

Report

EurA1c 2024

HbA1c Trial

EQA organisers



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 Carla Siebelder

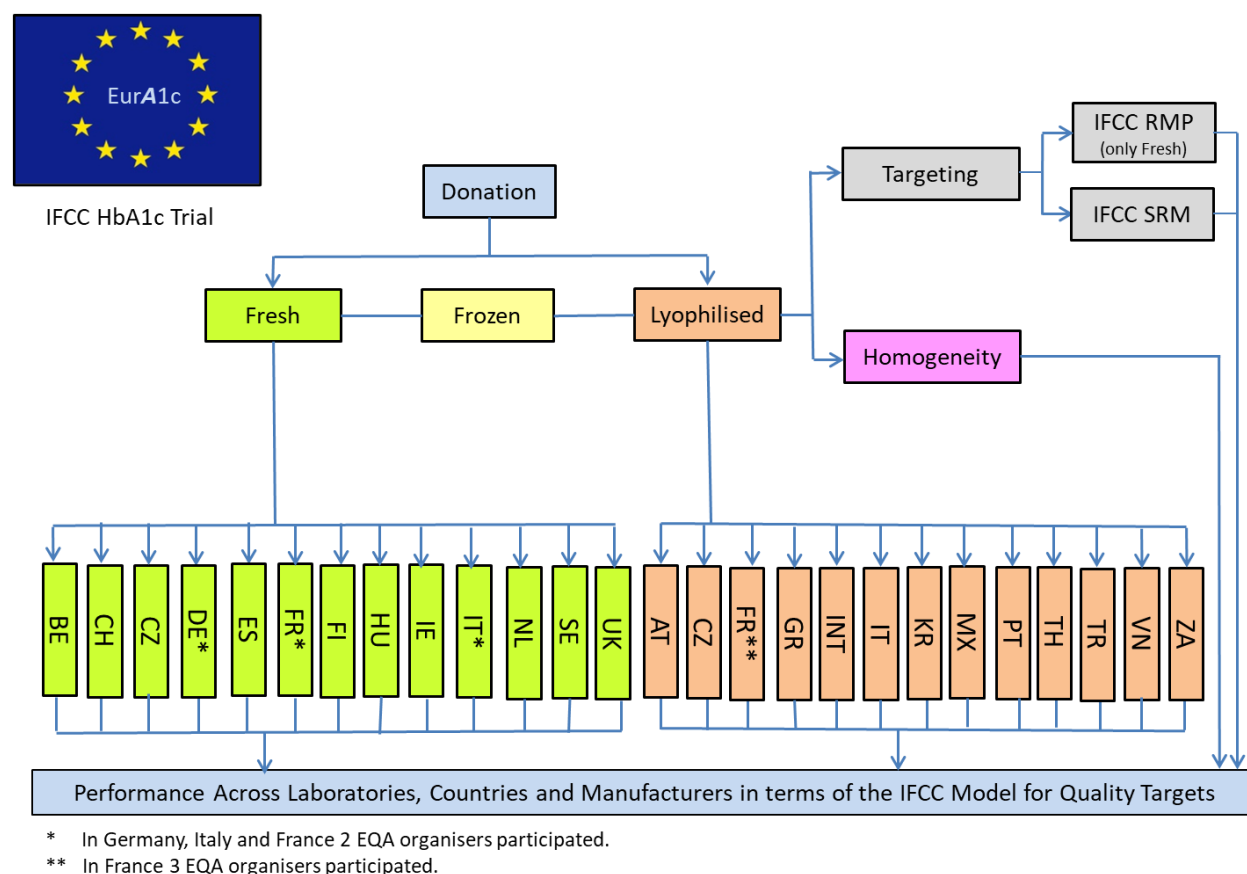
I Introduction and Overview of Results

Introduction

27 EQA organisers of 23 countries agreed to participate in the 9th “EurA1c” project. The design is shown in figure 1.

16 EQA organisers used fresh whole blood samples and 15 organisers used lyophilised hemolysate samples (4 organisations used both fresh and lyophilised samples). In October 2024 the fresh whole blood samples were sent to the participants and immediately assayed. In November 2024 the lyophilised hemolysate samples were sent. These are assayed by the participants up to April 2025.

Figure 1. Design EurA1c Trial 2024



Confidentiality and Ownership

The results of the EurA1c project are owned by all EQA organisers. We agreed that reports are confidential and will not be shared with other third parties until the definite report is completed.

Time schedule EurA1c 2024:

April 2025	Interim report fresh whole blood 2024 and definite target values sent to all participating EQA organisers.
July 2025:	Draft full report sent to all who are involved in EurA1c 2024. At the same time the invitation to participate in EurA1c 2025 is sent.
31 August 2025:	Deadline for comments and remarks.
30 September 2025:	Final full report sent to all who are involved and published on the IFCC-HbA1c website (www.ifcchba1c.org). Results may be shared with third parties after publication on the IFCC-HbA1c website.

Value Assignment

Definite target values are assigned with the IFCC RMP.

For EurA1c 2024-1 the assigned value is 60.2 mmol/mol (expanded uncertainty 0.9 mmol/mol).

For EurA1c 2024-2 the assigned value is 44.3 mmol/mol (expanded uncertainty 0.7 mmol/mol).

Outliers

Participant 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 17 results (0.6%) have been excluded from the database of the fresh whole blood samples and 13 results (0.8%) from the database of the lyophilised hemolysates.

Methods

Specification of the methods remains a point of consideration. Methods are described differently by the respective EQA organisers and also a significant number of labs did still do not report their manufacturer/method and/or their specific method. For details see resp. table 3/4 and 7/8.

