

# Report EurA1c 2023

*HbA1c Trial  
EQA organisers*



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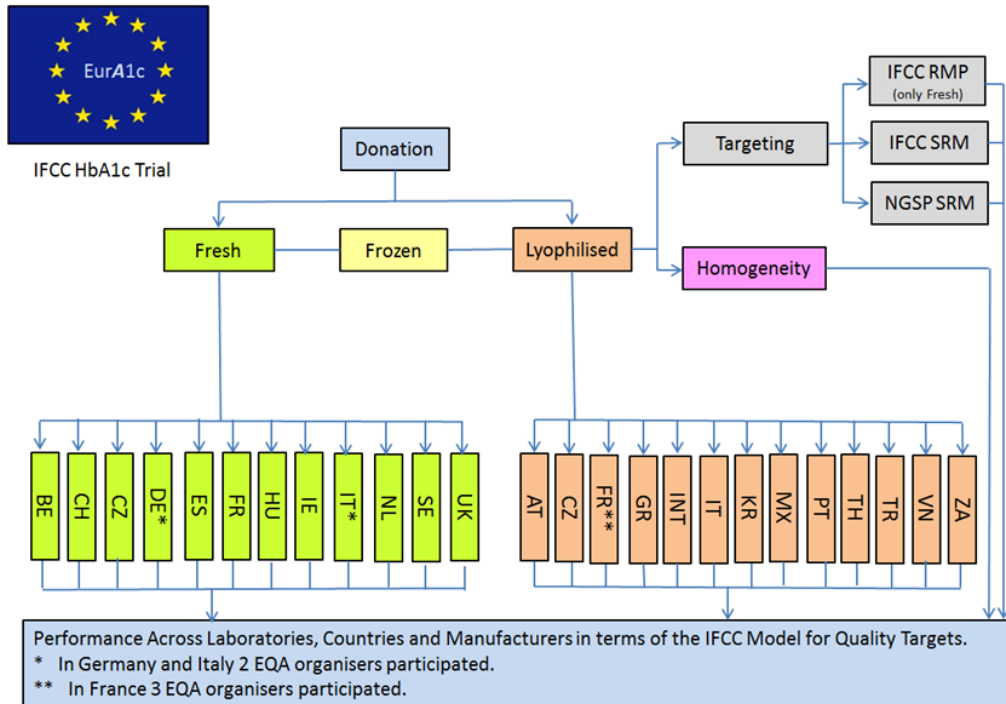
# I. Introduction and Overview of Results

## Introduction

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

14 EQA organisers used fresh whole blood samples and 15 organisers used lyophilised hemolysate samples (2 organisations used both fresh and lyophilised samples). In October 2023 the fresh whole blood samples were sent to the participants and immediately assayed. The interim report was sent in April 2024 to the participating organisers. In November 2023 the lyophilised samples were sent. These were assayed by the participants up to April 2024.

Figure 1. Design EurA1c Trial 2023



N.B. Unfortunately samples for Sweden were lost during transport; thus Equalis will not participate in this trial.

## 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 definitive report is completed.

The time schedule is:

- April 2024 Interim report fresh whole blood 2023 sent to all participating EQA organisers.
- July 2024: Draft full report sent to all who are involved in EurA1c 2023. Simultaneous invitation to participate in EurA1c 2024 is sent.
- 31 August 2024: Deadline for comments and remarks.
- 30 September 2024: Final full report sent to all who are involved and published on the IFCC-HbA1c website ([www.ifcchba1c.org](http://www.ifcchba1c.org)). Results may be shared with third parties after publication on the IFCC-HbA1c website

## Value Assignment

Usually values are assigned by five laboratories using the IFCC Reference Measurement Procedure. However, due to technical problems we had to make an exception in EurA1c 2023; we carried out the evaluation with the Secondary Reference Measurement Procedures.

For EurA1c 2023-1 the assigned value is 44.0 mmol/mol (expanded uncertainty 0.7 mmol/mol) and for EurA1c 2023-2 the assigned value is 59.7 mmol/mol (expanded uncertainty 0.8 mmol/mol). These values are the target values for both fresh whole blood and lyophilised hemolysates.

### 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 13 results (0.5%) have been excluded from the database of the fresh whole blood samples and 14 results (0.9%) from the database of the lyophilised hemolysates.

### Methods

Although more laboratories specified their method this year, this is still a point of consideration. Methods are described differently by the respective EQA organisers. Also a significant number of labs did still 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 2023

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				108	-2.3	5.1
Belgium	Sciensano	120	-0.2	3.0			
Czech Republic	SEKK	169	+0.6	3.9	165	+0.1	4.4
France	Asqualab				24	+1.2	5.6
France	CTCB	112	-0.7	4.0	142	-0.2	4.8
France	ProBioQual				558	-0.2	6.7
Germany	INSTAND	602	-0.2	4.0			
Germany	RfB	757	-0.1	3.8			
Greece	ESEAP				110	-0.2	5.8
Hungary	QualiCont	67	0.0	4.9			
International**	ERL				37	-0.4	5.8
Ireland	IEQAS	69	0.0	4.0			
Italy	CRB	35	-0.2	4.4	32	+0.9	4.1
Italy	CRRVEQ	135	+0.3	4.7			
Korea	Kor Ass. EQAS				74	-0.5	3.1
Mexico	Labs Biom Panuco				16	+1.1	5.8
Netherlands	SKML	136	-0.1	3.5			
Portugal	PNAEQ-INSA				41	+0.4	5.2
Spain	SEQC <sup>ML</sup>	139	+0.1	3.0			
South Africa	NHLS Stellenbosch University				6	+0.2	4.2
Switzerland	CSCQ	49	-0.8	4.1			
Thailand	NIH				161	+0.4	7.7
Turkey	TUBITAK UME				45	+0.1	6.9
United Kingdom	Weqas	156	+0.2	3.4			
Vietnam	QCC				17	+2.2	4.2
Overall		2546	-0.1	3.9	1536	-0.2	6.1

\* n = the number of datasets

\*\* Individual laboratories of a number of countries

In total 4082 datasets were submitted (2546 in fresh whole blood and 1536 in lyophilised hemolysate) for EurA1c 2023. The mean bias of all countries in the fresh whole blood programme is -0.1 mmol/mol and the between laboratory CV is 3.9%. In the lyophilised hemolysate programme the mean bias of all countries is -0.2 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 EQA 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 those with 6 or more data sets (table 3) and 5 or less data sets (table 4).

