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

Report
EurA1c 2018

HbA1c Trial
EQA organisers

I	Introduction and Overview of Results……	2
II	Results EQA Fresh Whole Blood samples…….……..	5
III	Results EQA Lyophilised Hemolysate samples……...	10
IV	Value Assignment (Targeting)…….	13
V	Homogeneity…….	13
VI	Stability…….	14
VII	Organisations and Persons involved……	16

Definitive Version
19 September 2019
Cas Weykamp
Carla Siebelder

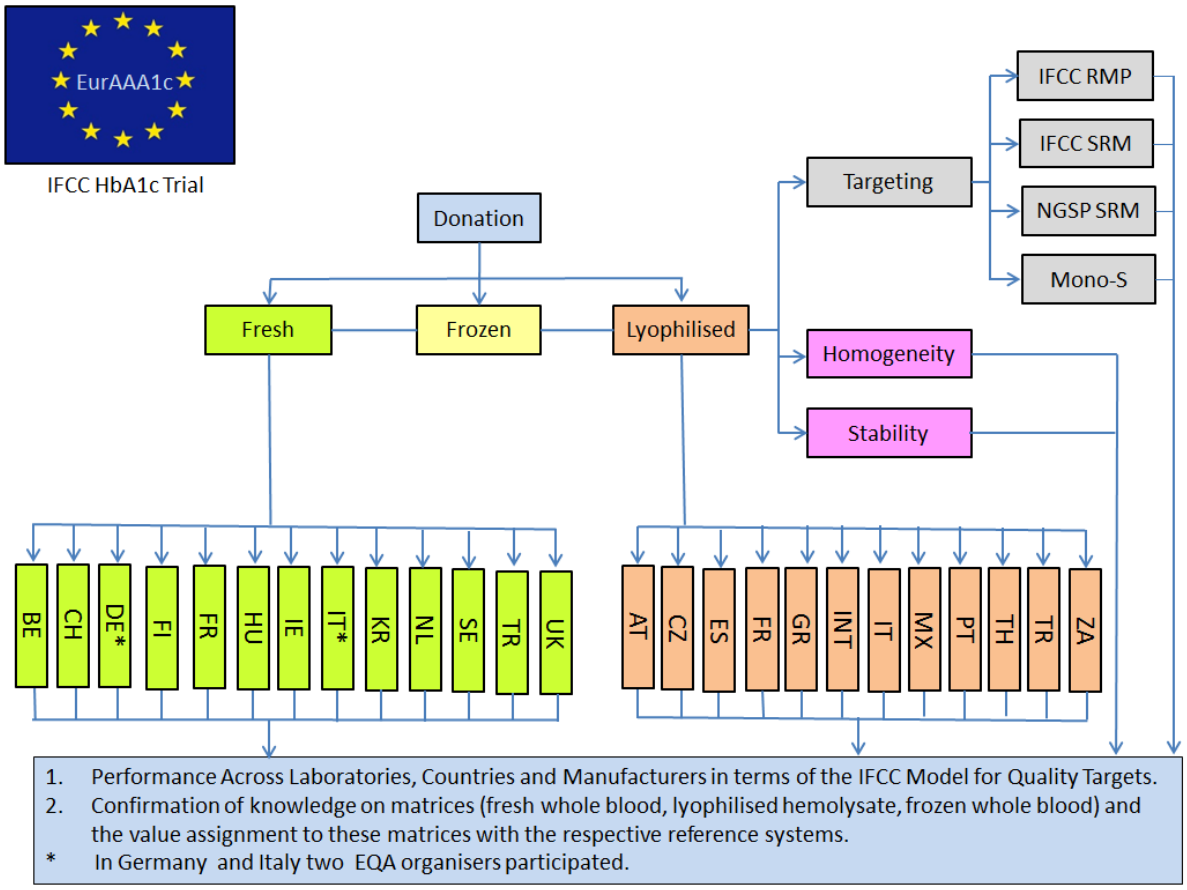
I Introduction and Overview of Results

Introduction

24 EQA organisers of 22 countries agreed to participate in the third “EurA1c” project. The design is shown in figure 1. You may notice that the logo of the project has been changed to EurAAA1c; this is to acknowledge the participation of EQA organisers in Asia, America and Africa.