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 2024

Country	EQA Organiser	Fresh Whole Blood			Lyophilised Hemolysate		
		n*	Mean Bias mmol/mol	Between Lab CV%	n*	Mean Bias mmol/mol	Between Lab CV%
Austria	ÖQUASTA				109	+1.1	4.3
Belgium	Sciensano	116	+0.7	3.1			
Czech Republic	SEKK	184	+1.1	4.1	164	+0.3	4.2
Finland	Labquality	198	0.0	4.1			
France	Asqualab	19	+0.4	4.4	26	+1.9	5.7
France	CTCB	138	+0.1	3.8	154	+0.1	3.2
France	ProBioQual				550	-0.4	5.3
Germany	INSTAND	582	+0.5	4.0			
Germany	RfB	724	+0.6	3.5			
Greece	ESEAP				109	-0.3	5.4
Hungary	QualiCont	67	+0.9	5.0			
International**	ERL				27	0.0	3.9
Ireland	IEQAS	60	+0.2	3.8			
Italy	CRB	38	+1.7	4.5	37	+0.4	4.9
Italy	CRRVEQ	46	+1.7	5.1			
Korea	Kor Ass. EQAS				74	-0.4	2.7
Mexico	Labs Biom Panuco				16	+1.2	4.8
Netherlands	SKML	129	+0.5	3.4			
Portugal	PNAEQ-INSA				24	+0.2	5.2
Spain	SEQC ^{ML} (now SEMEDLAB)	149	+1.2	4.1			
South Africa	NHLS				7	+0.5	4.3
Sweden	Equalis	92	+0.2	4.3			
Switzerland	CSCQ	54	+0.4	4.4			
Thailand	NIH				154	+0.3	8.8
Turkiye	TUBITAK UME				48	+0.1	6.4
United Kingdom	Weqas	157	+0.9	4.0			
Vietnam	QCC				32	+3.2	3.7
Overall		2753	+0.6	4.0	1531	+0.1	5.5

* n = the number of datasets

** Individual laboratories of a number of countries

In total 4284 datasets were submitted for EurA1c 2024 (2753 in fresh whole blood and 1531 in lyophilised hemolysate).

The mean bias of all countries in the fresh whole blood programme is +0.6 mmol/mol and the between laboratory CV is 4.0%. In the lyophilised hemolysate programme the mean bias of all countries is +0.1 mmol/mol and the between laboratory CV is 5.5%.

Differentiation of Results

Results are differentiated per sample and a) per country b) per manufacturer/method and c) per manufacturer/method per EQA organiser in the 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 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	EurA1c 2024-1 Target 60.2 mmol/mol				EurA1c 2024-2 Target 44.3 mmol/mol				Mean 2 Samples	
		n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Belgium	Sciensano	116	60.7	+0.5	2.8	116	45.2	+0.9	3.4	+0.7	3.1
Czech Republic	SEKK	184	61.4	+1.2	3.9	183	45.4	+1.1	4.4	+1.1	4.1
Finland	Labquality	197	60.2	0.0	3.9	198	44.3	0.0	4.3	0.0	4.1
France	Asqualab	19	60.3	+0.1	3.9	19	45.0	+0.7	4.8	+0.4	4.4
France	CTCB	138	60.3	+0.1	3.6	133	44.5	+0.2	4.1	+0.1	3.8
Germany	INSTAND	582	60.7	+0.5	3.9	579	44.8	+0.5	4.2	+0.5	4.0
Germany	RfB	723	60.8	+0.6	3.3	724	44.9	+0.6	3.8	+0.6	3.5
Hungary	QualiCont	67	60.8	+0.6	4.8	67	45.5	+1.2	5.1	+0.9	5.0
Ireland	IEQAS	60	60.3	+0.1	2.9	60	44.6	+0.3	4.7	+0.2	3.8
Italy	CRB	38	61.8	+1.6	4.3	38	46.2	+1.9	4.8	+1.7	4.5
Italy	CRRVEQ	45	61.8	+1.6	4.5	46	46.0	+1.7	5.8	+1.7	5.1
Netherlands	SKML	129	60.5	+0.3	3.4	129	45.0	+0.7	3.3	+0.5	3.4
Spain	SEQC ^{ML}	149	61.3	+1.1	3.8	149	45.6	+1.3	4.3	+1.2	4.1
Sweden	Equalis	88	60.0	-0.2	5.1	92	44.9	+0.6	3.5	+0.2	4.3
Switzerland	CSCQ	54	60.4	+0.2	5.2	54	44.9	+0.6	3.7	+0.4	4.4
United Kingdom	Weqas	157	61.0	+0.8	4.2	156	45.4	+1.1	3.7	+0.9	4.0
Overall		2746	60.7	+0.5	3.8	2743	45.0	+0.7	4.1	+0.6	4.0