Table 2. Results per EQA organiser for Fresh Whole Blood

Country	EQA Organiser	EurA1c 2023-1 Target 44.0 mmol/mol				EurA1c 2023-2 Target 59.7 mmol/mol				Mean 2 Samples	
		n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Belgium	Sciensano	120	44.0	0.0	3.0	120	59.3	-0.4	2.9	-0.2	3.0
Czech Republic	SEKK	168	44.5	+0.5	4.0	169	60.4	+0.7	3.8	+0.6	3.9
France	CTCB	111	43.4	-0.6	4.3	112	59.0	-0.7	3.7	-0.7	4.0
Germany	INSTAND	602	43.7	-0.3	4.1	602	59.5	-0.2	3.9	-0.2	4.0
Germany	RfB	757	44.0	0.0	3.9	756	59.6	-0.1	3.8	-0.1	3.8
Hungary	QualiCont	67	43.9	-0.1	5.1	67	59.8	+0.1	4.8	0.0	4.9
Ireland	IEQAS	69	44.1	+0.1	4.2	69	59.6	-0.1	3.8	0.0	4.0
Italy	CRB	35	43.9	-0.1	4.4	35	59.4	-0.3	4.3	-0.2	4.4
Italy	CRRVEQ	134	44.3	+0.3	5.5	135	59.9	+0.2	3.9	+0.3	4.7
Netherlands	SKML	136	43.9	-0.1	3.7	136	59.6	-0.1	3.3	-0.1	3.5
Spain	SEQC <sup>ML</sup>	139	44.1	+0.1	2.9	138	59.8	+0.1	3.1	+0.1	3.0
Switzerland	CSCQ	49	43.2	-0.8	4.6	49	59.0	-0.7	3.6	-0.8	4.1
United Kingdom	Weqas	156	44.3	+0.3	3.6	155	59.8	+0.1	3.3	+0.2	3.4
Overall		2543	43.9	-0.1	4.1	2543	59.6	-0.1	3.8	-0.1	3.9

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

Manufacturer/Method	EurA1c 2023-1 Target 44.0 mmol/mol				EurA1c 2023-2 Target 59.7 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	41	42.3	-1.7	4.2	40	58.0	-1.7	3.3	-1.7	3.7
Abbott ARCHITECT (enzymatic)	45	41.8	-2.2	2.7	45	57.2	-2.5	3.3	-2.4	3.0
Abbott/Alere Afinion	130	42.5	-1.5	3.2	130	58.0	-1.7	2.7	-1.6	3.0
ARKRAY Adams HA-8160 series	7	44.4	+0.4	2.8	7	59.5	-0.2	2.6	+0.1	2.7
ARKRAY Adams HA-8180 series	201	43.8	-0.2	3.3	201	59.3	-0.4	3.2	-0.3	3.3
ARKRAY Adams HA-8190 series	28	44.5	+0.5	1.5	28	59.7	0.0	1.5	+0.3	1.5
ARKRAY Adams not specified/other	13	44.5	+0.5	3.3	13	60.7	+1.0	3.5	+0.7	3.4
Beckman Coulter AU series	53	43.7	-0.3	4.6	53	58.9	-0.8	4.1	-0.6	4.4
Beckman Coulter Unicel DxC series	9	43.8	-0.2	4.1	9	59.8	+0.1	3.0	-0.1	3.5
Bio-Rad D-10 series	83	44.9	+0.9	4.0	83	60.5	+0.8	3.3	+0.8	3.6
Bio-Rad D-100 series	88	42.6	-1.4	2.6	88	58.0	-1.7	2.3	-1.6	2.5
Bio-Rad Variant series	70	44.0	0.0	4.7	71	59.1	-0.6	3.6	-0.3	4.2
Bio-Rad not specified/other	18	44.5	+0.5	4.2	18	60.2	+0.5	3.7	+0.5	4.0
EKF Diagnostics	21	45.1	+1.1	5.5	21	61.5	+1.8	4.2	+1.4	4.8
HemoCue HbA1c 501	13	43.8	-0.2	6.4	13	60.5	+0.8	5.2	+0.3	5.8
Menarini HbNEXT	29	44.0	0.0	4.2	29	60.6	+0.9	4.6	+0.4	4.4
Roche Diagnostics cobas b 101	22	42.5	-1.5	3.8	22	59.2	-0.5	3.5	-1.0	3.7
Roche Diagnostics cobas c 111/311	11	44.0	0.0	2.1	11	60.8	+1.1	2.2	+0.6	2.1
Roche Diagnostics cobas c 303/503	147	44.9	+0.9	2.4	147	61.3	+1.6	2.7	+1.3	2.5
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	248	43.9	-0.1	3.3	248	60.4	+0.7	3.4	+0.3	3.4
Roche Diagnostics cobas c 513	86	44.3	+0.3	2.2	86	60.2	+0.5	2.2	+0.4	2.2
Roche Diagnostics cobas Integra	53	42.9	-1.1	4.8	54	60.7	+1.0	3.9	0.0	4.3
Roche Diagnostics not specified/other	35	43.8	-0.2	3.4	36	60.6	+0.9	3.7	+0.3	3.5
Sebia CAPILLARYS 2	55	42.8	-1.2	3.3	55	58.2	-1.5	3.0	-1.3	3.2
Sebia CAPILLARYS 3	157	43.0	-1.0	2.7	157	58.4	-1.3	2.8	-1.2	2.7
Sebia MINICAP	12	44.4	+0.4	5.6	12	58.5	-1.2	4.5	-0.4	5.1
Siemens Advia (enzymatic)	6	42.6	-1.4	4.7	5	59.2	-0.5	2.9	-0.9	3.8
Siemens Atellica CH (enzymatic)	41	42.3	-1.7	2.7	41	58.0	-1.7	3.0	-1.7	2.9
Siemens DCA 2000/Vantage	161	44.3	+0.3	4.7	159	59.9	+0.2	4.9	+0.3	4.8
Siemens Dimension EXL series	32	43.4	-0.6	3.7	32	58.3	-1.4	3.1	-1.0	3.4
Siemens not specified/other	29	43.2	-0.8	3.5	29	58.3	-1.4	3.2	-1.1	3.3
Tosoh G7	9	45.0	+1.0	3.1	10	59.9	+0.2	4.4	+0.6	3.8
Tosoh G8	194	45.2	+1.2	2.6	195	60.4	+0.7	2.4	+0.9	2.5
Tosoh G11	253	45.1	+1.1	1.9	253	60.2	+0.5	1.8	+0.8	1.9
Tosoh GX	14	45.6	+1.6	3.0	14	60.6	+0.9	4.2	+1.3	3.6
Tosoh not specified/other	18	45.2	+1.2	3.8	19	61.1	+1.4	5.8	+1.3	4.8
Trinity Biotech Premier Hb9210	26	44.6	+0.6	3.5	26	60.9	+1.2	2.9	+0.9	3.2
Not specified/other	42	43.2	-0.8	6.7	41	58.7	-1.0	6.4	-0.9	6.6