15 EQA organisers used fresh whole blood samples and 13 organisers used lyophilised hemolysate samples (3 organisations used both fresh and lyophilised samples). In October 2018 the fresh whole blood samples were sent to the participants. From November 2018 up to April 2019 the lyophilised samples were assayed by the participants. This report shows all results

Figure 1. Design EurA1c Trial 2018



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:

12 July 2019:	Draft report sent to all who are involved in EurA1c 2018. At the same time the invitation to participate in EurA1c 2019 is sent.
31 August 2019:	Deadline for comments and remarks
30 September 2019:	Final report sent to all who are involved. By then all who are involved are free to share results with third parties

Value Assignment
Five Approved IFCC Network Laboratories performed the value assignment with the IFCC Reference Measurement Procedure. For EurA1c 2018-1 the assigned value is 58.1 mmol/mol (expanded uncertainty 0.9 mmol/mol) and for EurA1c 2018-2 the assigned value is 42.2 mmol/mol (expanded uncertainty 0.7 mmol/mol). The values are the target values for both fresh whole blood and lyophilised samples.

Outliers
Outliers have been removed before calculation of the mean and between laboratory CV. Instead of using statistical criteria we only considered "blunders" as outliers. The criterion used was a difference exceeding 25% of the target values. In our opinion these results are a relevant picture of "real life". In this way 43 results (0.7%) have been excluded from the database of fresh whole blood samples and 18 results (1.6%) from the database of lyophilised hemolysates.

Methods
This is a point of consideration. The definition of the methods varied per EQA organiser and for quite a number of laboratories the method was not reported at all (127 of the 2875 submitted results for fresh whole blood; 14 of 1105 for lyophilised hemolysates). In the reports you will see this reflected. It is desirable that this is improved in future trials.

Units
In some cases results were reported in NGSP units. We converted them to SI (IFCC) units using the Master Equation (NGSP = 0.0915IFCC + 2.15) prior to calculation of means, SDs and making comparisons. All results in the report are in SI units.

Summary of Results
Table 1 summarizes the results. The participating EQA organisers are ranked per country in alphabetical order. Results are given for the fresh whole blood and lyophilised hemolysate samples.

Table 1. Results of EurA1c 2018

Country	Fresh Whole Blood			Lyophilised Hemolysate		
	n*	Mean Bias in mmol/mol	Between Laboratory CV	n	Mean Bias in mmol/mol	Between Laboratory CV
Austria				140	+0.5	4.9%
Belgium	134	+0.7	3.6%			
Czech Republic				211	0.0	4.8%
Finland	364	-0.4	4.6%			
France	83	+1.1	3.6%	186	+0.8	5.6%
Germany INSTAND	658	+0.3	4.8%			
Germany RfB	693	+0.3	4.6%			
Ghana				1	+8.9	
Greece				87	+0.4	5.3%
Hungary	70	+0.2	5.7%			
International*				60	-0.1	3.8%
Ireland	34	+0.8	3.3%			
Italy CRB	60	+0.8	4.8%	54	+0.5	4.7%
Italy CRRVEQ	127	+1.2	5.1%			
Korea	49	+0.9	2.5%			
Mexico				21	-0.4	9.6%
Netherlands	127	+0.5	3.5%			
Portugal				45	+0.2	4.9%
South Africa				4	+2.0	3.6%
Spain				113	+0.4	3.8%
Sweden	130	-0.6	3.3%			
Switzerland	139	-0.3	4.1%			
Thailand				134	-0.2	8.8%
Turkey	41	+1.1	4.6%	49	+1.6	6.7%
United Kingdom	169	+0.5	4.1%			
Overall	2878	+0.3	4.6%	1105	+0.4	5.8%

** n = the number of datasets.*

In total 3983 datasets were submitted (2878 in fresh whole blood and 1105 in lyophilised hemolysate). The results are encouraging. The mean bias of all countries in the fresh whole blood programme is +0.3 mmol/mol and the between laboratory CV of 4.6% is also quite satisfying. In lyophilised hemolysate the mean bias of all laboratories is +0.4 mmol/mol and the between laboratory CV is 5.8%.

Differentiation of Results
Results are differentiated per sample and a) per country, b) per manufacturer and c) per manufacturer per country in fresh whole blood (section II), and in lyophilised hemolysates (section III)

Samples codes			
	Fresh	Lyophilised	Frozen
Low HbA1c	2018-2	2018-4	2018-6
High HbA1c	2018-1	2018-3	2018-5

II Results EQA Fresh Whole Blood samples

Table 2 shows the results per country for each sample. Tables 3 and 4 show the results per manufacturer for manufacturers with 6 or more participants (table 3) and those with 5 or less participants (table 4).