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

Manufacturer/Method	EurA1c 2024-1 Target 60.2 mmol/mol				EurA1c 2024-2 Target 44.3 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	45	58.8	-1.4	2.7	43	43.1	-1.2	2.9	-1.3	2.8
Abbott ARCHITECT (enzymatic)	38	58.7	-1.5	2.0	38	43.2	-1.1	2.0	-1.3	2.0
Abbott/Alere Afinion	257	59.5	-0.7	3.7	262	44.0	-0.3	3.7	-0.5	3.7
Abbott not specified/other	7	60.2	0.0	7.7	7	45.6	+1.3	6.8	+0.7	7.2
Aidian QuickRead go HbA1c	8	58.9	-1.3	8.3	8	43.9	-0.4	3.1	-0.9	5.7
ARKRAY ADAMS HA-8180 series	179	60.2	0.0	2.8	179	44.9	+0.6	2.9	+0.3	2.8
ARKRAY ADAMS HA-8190 series	44	60.5	+0.3	1.7	44	45.6	+1.3	2.1	+0.8	1.9
ARKRAY ADAMS HA-8380 series	6	62.2	+2.0	4.2	6	46.0	+1.7	4.6	+1.8	4.4
ARKRAY ADAMS not specified/other	12	61.4	+1.2	4.2	12	45.3	+1.0	4.4	+1.1	4.3
Beckman Coulter AU series	55	60.6	+0.4	4.1	54	44.9	+0.6	3.9	+0.5	4.0
Bio-Rad D-10 series	82	60.8	+0.6	3.4	81	44.6	+0.3	4.5	+0.4	3.9
Bio-Rad D-100 series	102	59.9	-0.3	2.1	102	43.9	-0.4	2.8	-0.3	2.4
Bio-Rad Variant series	50	60.1	-0.1	5.3	50	45.4	+1.1	3.9	+0.5	4.6
Bio-Rad not specified/other	18	61.7	+1.5	3.4	18	45.2	+0.9	4.3	+1.2	3.9
EKF Diagnostics	18	62.7	+2.5	3.0	17	46.5	+2.2	3.3	+2.4	3.1
HemoCue HbA1c 501	31	59.7	-0.5	7.9	31	43.6	-0.7	6.9	-0.6	7.4
Menarini HbNEXT	40	64.7	+4.5	4.4	41	47.4	+3.1	4.6	+3.8	4.5
Roche Diagnostics cobas b 101	29	59.6	-0.6	2.4	29	43.9	-0.4	4.0	-0.5	3.2
Roche Diagnostics cobas c 111/311	6	62.2	+2.0	2.9	6	45.7	+1.4	2.1	+1.7	2.5
Roche Diagnostics cobas c 303/503	176	62.3	+2.1	2.6	177	45.9	+1.6	2.8	+1.8	2.7
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	201	61.5	+1.3	2.8	200	45.4	+1.1	3.4	+1.2	3.1
Roche Diagnostics cobas c 513	76	61.7	+1.5	2.2	76	45.0	+0.7	1.9	+1.1	2.1
Roche Diagnostics cobas Integra	47	61.8	+1.6	2.8	47	44.8	+0.5	3.7	+1.0	3.3
Roche Diagnostics not specified/other	44	60.9	+0.7	3.5	43	44.5	+0.2	3.6	+0.5	3.5
Sebia CAPILLARYS 2	31	60.0	-0.2	2.2	31	44.4	+0.1	2.6	0.0	2.4
Sebia CAPILLARYS 3	190	59.6	-0.6	2.0	189	44.1	-0.2	2.3	-0.4	2.2
Sebia MINICAP	11	58.6	-1.6	3.1	11	43.7	-0.6	3.3	-1.1	3.2
Sebia not specified/other	11	59.5	-0.7	2.3	11	43.7	-0.6	2.3	-0.7	2.3
Siemens Atellica CH (enzymatic)	50	59.3	-0.9	2.6	51	42.9	-1.4	3.3	-1.1	3.0
Siemens DCA 2000/Vantage	180	60.4	+0.2	5.5	179	44.6	+0.3	5.0	+0.3	5.3
Siemens Dimension EXL series	27	59.0	-1.2	2.3	27	43.4	-0.9	3.3	-1.1	2.8
Siemens not specified/other	37	59.0	-1.2	3.7	37	43.7	-0.6	2.6	-0.9	3.2
Thermo Fisher Scientific	8	60.0	-0.2	4.2	8	45.0	+0.7	4.8	+0.3	4.5
Tosoh G7	9	62.3	+2.1	3.0	9	47.6	+3.3	6.7	+2.7	4.9
Tosoh G8	147	61.6	+1.4	2.4	146	46.3	+2.0	2.8	+1.7	2.6
Tosoh G11	315	61.5	+1.3	1.8	315	46.2	+1.9	2.3	+1.6	2.1
Tosoh GX	6	61.9	+1.7	1.5	6	46.6	+2.3	1.8	+2.0	1.7
Tosoh not specified/other	53	61.6	+1.4	3.1	53	46.3	+2.0	3.5	+1.7	3.3
Trinity Biotech Premier Hb9210	28	63.0	+2.8	3.4	28	47.3	+3.0	3.4	+2.9	3.4
Not specified/other	36	60.4	+0.2	4.6	36	44.3	0.0	6.1	+0.1	5.4

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

Manufacturer/Method	EurA1c 2024-1 Target 60.2 mmol/mol				EurA1c 2024-2 Target 44.3 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Aeroset multigent	1	62.1	+1.9		1	43.5	-0.8		+0.6	
ARKRAY ADAMS HA-8160 series	5	60.3	+0.1	2.6	5	44.7	+0.4	2.5	+0.2	2.5
Beckman Coulter Unicel DxC series	2	64.0	+3.8	13.3	2	47.0	+2.7	15.0	+3.3	14.2
Boditech AFIAS series	4	61.3	+1.1	8.2	4	44.4	+0.1	2.4	+0.6	5.3
Erba not specified/other	2	52.3	-7.9	11.2	2	38.8	-5.5	13.0	-6.7	12.1
Hitado	1	67.0	+6.8		1	43.0	-1.3		+2.8	
Horiba Pentra	3	60.8	+0.6	4.7	3	44.1	-0.2	7.5	+0.2	6.1
Menarini HA-8160 series (Lifotronic reagent)	1	63.0	+2.8		1	47.0	+2.7		+2.8	
Menarini HA-8180 series (Lifotronic reagent)	2	61.4	+1.2	0.8	2	45.7	+1.4	2.2	+1.3	1.5
Mindray not specified/other	5	64.1	+3.9	5.9	5	47.1	+2.8	4.0	+3.3	4.9
Ortho Clinical Diagnostics Vitros series	3	66.4	+6.2	7.2	2	48.6	+4.3	6.2	+5.2	6.7
Siemens Advia (enzymatic)	3	59.2	-1.0	2.9	3	43.1	-1.2	2.6	-1.1	2.7
Sysmex bx series	1	58.0	-2.2		1	42.0	-2.3		-2.3	
Sysmex not specified/other	2	65.0	+4.7	2.5	2	45.8	+1.5	4.5	+3.1	3.5
Thermo Fisher Scientific/Konelab	1	56.0	-4.2		1	42.5	-1.8		-3.0	

