

Report EurA1c 2021



HbA1c Trial EQA organisers

I	Introduction and Overview of Results	2
II	Results EQA Fresh Whole Blood samples	5
Ш	Results EQA Lyophilised Hemolysate samples	12
IV	Value Assignment (Targeting)	18
V	Homogeneity	18
VI	Stability	19
VII	Organisations and Persons involved	21

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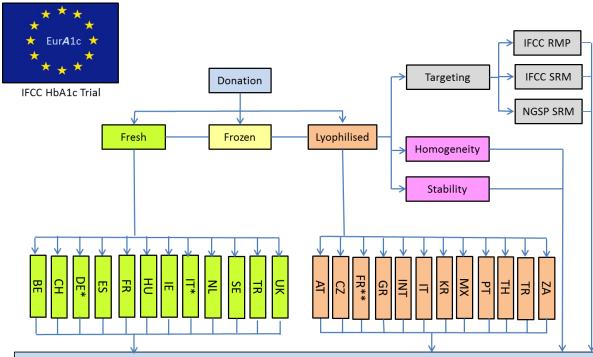
I Introduction and Overview of Results

Introduction

25 EQA organisers of 21 countries agreed to participate in the sixth "EurA1c" project. The design is shown in figure 1.

14 EQA organisers used fresh whole blood samples and 14 organisers used lyophilised hemolysate samples (3 organisations used both fresh and lyophilised samples). In October 2021 the fresh whole blood samples were sent to the participants. From November 2021 up to April 2022 the lyophilised samples are assayed by the participants.

Figure 1. Design EurA1c Trial 2021



- 1. Performance Across Laboratories, Countries and Manufacturers in terms of the IFCC Model for Quality Targets.
- 2. Confirmation of knowledge on matrices (fresh whole blood, lyophilised hemolysate, frozen whole blood) and the value assignment to these matrices with the respective reference systems.
- * In Germany and Italy 2 EQA organisers participated.
- ** In France 3 EQA organisers participated.

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 2022: Draft report sent to all who are involved in EurA1c 2021.

At the same time the invitation to participate in EurA1c 2022 is sent.

31 August 2022: Deadline for comments and remarks.

30 September 2022: 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. This year we saw a wide distribution of results between the network laboratories and between the three matrices with quite a high measurement uncertainty for the lyophilised samples. Although the mean values do not clearly reflect this there seems to be a difference between the three matrices which will further be investigated. Given these issues the assigned value is not based on the mean of the three matrices but there are different target values for fresh whole blood and for the lyophilised samples.

For fresh whole blood the target is the value as measured with the RMP. For EurA1c 2021-1 the assigned value is 44.1 mmol/mol (expanded uncertainty 0.8 mmol/mol) and for EurA1c 2021-2 the assigned value is 60.5 mmol/mol (expanded uncertainty 0.9 mmol/mol).

For the lyophilised samples the target is the mean of the SRM values as measured with the IFCC calibrated secondary RMPs. The first reason is that the Reference Measurement Procedure is only validated for fresh whole blood and not for lyophilised samples and secondly, the measured RMP value for lyo deviates too much from the mean as measured by the laboratories in EurA1c. For EurA1c 2021-1 the assigned value is 45.2 mmol/mol (expanded uncertainty 0.7 mmol/mol) and for EurA1c 2021-2 61.6 mmol/mol (expanded uncertainty 0.8 mmol/mol).

The table below shows the outcome of all measurements

Method / Value Assignment	Low (EU)	High (EU)
IFCC RMP		
Fresh whole blood	44.1 (0.8)	60.5 (0.9)
Lyophilsed hemolysate	43.6 (1.2)	59.0 (1.4)
Frozen whole blood	43.8 (1.2)	60.1 (1.1)
IFCC SRMs		
Fresh whole blood	44.7 (0.8)	61.4 (0.9)
Lyophilised hemolysate	45.2 (0.7)	61.6 (0.8)
Frozen whole blood	44.4 (0.8)	60.5 (0.8)
Mean all labs in EurA1c		
Fresh whole blood	44.8	61.6
Lyophilised hemolysate	45.6	62.1

For future EurA1c trials value assignment will carefully be reviewed.

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 19 results (0.8%) have been excluded from the database of the fresh whole blood samples and 17 results (1.1%) from the database of the lyophilised hemolysates.

Methods

This is a point of consideration. For fresh whole blood 125 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 = 0.0915*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 2021

		F	resh Whole E	Blood	Lyc	philised Hem	olysate
Country	EQA Organiser	n*	Mean Bias in mmol/mol	Between Laboratory CV%	n*	Mean Bias in mmol/mol	Between Laboratory CV%
Austria	ÖQUASTA				107	+0.1	5.6
Belgium	Sciensano	113	+1.0	3.1			
Czech Republic	SEKK s.r.o				171	+1.5	4.9
France	Asqualab				29	+0.9	6.0
France	CTCB	164	+0.6	4.5	154	+0.6	4.5
France	ProBioQual				564	+0.2	5.8
Germany	INSTAND	616	+0.7	4.4			
Germany	RfB	790	+1.0	4.0			
Greece	ESEAP				82	+0.1	6.4
Hungary	QualiCont	73	+1.1	5.6			
International**	ERL				54	0.0	4.6
Ireland	IEQAS	44	+1.2	2.9			
Italy	CRB	41	+2.0	3.2	41	+0.2	5.0
Italy	CRRVEQ	91	+0.9	4.4			
Korea	Korean Ass. EQAS				67	-0.3	5.2
Mexico	Labs Biom Panuco				38	+2.1	6.9
Netherlands	SKML	124	+0.9	3.5			
Portugal	PNAEQ-INSA				27	+0.8	6.0
South Africa	NHLS				4	-0.9	2.5
Spain	SEQC ^{ML}	97	+1.0	2.4			
Sweden	Equalis	107	+0.5	3.8			
Switzerland	CSCQ	64	-0.1	4.5			
Thailand	Nat. Inst. of Health				159	+0.7	7.6
Turkey	TUBITAK UME	49	+1.4	5.3	56	+0.4	6.5
United Kingdom	Weqas	151	+1.2	4.1			
Overall		2524	+0.9	4.1	1553	+0.5	5.9

^{*} n =the number of datasets.