Table 2. Results per Country for Fresh Whole Blood

Country	EurA1c 2018-1 Target 58.1 mmol/mol				EurA1c 2018-2 Target 42.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Belgium	134	58.8	+0.7	3.1	134	43.0	+0.8	4.0	+0.7	3.6
Finland	364	57.5	-0.6	4.3	362	42.0	-0.2	4.8	-0.4	4.6
France	83	59.1	+1.0	3.3	83	43.3	+1.1	3.8	+1.1	3.6
Germany INSTAND	658	58.3	+0.2	4.5	653	42.7	+0.5	5.0	+0.3	4.8
Germany RfB	692	58.2	+0.1	4.3	693	42.6	+0.4	4.9	+0.3	4.6
Hungary	70	58.4	+0.3	5.7	70	42.4	+0.2	5.6	+0.2	5.7
Ireland	34	58.7	+0.6	2.9	34	43.1	+0.9	3.7	+0.8	3.3
Italy CRB	60	58.8	+0.7	5.0	58	43.1	+0.9	4.6	+0.8	4.8
Italy CRRVEQ	125	59.2	+1.1	5.1	127	43.5	+1.3	5.1	+1.2	5.1
Korea	49	58.9	+0.8	2.3	49	43.2	+1.0	2.7	+0.9	2.5
Netherlands	127	58.5	+0.4	3.0	127	42.9	+0.7	3.9	+0.5	3.5
Sweden	130	57.4	-0.7	2.9	129	41.8	-0.4	3.6	-0.6	3.3
Switzerland	139	57.6	-0.5	3.9	136	42.1	-0.1	4.2	-0.3	4.1
Turkey	41	59.2	+1.1	4.2	41	43.3	+1.1	4.9	+1.1	4.6
UK	169	58.5	+0.4	3.8	169	42.9	+0.7	4.4	+0.5	4.1
Overall	2875	58.2	+0.1	4.3	2865	42.6	+0.4	4.8	+0.3	4.6

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

Manufacturer	EurA1c 2018-1 Target 58.1 mmol/mol				EurA1c 2018-2 Target 42.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott ARCHITECT	75	57.1	-1.0	3.1	75	41.4	-0.8	3.0	-0.9	3.1
Alere Afinion	274	57.4	-0.7	3.1	269	41.6	-0.6	3.6	-0.7	3.4
Beckman Coulter AU series	58	57.6	-0.5	6.7	59	42.8	+0.6	6.9	0.0	6.8
Beckman Coulter Other	6	57.7	-0.4	2.8	6	42.8	+0.6	1.5	+0.1	2.2
Beckman Coulter Unicel DxC series	27	58.0	-0.1	3.5	27	42.1	-0.1	3.6	-0.1	3.6
Bio-Rad D-10 series	72	60.5	+2.4	5.3	72	43.9	+1.7	5.4	+2.1	5.4
Bio-Rad D-100 series	59	57.4	-0.7	3.5	59	42.1	-0.1	3.9	-0.4	3.7
Bio-Rad Other	10	60.9	+2.8	2.3	10	44.4	+2.2	4.9	+2.5	3.6
Bio-Rad Variant series	147	59.8	+1.7	4.1	148	43.1	+0.9	4.9	+1.3	4.5
Diasys InnovaStar	7	55.4	-2.7	6.7	7	41.7	-0.5	3.8	-1.6	5.3
HemoCue HbA1c 501	38	56.4	-1.7	7.0	38	41.2	-1.0	8.0	-1.4	7.5
Medinor NycoCard	9	59.4	+1.3	8.6	9	45.7	+3.5	7.6	+2.4	8.1
Menarini (ARKRAY) HA-8160 series	82	58.3	+0.2	3.8	81	42.2	0.0	3.8	+0.1	3.8
Menarini (ARKRAY) HA-8180 series	144	58.8	+0.7	2.8	144	43.0	+0.8	3.0	+0.7	2.9
Menarini Other	6	57.7	-0.4	3.6	6	42.2	0.0	5.1	-0.2	4.4
Not Known	127	57.9	-0.2	6.4	124	42.7	+0.5	6.0	+0.1	6.2
Roche Diagnostics	597	58.1	0.0	3.6	598	42.0	-0.2	4.0	-0.1	3.8
SEBIA Capillarys 2 flex-piercing	103	58.2	+0.1	2.6	102	42.4	+0.2	3.2	+0.1	2.9
SEBIA Capillarys 3 Tera	26	58.2	+0.1	1.9	26	42.4	+0.2	2.1	+0.1	2.0
SEBIA Minicap flex-piercing	17	57.7	-0.4	4.1	17	41.6	-0.6	3.0	-0.5	3.6
Siemens Advia series	21	60.3	+2.2	7.3	20	43.9	+1.7	7.8	+2.0	7.6
Siemens DCA 2000/Vantage	322	57.2	-0.9	3.5	321	41.8	-0.4	3.8	-0.7	3.7
Siemens Dimension series	93	57.3	-0.8	3.8	93	44.2	+2.0	5.3	+0.6	4.6
Thermo Scientific	17	58.1	0.0	5.5	17	43.3	+1.1	6.5	+0.5	6.0
TOSOH G7	23	59.5	+1.4	5.2	24	43.9	+1.7	4.4	+1.6	4.8
TOSOH G8	351	59.7	+1.6	2.9	349	44.3	+2.1	2.7	+1.9	2.8
TOSOH G11	75	59.2	+1.1	1.8	76	43.6	+1.4	2.1	+1.3	2.0
Trinity Biotech Premier Hb9210	38	59.7	+1.6	3.0	37	43.2	+1.0	4.0	+1.3	3.5