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

Manufacturer/Method	EurA1c 2023-1 Target 44.0 mmol/mol				EurA1c 2023-2 Target 59.7 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott not specified/other	5	45.1	+1.1	3.9	5	59.4	-0.3	6.3	0.4	5.1
ARKRAY Adams HA-8380 series	2	47.0	+3.0	0.0	2	63.0	+3.3	0.0	+3.2	0.0
Boditech AFIAS series	4	43.7	-0.3	4.8	4	56.6	-3.1	3.9	-1.7	4.3
Erba not specified/other	3	42.2	-1.8	2.5	3	57.7	-2.0	0.8	-1.9	1.6
Eurolyser	1	41.0	-3.0		1	57.4	-2.3		-2.7	
Hitado	4	42.8	-1.2	8.5	4	58.5	-1.2	11.9	-1.2	10.2
Horiba Pentra	3	45.6	+1.6	1.9	3	60.2	+0.5	1.9	+1.1	1.9
Lifotronic	1	43.1	-0.9		1	60.6	+0.9		0.0	
Menarini HA-8160 series (Lifotronic reagent)	1	40.0	-4.0		1	57.0	-2.7		-3.4	
Menarini HA-8180 series (Lifotronic reagent)	2	44.7	+0.6	1.1	1	60.7	+1.0		+0.8	
Menarini not specified/other					1	52.9	-6.8		-6.8	
Mindray not specified/other	4	44.0	0.0	0.0	4	59.7	0.0	2.0	0.0	1.0
Ortho Clinical Diagnostics Vitros series	1	42.1	-1.9							
Sebia not specified/other	5	42.8	-1.2	1.0	5	57.8	-1.9	2.3	-1.6	1.7
Siemens Dimension Vista series	1	46.0	+2.0		1	61.0	+1.3		+1.7	
Sysmex not specified/other	1	45.9	+1.9		1	60.9	+1.2		+1.6	
Thermo Fisher Scientific	1	49.4	+5.4		1	62.4	+2.7		+4.1	
Thermo Fisher Scientific/Konelab	4	44.8	+0.8	11.0	4	58.5	-1.2	7.5	-0.2	9.3