In total 4077 datasets were submitted (2524 in fresh whole blood and 1553 in lyophilised hemolysate). The results are encouraging and quite satisfying. With different target values being used, the mean bias of all countries in the fresh whole blood programme is +0.9 mmol/mol and the between laboratory CV of 4.1%. In the lyophilised hemolysate programme the mean bias of all countries is +0.5 mmol/mol and the between laboratory CV is 5.9%.

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)

^{**} Individual laboratories of a number of countries

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 6 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	Tai	EurA1c rget 44.1	-	nol	Ta	EurA1c rget 60.5	Mean 2 Samples			
	0. g00.	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Belgium	Sciensano	113	45.1	+1.0	3.3	113	61.5	+1.0	2.9	+1.0	3.1
France	СТСВ	161	44.5	+0.4	4.9	164	61.2	+0.7	4.1	+0.6	4.5
Germany	INSTAND	616	44.5	+0.4	4.6	613	61.4	+0.9	4.2	+0.7	4.4
Germany	RfB	789	44.9	+0.8	4.1	790	61.8	+1.3	3.9	+1.0	4.0
Hungary	QualiCont	73	44.9	+0.8	6.5	72	61.9	+1.4	4.6	+1.1	5.6
Ireland	IEQAS	44	44.9	+0.8	3.1	44	62.0	+1.5	2.7	+1.2	2.9
Italy	CRB	40	45.8	+1.7	3.3	41	62.7	+2.2	3.1	+2.0	3.2
Italy	CRRVEQ	91	44.8	+0.7	5.0	90	61.7	+1.2	3.7	+0.9	4.4
Netherlands	SKML	124	45.0	+0.9	3.7	123	61.5	+1.0	3.3	+0.9	3.5
Spain	SEQCML	97	44.9	+0.8	2.7	96	61.7	+1.2	2.1	+1.0	2.4
Sweden	Equalis	107	44.3	+0.2	3.8	96	61.3	+0.8	3.8	+0.5	3.8
Switzerland	CSCQ	64	43.9	-0.2	5.1	61	60.5	+0.0	4.0	-0.1	4.5
Turkey	TUBITAK UME	49	44.9	+0.8	5.4	48	62.4	+1.9	5.3	+1.4	5.3
United Kingdom	Weqas	151	45.1	+1.0	3.9	151	61.8	+1.3	4.3	+1.2	4.1
Overall	Overall			+0.7	4.4	2502	61.6	+1.1	3.9	+0.9	4.1

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

Manufacturer/Method	Та	EurA1c rget 44.1	-	nol	Та	EurA1c rget 60.5		nol	Mean 2 Samples		
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%	
Abbott Alinity	15	43.3	-0.8	1.5	15	61.9	+1.4	0.9	+0.3	1.2	
Abbott ARCHITECT (enzymatic)	7	43.7	-0.4	2.6	7	62.0	+1.5	1.6	+0.5	2.1	
Abbott ARCHITEXT not specified/other	26	43.4	-0.7	4.3	26	61.7	+1.2	3.8	+0.3	4.0	
Abbott not specified/other	33	43.6	-0.5	3.0	33	60.6	+0.1	4.1	-0.2	3.6	
Abbott/Alere Afinion	122	42.6	-1.5	3.7	121	58.3	-2.2	3.1	-1.8	3.4	
Beckman Coulter AU series	62	44.3	+0.2	6.1	61	60.3	-0.2	6.2	0.0	6.2	
Beckman Coulter Unicel DxC series	6	45.1	+1.0	5.0	6	62.0	+1.5	4.6	+1.2	4.8	
Beckman Coulter not specified/other	11	45.0	+0.9	5.7	11	60.6	+0.1	8.2	+0.5	7.0	
Bio-Rad D-10 series	38	45.5	+1.4	5.0	38	62.4	+1.9	4.0	+1.7	4.5	
Bio-Rad D-100 series	55	44.9	+0.8	3.2	55	60.9	+0.4	2.4	+0.6	2.8	
Bio-Rad Variant series	62	44.6	+0.5	7.0	61	61.5	+1.0	5.6	+0.8	6.3	
Bio-Rad not specified/other	114	45.3	+1.2	3.7	114	61.5	+1.0	3.6	+1.1	3.7	
EKF Diagnostics	13	46.0	+1.9	4.4	14	63.3	+2.8	2.9	+2.4	3.6	
HemoCue HbA1c 501	15	41.3	-2.8	8.0	15	56.8	-3.7	5.4	-3.3	6.7	
Lifotronic	6	46.6	+2.5	4.2	5	62.4	+1.9	7.6	+2.2	5.9	
Medinor NycoCard	6	44.8	+0.7	4.7	6	55.6	-4.9	7.2	-2.1	5.9	
Menarini (ARKRAY) HA-8160 series	38	44.1	0.0	4.4	39	60.6	+0.1	3.6	+0.1	4.0	
Menarini (ARKRAY) HA-8180 series	175	44.9	+0.8	3.0	174	61.5	+1.0	2.7	+0.9	2.9	
Menarini (ARKRAY) not specified/other	9	44.6	+0.5	3.0	9	61.3	+0.8	2.7	+0.6	2.8	
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	186	44.7	+0.6	3.3	184	62.3	+1.8	2.9	+1.2	3.1	
Roche Diagnostics cobas c 503 (cobas pro)	10	45.1	+1.0	4.4	9	62.2	+1.7	4.2	+1.3	4.3	
Roche Diagnostics cobas c 513	34	45.3	+1.2	3.2	34	62.5	+2.0	2.9	+1.6	3.0	
Roche Diagnostics cobas Integra	38	44.2	+0.1	2.9	38	62.8	+2.3	2.4	+1.2	2.7	
Roche Diagnostics cobas not specified/other	7	45.0	+0.9	3.1	7	62.6	+2.1	1.7	+1.5	2.4	
Roche Diagnostics not specified/other	309	44.7	+0.6	3.3	309	62.4	+1.9	3.0	+1.3	3.1	
Sebia CAPILLARYS 2	46	44.0	-0.1	3.5	46	60.6	+0.1	2.6	0.0	3.1	
Sebia CAPILLARYS 3	98	44.4	+0.3	2.5	98	61.7	+1.2	1.9	+0.7	2.2	
Sebia MINICAP	7	44.1	0.0	1.2	7	61.5	+1.0	2.1	+0.5	1.7	
Sebia not specified/other	63	44.0	-0.1	2.7	63	61.1	+0.6	2.7	+0.3	2.7	
Siemens Advia not specified/other	47	44.2	+0.1	4.9	47	61.7	+1.2	4.6	+0.7	4.8	
Siemens Atellica not specified/other	15	43.9	-0.2	4.1	15	61.9	+1.4	3.8	+0.6	4.0	
Siemens DCA 2000/Vantage	190	44.9	+0.8	3.7	181	62.3	+1.8	4.3	+1.3	4.0	
Siemens Dimension series	80	45.5	+1.4	4.5	80	60.6	+0.1	3.3	+0.8	3.9	
Tosoh G7	9	44.7	+0.6	8.9	8	62.4	+1.9	1.9	+1.2	5.4	
Tosoh G8	160	46.1	+2.0	2.4	159	62.5	+1.9	1.9	+1.2	2.1	
Tosoh G11	116	45.9	+2.0	1.9	116	61.9	+2.0	1.9	+2.0	1.9	
Tosoh GX	9	45.9			9					2.9	
			+0.7	3.5		62.1	+1.6	2.2	+1.2		
Tosoh not specified/other Trinity Piotoch Promier Hh0210	99	46.2	+2.1	2.6	100	62.3	+1.8	2.0	+2.0	2.3	
Trinity Biotech Premier Hb9210	29	45.1	+1.0	3.8	29	62.5	+2.0	3.8	+1.5	3.8	
Not specified/other	125	44.3	+0.2	7.4	121	61.1	+0.6	5.8	+0.4	6.6	