The results in tables 2 and 3 are consistent: for each of the samples low (nearly always positive) biases are seen per country and per manufacturer.
Also quite acceptable are the between laboratory CVs. Unfortunately quite a number (n=127) laboratories did not specify their method. These laboratories are in the group “Not Known”.

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

Manufacturer	EurA1c 2018-1 Target 58.1 mmol/mol				EurA1c 2018-2 Target 42.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	1	57.1	-1.0		1	42.3	+0.1		-0.5	
Abbott AxSym	2	60.9	+2.8	4.5	2	43.2	+1.0	7.1	+1.9	5.8
Beckman Coulter P / ACE MDQ	2	58.1	0.0	3.8	2	43.5	+1.3	2.6	+0.6	3.2
Boditech	1	50.8	-7.3		1	35.5	-6.7		-7.0	
DIAGON	1	59.5	+1.4		1	44.0	+1.8		+1.6	
Dialab Prestige-24	1	60.5	+2.4		1	41.0	-1.2		+0.6	
EKF Diagnostics	5	58.3	+0.2	1.1	5	43.3	+1.1	1.8	+0.6	1.5
Eurolyser Smart 700/340	3	53.0	-5.1	5.5	3	39.5	-2.7	4.3	-3.9	4.9
EuroMedix	1	56.3	-1.8		1	43.2	+1.0		-0.4	
Hitado	5	50.7	-7.4	4.5	5	40.3	-1.9	6.3	-4.7	5.4
Horiba Pentra	4	56.6	-1.5	3.3	4	42.4	+0.2	3.3	-0.7	3.3
HumaNex A1c HUMAN	1	54.1	-4.0		1	37.7	-4.5		-4.3	
IL/Werfen	1	65.0	+6.9		1	47.0	+4.8		+5.9	
ISE S.r.l. Hemo One ISE HbA1c	1	57.1	-1.0		1	42.7	+0.5		-0.3	
KONE LAB/SIEMENS	1	55.0	-3.1		1	39.0	-3.2		-3.2	
Menarini (ARKRAY) HA-8140 series	1	58.0	-0.1		1	43.0	+0.8		+0.3	
Mindray	1	50.8	-7.3		1	43.1	+0.9		-3.2	
Mono-S	1	56.2	-1.9		1	42.2	0.0		-0.9	
MTD Diagnostics	4	54.5	-3.6	7.8	4	40.7	-1.5	9.3	-2.6	8.6
Nihon Koh.	1	55.2	-2.9		1	42.1	-0.1		-1.5	
Randox	2	55.1	-3.0	4.1	2	38.2	-4.0	4.5	-3.5	4.3
Shimadzu	1	56.7	-1.4		1	42.0	-0.2		-0.8	
Siemens Atellica CH	1	58.5	+0.4		1	44.3	+2.1		+1.3	
Siemens Other	1	57.0	-1.1		1	43.0	+0.8		-0.2	
SmartTester	1	58.3	+0.2		1	42.4	+0.2		+0.2	
Sysmex	1	61.0	+2.9		1	44.0	+1.8		+2.4	
THERMO FISHER Konelab Prime 60iA	1	59.0	+0.9		1	44.0	+1.8		+1.4	
TOSOH GX	5	60.6	+2.5	2.2	5	44.6	+2.4	2.0	+2.5	2.1

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

Table 5. Fresh Whole Blood Results per Manufacturer and Country (n>5)