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

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

Manufacturer/Method/EQA	n	EurA1c 2024-1 Target 60.2 mmol/mol		EurA1c 2024-2 Target 44.3 mmol/mol		Mean		
		Bias	CV%	Bias	CV%	Bias	CV%	
Abbott Alinity								
Overall	45	-1.4	2.7	-1.2	2.9	-1.3	2.8	
DE-INSTAND	10	-1.2	2.3	-1.2	2.0	-1.2	2.1	
DE-RfB	15	-2.4	3.3	-1.7	3.5	-2.1	3.4	
SE-Equalis	9	-1.3	0.5	-1.1	0.8	-1.2	0.7	
Abbott ARCHITECT (enzymatic)								
Overall	38	-1.5	2.0	-1.1	2.0	-1.3	2.0	
DE-INSTAND	12	-1.2	2.0	-0.8	1.8	-1.0	1.9	
DE-RfB	17	-1.3	1.6	-1.2	1.3	-1.3	1.5	
Abbott/Alere Afinion								
Overall	257	-0.7	3.7	-0.3	3.7	-0.5	3.7	
CH-CSCQ	14	-0.2	2.5	+0.3	2.6	0.0	2.6	
DE-INSTAND	53	-0.9	2.9	-0.5	3.9	-0.7	3.4	
DE-RfB	26	-1.8	3.7	-1.4	3.3	-1.6	3.5	
FI-Labquality	93	-0.7	3.1	-0.6	3.9	-0.7	3.5	
IE-IEQAS	8	+0.5	2.3	+0.1	2.4	+0.3	2.3	
NL-SKML	21	+0.3	3.5	+0.5	3.2	+0.4	3.3	
SE-Equalis	28	-1.0	6.7	+0.6	3.4	-0.2	5.1	
UK-Wegas	11	-0.1	1.9	0.0	2.0	-0.1	2.0	
ARKRAY ADAMS HA-8180 series								
Overall	179	0.0	2.8	+0.6	2.9	+0.3	2.8	
BE-Sciensano	25	-0.1	2.8	+0.5	3.2	+0.2	3.0	
CZ-SEKK	38	+0.7	2.9	+0.9	3.2	+0.8	3.1	
DE-INSTAND	31	0.0	2.2	+0.5	2.5	+0.2	2.3	
DE-RfB	26	+0.4	1.7	+1.0	1.9	+0.7	1.8	
ES-SEQC ^{ML}	6	0.0	2.0	+0.2	1.8	+0.1	1.9	
HU-QualiCont	23	+0.1	3.9	+0.7	3.3	+0.4	3.6	
IE-IEQAS	7	-0.6	2.5	+0.3	3.1	-0.2	2.8	
NL-SKML	13	-1.8	2.2	-0.8	2.8	-1.3	2.5	
UK-Wegas	8	-0.3	1.1	+0.5	1.0	+0.1	1.1	
ARKRAY Adams HA-8190 series								
Overall	44	+0.3	1.7	+1.3	2.1	+0.8	1.9	
ES-SEQC ^{ML}	25	+0.4	1.5	+1.4	1.4	+0.9	1.4	
IE-IEQAS	8	+0.3	1.1	+1.5	1.6	+0.9	1.3	
Beckman Coulter AU series								
Overall	55	+0.4	4.1	+0.6	3.9	+0.5	4.0	
DE-INSTAND	15	+0.6	3.9	+0.9	3.3	+0.8	3.6	
DE-RfB	25	+1.1	3.6	+0.8	2.9	+0.9	3.2	
HU-QualiCont	9	-0.6	3.5	+0.7	4.3	0.0	3.9	
Bio-Rad D-10 series								
Overall	82	+0.6	3.4	+0.3	4.5	+0.4	3.9	
CZ-SEKK	20	+1.5	2.9	+0.9	2.9	+1.2	2.9	
DE-INSTAND	22	0.0	3.0	-0.4	5.3	-0.2	4.1	
DE-RfB	22	+0.8	1.9	+0.9	2.5	+0.9	2.2	
FR-CTCB	6	-1.7	4.7	-2.4	5.6	-2.1	5.2	
Bio-Rad D-100 series								
Overall	102	-0.3	2.1	-0.4	2.8	-0.3	2.4	
BE-Sciensano	8	+0.7	1.4	-0.1	2.4	+0.3	1.9	
CZ-SEKK	8	+0.3	2.6	-0.3	3.4	0.0	3.0	
DE-INSTAND	16	0.0	2.0	+0.2	2.6	+0.1	2.3	
DE-RfB	32	-0.4	1.3	-0.8	2.1	-0.6	1.7	
ES-SEQC ^{ML}	19	-0.7	2.7	-0.6	3.8	-0.7	3.3	
FR-CTCB	7	0.0	1.4	-0.2	0.9	-0.1	1.2	