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

Manufacturer/Method	Ta	EurA1darget 44.	2021-1 1 mmol/		Ta	EurA1darget 60.	Mean 2 Samples			
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott AxSym	2	43.5	-0.6	8.1	2	60.8	+0.3	5.2	-0.2	6.7
Hitado	3	43.0	-1.2	6.2	3	59.9	-0.6	3.1	-0.9	4.6
Horiba Pentra	3	47.0	+2.9	7.4	3	65.0	+4.5	11.7	+3.7	9.5
ISE S.r.l. Hemo One ISE HbA1c					1	68.8	+8.3			
Mindray not specified/other	3	45.7	+1.6	2.5	3	63.7	+3.2	3.3	+2.4	2.9
Ortho Clinical Diagnostics Vitros series	1	45.9	+1.8		2	58.3	-2.2	7.6	-0.2	7.6
Roche Diagnostics cobas b 101	5	44.0	-0.1	3.2	5	62.4	+1.9	2.0	+0.9	2.6
Siemens Atellica CH (enzymatic)	3	43.6	-0.5	3.9	3	61.8	+1.3	6.3	+0.4	5.1
Siemens Atellica CH (immunoassay)	1	42.0	-2.1		1	59.0	-1.5		-1.8	
Sysmex not specified/other	1	46.0	+1.9		1	63.0	+2.5		+2.2	
Thermo Fisher Scientific	3	43.0	-1.1	6.8	3	59.9	-0.6	5.6	-0.9	6.2
Thermo Fisher Scientific/Konelab	4	44.3	+0.1	5.9	4	59.8	-0.8	4.6	-0.3	5.3
Wondfo Finecare™ FIA Meter					1	49.0	-11.5			

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)

·		EurA1c	2021-1	EurA1c	2021-2			
Method	n	Targe	t 44.1	Target	60.5	Mean		
Metriod	"	mmo	l/mol	mmol	/mol			
		Bias	CV%	Bias	CV%	Bias	CV%	
Abbott/Alere Afinion								
Overall	122	-1.5	3.7	-2.2	3.1	-1.8	3.4	
CH-CSCQ	19	-1.7	3.0	-2.5	2.8	-2.1	2.9	
DE-INSTAND	47	-1.8	3.8	-2.4	3.2	-2.1	3.5	
NL-SKML	13	-1.6	3.8	-2.0	2.2	-1.8	3.0	
SE-Equalis	29	-1.0	3.4	-1.5	2.8	-1.3	3.1	
UK-Weqas	9	-1.5	3.7	-3.3	2.9	-2.4	3.3	
Beckman Coulter AU series								
Overall	62	+0.2	6.1	-0.2	6.2	0.0	6.2	
DE-INSTAND	22	0.0	5.7	-0.6	5.2	-0.3	5.4	
DE-RfB	29	+0.6	5.6	+0.5	6.9	+0.6	6.3	
Bio-Rad D-10 series								
Overall	38	+1.4	5.0	+1.9	4.0	+1.7	4.5	
DE-INSTAND	20	+2.0	4.0	+2.3	4.1	+2.2	4.0	
FR-CTCB	11	-0.1	6.7	+1.2	4.7	+0.5	5.7	
Bio-Rad D-100 series	''	5.1	J.,			. 5.5	0	
Overall	55	+0.8	3.2	+0.4	2.4	+0.6	2.8	
BE-Sciensano	8	+0.7	2.5	-0.4	1.3	+0.0	1.9	
DE-INSTAND	15	+1.0	3.0	+0.9	2.4	+0.1	2.7	
ES-SEQC	14	+0.9	1.7	+0.3	1.5	+0.9	1.6	
Bio-Rad Variant series	14	+0.9	1.7	+0.1	1.5	+0.0	1.0	
	62	. O E	7.0	.10	5.6	.00	6.3	
Overall		+0.5		+1.0		+0.8		
DE-INSTAND	16	+1.7	2.3	+1.9	2.4	+1.8	2.4	
FR-CTCB	10	-2.8	11.8	-3.2	10.8	-3.0	11.3	
HU-QualiCont	8	+0.4	9.8	+2.0	1.1	+1.2	5.5	
IT-CRRVEQ	8	+0.4	5.0	+2.0	3.4	+1.2	4.2	
TR-TUBITAK UME	9	+0.7	4.7	+1.6	4.5	+1.2	4.6	
HemoCue HbA1c 501								
Overall	15	-2.8	8.0	-3.7	5.4	-3.3	6.7	
DE-INSTAND	9	-3.3	6.1	-4.2	6.4	-3.8	6.3	
DE-RfB	6	-1.9	10.3	-3.0	3.6	-2.5	7.0	
Menarini (ARKRAY) HA-8180 se								
Overall	175	+0.8	3.0	+1.0	2.7	+0.9	2.9	
BE-Sciensano	30	+1.1	4.0	+0.9	3.6	+1.0	3.8	
DE-INSTAND	23	+0.8	3.3	+1.3	3.0	+1.0	3.1	
ES-SEQC	40	+0.8	2.4	+1.1	2.4	+0.9	2.4	
HU-QualiCont	21	+0.3	3.1	+0.3	3.1	+0.3	3.1	
IE-IEQAS	11	+1.0	1.2	+1.0	1.1	+1.0	1.2	
IT-CRRVEQ	13	+0.9	1.8	+1.4	1.9	+1.2	1.9	
NL-SKML	18	+1.3	1.5	+0.6	1.7	+1.0	1.6	
UK-Wegas	8	-0.2	2.8	+0.3	2.4	0.0	2.6	
Roche Diagnostics cobas c 501					•			
Overall	186	+0.6	3.3	+1.8	2.9	+1.2	3.1	
CH-CSCQ	13	-0.3	2.2	+1.2	2.6	+0.5	2.4	
DE-INSTAND	119	+0.6	2.7	+1.6	2.6	+1.1	2.6	
IT-CRRVEQ	8	-0.5	4.3	+0.8	2.7	+0.2	3.5	
NL-SKML	17	+0.9	2.7	+2.0	2.7	+1.4	2.7	
TR-TUBITAK UME	10	+1.0	4.6	+3.6	2.7	+2.3	3.8	
	10	+1.0	4.0	+3.0	۷.۶	+2.3	3.0	
Sebia CAPILLARYS 2	46	0.4	2 5	.04	2.6	0.01	2.4	
Overall PE Sciences	46	-0.1	3.5	+0.1	2.6	0.0	3.1	
BE-Sciensano	6	-0.8	3.5	-0.3	2.9	-0.6	3.2	
FR-CTCB	14	-0.7	4.1	-0.4	2.3	-0.5	3.2	
IT-CRRVEQ	10	+0.1	2.8	+0.6	2.2	+0.4	2.5	