Method	n	HbA1c High (2018-1)		HbA1c Low (2018-2)		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Abbott ARCHITECT							
Overall	75	-1.0	3.1	-0.8	3.0	-0.9	3.1
CH	6	-1.4	2.0	-1.2	2.4	-1.3	2.2
FR	11	-0.7	2.1	-0.6	3.2	-0.7	2.7
DE-INSTAND	16	-1.0	1.2	-1.2	2.0	-1.1	1.6
DE-RfB	23	-1.5	3.4	-0.8	3.3	-1.2	3.4
FI	7	-1.0	1.6	-0.8	1.8	-0.9	1.7
Alere Afinion							
Overall	274	-0.7	3.1	-0.6	3.6	-0.7	3.4
CH	56	+0.2	2.9	0.0	3.3	+0.1	3.1
DE-INSTAND	43	+0.2	3.1	+0.1	3.5	+0.1	3.3
FI	112	-1.2	2.8	-0.9	3.1	-1.1	3.0
NL	9	-1.5	2.5	-0.9	3.6	-1.2	3.1
SE	39	-1.4	2.4	-1.4	3.0	-1.4	2.7
UK	6	-2.4	1.5	-1.0	5.0	-1.7	3.3
Beckman Coulter AU series							
Overall	58	-0.5	6.7	+0.6	6.9	0.0	6.8
DE-INSTAND	25	-0.5	5.8	+0.4	6.1	-0.1	6.0
DE-RfB	25	-0.3	6.7	+0.8	6.0	+0.2	6.4
Beckman Coulter Unicel DxC series							
Overall	27	-0.1	3.5	-0.1	3.6	-0.1	3.6
DE-INSTAND	10	-1.0	2.5	-0.4	2.0	-0.7	2.3
DE-RfB	14	+0.2	3.1	-0.1	4.3	0.0	3.7
Bio-Rad D-10 series							
Overall	72	+2.4	5.3	+1.7	5.4	+2.1	5.4
DE-INSTAND	24	+2.8	5.2	+2.5	4.3	+2.7	4.8
DE-RfB	28	+1.9	6.5	+0.9	6.9	+1.4	6.7
Bio-Rad D-100 series							
Overall	59	-0.7	3.5	-0.3	4.6	-0.5	4.1
BE	6	-0.7	3.2	-0.3	3.4	-0.5	3.3
DE-INSTAND	9	-0.2	1.7	-0.3	1.8	-0.3	1.8
DE-RfB	19	-0.8	1.6	+0.1	5.3	-0.4	3.5
KR	15	-0.2	2.1	+0.2	2.1	0.0	2.1
Bio-Rad Variant series							
Overall	147	+1.7	4.1	+0.9	4.9	+1.3	4.5
DE-INSTAND	24	+2.0	3.2	+1.3	3.7	+1.7	3.5
DE-RfB	52	+0.9	4.6	+0.2	6.2	+0.5	5.4
FR	9	+2.7	2.9	+1.9	3.1	+2.3	3.0
HU	7	+1.6	7.8	+1.7	3.8	+1.7	5.8
IT-CRRVEQ	21	+2.5	3.9	+1.1	4.9	+1.8	4.4
SE	8	+1.4	0.8	+1.2	1.4	+1.3	1.1
TR	11	+2.2	2.6	+1.3	3.3	+1.8	3.0
Menarini (ARKRAY) HA-8160 series							
Overall	82	+0.2	3.8	0.0	3.8	+0.1	3.8
BE	22	+0.5	3	+0.1	3.1	+0.3	3.1
HU	18	0.0	5.7	-0.4	5.1	-0.2	5.4
IT-CRB	11	-0.7	4.7	-0.3	4.6	-0.5	4.7
NL	13	+0.4	2.7	+0.5	3.5	+0.4	3.1
Menarini (ARKRAY) HA-8180 series							
Overall	144	+0.7	2.8	+0.8	3.0	+0.7	2.9
BE	39	+0.6	2.9	+0.7	3.0	+0.6	3.0
DE-INSTAND	11	+1.3	2.5	+1.1	3.2	+1.2	2.9
DE-RfB	20	+0.4	3.4	+0.5	3.6	+0.4	3.5
IE	6	+1.4	2.1	+1.5	1.2	+1.5	1.7
IT-CRB	10	+0.5	2.3	+0.5	1.9	+0.5	2.1
IT-CRRVEQ	7	+1.6	3.0	+1.7	2.1	+1.7	2.6
NL	21	+0.8	2.0	+1.0	2.2	+0.9	2.1
TR	7	-0.3	3.5	-0.2	4.9	-0.3	4.2
UK	12	+0.1	2.5	+0.5	2.5	+0.3	2.5
Not Known							
Overall	127	-0.2	6.4	+0.5	6	+0.1	6.2
DE-INSTAND	113	+0.1	1.7	+0.7	2.3	+0.4	2.0
DE-RfB	10	-2.2	6	-0.8	7.2	-1.5	6.6