Manufacturer/Method/EQA	n	EurA1c 2024-1 Target 60.2 mmol/mol		EurA1c 2024-2 Target 44.3 mmol/mol		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Bio-Rad Variant series							
Overall	50	-0.1	5.3	+1.1	3.9	+0.5	4.6
DE-INSTAND	12	-0.6	4.1	+1.0	4.2	+0.2	4.2
DE-RfB	24	+0.3	3.6	+1.1	2.1	+0.7	2.9
HemoCue HbA1c 501							
Overall	31	-0.5	7.9	-0.7	6.9	-0.6	7.4
DE-INSTAND	13	-1.7	7.9	-2.0	5.7	-1.8	6.8
FI-Labquality	11	0.0	8.8	+0.4	6.9	+0.2	7.8
Menarini HbNEXT							
Overall	40	+4.5	4.4	+3.1	4.6	+3.8	4.5
ES-SEQC ^{ML}	21	+3.9	5.2	+2.7	4.9	+3.3	5.0
IT-CRRVEQ	8	+5.6	2.5	+4.4	4.6	+5.0	3.5
Roche Diagnostics cobas c 303/503							
Overall	176	+2.1	2.6	+1.6	2.8	+1.8	2.7
DE-INSTAND	67	+2.3	2.3	+1.5	2.3	+1.9	2.3
DE-RfB	82	+2.0	2.9	+1.5	3.3	+1.8	3.1
NL-SKML	11	+2.2	2.0	+1.5	2.1	+1.8	2.1
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)							
Overall	201	+1.3	2.8	+1.1	3.4	+1.2	3.1
CH-CSCQ	10	+1.7	2.2	+1.5	1.6	+1.6	1.9
DE-INSTAND	70	+1.3	2.7	+1.4	2.8	+1.4	2.8
DE-RfB	93	+1.2	2.8	+0.7	3.3	+0.9	3.0
IT-CRRVEQ	7	+1.1	2.0	+1.9	5.2	+1.5	3.6
NL-SKML	9	+1.7	4.7	+1.5	4.3	+1.6	4.5
Roche Diagnostics cobas c 513							
Overall	76	+1.5	2.2	+0.7	1.9	+1.1	2.1
DE-INSTAND	22	+1.0	1.9	+0.5	1.7	+0.8	1.8
DE-RfB	44	+1.6	2.0	+0.7	1.8	+1.1	1.9
Roche Diagnostics cobas Integra							
Overall	47	+1.6	2.8	+0.5	3.7	+1.0	3.3
DE-INSTAND	21	+1.6	2.6	+0.9	2.5	+1.3	2.6
DE-RfB	21	+1.9	2.6	+0.7	3.1	+1.3	2.9
Sebia CAPILLARYS 2							
Overall	31	-0.2	2.2	+0.1	2.6	0.0	2.4
DE-RfB	7	+0.5	1.7	+0.9	1.9	+0.7	1.8
FR-CTCB	8	-0.4	2.5	-0.6	2.3	-0.5	2.4
Sebia CAPILLARYS 3							
Overall	190	-0.6	2.0	-0.2	2.3	-0.4	2.2
BE-Sciensano	15	-0.4	1.4	-0.4	2.2	-0.4	1.8
DE-INSTAND	14	-0.6	1.8	-0.2	1.9	-0.4	1.9
DE-RfB	47	-0.7	1.6	0.0	1.7	-0.3	1.6
ES-SEQC ^{ML}	12	-0.5	1.4	-0.3	1.9	-0.4	1.6
FR-CTCB	58	-0.6	2.6	-0.1	3.0	-0.3	2.8
IT-CRB	6	-1.0	2.0	0.0	1.8	-0.5	1.9
IT-CRRVEQ	6	-1.7	1.8	-1.0	1.2	-1.3	1.5
NL-SKML	7	-0.4	1.9	-0.1	2.6	-0.3	2.3
SE-Equalis	16	-0.6	1.6	0.0	1.8	-0.3	1.7
Siemens Atellica CH (enzymatic)							
Overall	50	-0.9	2.6	-1.4	3.3	-1.1	3.0
DE-INSTAND	12	-1.7	4.3	-2.0	4.8	-1.8	4.6
DE-RfB	23	-0.7	2.1	-1.1	2.0	-0.9	2.0
NL-SKML	8	-0.3	1.6	-0.6	1.9	-0.4	1.8
Siemens DCA 2000/Vantage							
Overall	180	+0.2	5.5	+0.3	5.0	+0.3	5.3
CH-CSCQ	10	+0.5	7.6	-0.1	5.8	+0.2	6.7
DE-INSTAND	35	-0.3	5.7	-0.1	5.6	-0.2	5.7
DE-RfB	24	-0.3	5.5	+0.1	5.2	-0.1	5.4
FI-Labquality	11	+2.5	6.5	+1.7	5.5	+2.1	6.0
IE-IEQAS	25	+0.1	3.9	-0.3	6.5	-0.1	5.2
NL-SKML	10	-1.2	5.0	-0.1	2.6	-0.6	3.8
SE-Equalis	10	+1.8	4.0	+1.5	5.4	+1.7	4.7
UK-Weqas	51	+0.2	5.4	+0.8	3.5	+0.5	4.4

Manufacturer/Method/EQA	n	EurA1c 2024-1 Target 60.2 mmol/mol		EurA1c 2024-2 Target 44.3 mmol/mol		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Tosoh G8							
Overall	147	+1.4	2.4	+2.0	2.8	+1.7	2.6
BE-Sciensano	16	+1.1	1.2	+2.1	1.8	+1.6	1.5
CZ-SEKK	29	+2.3	2.0	+2.7	2.0	+2.5	2.0
DE-INSTAND	20	+0.6	1.2	+1.7	1.7	+1.2	1.4
DE-RfB	26	+0.8	1.6	+1.7	1.9	+1.2	1.7
FR-CTCB	18	+1.9	4.4	+1.9	5.0	+1.9	4.7
NL-SKML	15	+0.6	1.8	+1.5	2.2	+1.0	2.0
Tosoh G11							
Overall	315	+1.3	1.8	+1.9	2.3	+1.6	2.1
BE-Sciensano	29	+1.4	1.5	+1.9	1.4	+1.7	1.4
DE-INSTAND	33	+1.1	1.5	+1.6	1.4	+1.4	1.5
DE-RfB	103	+1.4	2.0	+1.8	2.2	+1.6	2.1
ES-SEQC ^{ML}	38	+1.1	1.2	+2.1	3.2	+1.6	2.2
FR-CTCB	16	+0.9	2.0	+1.4	2.5	+1.1	2.2
IT-CRRVEQ	7	+1.9	2.2	+2.1	2.7	+2.0	2.5
NL-SKML	18	+1.1	1.4	+1.9	1.9	+1.5	1.6
SE-Equalis	11	+1.5	1.3	+2.1	1.2	+1.8	1.2
UK-Wegas	38	+1.3	1.6	+1.6	1.6	+1.5	1.6
Trinity Biotech Premier Hb9210							
Overall	28	+2.8	3.4	+3.0	3.4	+2.9	3.4
IT-CRB	7	+2.9	3.9	+2.8	5.0	+2.9	4.4
UK-Wegas	16	+3.1	3.5	+3.3	2.8	+3.2	3.1

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/method for those with 6 or more data sets (table 7) and 5 or less data sets (table 8).

Table 6. Results per EQA organiser for Lyophilised Hemolysate

Country	EQA Organiser	EurA1c 2024-1 Target 60.2 mmol/mol				EurA1c 2024-2 Target 44.3 mmol/mol				Mean 2 Samples	
		n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Austria	ÖQUASTA	109	61.9	+1.7	4.3	109	44.8	+0.5	4.3	+1.1	4.3
Czech Republic	SEKK	164	60.6	+0.4	4.2	164	44.4	+0.1	4.2	+0.3	4.2
France	Asqualab	26	62.5	+2.3	6.4	26	45.8	+1.5	5.0	+1.9	5.7
France	CTCB	154	60.6	+0.4	3.0	146	44.2	-0.1	3.3	+0.1	3.2
France	ProBioQual	550	59.9	-0.3	5.0	543	43.9	-0.4	5.7	-0.4	5.3
Greece	ESEAP	109	60.5	+0.3	5.2	106	43.4	-0.9	5.7	-0.3	5.4
International*	ERL	25	60.6	+0.4	4.4	27	43.9	-0.4	3.4	0.0	3.9
Italy	CRB	37	60.8	+0.6	3.8	37	44.4	+0.1	5.9	+0.4	4.9
Korea	Kor Ass. EQAS	74	59.9	-0.3	2.9	74	43.9	-0.4	2.5	-0.4	2.7
Mexico	Labs Biom Panuco	16	61.1	+0.9	4.0	16	45.8	+1.5	5.6	+1.2	4.8
Portugal	PNAEQ-INSA	24	60.8	+0.6	4.8	24	44.1	-0.2	5.6	+0.2	5.2
South Africa	NHLS	7	60.6	+0.4	3.5	7	45.0	+0.7	5.0	+0.5	4.3
Thailand	NIH	154	61.1	+0.9	8.4	153	44.1	-0.2	9.2	+0.3	8.8
Turkiye	TUBITAK UME	48	60.3	+0.1	5.7	48	44.5	+0.2	7.2	+0.1	6.4
Vietnam	QCC	32	64.4	+4.2	3.5	32	46.4	+2.1	3.8	+3.2	3.7
Overall		1529	60.6	+0.4	5.3	1512	44.2	-0.1	5.7	+0.1	5.5

