9	3.3	+0.9	3.1
Bio-Rad D-100 series							
Overall	76	-0.2	6.5	-0.6	3.9	-0.4	5.2
AT- ÖQUASTA	13	+5.0	1.9	+3.5	0.9	+4.2	1.4
FR-Probioqual	31	-1.2	3.9	-1.3	2.8	-1.2	3.3
KR-Kor Ass. EQAS	24	-1.3	2.6	-1.3	1.7	-1.3	2.2
Bio-Rad Variant series							
Overall	55	-1.4	7.0	-1.5	4.9	-1.4	6.0
FR-CTBC	7	-1.2	4.6	-1.6	6.0	-1.4	5.3
FR-Probioqual	30	-2.2	7.8	-2.1	4.8	-2.1	6.3
TR-TUBITAK UME	8	+0.3	6.2	+0.5	4.2	+0.4	5.2
Roche Diagnostics cobas c 303/503							
Overall	35	+3.5	5.2	+3.7	4.2	+3.6	4.7
FR-Probioqual	16	+4.1	5.0	+4.0	3.4	+4.0	4.2
TH-NIH	15	+2.6	4.7	+3.3	5.0	+3.0	4.8
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)							
Overall	150	+1.8	5.5	+3.1	4.5	+2.5	5.0
AT-ÖQUASTA	36	+4.7	3.7	+6.4	3.3	+5.6	3.5
GR-ESEAP	12	+1.4	3.8	+1.6	3.4	+1.5	3.6
PT-PNAEQ-INSA	6	+2.7	4.7	+3.1	3.4	+2.9	4.0
TH-NIH	77	+0.6	3.9	+2.0	3.2	+1.3	3.6
TR-TUBITAK UME	9	0.0	4.6	+1.7	3.6	+0.8	4.1
Roche Diagnostics cobas Integra							
Overall	26	+0.8	5.8	+2.8	5.2	+1.8	5.5
GR-ESEAP	7	-0.3	5.0	+1.3	5.4	+0.5	5.2
TH-NIH	12	+0.1	5.7	+2.7	5.1	+1.4	5.4
Sebia CAPILLARYS 2							
Overall	94	-1.3	3.7	-1.3	2.8	-1.3	3.2
FR-CTBC	13	-1.2	3.0	-0.9	1.6	-1.1	2.3
FR-Probioqual	73	-1.4	3.6	-1.6	2.8	-1.5	3.2
Sebia CAPILLARYS 3							
Overall	183	-0.8	2.7	-1.3	2.1	-1.1	2.4
FR-CTBC	35	-0.4	2.3	-0.7	1.9	-0.5	2.1

Method	n	EurA1c 2022-1 Target 41.7 mmol/mol		EurA1c 2022-2 Target 58.2 mmol/mol		Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
FR-Probioqual	135	-1.0	2.7	-1.5	2.1	-1.2	2.4
Tosoh G8							
Overall	144	+0.4	4.7	-0.2	3.4	+0.1	4.1
AT-ÖQUASTA	11	+5.6	2.7	+4.0	3.1	+4.8	2.9
CZ-SEKK	22	+0.6	4.1	+0.2	4.1	+0.4	4.1
FR-ASQ	5	-0.3	1.3	-1.4	1.5	-0.9	1.4
FR-CTCB	10	-0.2	1.2	-0.5	1.0	-0.3	1.1
FR-Probioqual	71	-0.3	2.8	-0.7	2.3	-0.5	2.5
GR-ESEAP	8	+0.3	3.8	-0.2	3.0	0.0	3.4
Tosoh G11							
Overall	131	-0.4	2.2	-0.9	1.6	-0.7	1.9
FR-CTBC	11	-0.2	1.5	-0.8	1.2	-0.5	1.4
FR-Probioqual	75	-0.4	1.9	-0.9	1.3	-0.6	1.6
KR- Kor Ass. EQAS	29	-0.8	2.4	-1.3	1.5	-1.1	1.9
Tosoh GX							
Overall	17	-0.1	3.1	-1.0	2.6	-0.5	2.9
FR-CTBC	7	+0.4	3.0	-0.2	2.6	+0.1	2.8
FR-Probioqual	9	-0.6	3.1	-1.7	1.9	-1.2	2.5

** 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, and the US NGSP SRLs. Table 12 shows the results.
The assigned values are the values assigned with the IFCC RMP as measured in fresh whole blood. Values of the other matrixes and other methods are for comparison and information.