Method	n	HbA1c High (2018-1)		HbA1c Low (2018-2)		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Roche Diagnostics							
Overall	597	0.0	3.6	-0.2	4.0	-0.1	3.8
BE	6	-1.1	1.7	-0.4	2.7	-0.8	2.2
CH	27	-0.2	2.0	-0.1	3.2	-0.2	2.6
DE-INSTAND	203	-0.1	3.4	-0.3	3.8	-0.2	3.6
DE-RfB	258	+0.2	3.6	0.0	4.1	+0.1	3.9
FI	34	-0.3	5.6	-0.9	5.6	-0.6	5.6
KR	6	+0.2	1.4	+0.4	2.1	+0.3	1.8
NL	22	+0.3	3.0	+0.4	4.0	+0.3	3.5
SE	8	-0.9	2.7	-0.1	3.1	-0.5	2.9
UK	10	-0.5	3.3	-0.8	4.1	-0.7	3.7
SEBIA Capillarys 2 flex-piercing							
Overall	103	+0.1	2.6	+0.2	3.2	+0.1	2.9
BE	9	-0.2	2.0	-0.7	3.2	-0.5	2.6
DE-INSTAND	10	-0.6	2.1	+0.5	2.9	-0.1	2.5
DE-RfB	37	+0.2	2.7	-0.2	3.4	0.0	3.1
FR	21	+0.3	2.6	+0.7	3.4	+0.5	3.0
IT-CRRVEQ	7	+0.5	3.8	+0.1	1.8	+0.3	2.8
UK	6	-0.3	1.3	+0.8	2.1	+0.2	1.7
SEBIA Capillarys 3 Tera							
Overall	26	+0.1	1.9	+0.2	2.1	+0.1	2.0
FR	7	0.0	1.8	+0.3	2.5	+0.1	2.2
IT-CRRVEQ	6	+0.6	2.6	+0.6	1.8	+0.6	2.2
SE	6	-0.3	1.3	+0.1	1.2	-0.1	1.3
Siemens Advia series							
Overall	21	+2.2	7.3	+1.7	7.8	+2.0	7.6
DE-INSTAND	9	+3.4	7.4	+2.2	5.7	+2.8	6.6
DE-RfB	11	+1.1	7.3	+1.2	9.4	+1.2	8.4
Siemens DCA 2000/Vantage							
Overall	322	-0.9	3.5	-0.4	3.8	-0.7	3.7
CH	25	-1.8	4.1	-0.5	4.2	-1.2	4.2
DE-INSTAND	48	-1.3	3.3	-0.5	4.0	-0.9	3.7
DE-RfB	30	-0.9	4.0	-0.3	3.1	-0.6	3.6
FI	85	-0.5	3.5	-0.4	4.1	-0.5	3.8
IE	13	-0.9	2.4	-0.1	2.8	-0.5	2.6
NL	14	-1.2	2.7	-0.7	4.2	-1.0	3.5
SE	50	-0.8	3.0	-0.4	3.6	-0.6	3.3
UK	55	-0.8	3.8	-0.4	3.6	-0.6	3.7
Siemens Dimension series							
Overall	93	-0.8	3.8	+2.0	5.3	+0.6	4.6
DE-INSTAND	38	-0.7	3.2	+2.2	5.4	+0.7	4.3
DE-RfB	47	-1.2	4.2	+1.6	5.3	+0.2	4.8
TOSOH G8							
Overall	351	+1.6	2.9	+2.1	2.7	+1.9	2.8
BE	36	+1.9	2.1	+2.6	2.0	+2.3	2.1
DE-INSTAND	25	+1.8	1.9	+2.2	2.8	+2.0	2.4
DE-RfB	53	+1.5	2.4	+2.0	2.8	+1.8	2.6
FI	59	0.0	4.1	+1.5	2.8	+0.8	3.5
FR	18	+1.7	1.3	+2.1	1.2	+1.9	1.3
IT-CRB	10	+1.6	2.1	+2.5	2.4	+2.1	2.3
IT-CRRVEQ	39	+2.2	3	+2.4	3.8	+2.3	3.4
KR	13	+2.1	1.7	+2.2	2.0	+2.2	1.9
NL	30	+1.7	2.3	+2.1	2.4	+1.9	2.4
SE	11	+1.0	1.7	+1.3	2.2	+1.2	2.0
UK	46	+2.5	1.5	+2.6	1.8	+2.6	1.7
TOSOH G11							
Overall	75	+1.1	1.8	+1.4	2.1	+1.3	2.0
DE-INSTAND	14	+1.0	2.2	+1.7	2.4	+1.4	2.3
DE-RfB	33	+1.3	1.6	+1.4	2.0	+1.4	1.8
FI	8	0.0	1.1	+0.6	1.0	+0.3	1.1
KR	9	+0.9	1.3	+1.1	1.5	+1.0	1.4
Trinity Biotech Premier Hb9210							
Overall	38	+1.6	3.0	+1.0	4.0	+1.3	3.5
FR	6	+3.0	2.4	+2.7	2.6	+2.9	2.5
IT-CRB	6	+2.7	2.2	+2.6	1.9	+2.7	2.1
UK	13	+0.8	2.6	-0.1	3.0	+0.3	2.8