* Individual laboratories of a number of countries

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

Manufacturer/Method	EurA1c 2024-1 Target 60.2 mmol/mol				EurA1c 2024-2 Target 44.3 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	57	58.5	-1.7	5.3	57	42.5	-1.8	6.1	-1.7	5.7
Abbott ARCHITECT (enzymatic)	33	57.9	-2.3	6.8	32	41.7	-2.6	8.3	-2.4	7.5
ARKRAY ADAMS HA-8180 series	57	58.6	-1.6	3.4	57	43.2	-1.1	3.6	-1.3	3.5
ARKRAY ADAMS HA-8190 series	10	58.9	-1.3	2.2	9	43.8	-0.5	2.2	-0.9	2.2
ARKRAY ADAMS HA-8380 series	7	56.3	-3.9	9.8	8	41.3	-3.1	9.3	-3.5	9.6
ARKRAY ADAMS not specified/other	13	58.8	-1.4	4.3	13	42.9	-1.4	3.6	-1.4	4.0
Beckman Coulter AU series	9	59.0	-1.2	9.0	8	44.1	-0.2	9.2	-0.7	9.1
BioMajesty JCA-BM6010	6	60.2	0.0	3.5	6	42.3	-2.0	4.3	-1.0	3.9
Bio-Rad D-10 series	73	60.6	+0.4	4.3	74	44.9	+0.6	4.4	+0.5	4.4
Bio-Rad D-100 series	81	60.1	-0.1	1.9	81	43.7	-0.6	2.5	-0.4	2.2
Bio-Rad Variant series	51	58.5	-1.7	6.7	51	43.9	-0.4	5.4	-1.1	6.0
Bio-Rad not specified/other	15	61.1	+0.9	2.9	15	44.9	+0.6	3.3	+0.8	3.1
Lifotronic	13	59.7	-0.5	9.6	12	42.0	-2.3	9.8	-1.4	9.7
Menarini HbNEXT	26	62.1	+1.9	3.8	25	44.1	-0.2	3.5	+0.8	3.7
Mindray bs series	25	60.0	-0.2	7.6	25	43.2	-1.1	9.2	-0.6	8.4
Ortho Clinical Diagnostics Vitros series	8	54.5	-5.7	8.2	9	39.7	-4.6	10.1	-5.2	9.2
Roche Diagnostics cobas c 111/311	10	62.1	+1.9	4.8	11	43.3	-1.0	5.2	+0.4	5.0
Roche Diagnostics cobas c 303/503	95	63.9	+3.7	3.2	92	46.7	2.4	4.8	+3.0	4.0
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	104	63.4	+3.2	3.8	103	45.3	+1.0	4.9	+2.1	4.4
Roche Diagnostics cobas c 513	19	63.3	+3.1	2.8	19	45.8	+1.5	3.2	+2.3	3.0
Roche Diagnostics cobas Integra	17	62.3	+2.1	5.4	16	44.3	0.0	6.1	+1.1	5.7
Roche Diagnostics not specified/other	43	62.2	+2.0	5.3	40	43.4	-0.9	6.6	+0.6	6.0
Sebia CAPILLARYS 2	60	58.7	-1.5	3.0	60	42.7	-1.6	3.6	-1.5	3.3
Sebia CAPILLARYS 3	215	59.6	-0.6	2.2	213	43.3	-1.0	2.9	-0.8	2.5
Sebia MINICAP	13	58.9	-1.3	3.6	13	43.3	-1.0	4.0	-1.1	3.8
Siemens Atellica CH (enzymatic)	22	60.2	0.0	2.9	22	42.6	-1.7	4.0	-0.9	3.5
Siemens DCA 2000/Vantage	42	65.4	+5.2	4.8	38	48.9	+4.6	6.0	+4.9	5.4
Siemens Dimension EXL series	10	62.1	+1.9	4.2	10	46.0	+1.7	6.2	+1.8	5.2
Tosoh G8	127	60.1	-0.1	3.7	128	44.6	+0.3	2.8	+0.1	3.2
Tosoh G11	157	60.2	0.0	2.5	155	44.3	0.0	2.0	0.0	2.2
Tosoh GX	18	59.6	-0.6	2.4	17	44.6	+0.3	3.1	-0.1	2.7
Tosoh not specified/other	11	62.2	+2.0	6.0	11	46.4	+2.1	6.0	+2.0	6.0
Trinity Biotech Premier Hb9210	9	61.1	+0.9	6.7	9	46.2	+1.9	9.2	+1.4	7.9
Not specified/other	41	60.6	+0.4	7.3	40	44.4	+0.1	8.4	+0.2	7.8