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

Manufacturer/Method/EQA	n	EurA1c 2023-1 Target 44.0 mmol/mol		EurA1c 2023-2 Target 59.7 mmol/mol		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
<b>Abbott Alinity</b>							
Overall	41	-1.7	4.2	-1.7	3.3	-1.7	3.7
BE-Sciensano	6	-1.3	1.9	-1.6	1.5	-1.4	1.7
DE-INSTAND	9	-1.6	4.6	-1.2	5.2	-1.4	4.9
DE-RfB	14	-2.6	4.3	-2.7	1.8	-2.6	3.0
<b>Abbott ARCHITECT (enzymatic)</b>							
Overall	45	-2.2	2.7	-2.5	3.3	-2.4	3.0
DE-INSTAND	17	-2.1	2.4	-2.1	2.3	-2.1	2.4
DE-RfB	17	-2.0	1.7	-2.3	2.0	-2.2	1.9
<b>Abbott/Alere Afinion</b>							
Overall	130	-1.5	3.2	-1.7	2.7	-1.6	3.0
CH-CSCQ	7	-1.9	2.6	-2.2	2.8	-2.0	2.7
DE-INSTAND	56	-1.7	3.5	-1.8	2.9	-1.8	3.2
DE-RfB	17	-1.4	2.5	-2.3	1.7	-1.8	2.1
IE-IEQAS	13	-0.7	2.4	-1.2	3.4	-1.0	2.9
NL-SKML	19	-1.8	3.8	-1.1	2.9	-1.5	3.3
UK-Wegas	16	-1.4	2.6	-1.9	2.0	-1.7	2.3
<b>ARKRAY ADAMS HA-8180 series</b>							
Overall	201	-0.2	3.3	-0.4	3.2	-0.3	3.3
BE-Sciensano	24	-0.6	2.6	-1.3	2.8	-0.9	2.7
CZ-SEKK	39	+0.3	3.1	+0.8	2.9	+0.6	3.0
DE-INSTAND	30	-0.4	2.7	-0.6	3.1	-0.5	2.9
DE-RfB	28	0.0	3.1	-0.3	2.9	-0.2	3.0
ES-SEQC <sup>ML</sup>	16	+0.4	3.5	0.0	3.3	+0.2	3.4
HU-QualiCont	23	-0.8	3.6	-1.0	3.9	-0.9	3.7
IE-IEQAS	9	-0.1	2.1	-0.3	1.7	-0.2	1.9
IT-CRRVEQ	7	-2.5	6.9	-2.1	3.4	-2.3	5.2
NL-SKML	15	-0.1	2.7	-1.2	2.3	-0.7	2.5
UK-Wegas	9	-0.3	1.6	-0.6	1.6	-0.5	1.6
<b>ARKRAY Adams HA-8190 series</b>							
Overall	28	+0.5	1.5	0.0	1.5	+0.3	1.5
ES-SEQC <sup>ML</sup>	13	+0.2	1.6	-0.2	1.5	0.0	1.5
IE-IEQAS	6	+0.5	1.2	-0.3	1.0	+0.1	1.1
<b>Beckman Coulter AU series</b>							
Overall	53	-0.3	4.6	-0.8	4.1	-0.6	4.4
DE-INSTAND	15	-1.0	3.1	-1.4	3.1	-1.2	3.1
DE-RfB	26	0.0	2.8	-0.2	2.7	-0.1	2.7
<b>Bio-Rad D-10 series</b>							
Overall	83	+0.9	4.0	+0.8	3.3	+0.8	3.6
CZ-SEKK	22	+1.5	3.0	+1.1	3.0	+1.3	3.0
DE-INSTAND	22	+0.8	3.1	+1.0	2.8	+0.9	2.9
DE-RfB	24	+0.8	4.1	+0.5	3.2	+0.7	3.7
FR-CTCB	6	-1.4	5.8	-0.9	4.0	-1.1	4.9
<b>Bio-Rad D-100 series</b>							
Overall	88	-1.4	2.6	-1.7	2.3	-1.6	2.5
BE-Sciensano	7	-1.1	2.0	-1.8	1.7	-1.5	1.9
DE-INSTAND	17	-1.2	2.5	-1.4	1.6	-1.3	2.1
DE-RfB	32	-1.6	1.8	-2.0	1.9	-1.8	1.9
ES-SEQC <sup>ML</sup>	19	-1.5	2.2	-2.0	2.4	-1.7	2.3
<b>Bio-Rad Variant series</b>							
Overall	70	0.0	4.7	-0.6	3.6	-0.3	4.2
DE-INSTAND	16	-0.2	2.7	-1.5	2.5	-0.8	2.6
DE-RfB	36	+0.4	3.4	-0.3	3.2	0.0	3.3
HU-QualiCont	6	-0.5	9.9	+0.1	6.3	-0.2	8.1



Manufacturer/Method/EQA	n	EurA1c 2023-1 Target 44.0 mmol/mol		EurA1c 2023-2 Target 59.7 mmol/mol		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
<b>Roche Diagnostics cobas c 303/503</b>							
Overall	147	+0.9	2.4	+1.6	2.7	+1.3	2.5
DE-INSTAND	50	+0.8	2.5	+1.5	2.5	+1.2	2.5
DE-RfB	80	+1.0	2.3	+1.7	2.9	+1.4	2.6
NL-SKML	11	+0.3	1.7	+1.0	1.7	+0.6	1.7
<b>Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)</b>							
Overall	248	-0.1	3.3	+0.7	3.4	+0.3	3.4
CH-CSCQ	12	-0.3	4.7	+0.6	2.9	+0.2	3.8
DE-INSTAND	90	0.0	2.9	+0.8	2.6	+0.4	2.7
DE-RfB	110	-0.1	3.6	+0.3	4.1	+0.1	3.8
ES-SEQC <sup>ML</sup>	6	-0.2	3.1	+1.7	2.3	+0.8	2.7
IT-CRRVEQ	10	-0.5	2.9	+0.3	4.2	-0.1	3.6
NL-SKML	10	+0.3	3.1	+1.9	2.9	+1.1	3.0
<b>Roche Diagnostics cobas c 513</b>							
Overall	86	+0.3	2.2	+0.5	2.2	+0.4	2.2
DE-INSTAND	22	+0.2	1.9	+0.3	2.1	+0.2	2.0
DE-RfB	55	+0.5	2.2	+0.8	2.2	+0.6	2.2
<b>Roche Diagnostics cobas Integra</b>							
Overall	53	-1.1	4.8	+1.0	3.9	0.0	4.3
DE-INSTAND	21	-1.6	3.8	+0.4	3.5	-0.6	3.7
DE-RfB	25	-0.7	5.5	+1.4	4.3	+0.3	4.9
<b>Sebia CAPILLARYS 2</b>							
Overall	55	-1.2	3.3	-1.5	3.0	-1.3	3.2
BE-Sciensano	7	-0.9	4.7	-1.2	4.2	-1.0	4.5
DE-RfB	12	-0.8	2.1	-0.9	2.3	-0.8	2.2
FR-CTCB	11	-1.6	2.6	-2.4	1.8	-2.0	2.2
IT-CRRVEQ	11	-1.0	3.9	-1.5	4.0	-1.3	3.9
<b>Sebia CAPILLARYS 3</b>							
Overall	157	-1.0	2.7	-1.3	2.8	-1.2	2.7
BE-Sciensano	18	-0.8	1.5	-0.8	2.4	-0.8	2.0
DE-INSTAND	14	-1.1	2.4	-2.5	2.4	-1.8	2.4
DE-RfB	47	-0.9	2.6	-1.6	2.2	-1.2	2.4
ES-SEQC <sup>ML</sup>	11	-0.6	2.6	-1.0	2.2	-0.8	2.4
FR-CTCB	35	-1.4	2.5	-1.3	2.6	-1.3	2.6
IT-CRB	6	-1.2	2.7	-2.4	4.6	-1.8	3.7
IT-CRRVEQ	12	-0.8	4.7	-0.2	4.0	-0.5	4.4
NL-SKML	7	-0.6	1.8	-0.3	3.2	-0.5	2.5
UK-Wegas	6	-0.7	1.9	-1.2	2.4	-0.9	2.1
<b>Siemens Atellica CH (enzymatic)</b>							
Overall	41	-1.7	2.7	-1.7	3.0	-1.7	2.9
DE-INSTAND	9	-1.3	5.0	-1.8	6.3	-1.6	5.6
DE-RfB	18	-1.6	1.1	-1.6	1.4	-1.6	1.2
NL-SKML	6	-1.9	2.5	-2.1	0.9	-2.0	1.7
<b>Siemens DCA 2000/Vantage</b>							
Overall	161	+0.3	4.7	+0.2	4.9	+0.3	4.8
DE-INSTAND	46	0.0	5.8	0.0	5.2	0.0	5.5
DE-RfB	29	+0.2	4.6	-0.5	5.4	-0.1	5.0
IE-IEQAS	22	+1.2	4.6	+1.0	4.2	+1.1	4.4
NL-SKML	14	+0.7	4.0	0.0	5.8	+0.4	4.9
UK-Wegas	42	+0.4	3.9	+0.7	4.1	+0.6	4.0
<b>Tosoh G8</b>							
Overall	194	+1.2	2.6	+0.7	2.4	+0.9	2.5
BE-Sciensano	24	+1.1	1.6	+0.9	1.9	+1.0	1.7
CZ-SEKK	25	+1.4	2.6	+1.0	2.3	+1.2	2.5
DE-INSTAND	22	+0.8	3.5	0.0	2.5	+0.4	3.0
DE-RfB	27	+0.7	2.1	+0.1	1.7	+0.4	1.9
ES-SEQC <sup>ML</sup>	11	+0.4	1.1	+1.0	2.4	+0.7	1.7
FR-CTCB	9	+1.7	2.0	+1.5	3.0	+1.6	2.5
IT-CRRVEQ	32	+1.4	2.3	+1.2	1.9	+1.3	2.1
NL-SKML	18	+1.3	2.8	+0.6	2.0	+1.0	2.4
UK-Wegas	19	+1.4	3.0	+0.7	2.8	+1.0	2.9