Method	n	EurA1c Target mmol	t 44.1 /mol	EurA1c Target mmol	t 60.5 /mol	Mea	
		Bias	CV%	Bias	CV%	Bias	CV%
Sebia CAPILLARYS 3		,		1			
Overall	98	+0.3	2.5	+1.2	1.9	+0.7	2.2
BE-Sciensano	9	+0.9	1.6	+1.3	1.6	+1.1	1.6
DE-INSTAND	9	+0.5	2.5	+0.8	2.7	+0.6	2.6
FR-CTCB	42	+0.3	2.4	+1.1	1.7	+0.7	2.0
SE-Equalis	11	-0.6	2.6	+0.4	1.4	-0.1	2.0
UK-Weqas	10	+0.6	2.1	+1.5	1.3	+1.1	1.7
Siemens DCA 2000/Vantage							
Overall	190	+0.8	3.7	+1.8	4.3	+1.3	4.0
DE-INSTAND	57	+0.5	4.6	+1.4	3.8	+1.0	4.2
IE-IEQAS	21	+0.8	3.2	+2.0	3.2	+1.4	3.2
NL-SKML	14	+0.7	3.6	+1.8	4.2	+1.3	3.9
SE-Equalis	40	+1.1	3.0	+2.6	3.3	+1.9	3.2
UK-Weqas	49	+0.7	3.4	+1.7	5.6	+1.2	4.5
Siemens Dimension series							
Overall	80	+1.4	4.5	+0.1	3.3	+0.8	3.9
DE-INSTAND	34	+1.3	3.0	+0.2	3.4	+0.7	3.2
DE-RfB	43	+1.8	4.3	+0.1	3.0	+0.9	3.7
Tosoh G8							
Overall	160	+2.0	2.4	+2.0	1.9	+2.0	2.1
BE-Sciensano	24	+2.0	1.8	+2.0	1.6	+2.0	1.7
DE-INSTAND	20	+2.0	2.0	+2.2	1.9	+2.1	1.9
ES-SEQC	10	+1.7	1.7	+1.4	1.2	+1.5	1.5
FR-CTCB	24	+1.8	1.3	+1.6	1.6	+1.7	1.4
IT-CRB	6	+2.7	5.3	+2.7	3.6	+2.7	4.5
IT-CRRVEQ	16	+1.3	2.9	+1.9	2.3	+1.6	2.6
NL-SKML	21	+2.5	2.1	+2.0	2.0	+2.3	2.1
SE-Equalis	8	+1.4	2.2	+1.5	1.0	+1.5	1.6
TR-TUBITAK UME	6	+1.9	4.4	+2.5	3.0	+2.2	3.7
UK-Wegas	22	+2.2	1.8	+2.2	1.3	+2.2	1.6
Tosoh G11		.					
Overall	116	+1.8	1.9	+1.4	1.9	+1.6	1.9
DE-INSTAND	23	+2.2	1.9	+1.7	1.9	+1.9	1.9
ES-SEQC	8	+1.2	1.0	+1.0	1.1	+1.1	1.0
FR-CTCB	29	+1.8	2.2	+1.3	2.9	+1.5	2.6
IT-CRRVEQ	10	+1.7	1.7	+1.9	1.5	+1.8	1.6
NL-SKML	12	+1.6	1.5	+1.1	1.1	+1.4	1.3
UK-Wegas	19	+2.2	2.2	+1.5	0.8	+1.9	1.5

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 8) and 5 or less participants (table 8).