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

Manufacturer/Method	EurA1c 2024-1 Target 60.2 mmol/mol				EurA1c 2024-2 Target 44.3 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott not specified/other	5	60.0	-0.2	3.5	5	43.8	-0.5	6.1	-0.4	4.8
ARKRAY ADAMS HA-8160 series	3	61.0	+0.8	1.6	3	44.3	0.0	1.3	+0.4	1.5
Beckman Coulter Unicel DxC series	1	61.0	+0.8		1	45.0	+0.7		+0.8	
Beckman Coulter not specified/other	3	66.3	+6.1	6.1	3	48.4	+4.1	2.9	+5.1	4.5
Erba XL series	3	71.2	+11.0	3.6	3	50.4	+6.1	3.3	+8.6	3.4
Medconn MQ-2000PT	1	58.5	-1.7		1	44.3	0.0		-0.9	
Menarini HA-8160 series (Lifotronic reagent)	1	60.0	-0.2		1	44.0	-0.3		-0.3	
Menarini HA-8180 series (Lifotronic reagent)	1	56.0	-4.2		1	38.0	-6.3		-5.3	
Mindray not specified/other	2	60.7	+0.5	0.1	2	45.2	+0.9	4.2	+0.7	2.2
Roche Diagnostics cobas b 101	5	58.8	-1.4	12.0	5	40.9	-3.4	10.1	-2.4	11.1
Siemens Dimension Vista series	1	63.0	+2.8		1	44.0	-0.3		+1.3	
Siemens not specified/other	2	59.0	-1.2	2.4	3	43.3	-1.0	5.8	-1.1	4.1
Sysmex bx series	1	64.3	+4.1		1	47.4	+3.1		+3.6	
Thermo Fisher Scientific	1	53.0	-7.2		1	36.6	-7.7		-7.5	
Tosoh G7	2	59.5	-0.7	1.2	2	45.0	+0.7	0.0	0.0	0.6

Table 9 shows results per manufacturer/method per EQA organiser. Included are only manufacturers/methods meeting 2 criteria: at least 6 data sets per EQA organiser and at least two EQA organisers with at least 6 data sets each. High biases (>2 mmol/mol) and high between laboratory CVs (>6%) are marked.

Table 9. Results per Manufacturer/Method and EQA organiser for Lyophilised Hemolysate (n>5)

Manufacturer/Method/EQA	n	EurA1c 2024-1 Target 60.2 mmol/mol		EurA1c 2024-2 Target 44.3 mmol/mol		Mean 2 Samples		
		Bias	CV%	Bias	CV%	Bias	CV%	
Abbott Alinity								
Overall	57	-1.7	5.3	-1.8	6.1	-1.7	5.7	
AT-ÖQUASTA	6	+0.1	2.5	-0.8	1.9	-0.3	2.2	
FR-CTCB	6	-0.8	2.8	-1.1	2.9	-1.0	2.8	
FR-ProBioQual	21	+0.4	2.0	0.0	2.9	+0.2	2.5	
GR-ESEAP	8	-3.6	1.6	-3.3	3.2	-3.4	2.4	
TH-NIH	13	-5.4	6.0	-4.7	7.7	-5.1	6.8	
Abbott ARCHITECT (enzymatic)								
Overall	33	-2.3	6.8	-2.6	8.3	-2.4	7.5	
GR-ESEAP	12	-2.5	4.5	-3.2	4.8	-2.9	4.6	
TH-NIH	8	-6.0	4.2	-5.5	4.5	-5.8	4.3	
ARKRAY ADAMS HA-8180 series								
Overall	57	-1.6	3.4	-1.1	3.6	-1.3	3.5	
AT-ÖQUASTA	14	-0.5	2.2	-0.3	2.4	-0.4	2.3	
CZ-SEKK	34	-1.8	3.0	-1.3	3.2	-1.6	3.1	
Bio-Rad D-10 series								
Overall	73	+0.4	4.3	+0.6	4.4	+0.5	4.4	
CZ-SEKK	21	+1.3	3.6	+1.2	3.4	+1.2	3.5	
FR-CTCB	7	+0.9	4.2	+0.2	4.8	+0.6	4.5	
FR-ProBioQual	23	-1.1	4.5	-0.6	4.4	-0.8	4.4	
MX-Labs Biom. Panuco	12	+1.6	3.4	+2.1	3.0	+1.9	3.2	
Bio-Rad D-100 series								
Overall	81	-0.1	1.9	-0.6	2.5	-0.4	2.2	
AT-ÖQUASTA	12	-0.7	2.9	-0.5	2.9	-0.6	2.9	
FR-ProBioQual	25	+0.1	1.8	-0.2	2.6	-0.1	2.2	
KR-Kor Ass. EQAS	22	-0.2	1.3	-0.7	1.5	-0.4	1.4	
TR-TUBITAK UME	6	-0.2	2.0	-0.6	4.0	-0.4	3.0	
Bio-Rad Variant series								
Overall	51	-1.7	6.7	-0.4	5.4	-1.1	6.0	
FR-ProBioQual	31	-2.9	7.5	-1.0	5.3	-2.0	6.4	
TR-TUBITAK UME	6	+1.2	5.2	+1.3	5.9	+1.3	5.6	
Roche Diagnostics cobas c 303/503								
Overall	95	+3.7	3.2	+2.4	4.8	+3.0	4.0	
AT-ÖQUASTA	15	+4.1	2.3	+2.4	4.3	+3.3	3.3	
FR-ProBioQual	31	+3.5	3.7	+2.5	6.2	+3.0	5.0	
GR-ESEAP	7	+3.2	4.4	+2.4	3.6	+2.8	4.0	
TH-NIH	27	+4.2	3.0	+2.6	3.8	+3.4	3.4	
VN-QCC	7	+3.0	2.8	+1.5	2.9	+2.2	2.9	
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)								
Overall	104	+3.2	3.8	+1.0	4.9	+2.1	4.4	
AT-ÖQUASTA	23	+3.0	3.1	+1.0	4.3	+2.0	3.7	
GR-ESEAP	11	+2.2	2.8	-0.5	2.8	+0.8	2.8	
TH-NIH	36	+3.0	4.5	+0.6	5.5	+1.8	5.0	
VN-QCC	21	+4.7	3.8	+2.3	4.1	+3.5	4.0	
Roche Diagnostics cobas Integra								
Overall	17	+2.1	5.4	0.0	6.1	+1.1	5.7	
GR-ESEAP	6	+1.8	2.9	-0.5	1.9	+0.6	2.4	
TH-NIH	7	+3.2	5.7	+1.1	7.6	+2.2	6.6	
Sebia CAPILLARYS 2								
Overall	60	-1.5	3.0	-1.6	3.6	-1.5	3.3	
FR-CTCB	6	-0.3	0.9	-0.2	1.1	-0.2	1.0	
FR-ProBioQual	49	-1.7	3.2	-1.8	3.6	-1.8	3.4	