Manufacturer/Method/EQA	n	EurA1c 2023-1 Target 44.0 mmol/mol		EurA1c 2023-2 Target 59.7 mmol/mol		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Tosoh G11							
Overall	253	+1.1	1.9	+0.5	1.8	+0.8	1.9
BE-Sciensano	17	+1.0	1.6	+0.1	1.2	+0.6	1.4
DE-INSTAND	28	+1.0	1.9	+0.2	2.0	+0.6	1.9
DE-RfB	84	+1.2	1.9	+0.6	1.9	+0.9	1.9
ES-SEQC <sup>ML</sup>	29	+0.9	1.6	+0.7	1.3	+0.8	1.4
FR-CTCB	13	+0.8	1.5	+0.6	1.7	+0.7	1.6
IT-CRRVEQ	22	+0.9	2.7	+0.5	1.8	+0.7	2.2
NL-SKML	16	+0.9	1.4	+0.2	1.4	+0.6	1.4
UK-Wegas	29	+1.0	1.7	+0.2	1.5	+0.6	1.6
Trinity Biotech Premier Hb9210							
Overall	26	+0.6	3.5	+1.2	2.9	+0.9	3.2
IT-CRB	8	+0.5	2.1	+1.4	1.8	+1.0	2.0
UK-Wegas	12	+0.5	3.9	+0.7	3.3	+0.6	3.6

### 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 2023-1 Target 44.0 mmol/mol				EurA1c 2023-2 Target 59.7 mmol/mol				Mean 2 Samples	
		n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Austria	ÖQUASTA	108	41.2	-2.8	5.5	108	57.8	-1.9	4.8	-2.3	5.1
Czech Republic	SEKK	164	43.7	-0.3	4.3	165	60.1	+0.4	4.4	+0.1	4.4
France	Asqualab	24	44.4	+0.4	6.8	24	61.7	+2.0	4.4	+1.2	5.6
France	CTCB	141	43.4	-0.6	5.0	142	59.8	+0.1	4.6	-0.2	4.8
France	ProBioQual	558	43.5	-0.5	7.2	558	59.9	+0.2	6.1	-0.2	6.7
Greece	ESEAP	108	43.1	-0.9	6.2	110	60.2	+0.5	5.4	-0.2	5.8
International*	ERL	35	43.5	-0.5	6.8	37	59.5	-0.2	4.7	-0.4	5.8
Italy	CRB	32	44.6	+0.6	1.9	32	61.0	1.3	3.9	+0.9	4.1
Korea	Kor Ass. EQAS	74	43.3	-0.7	3.2	73	59.4	-0.3	3.0	-0.5	3.1
Mexico	Labs Biom Panuco	16	44.3	+0.3	5.1	16	61.5	+1.8	6.5	+1.1	5.8
Portugal	PNAEQ-INSA	41	43.7	-0.3	5.4	41	60.7	+1.0	5.1	+0.4	5.2
South Africa	NHLS	6	43.7	-0.3	3.4	6	60.5	+0.8	4.9	+0.2	4.2
Thailand	NIH	160	43.5	-0.5	7.9	161	60.9	+1.2	7.4	+0.4	7.7
Turkey	TUBITAK UME	45	43.8	-0.2	6.4	45	60.1	+0.4	7.3	+0.1	6.9
Vietnam	QCC	17	45.0	+1.0	4.9	17	63.1	+3.4	3.5	+2.2	4.2
Overall		1529	43.4	-0.6	6.5	1535	60.0	+0.3	5.8	-0.2	6.1