III Results EQA Lyophilised Hemolysate samples

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

Table 6. Results per Country for Lyophilised Hemolysate

Country	EurA1c 2018-1 Target 58.1 mmol/mol				EurA1c 2018-2 Target 42.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Austria	140	58.8	+0.7	4.7	140	42.6	+0.4	5.0	+0.5	4.9
Czech Republic	211	57.9	-0.2	4.5	209	42.5	+0.3	5.0	0.0	4.8
France	186	58.5	+0.4	4.8	186	43.4	+1.2	6.3	+0.8	5.6
Ghana	1	69.0	+10.9		1	49.0	+6.8		+8.9	
Greece	87	58.4	+0.3	5.0	87	42.8	+0.6	5.5	+0.4	5.3
International*	60	57.7	-0.4	3.9	50	42.4	+0.2	3.6	-0.1	3.8
Italy CRB	54	58.4	+0.3	4.7	55	43	+0.8	4.7	+0.5	4.7
Mexico	21	56.8	-1.3	8.4	22	42.8	+0.6	10.7	-0.4	9.6
Portugal	45	58.4	+0.3	4.8	45	42.4	+0.2	4.9	+0.2	4.9
South Africa	4	60.0	+1.9	2.4	4	44.3	+2.1	4.7	+2.0	3.6
Spain	113	58.4	+0.3	3.9	114	42.8	+0.6	3.6	+0.4	3.8
Thailand	134	58.2	+0.1	7.7	134	41.8	-0.4	9.8	-0.2	8.8
Turkey	49	59.6	+1.5	6.4	49	43.9	+1.7	7.0	+1.6	6.7
Overall	1105	58.3	+0.2	5.4	1096	42.8	+0.6	6.2	+0.4	5.8

** Individual laboratories of a number of countries*

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

Manufacturer	EurA1c 2018-1 Target 58.1 mmol/mol				EurA1c 2018-2 Target 42.2 mmol/mol				Mean 2 Samples	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott ARCHITECT	42	54.6	-3.5	6.1	42	38.6	-3.6	8.0	-3.5	7.1
Beckman Coulter AU series	13	60.8	+2.7	7.8	11	44.4	+2.2	7.1	+2.4	7.4
BIOMAJESTY JCABM6010	7	58.9	+0.8	10.8	7	40.7	-1.5	13.7	-0.4	12.2
Bio-Rad D-10 series	36	57.0	-1.1	4.9	37	42.0	-0.2	5.8	-0.6	5.4
Bio-Rad D-100 series	28	57.0	-1.1	2.1	28	42.4	+0.2	2.8	-0.5	2.4
Bio-Rad other	47	57.9	-0.2	5.3	47	43.0	+0.8	5.5	+0.3	5.4
Bio-Rad Variant series	47	62.1	+4.0	4.7	47	45.5	+3.3	5.3	+3.7	5.0
Menarini (ARKRAY) HA-8160 series	66	57.6	-0.5	4.2	66	42.1	-0.1	4.4	-0.3	4.3
Menarini (ARKRAY) HA-8180 series	121	57.1	-1.0	4.5	116	41.8	-0.4	5.2	-0.7	4.8
Menarini (ARKRAY) other	48	56.8	-1.3	3.0	47	41.5	-0.7	3.2	-1.0	3.1
Other	14	56.6	-1.5	4.9	14	41.4	-0.8	5.8	-1.2	5.4
Roche Diagnostics	239	60.1	+2.0	4.9	239	43.3	+1.1	5.4	+1.5	5.2
SEBIA Capillarys 2 flex-piercing	56	58.4	+0.3	2.8	57	42.4	+0.2	3.9	+0.2	3.4
SEBIA Capillarys 3 Tera	36	57.9	-0.2	2.0	36	42.6	+0.4	2.0	+0.1	2.0
SEBIA Minicap flex-piercing	13	56.9	-1.2	2.9	13	41.7	-0.5	3.4	-0.8	3.2
Siemens DCA 2000/Vantage	9	60.6	+2.5	3.5	8	44.4	+2.2	4.4	+2.4	4.0
Siemens Dimension series	23	59.7	+1.6	5.4	23	46.6	+4.4	4.8	+3.0	5.1
Sysmex	7	54.1	-4.0	5.8	7	38.7	-3.5	6.1	-3.7	5.9
TOSOH G11	8	59.3	+1.2	4.4	8	44.9	+2.7	6.8	+2.0	5.6
TOSOH G7	17	59.2	+1.1	4.2	17	43.4	+1.2	5.2	+1.1	4.7
TOSOH G8	98	57.7	-0.4	3.4	97	43.6	+1.4	4.6	+0.5	4.0
TOSOH other	58	58.5	+0.4	2.9	58	43.2	+1.0	3.4	+0.7	3.2
Trinity Biotech Premier Hb9210	17	56.9	-1.2	4.3	16	42.2	0.0	3.9	-0.6	4.1