Table 6. Results per EQA organiser for Lyophilised Hemolysate

Country	EQA Organiser	Tai	EurA1c rget 45.2		nol	EurA1c 2021-2 Target 61.6 mmol/mol				Mean 2 Samples	
	0.ga	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Austria	ÖQUASTA	107	45.3	+0.1	6.5	107	61.8	+0.2	4.7	+0.1	5.6
Czech Republic	SEKK s.r.o	171	46.7	+1.5	5.5	171	63.2	+1.6	4.4	+1.5	4.9
France	Asqualab	29	45.9	+0.7	6.8	29	62.7	+1.1	5.1	+0.9	6.0
France	СТСВ	154	45.8	+0.6	5.1	153	62.2	+0.6	3.8	+0.6	4.5
France	ProBioQual	561	45.4	+0.2	7.0	564	61.8	+0.2	4.5	+0.2	5.8
Greece	ESEAP	82	44.9	-0.3	7.4	80	62.1	+0.5	5.5	+0.1	6.4
International*	ERL	52	45.6	+0.4	5.2	54	61.1	-0.5	4.0	0.0	4.6
Italy	CRB	41	45.6	+0.4	5.5	40	61.7	+0.1	4.6	+0.2	5.0
Korea	Kor Ass. EQAS	67	45.3	+0.1	5.7	67	60.8	-0.8	4.8	-0.3	5.2
Mexico	Labs Biom Panuco	37	47.3	+2.1	8.4	38	63.8	+2.2	5.4	+2.1	6.9
Portugal	PNAEQ-INSA	26	45.9	+0.7	6.0	27	62.5	+0.9	5.9	+0.8	6.0
South Africa	NHLS	4	43.3	-2.0	2.2	4	61.8	+0.1	2.8	-0.9	2.5
Thailand	NIH	156	45.3	+0.1	8.0	159	62.8	+1.2	7.3	+0.7	7.6
Turkey	TUBITAK UME	56	46.0	+0.8	7.1	54	61.6	0.0	6.0	+0.4	6.5
Overall	Overall		45.6	+0.4	6.7	1547	62.1	+0.5	5.1	+0.5	5.9

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

Manufacturer		EurA1c get 45.2				EurA1c get 61.6			Mean 2 Samples		
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%	
Abbott Alinity	22	40.6	-4.6	5.7	23	58.6	-3.0	4.9	-3.8	5.3	
Abbott ARCHITECT (enzymatic)	27	41.1	-4.1	7.7	27	58.5	-3.1	5.4	-3.6	6.6	
Abbott ARCHITECT not specified/other	27	41.0	-4.2	6.4	27	58.9	-2.7	5.2	-3.4	5.8	
Beckman Coulter AU series	17	46.8	+1.6	5.9	19	63.4	+1.8	5.1	+1.7	5.5	
Bio-Rad D-10 series	90	48.6	+3.4	4.9	89	63.7	+2.1	3.9	+2.7	4.4	
Bio-Rad D-100 series	80	46.8	+1.6	2.7	80	62.2	+0.6	1.8	+1.1	2.3	
Bio-Rad Variant series	60	46.2	+1.0	5.8	60	61.8	+0.2	3.4	+0.6	4.6	
Bio-Rad not specified/other	8	48.0	+2.8	3.7	8	63.0	+1.4	2.4	+2.1	3.0	
Lifotronic	8	44.3	-0.9	6.4	8	60.6	-1.0	4.7	-1.0	5.5	
Menarini (ARKRAY) HA-8160 series	29	44.7	-0.5	3.2	27	61.2	-0.4	3.9	-0.5	3.5	
Menarini (ARKRAY) HA-8180 series	88	44.4	-0.8	4.9	88	60.2	-1.4	4.4	-1.1	4.6	
Menarini (ARKRAY) not specified/other	19	43.7	-1.5	6.5	19	59.6	-2.0	5.6	-1.8	6.0	
Ortho Clinical Diagnostics Vitros series	10	45.1	-0.1	5.8	11	62.9	+1.3	5.5	+0.6	5.7	
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	139	46.4	+1.2	4.2	143	64.2	+2.6	3.9	+1.9	4.1	
Roche Diagnostics cobas c 503 (cobas pro)	10	48.2	+3.0	2.5	10	65.1	+3.5	2.3	+3.3	2.4	
Roche Diagnostics cobas c 513	17	47.1	+1.9	3.8	16	65.2	+3.6	3.5	+2.7	3.7	
Roche Diagnostics cobas Integra	27	46.4	+1.2	5.1	27	64.9	+3.3	5.0	+2.3	5.0	
Roche Diagnostics cobas not specified/other	84	44.5	-0.7	10.4	87	63.4	+1.8	6.3	+0.5	8.4	
Sebia CAPILLARYS 2	103	43.7	-1.5	3.0	103	60.1	-1.5	2.8	-1.5	2.9	
Sebia CAPILLARYS 3	157	44.1	-1.1	2.9	158	60.6	-1.0	2.0	-1.0	2.5	
Sebia MINICAP	18	43.5	-1.7	3.5	18	60.0	-1.6	2.9	-1.6	3.2	
Siemens DCA 2000/Vantage	52	51.2	+6.0	5.1	52	67.3	+5.7	3.4	+5.8	4.3	
Siemens Dimension series	27	47.8	+2.6	4.7	26	63.2	+1.6	4.1	+2.1	4.4	
Tosoh G7	36	47.5	+2.3	3.5	34	63.9	+2.3	3.4	+2.3	3.4	
Tosoh G8	153	46.5	+1.3	4.0	152	62.2	+0.6	3.0	+1.0	3.5	
Tosoh G11	113	46.1	+0.9	3.4	112	61.7	+0.1	2.8	+0.5	3.1	
Tosoh GX	18	45.6	+0.4	5.3	18	61.8	+0.2	4.2	+0.3	4.7	
Trinity Biotech Premier Hb9210	23	44.0	-1.2	4.7	23	60.4	-1.2	3.5	-1.2	4.1	
Not specified/Other	20	44.9	-0.3	11.6	21	62.8	+1.2	8.8	+0.4	10.2	