\* Individual laboratories of a number of countries

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

Manufacturer/Method	EurA1c 2023-1 Target 44.0 mmol/mol				EurA1c 2023-2 Target 59.7 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	37	40.8	-3.2	5.0	37	57.1	-2.6	4.4	-2.9	4.7
Abbott ARCHITECT (enzymatic)	46	40.3	-3.7	6.3	48	57.0	-2.7	5.4	-3.2	5.8
ARKRAY Adams HA-8180 series	44	41.5	-2.5	4.6	44	57.0	-2.7	4.5	-2.6	4.6
ARKRAY Adams HA-8190 series	7	42.1	-1.9	0.0	7	57.8	-1.9	1.5	-1.9	0.7
ARKRAY Adams HA-8380 series	6	41.9	-2.1	6.5	6	57.5	-2.2	6.4	-2.1	6.4
ARKRAY Adams not specified/other	33	42.3	-1.7	3.0	33	58.0	-1.7	3.2	-1.7	3.1
Beckman Coulter AU series	14	44.8	+0.8	7.9	13	61.7	+2.0	9.5	+1.4	8.7
Bio-Rad D-10 series	62	43.2	-0.8	3.5	65	59.8	+0.1	4.0	-0.3	3.8
Bio-Rad D-100 series	72	42.2	-1.8	2.8	71	58.6	-1.1	1.8	-1.5	2.3
Bio-Rad Variant series	52	42.6	-1.4	7.8	52	57.4	-2.3	6.6	-1.9	7.2
Bio-Rad not specified/other	33	43.6	-0.4	4.8	34	60.6	+0.9	5.3	+0.3	5.0
Lifotronic	12	43.4	-0.6	4.7	12	58.6	-1.1	5.9	-0.8	5.3
Menarini HbNEXT	27	41.6	-2.4	5.8	29	58.1	-1.6	4.8	-2.0	5.3
Mindray bs series	16	42.1	-1.9	6.2	16	59.7	0.0	7.1	-0.9	6.7
Ortho Clinical Diagnostics Vitros series	9	38.8	-5.2	13.6	9	54.5	-5.2	11.6	-5.2	12.6
Roche Diagnostics cobas c 111/311	11	42.8	-1.2	8.9	11	62.7	+3.0	5.8	+0.9	7.4
Roche Diagnostics cobas c 303/503	58	46.7	+2.7	5.4	59	64.6	+4.9	3.9	+3.8	4.7
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)	125	44.3	+0.3	5.8	126	62.3	+2.6	4.2	+1.4	5.0
Roche Diagnostics cobas c 513	20	45.5	+1.5	4.5	20	63.1	+3.4	4.4	+2.4	4.4
Roche Diagnostics cobas Integra	20	43.9	-0.1	6.6	21	62.9	+3.2	5.2	+1.5	5.9
Roche Diagnostics not specified/other	53	42.9	-1.1	9.5	52	62.3	+2.6	6.3	+0.7	7.9
Sebia CAPILLARYS 2	78	42.6	-1.4	3.2	77	58.8	-0.9	2.6	-1.2	2.9
Sebia CAPILLARYS 3	201	42.8	-1.2	2.9	199	59.0	-0.7	2.1	-1.0	2.5
Sebia MINICAP	14	42.3	-1.7	1.7	15	59.3	-0.4	3.0	-1.1	2.4
Siemens Atellica CH (enzymatic)	17	41.6	-2.4	7.0	17	58.1	-1.6	5.1	-2.0	6.1
Siemens DCA 2000/Vantage	37	51.0	+7.0	5.3	41	68.1	+8.4	5.0	+7.7	5.2
Siemens Dimension EXL series	13	44.8	+0.8	5.1	13	62.2	+2.5	5.3	+1.7	5.2
Tosoh G8	127	43.8	-0.2	3.6	128	59.7	0.0	3.5	-0.1	3.6
Tosoh G11	137	44.0	0.0	3.2	132	59.8	+0.1	2.8	+0.1	3.0
Tosoh GX	19	43.4	-0.6	2.2	21	59.6	-0.1	3.2	-0.3	2.7
Tosoh not specified/other	41	44.6	+0.6	3.1	41	60.8	+1.1	2.6	+0.9	2.9
Trinity Biotech Premier Hb9210	10	44.7	+0.7	6.2	11	62.7	+3.0	4.1	+1.9	5.2
Not specified/other	37	43.7	-0.3	7.3	35	60.2	+0.5	6.9	0.1	7.1

For Siemens DCA/Vantage it is known that there is a positive matrix effect for lyophilised samples, for Abbott, 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/Method	EurA1c 2023-1 Target 44.0 mmol/mol				EurA1c 2023-2 Target 59.7 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Aeroset multigent	1	43.0	-1.0		1	63.0	3.3		1.2	
Abbott not specified/other	3	42.7	-1.3	3.6	2	57.0	-2.7	2.5	-2.0	3.0
ARKRAY Adams HA-8160 series	3	43.3	-0.7	2.7	3	59.3	-0.4	1.9	-0.5	2.3
Beckman Coulter P/ACE MDQ					1	65.0	5.3		5.3	
Beckman Coulter Unicel DxC series	1	43.0	-1.0		1	61.0	1.3		0.1	
Beckman Coulter not specified/other	3	46.1	2.1	5.9	3	62.1	2.4	4.4	2.3	5.1
BioMajesty JCA-BM6010	5	43.1	-0.9	14.8	5	61.4	1.7	12.8	0.4	13.8
Boditech AFIAS Series	1	40.2	-3.8		1	49.9	-9.8		-6.8	
Erba XL series	2	45.4	1.4	10.2	2	61.8	2.1	12.5	1.7	11.4
Erba not specified/other	1	47.0	3.0		1	66.4	6.7		4.9	
Medconn MQ-2000PT	2	43.2	-0.8	3.6	2	59.0	-0.7	1.3	-0.8	2.4
Osang Clover A1c	1	42.1	-1.9		1	61.8	2.1		0.1	
Roche Diagnostics cobas b 101	4	38.8	-5.3	3.9	4	55.5	-4.2	4.3	-4.7	4.1
Sebia not specified/other	5	41.2	-2.8	2.7	5	58.1	-1.6	2.0	-2.2	2.3
Siemens Dimension Vista series	2	40.9	-3.1	7.3	2	58.4	-1.4	5.7	-2.2	6.5
Sysmex bx series	2	40.3	-3.7	2.7	2	56.5	-3.2	1.9	-3.4	2.3
Thermo Fisher Scientific	1	53.0	9.0		1	67.2	7.5		8.3	
Tosoh G7	4	44.5	0.5	5.3	3	60.7	1.0	4.8	0.7	5.1