Table 12. Results of Reference Measurement Procedures

Matrix	EurA1c 2022-1			EurA1c 2022-2		
	IFCC RMP	IFCC SRLs	US NGSP SRLs*	IFCC RMP	IFCC SRLs	US NGSP SRLs*
	n = 5	n = 8	n = 3	n = 5	n = 8	n = 3
Fresh Whole Blood	41.7	42.3	41.8	58.2	58.7	58.3
Lyophilised Hemolysate	40.0	41.6	40.7	56.1	58.2	57.1
Frozen Whole Blood	41.4	41.7	41.1	58.4	58.0	57.6

** US-NGSP results in % are converted to SI (IFCC) units with the respective Master Equations*

The RMP SOP is only validated for fresh whole blood and does not fully apply to frozen whole blood or lyophilised hemolysate. Investigations in these matrix samples have shown that results in lyophilised hemolysates are clearly lower than in fresh whole blood and that results in frozen whole blood are questionable. Therefore the C-EUBD has decided that from now on the EurA1c target value will be assigned in fresh whole blood only with the IFCC RMP as this is the best option for value assignment. For research purposes all matrixes might also be measured with SRLs.

V. Homogeneity

Homogeneity testing of EurA1c 2022-1 (fresh 2022-1, lyophilised 2022-3 and frozen 2022-5) is performed according to ISO 13528:2015 (Annex B) with the ARKRAY HA-8180V. The results in table 13 show that the samples are homogeneous.

Table 13. Homogeneity test of EurA1c 2022

Vial	Fresh Whole Blood				Lyophilised Hemolysate				Frozen Whole Blood			
	EurA1c 2022-1				EurA1c 2022-3				EurA1c 2022-5			
	1	2	mean	Δ	1	2	mean	Δ	1	2	mean	Δ
1	42.0	41.9	41.95	0.1	41.7	41.7	41.70	0.0	41.4	41.2	41.30	0.2
2	41.9	41.6	41.75	0.3	41.7	41.5	41.60	0.2	41.4	41.5	41.45	0.1
3	41.9	41.7	41.80	0.2	41.7	41.5	41.60	0.2	41.7	41.7	41.70	0.0
4	41.7	41.6	41.65	0.1	41.5	41.7	41.60	0.2	41.7	41.7	41.70	0.0
5	41.9	41.7	41.80	0.2	41.5	41.7	41.60	0.2	41.5	41.2	41.35	0.3
6	41.6	41.6	41.60	0.0	41.7	41.4	41.55	0.3	41.7	41.5	41.60	0.2
7	41.9	41.6	41.75	0.3	41.7	41.7	41.70	0.0	41.4	41.7	41.55	0.3
8	41.9	41.7	41.80	0.2	41.7	41.5	41.60	0.2	41.7	41.7	41.70	0.0
9	41.7	41.6	41.65	0.1	41.5	41.7	41.60	0.2	41.8	41.7	41.75	0.1
10	41.7	41.7	41.70	0.0	41.8	41.5	41.65	0.3	41.7	41.7	41.70	0.0
11	41.6	41.6	41.60	0.0	41.7	41.4	41.55	0.3	41.7	41.7	41.70	0.0
12	41.6	41.9	41.75	0.3	41.5	41.5	41.50	0.0	41.8	41.7	41.75	0.1
average			41.7				41.6				41.6	
SD		0.037	0.101	0.132		0.000	0.058	0.146		0.137	0.157	0.110
0.3 x SD_{RL}			0.283				0.282				0.282	
Criterion			-0.245				-0.282				-0.145	
Homogeneity:			**Pass**				**Pass**				**Pass**	