For Siemens DCA/Vantage it is known that there is a positive matrix effect for lyophilised samples, for Abbott enzymatic a negative 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 get 45.2	-			EurA1c get 61.6	-		Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Aeroset multigent	3	46.3	+1.1	2.3	2	62.0	+0.4	4.5	+0.7	3.4
Abbott not specified/other	2	42.0	-3.2	3.4	2	60.5	-1.1	1.2	-2.2	2.3
Beckman Coulter P / ACE MDQ					1	58.5	-3.1		-3.1	
Beckman Coulter not specified/other	1	50.4	+5.2		1	67.1	+5.5		+5.3	
BioMajesty JCA-BM6010	5	45.8	+0.6	9.5	6	61.8	+0.2	10.8	+0.4	10.1
Erba XL series	2	49.2	+4.0	17.3	2	67.2	+5.6	16.1	+4.8	16.7
ISE S.r.l. Hemo One ISE HbA1c	1	44.9	-0.3		1	65.5	+3.9		+1.8	
Medconn MQ-2000PT	2	47.5	+2.3	0.1	2	58.5	-3.1	13.2	-0.4	6.6
Menarini (ARKRAY) HA-8140 series	2	46.5	+1.3	1.5	2	63.0	+1.4	0.0	+1.4	0.8
Menarini (ARKRAY) HA-8190 series	3	40.2	-5.0	1.6	3	55.5	-6.1	1.1	-5.5	1.4
Menarini HbNEXT	2	48.7	+3.5	12.6	2	58.5	-3.1	5.3	+0.2	9.0
Mindray bs series	5	44.7	-0.5	6.4	5	64.2	+2.6	9.8	+1.0	8.1
Osang Clover A1c	2	44.1	-1.2	6.3	2	58.0	-3.7	14.8	-2.4	10.5
Randox RX series	3	44.6	-0.6	12.0	3	64.7	+3.1	10.1	+1.3	11.1
Roche Diagnostics cobas b 101	1	38.0	-7.2		1	60.0	-1.6		-4.4	
Roche Diagnostics cobas c 111	3	46.8	+1.6	5.5	3	63.3	+1.7	5.3	+1.7	5.4
Roche Diagnostics cobas c 311	2	45.2	0.0	0.6	2	63.4	+1.8	1.3	+0.9	0.9
Roche Diagnostics not specified/other	2	46.8	+1.6	1.5	2	65.1	+3.5	2.8	+2.6	2.2
Sebia not specified/other	5	44.0	-1.2	1.6	5	60.6	-1.0	1.5	-1.1	1.5
Siemens Advia not specified/other	1	49.7	+4.5							
Siemens Atellica CH (enzymatic)	1	41.0	-4.2		1	57.4	-4.2		-4.2	
Siemens Atellica CH not specified/other	5	41.4	-3.8	6.9	5	60.9	-0.7	7.8	-2.2	7.3
Spinreact Spinlab 200 E	1	44.0	-1.2		1	67.0	+5.4		+2.1	
Sysmex bx series	2	44.7	-0.5	12.7	2	58.6	-3.0	3.4	-1.8	8.0
Thermo Fisher Scientific	1	48.0	+2.8		1	66.0	+4.4		+3.6	
Tosoh not specified/other	4	47.9	+2.7	1.4	4	64.5	+2.9	1.6	+2.8	1.5

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 Targe	t 45.2	EurA1c Target	61.6	Mear 2 Samp	
		mmo Bias	CV%	mmol Bias	/mol CV%	Bias	CV%
Abbott ARCHITECT (enzymatic		Dias	C V /0	Dias	C V /0	Dias	C V /0
Overall	27	-4.1	7.7	-3.1	5.4	-3.6	6.6
AT-ÖQUASTA	9	-5.3	3.4	-3.9	2.5	-4.6	2.9
GR-ESEAP	9	-4.8	8.1	-4.3	5.3	-4.6	6.7
Bio-Rad D-10 series			<u> </u>		0.0		0
Overall	90	+3.4	4.9	+2.1	3.9	+2.7	4.4
CZ-SEKK	31	+3.8	4.0	+2.8	3.5	+3.3	3.8
FR-CTBC	10	+3.7	3.6	+1.5	3.8	+2.6	3.7
FR-Probioqual	27	+2.3	4.7	+0.7	3.3	+1.5	4.0
MX-Labs Biom. Panuco	10	+4.4	3.8	+3.0	3.5	+3.7	3.7
Bio-Rad D-100 series				1			
Overall	80	+1.6	2.7	+0.6	1.8	+1.1	2.3
AT- ÖQUASTA	11	+1.4	3.2	+0.3	1.3	+0.9	2.3
FR-Probioqual	32	+1.4	2.8	+0.9	1.3	+1.2	2.0
KR-Kor Ass. of EQAS	23	+2.0	2.0	+0.3	2.4	+1.2	2.2
Bio-Rad Variant series						1	
Overall	55	+0.9	6.0	+0.1	3.5	+0.5	4.7
FR-CTBC	10	+2.0	4.2	+1.2	3.6	+1.6	3.9
FR-Probiogual	31	+0.3	5.3	0.0	3.3	+0.2	4.3
TR-TUBITAK UME	9	+2.1	9.1	-0.1	4.1	+1.0	6.6
Menarini (ARKRAY) HA-8160 se			•••				0.0
Overall	29	-0.5	3.2	-0.4	3.9	-0.5	3.5
GR-ESEAP	13	-0.8	2.9	-0.5	3.1	-0.6	3.0
PT-PNAEQ-INSA	8	-0.5	2.6	-0.7	2.7	-0.6	2.7
Menarini (ARKRAY) HA-8180 se		3.5					
Overall	88	-0.8	4.9	-1.4	4.4	-1.1	4.6
AT-ÖQUASTA	22	-0.3	4.6	-1.1	2.8	-0.7	3.7
CZ-SEKK	24	-1.2	4.4	-0.5	4.8	-0.9	4.6
International*	19	+0.2	2.7	-1.5	2.0	-0.6	2.3
TR-TUBITAK UME	6	-3.1	6.3	-4.6	6.8	-3.8	6.6
Roche Diagnostics cobas c 501/							
Overall	139	+1.2	4.2	+2.6	3.9	+1.9	4.1
AT-ÖQUASTA	30	+1.1	3.2	+2.7	2.9	+1.9	3.1
CZ-SEKK	7	+1.7	4.0	+4.2	3.1	+2.9	3.6
GR-ESEAP	8	+0.7	4.2	+2.3	3.6	+1.5	3.9
PT-PNAEQ-INSA	6	+0.5	7.4	+2.2	6.4	+1.3	6.9
TH-NIH	72	+1.2	4.0	+2.5	4.3	+1.9	4.1
TR-TUBITAK UME	11	+1.5	4.1	+2.8	3.0	+2.2	3.6
Sebia CAPILLARYS 2		- 1					•
Overall	103	-1.5	3.0	-1.5	2.8	-1.5	2.9
FR-CTBC	16	-1.1	3.0	-0.8	2.0	-1.0	2.5
FR-Probioqual	77	-1.7	2.8	-1.8	2.7	-1.8	2.7
Sebia CAPILLARYS 3	· ·			· '			
Overall	157	-1.1	2.9	-1.0	2.0	-1.0	2.5
FR-CTBC	39	-0.4	3.0	-0.4	1.5	-0.4	2.2
FR-Probiogual	111	-1.4	2.7	-1.2	2.1	-1.3	2.4
Siemens Dimension series				· · · · · · · · · · · · · · · · · · ·			
Overall	27	+2.6	4.7	+1.6	4.1	+2.1	4.4
Overall FR-Probioqual	27 11	+2.6 +3.3	4.7 6.0	+1.6 +2.7	4.1 4.2	+2.1 +3.0	4.4 5.1