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 2023-1 Target 44.0 mmol/mol		EurA1c 2023-2 Target 59.7 mmol/mol		Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
Abbott Alinity							
Overall	37	-3.2	5.0	-2.6	4.4	-2.9	4.7
AT-ÖQUASTA	7	-5.0	4.2	-4.7	2.6	-4.9	3.4
FR-ProBioQual	10	-1.0	2.6	-0.1	2.3	-0.5	2.5
GR-ESEAP	7	-3.0	2.4	-2.3	3.4	-2.7	2.9
TH-NIH	6	-5.4	2.8	-5.3	2.7	-5.3	2.8
Abbott ARCHITECT (enzymatic)							
Overall	48	-3.7	6.3	-2.7	5.4	-3.2	5.8
AT-ÖQUASTA	8	-6.0	4.4	-5.3	2.8	-5.7	3.6
FR- Probioqual	8	-2.3	4.7	-0.9	2.6	-1.6	3.7
GR-ESEAP	14	-1.8	4.0	-0.9	4.7	-1.4	4.4
TH-NIH	15	-5.0	6.1	-4.2	5.7	-4.6	5.9
ARKRAY ADAMS HA-8180 series							
Overall	44	-2.5	4.6	-2.7	4.5	-2.6	4.6
AT-ÖQUASTA	18	-3.0	3.9	-3.0	3.7	-3.0	3.8
CZ-SEKK	14	-1.6	3.9	-2.0	4.4	-1.8	4.1
Bio-Rad D-10 series							
Overall	65	-0.8	3.5	+0.1	4.0	-0.3	3.8
CZ-SEKK	9	+0.5	2.8	+1.7	1.8	+1.1	2.3
FR-CTBC	9	-0.8	3.0	-1.0	4.8	-0.9	3.9
FR-Probioqual	25	-1.1	3.1	+0.2	3.6	-0.5	3.4
MX-Labs Biom. Panuco	10	-0.6	3.6	0.0	5.1	-0.3	4.4
Bio-Rad D-100 series							
Overall	72	-1.8	2.8	-1.1	1.8	-1.5	2.3
AT-ÖQUASTA	11	-3.3	3.3	-2.6	0.9	-2.9	2.1
FR-CTCB	6	-1.0	2.5	-0.3	1.8	-0.7	2.2
FR-Probioqual	24	-1.4	2.5	-0.7	1.7	-1.1	2.1
KR-Kor Ass. EQAS	22	-1.7	1.7	-1.3	1.1	-1.5	1.4
Bio-Rad Variant series							
Overall	52	-1.4	7.8	-2.3	6.6	-1.9	7.2
FR-Probioqual	33	-2.5	8.0	-3.7	6.7	-3.1	7.4
TR-TUBITAK UME	6	+0.2	3.0	+0.3	4.3	+0.2	3.7
Menarini HbNEXT							
Overall	29	-2.4	5.8	-1.6	4.8	-2.0	5.3
GR-ESEAP	12	-3.7	3.1	-2.7	3.3	-3.2	3.2
INT*-ERL	8	-3.0	5.8	-2.8	3.3	-2.9	4.5
PT-PNAEQ-INSA	7	-1.2	3.8	-0.2	2.6	-0.7	3.2
Roche Diagnostics cobas c 303/503							
Overall	59	+2.7	5.4	+4.9	3.9	+3.8	4.7
AT-ÖQUASTA	6	+0.8	4.3	+2.0	2.4	+1.4	3.4
FR-Probioqual	24	+3.7	6.3	+5.8	5.0	+4.8	5.7
TH-NIH	21	+2.4	3.1	+4.8	2.0	+3.6	2.5
Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000)							
Overall	126	+0.3	5.8	+2.6	4.2	+1.4	5.0
AT-ÖQUASTA	26	-2.3	4.2	+0.1	2.8	-1.1	3.5
GR-ESEAP	14	+1.4	4.7	+3.6	3.8	+2.5	4.3
TH-NIH	53	+0.7	4.5	+3.1	3.7	+1.9	4.1
TR-TUBITAK UME	10	+1.5	7.0	+2.1	6.7	+1.8	6.8
VN	12	+0.4	5.3	+3.5	2.8	+2.0	4.0
Roche Diagnostics cobas Integra							
Overall	21	-0.1	6.6	+3.2	5.2	+1.5	5.9
GR-ESEAP	6	+0.8	6.0	+3.5	3.7	+2.1	4.8
TH-NIH	9	-1.8	6.9	+1.9	5.8	+0.1	6.3