VI. Stability

Fresh Whole Blood

Fresh whole blood samples EurA1c 2022-1 (HbA1c 41.7 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						
ARKRAY HA-8180V	0	0	0	0	-1	-2
Sebia CAPILLARYS 3 Octa	0	+1	0	0	-1	-2
Roche cobas c 513	0	+1	0	+1	0	+1
Abbott enzymatic Alinity	0	0	0	0	0	0
Tosoh G11	0	+1	0	+1	0	+1
Trinity Biotech Premier Hb9210	0	0	0	+-1	-1	-2
Storage Refrigerator						
ARKRAY HA-8180V	0	0	0	0	-1	0
Sebia CAPILLARYS 3 Octa	0	0	+1	+1	0	0
Roche cobas c 513	0	0	0	-1	0	0
Abbott enzymatic Alinity	0	0	+1	+1	0	0
Tosoh G11	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, 37, 49 and 61 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	months							
	0	6	13	18	25	37	49	61
Storage Freeze -20°C								
ARKRAY HA-8180V	0	0	-5	n.m.**	n.m.**	-1	+3	-5
Sebia CAPILLARYS 3 Octa***	0	+2	+3	n.m.**	n.m.**	n.m.**	n.m.**	n.m.**
Roche Cobas c 513	0	+1	0	+1	+1	+3	+2	+2
Abbott enzymatic Alinity****	0	+1	+2	+2	+2	+4	+5	+6
Tosoh G11*****	0	-3	-2	-1	-1	-3	-5	-15
Trinity Biotech Premier Hb9210	0	-5	-11	-3	-3	+8	-1	n.m.**
Storage Freezer <-70°C								
ARKRAY HA-8180V	0	0	0	-1	-1	0	0	-1
Sebia CAPILLARYS 3 Octa***	0	0	+1	+2	+2	+2	+3	+3
Roche Cobas c 513	0	1	-1	0	0	+2	0	+1
Abbott enzymatic Alinity****	0	1	1	0	0	+1	+1	+1
Tosoh G11*****	0	1	1	1	1	0	0	0
Trinity Biotech Premier Hb9210	0	0	+2	0	0	+1	-1	0

** difference between Month X and Month 0 in mmol/mol*
*** not measurable*
**** initial measurement (0 month) on Sebia CAPILLARYS 2 FP*
***** until 18 months on Abbott ARCHITECT C4000*
****** until 49 months on Tosoh G8*

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, 37, 49 and 61 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	**months**							
	0	**6**	**13**	**18**	**25**	**37**	**49**	**61**
Storage Refrigerator								
ARKRAY HA-8180V	0	0	-1	0	-1	-1	0	+2
Sebia CAPILLARYS 3 Octa**	0	-2	+1	0	-1	0	+1	0
Roche Cobas c 513	0	0	0	+1	+1	+2	+1	+1
Abbott enzymatic Alinity***	0	-3	-5	-5	-8	-7	-9	-11
Tosoh G11*****	0	-1	+1	-2	-2	+4	-2	+5
Trinity Biotech Premier Hb9210	0	0	0	-1	0	+1	+2	+1
Storage Freezer -20°C								
ARKRAY HA-8180V	0	+1	0	0	+1	+1	+2	+1
Sebia CAPILLARYS 3 Octa**	0	-1	+1	+1	-1	0	0	0
Roche Cobas c 513	0	+1	0	0	+1	+2	+1	+1
Abbott enzymatic Alinity***	0	+2	+2	+2	0	+3	+1	+1
Tosoh G11*****	0	+1	+1	+1	+1	+1	0	+1
Trinity Biotech Premier Hb9210	0	+1	+1	+1	+2	+2	+2	+2
Storage Freezer <-70°C								
ARKRAY HA-8180V	0	+1	0	0	+1	+1	+2	+1
Sebia CAPILLARYS 3 Octa**	0	-1	+1	0	-1	0	0	+1
Roche Cobas c 513	0	+1	0	0	+2	+1	+1	+1
Abbott enzymatic Alinity***	0	+2	+3	+3	+1	+2	+2	+2
Tosoh G11*****	0	+1	+1	+1	+1	+1	+1	+1
Trinity Biotech Premier Hb9210	0	+1	+1	+1	+2	+2	+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*
****** until 49 months on Tosoh G8*

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