Method	n	EurA1c Targe mmo	t 45.2 I/mol	EurA1c Targe mmo	t 61.6 I/mol	Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
Tosoh G8							
Overall	153	+1.3	4.0	+0.6	3.0	+1.0	3.5
FR-ASQ	7	+1.9	5.4	+1.3	5.1	+1.6	5.2
FR-CTCB	18	+1.0	1.9	+0.2	1.2	+0.6	1.6
FR-PBQ	67	+1.1	4.2	+0.4	3.0	+0.8	3.6
KR	6	+0.1	3.0	-0.6	2.7	-0.2	2.9
International	6	+0.5	4.0	-0.5	1.4	0.0	2.7
TR	6	+3.6	3.3	+3.4	2.4	+3.5	2.9
Tosoh G11							
Overall	113	+0.9	3.4	+0.1	2.8	+0.5	3.1
FR-CTBC	20	+0.9	0.8	+0.1	0.9	+0.5	0.9
FR-Probioqual	57	+1.2	2.4	+0.3	1.6	+0.8	2.0
KR- Kor Ass. of EQAS	22	-0.7	4.3	-1.6	3.8	-1.2	4.0
Tosoh GX							
Overall	18	+0.4	5.3	+0.2	4.2	+0.3	4.7
FR-CTBC	8	+0.7	7.6	+1.0	5.6	+0.9	6.6
FR-Probioqual	9	-0.1	1.5	-0.9	1.6	-0.5	1.6
Trinity Biotech Premier Hb9210							
Overall	23	-1.2	4.7	-1.2	3.5	-1.2	4.1
IT-CRB	8	-0.8	2.4	-0.4	2.4	-0.6	2.4
International*	6	-2.4	2.6	-1.1	1.6	-1.7	2.1
TR-TUBITAK UME	7	-0.2	7.0	-2.0	5.6	-1.1	6.3

^{*} 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 for fresh whole blood are the IFCC RMP values as assigned in fresh whole, for the lyophilised samples the values as assigned with the IFCC SRLs in the lyophilised samples. Values of the other methods are for comparison and information.

Table 12. Results of Reference Measurement Procedures

	E	urA1c 2021-1		EurA1c 2021-2				
Matrix	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	44.1	44.7	45.4	60.5	61.4	61.6		
Lyophilised Hemolysate	43.6	45.2	46.3	59.0	61.6	61.9		
Frozen Whole Blood	43.8	44.4	44.8	60.1	60.5	60.4		

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

V. Homogeneity

Homogeneity testing of the samples EurA1c 2021-2. 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 2021

	F	resh Wh	ole Bloc	d	Lyo	philised	Hemoly	sate	Fr	ozen Wł	nole Bloc	od
Vial	EurA1c 2021-2			EurA1c 2021-4				EurA1c 2021-6				
	1	2	mean	Δ	1	2	mean	Δ	1	2	mean	Δ
1	61.4	60.8	61.10	0.6	61.4	62.0	61.70	0.6	60.3	60.0	60.15	0.3
2	61.4	60.9	61.15	0.5	61.5	62.0	61.75	0.5	60.2	59.9	60.05	0.3
3	61.3	61.0	61.15	0.3	61.5	62.0	61.75	0.5	60.3	60.0	60.15	0.3
4	60.5	60.9	60.70	0.4	61.7	62.0	61.85	0.3	60.3	60.2	60.25	0.1
5	61.4	61.1	61.25	0.3	61.8	62.0	61.90	0.2	60.3	60.0	60.15	0.3
6	62.6	61.4	62.00	1.2	61.7	61.8	61.75	0.1	60.3	59.9	60.10	0.4
7	60.8	60.9	60.85	0.1	61.8	61.8	61.80	0.0	60.3	60.2	60.25	0.1
8	61.1	60.9	61.00	0.2	61.8	62.0	61.90	0.2	60.3	60.2	60.25	0.1
9	60.9	61.0	60.95	0.1	62.0	61.8	61.90	0.2	60.3	60.2	60.25	0.1
10	61.1	61.0	61.05	0.1	62.0	62.0	62.00	0.0	60.2	60.0	60.10	0.2
11	61.4	61.6	61.50	0.2	61.8	61.8	61.80	0.0	60.2	60.3	60.25	0.1
12	61.0	61.4	61.20	0.4	62.0	61.8	61.90	0.2	60.0	60.3	60.15	0.3
average			61.2				61.8				60.2	
SD		0.236	0.334	0.333		0.000	0.089	0.216		0.000	0.072	0.171
0.3 x SD _{RL}		0.433				0.438				0.426		
Criterion		-0.197				-0.438				-0.426		
Homogene	eity:		Pass				Pass		Pass			

VI. Stability

Fresh Whole Blood

Fresh whole blood samples EurA1c 2021-2 (HbA1c 60.5 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	-1	-1	-1	-1	-2
Sebia CAPILLARYS 3 Octa	0	-2	-1	0	-1	-3
Roche cobas c 513	0	0	+1	+1	+1	0
Abbott enzymatic Alinity	0	+1	+1	+1	+1	+1
Tosoh G8	0	0	0	+1	-1	-1
Trinity Biotech Premier Hb9210	0	0	0	0	0	-2
Storage Refrigerator						
Menarini/ARKRAY HA-8180V	0	-1	-1	-1	-1	-1
Sebia CAPILLARYS 3 Octa	0	-1	0	-1	-1	0
Roche cobas c 513	0	0	+1	+1	+1	0
Abbott enzymatic Alinity	0	+1	+1	+1	+1	+1
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, 37 and 49 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