Manufacturer/Method/EQA	n	EurA1c 2024-1 Target 60.2 mmol/mol		EurA1c 2024-2 Target 44.3 mmol/mol		Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
Sebia CAPILLARYS 3							
Overall	215	-0.6	2.2	-1.0	2.9	-0.8	2.5
FR-CTCB	66	+0.2	1.9	-0.3	2.4	-0.1	2.2
FR-ProBioQual	130	-1.1	2.0	-1.3	2.7	-1.2	2.4
Siemens DCA 2000/Vantage							
Overall	42	+5.2	4.8	+4.6	6.0	+4.9	5.4
FR-ASQUALAB	8	+6.2	6.6	+3.8	4.6	+5.0	5.6
FR-ProBioQual	31	+4.9	4.3	+4.9	6.3	+4.9	5.3
Tosoh G8							
Overall	127	-0.1	3.7	+0.3	2.8	+0.1	3.2
AT-ÖQUASTA	6	-0.4	1.3	0.0	2.3	-0.2	1.8
CZ-SEKK	30	+0.7	2.3	+0.6	2.7	+0.6	2.5
FR-CTCB	12	-0.4	1.9	0.0	3.0	-0.2	2.4
FR-ProBioQual	51	-0.8	4.5	0.0	2.6	-0.4	3.5
GR-ESEAP	10	+1.0	5.5	+0.7	3.3	+0.9	4.4
Tosoh G11							
Overall	157	0.0	2.5	0.0	2.0	0.0	2.2
AT-ÖQUASTA	6	+0.6	1.6	+0.9	1.7	+0.8	1.6
FR-CTCB	16	-0.1	1.4	+0.5	1.8	+0.2	1.6
FR-ProBioQual	87	+0.1	2.7	0.0	1.6	+0.1	2.2
KR- Kor Ass. EQAS	32	-1.0	1.8	-0.6	2.2	-0.8	2.0
Tosoh GX							
Overall	18	-0.6	2.4	+0.3	3.1	-0.1	2.7
FR-CTCB	8	-0.6	2.0	+0.5	1.9	0.0	1.9
FR-ProBioQual	7	-1.1	2.1	-0.5	2.8	-0.8	2.4

* Individual laboratories of a number of countries

IV. Value Assignment (Targeting)

The assigned values are the values as measured with the IFCC RMP in fresh whole blood. The samples have also been measured with the IFCC SRLs in the respective matrices. Table 12 shows the results; these values are for comparison and information.

Table 12. Results of Reference Measurement Procedures

Matrix	EurA1c 2024-1		EurA1c 2024-2	
	IFCC RMP mmol/mol	IFCC SRLs mmol/mol	IFCC RMP mmol/mol	IFCC SRLs mmol/mol
Fresh Whole Blood	60.2	59.7	44.3	44.0
Lyophilised Hemolysate		60.6		44.0
Frozen Whole Blood		58.7		43.5

V. Homogeneity

Homogeneity testing of EurA1c 2024-2 (fresh 2024-2 and lyophilised 2024-4) was performed according to ISO 13528:2022 Annex B with the ARKRAY HA-8190V (12 samples in duplicate). The samples may be considered to be adequately homogeneous if $s_s \leq 0.3 \text{ SD}_{PT}$. The results in table 13 show that the samples are homogeneous.

Table 13. Homogeneity test (HbA1c results in mmol/mol)

Vial	Fresh Whole Blood				Lyophilised Hemolysate			
	EurA1c 2024-2				EurA1c 2024-4			
	1	2	mean	Δ	1	2	mean	Δ
1	45.1	45.1	45.10	0.0	44.4	44.9	44.65	0,5
2	45.1	44.8	44.95	0.3	44.2	44.9	44.55	0,7
3	44.9	44.9	44.90	0.0	44.8	44.9	44.85	0,1
4	45.4	44.9	45.15	0.5	44.8	44.8	44.80	0,0
5	45.2	44.8	45.00	0.4	44.7	44.8	44.75	0,1
6	45.2	45.4	45.30	0.2	44.7	44.9	44.80	0,2
7	45.1	44.9	45.00	0.2	44.8	44.4	44.60	0,4
8	45.2	45.2	45.20	0.0	44.8	44.8	44.80	0,0
9	45.4	45.1	45.25	0.3	44.8	44.8	44.80	0,0
10	44.9	45.4	45.15	0.5	44.8	44.4	44.60	0,4
11	45.4	44.9	45.15	0.5	44.8	44.8	44.80	0,0
12	45.4	45.1	45.25	0.3	44.8	44.9	44.85	0,1
average			45.1				44.7	
SD			0.129	0.229			0.107	0.217
S_s		0.000				0.000		
Criterion ($0.3 \times \text{SD}_{PT}$)			0.405				0.402	
Homogeneity:			Pass				Pass	

VI. Stability

Stability studies of the fresh whole blood and lyophilised hemolysate samples were completed. Results show that Fresh Whole Blood samples are stable for 5 days at room temperature and for at least 8 days in the refrigerator. Lyophilised Hemolysate samples are stable for five years when stored in the freezer at -20°C or lower.

VII. Organisations and Persons Involved

Country	Organisation	Person
EQA Organisers		
AT	ÖQUASTA	Christoph Buchta
BE	Sciensano	Yolande Lenga
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CZ	SEKK	Marek Budina, Josef Kratochvila, Ondrej Wiewiorka
DE	INSTAND	Patricia Kaiser
DE	Reference Institute for Bioanalytics	Anja Kessler
ES	SEQC ^{ML} (now SEMEDLAB)	Sandra Bullich, Montserrat Ventura, Mariona Panadès, Berta Piqueras, Pilar Fernández Calle
FI	Labquality	Päivi Ranta
FR	Asqualab	Anne Vassault
FR	CTCB	Erick Sanchez, Stéphanie Albarède, Safouane Hamdi
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INT	ERL	Carla Siebelder
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NL	Queen Beatrix Hospital	Carla Siebelder, Sanne Leppink, Laura Reijnders
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CZ	University of Prague	Jan Skrha
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US	Abbott	Liza Kunz
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NL	Queen Beatrix Hospital	Carla Siebelder
NL	Isala	Erna Lenters
Trial Management (European Reference Laboratory, Queen Beatrix Hospital)		
NL	Overview	Carla Siebelder
NL	Coordination	Carla Siebelder
NL	Quality Assurance	Liesbeth Janssen
NL	Data Processing	Irene de Graaf
NL	Sample Logistics	Marieke te Winkel