Manufacturer/Method/EQA	n	EurA1c 2023-1 Target 44.0 mmol/mol		EurA1c 2023-2 Target 59.7 mmol/mol		Mean 2 Samples	
		Bias	CV%	Bias	CV%	Bias	CV%
<b>Sebia CAPILLARYS 2</b>							
Overall	78	-1.4	3.2	-0.9	2.6	-1.2	2.9
FR-CTBC	10	-1.6	2.7	-1.5	2.4	-1.5	2.6
FR-Probioqual	62	-1.5	3.4	-0.9	2.7	-1.2	3.0
<b>Sebia CAPILLARYS 3</b>							
Overall	201	-1.2	2.9	-0.7	2.1	-1.0	2.5
FR-CTBC	58	-0.8	2.7	0.0	1.8	-0.4	2.2
FR-Probioqual	127	-1.4	2.9	-1.0	1.9	-1.2	2.4
<b>Tosoh G8</b>							
Overall	128	-0.2	3.6	0.0	3.5	-0.1	3.6
AT-ÖQUASTA	11	-3.3	1.6	-3.3	1.6	-3.3	1.6
CZ-SEKK	8	+0.3	2.3	+0.7	1.5	+0.5	1.9
FR-CTCB	9	+0.3	1.7	-0.3	1.5	0.0	1.6
FR-Probioqual	64	-0.1	3.2	-0.1	3.2	-0.1	3.2
GR-ESEAP	12	-0.5	2.1	+0.6	2.6	+0.1	2.4
PT-PNAEQ-INSA	6	+0.7	3.9	+1.0	2.5	+0.8	3.2
<b>Tosoh G11</b>							
Overall	137	0.0	3.2	+0.1	2.8	0.1	3.0
FR-CTBC	12	-0.3	2.0	-0.3	1.0	-0.3	1.5
FR-Probioqual	74	+0.1	3.4	+0.4	3.4	+0.2	3.4
KR- Kor Ass. EQAS	32	-0.3	2.2	-0.1	1.7	-0.2	2.0
<b>Tosoh GX</b>							
Overall	21	-0.6	2.2	-0.1	3.2	-0.3	2.7
FR-CTBC	11	-1.1	1.7	-0.1	2.9	-0.6	2.3
FR-Probioqual	8	-0.3	2.2	-0.4	4.0	-0.3	3.1

\* Individual laboratories of a number of countries

## IV. Value Assignment (Targeting)

The samples in their respective matrices have been measured with the IFCC SRLs, and the US NGSP SRLs. Table 12 shows the results. Values of the other matrices and other methods are for comparison and information only.

Table 12. Results of Reference Measurement Procedures

Matrix	EurA1c 2023-1		EurA1c 2023-2	
	IFCC SRLs	US NGSP SRLs*	IFCC SRLs	US NGSP SRLs*
	n = 8	n = 3	n = 8	n = 3
Fresh Whole Blood	44.0	44.1	59.7	58.4
Lyophilised Hemolysate	44.0	42.7	60.6	58.9
Frozen Whole Blood	43.5	42.9	58.7	57.8

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

## V. Homogeneity

Homogeneity testing of EurA1c 2023-2 (fresh 2023-2 and lyophilised 2023-4) was performed according to ISO 13528:2015 Annex B with the ARKRAY HA-8190V (12 samples in duplicate). The results in table 13 show that the samples are homogeneous.

Table 13. Homogeneity test of EurA1c 2023

Vial	Fresh Whole Blood				Lyophilised Hemolysate			
	EurA1c 2023-2				EurA1c 2023-4			
	1	2	mean	$\Delta$	1	2	mean	$\Delta$
1	59,8	59,8	59,80	0,0	62,7	62,6	62,65	0,1
2	60,2	60,1	60,15	0,1	62,7	62,7	62,70	0,0
3	60,1	60,1	60,10	0,0	62,7	62,6	62,65	0,1
4	61,3	61,1	61,20	0,2	62,6	62,6	62,60	0,0
5	61,3	60,5	60,90	0,8	62,7	62,4	62,55	0,3
6	60,5	60,6	60,55	0,1	62,6	62,8	62,70	0,2
7	60,9	60,8	60,85	0,1	62,7	62,7	62,70	0,0
8	60,1	61,3	60,70	1,2	62,7	62,7	62,70	0,0
9	60,6	60,9	60,75	0,3	62,6	62,6	62,60	0,0
10	61,7	61,3	61,50	0,4	62,8	62,7	62,75	0,1
11	60,6	60,6	60,60	0,0	62,8	62,7	62,75	0,1
12	60,6	61,2	60,90	0,6	62,8	62,7	62,75	0,1
average			60,7				62,7	
SD		0,411	0,475	0,339		0,024	0,066	0,087
0.3 x SD <sub>RL</sub>			0,411				0,425	
Criterion			-0,001				-0,401	
<b>Homogeneity:</b>			<b>Pass</b>				<b>Pass</b>	

## 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
<b>EQA Organisers</b>		
AT	ÖQUASTA	Christoph Buchta
BE	Sciensano	Yolande Lenga
CH	CSCQ	Dagmar Kesseler, Pierre-Alain Morandi
CZ	SEKK	Marek Budina, Josef Kratochvila, Ondrej Wiewiorka
DE	INSTAND	Patricia Kaiser
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FR	CTCB	Erick Sanchez, Stéphanie Albarède, Safouane Hamdi
FR	ProBioQual	Philippe Joly, Bernard Poggi
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INT	ERL	Carla Siebelder
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IT	CRRVEQ	Massimo Quercioli, Paola Pezzati, Francesca Masi
KR	Korean Association of External Quality Assessment Service	Junghan Song, Sail Chun, Kyunghoon Lee
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TR	TUBITAK UME / Pamukkale University	Müslüm Akgöz, Diler Aslan, Gonca Altin
UK	Weqas	Annette Thomas, Samantha Jones, Gareth Davies
VN	Quality Control Center for Medical Laboratory- Hanoi Medical University	Trinh Phuong Dung
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<b>IFCC Network Laboratories</b>		
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DE	INSTAND	Patricia Kaiser
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NL	Queen Beatrix Hospital	Carla Siebelder, Sanne Leppink, Laura Reijnders
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<b>NGSP Network Laboratories</b>		
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US	University of Minnesota	Cassandra Carlson
<b>Oversight Committee (members IFCC C-EUBD)</b>		
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NL	Queen Beatrix Hospital	Eline van der Hagen
CZ	University of Prague	Jan Skrha
	Sidra, Qatar	Eric Kilpatrick
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NL	Queen Beatrix Hospital	Carla Siebelder
NL	Isala	Erna Lenters
<b>Trial Management (European Reference Laboratory, Queen Beatrix Hospital)</b>		
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