Mothed	months							
Method	0	6	13	18	25	37	49	
Storage Freeze -20°C								
Menarini/ARKRAY HA-8180V	0	0	-5	n.m.**	n.m.**	-1	+3	
Sebia CAPILLARYS 3 Octa***	0	+2	+3	n.m.**	n.m.**	n.m.**	n.m.**	
Roche Cobas c 513	0	+1	0	+1	+1	+3	+2	
Abbott enzymatic Alinity****	0	+1	+2	+2	+2	+4	+5	
Tosoh G8	0	-3	-2	-1	-1	-3	-5	
Trinity Biotech Premier Hb9210	0	-5	-11	-3	-3	+8	-1	
Storage Freezer <-70°C								
Menarini/ARKRAY HA-8180V	0	0	0	-1	-1	0	0	
Sebia CAPILLARYS 3 Octa***	0	0	+1	+2	+2	+2	+3	
Roche Cobas c 513	0	1	-1	0	0	+2	0	
Abbott enzymatic Alinity****	0	1	1	0	0	+1	+1	
Tosoh G8	0	1	1	1	1	0	0	
Trinity Biotech Premier Hb9210	0	0	+2	0	0	+1	-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, 37 and 49 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								
Wethod	0	6	13	18	25	37	49		
Storage Refrigerator									
Menarini/ARKRAY HA-8180V	0	0	-1	0	-1	-1	0		
Sebia CAPILLARYS 3 Octa**	0	-2	+1	0	-1	0	+1		
Roche Cobas c 513	0	0	0	+1	+1	+2	+1		
Abbott enzymatic Alinity***	0	-3	-5	-5	-8	-7	-9		
Tosoh G8	0	-1	+1	-2	-2	+4	-2		
Trinity Biotech Premier Hb9210	0	0	0	-1	0	+1	+2		
Storage Freezer -20°C		•		•		•			
Menarini/ARKRAY HA-8180V	0	+1	0	0	+1	+1	+2		
Sebia CAPILLARYS 3 Octa**	0	-1	+1	+1	-1	0	0		
Roche Cobas c 513	0	+1	0	0	+1	+2	+1		
Abbott enzymatic Alinity***	0	+2	+2	+2	0	+3	+1		
Tosoh G8	0	+1	+1	+1	+1	+1	0		
Trinity Biotech Premier Hb9210	0	+1	+1	+1	+2	+2	+2		
Storage Freezer <-70°C									
Menarini/ARKRAY HA-8180V	0	+1	0	0	+1	+1	+2		
Sebia CAPILLARYS 3 Octa**	0	-1	+1	0	-1	0	0		
Roche Cobas c 513	0	+1	0	0	+2	+1	+1		
Abbott enzymatic Alinity***	0	+2	+3	+3	+1	+2	+2		
Tosoh G8	0	+1	+1	+1	+1	+1	+1		
Trinity Biotech Premier Hb9210	0	+1	+1	+1	+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

VII Organisations and Persons Involved

Cour	ntry Organisation	Person
		1 013011
	Organisers	
AT	ÖQUASTA	Christoph Buchta
BE	Sciensano	Yolande Lenga
CH	CSCQ	Dagmar Kesseler, Pierre-Alain Morandi
CZ DE	SEKK s.r.o. INSTAND	Marek Budina, Josef Kratochvila, Ondrej Wiewiorka Patricia Kaiser
DE	Reference Institute for Bioanalytics	Anja Kessler
		Sandra Bullich, Carmen Perich, Montserrat Ventura, Mariona
ES	SEQC ^{ML}	Panadès
FR	Asqualab	Anne Vassault
FR	CTCB	Erick Sanchez, Stéphanie Albarède,
FR	ProBioQuaL	Philippe Joly
GR	ESEAP/General Hospital	Alexander Haliassos, Konstantinos Makris, Otto Panagiotakis
HU	QualiCont Nonprofit Kft.	Virag Gyongyosi, Erika Sarkany
ΙE	IEQAS	Hazel Graham, Anne Kane, Thomas P, Smith, Ned Barrett
INT	ERL	Carla Siebelder, Eline van der Hagen
IT	Centro di Ricerca Biomedica	Laura Sciacovelli, Mario Plebani
IT	CRRVEQ	Massimo Quercioli, Francesca Masi
KR	Korean Association of External	Junghan Song, Sail Chun,, Kyunghoon Lee
	Quality Assessment Service	
MX	Laboratorios Biomedicos Panuco	Eduardo Rojano Rodriguez
NL	SKML PNAEQ-INSA	Eline van der Hagen, Hans van der Vuurst
PT SE	Equalis	Ana Andrade Faria, Ana Cardoso, Helena Correia Carolina Kristoffersson, Jim Andersson
TH	National Institute of Health	Supaporn Suparak
	TUBITAK UME / Pamukkale	
TR	University	Fatma Akcadag, Müslüm Akgöz, Diler Aslan
UK	Wegas	Annette Thomas, Samantha Jones, Gareth Davies
ZA	NHLS/Stellenbosch University	Annalise Zemlin
IFCC	Network Laboratories	
FR	CHU Reims	Philippe Gillery, Stéphane Jaisson
DE	INSTAND	Patricia Kaiser
	Reference Institute for Bioanalytics,	
DE	Calibration Laboratory 1	Caroline Stobe, Anja Kessler
IT	CIRME	Renata Paleari, Andrea Mosca
NL	Isala	Erna Lenters-Westra, Robbert Slingerland, Janine Slootstra
NL	Queen Beatrix Hospital	Carla Siebelder, Eline vd Hagen, Sanne Leppink, Laura Reijnders
IFCC	Secondary Reference Laboratori	es
IT	CIRME	Renata Paleari, Andrea Mosca
NL	Isala	Erna Lenters, Robbert Slingerland
NL	Queen Beatrix Hospital	Carla Siebelder, Eline vd Hagen, Sanne Leppink, Laura Reijnders
NGS	P Network Laboratories	
US	University of Missouri	Randie Little, Shawn Connolly
US	University of Minnesota	Joan Anderson
	rsight Committee (members IFCC	
UK	University of East Anglia	Emma English
JP	Tokyo Women's Medical Hospital	Asako Sato
NL	Queen Beatrix Hospital	Eline van der Hagen
CZ	University of Prague	Jan Skrha
UK	Manchester University	Eric Kilpatrick
US	National Institutes of Health	David B, Sacks
NL	Queen Beatrix Hospital	Carla Siebelder
NL	Isala	Erna Lenters
	Management	
NL	Overview	Carla Siebelder
NL NL	Coordination	Carla Siebelder
NL	Quality Assurance	Liesbeth Janssen
NL	Data Processing	Irene de Graaf
NL	Sample Logistics	Marieke te Winkel
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