For Siemens DCA/Vantage it is known that there is a positive matrix effect for lyophilised samples. For the Abbott enzymatic test we investigated the negative bias in relation to stability. Fresh whole blood and lyophilised hemolysates were assayed on our Abbott instrument after manufacture of the samples and we did not find a difference in results. However, on storage in the refrigerator for 6, 18 and 24 months we found a decrease in measured HbA1c which we did not see in the same samples stored in the freezer (see section on stability on page 13). As samples have not been stored in the freezer the negative bias of Abbott might be contributed to instability of the samples for this method.

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

Manufacturer	**EurA1c 2018-1 Target 58.1 mmol/mol**				**EurA1c 2018-2 Target 42.2 mmol/mol**				**Mean 2 Samples**	
	n	Mean	Bias	CV%	n	Mean	Bias	CV%	Bias	CV%
Abbott Alinity	1	52.0	-6.1		1	37.0	-5.2		-5.7	
Abbott other	4	57.7	-0.4	3.4	4	41.7	-0.5	2.2	-0.5	2.8
Beckman Coulter other	3	58.0	-0.1	6.3	3	43.1	+0.9	9.2	+0.4	7.8
Beckman Coulter P / ACE MDQ	1	60.0	+1.9		1	39.0	-3.2		-0.7	
Beckman Coulter Unicel DxC series	3	61.7	+3.6	1.0	3	45.0	+2.8	0.0	+3.2	0.5
Ceragem Labona Check A1c	1	54.0	-4.1		1	42.0	-0.2		-2.2	
CERA-STAT	1	49.0	-9.1		1	44.0	+1.8		-3.7	
Dirui CS 300B	1	51.0	-7.1		1	43.0	+0.8		-3.2	
Erba Lachema	3	54.7	-3.4	12.6	3	39.9	-2.3	17.2	-2.9	14.9
EuroMedix	1	64.0	+5.9		1	50.0	+7.8		+6.9	
Finecare wondfo	1	57.0	-1.1		1	49.0	+6.8		+2.9	
ISE S.r.l. Hemo One ISE HbA1c	1	60.2	+2.1		1	44.0	+1.8		+2.0	
Lifotronic GH-900	2	56.0	-2.1	2.5	2	46.0	+3.8	6.1	+0.8	4.3
Lifotronic H9	1	54.0	-4.1		1	36.0	-6.2		-5.2	
Menarini (ARKRAY) HA-8140 series	3	56.8	-1.3	3.1	3	41.4	-0.8	2.8	-1.1	3.0
Mindray	1	64.6	+6.5		1	45.6	+3.4		+5.0	
Olympus	1	60.0	+1.9		1	44.4	+2.2		+2.1	
Ortho Clin. Diagn. Vitros	2	61.5	+3.4	1.1	2	41.5	-0.7	1.7	+1.4	1.4
Ortho Clinical Diagnostics Vitros 5,1 FS	1	61.5	+3.4		1	41.9	-0.3		+1.5	
QuoLab	1	63.0	+4.9						+4.9	
Quo-Test HbA1c	1	64.0	+5.9		1	50.0	+7.8		+6.9	
Randox	2	65.3	+7.2	1.5	2	44.7	+2.5	4.1	+4.9	2.8
Rx Imola	4	56.3	-1.9	3.9	4	35.5	-6.7	6.7	-4.3	5.3
SEBIA other	2	56.5	-1.6	1.3	2	41.5	-0.7	1.7	-1.2	1.5
Sekisui CS T240	1	62.0	+3.9		1	45.0	+2.8		+3.4	
Siemens Advia series	3	60.0	+1.9	3.3	3	41.7	-0.5	1.4	+0.7	2.4
Siemens other	2	58.5	+0.4	13.3	2	44.8	+2.6	7.1	+1.5	10.2
SpinReact Spinlab 200E	1	68.0	+9.9		2	50.5	+8.3	1.4	+9.1	1.4
Thermo Electron corporation 4001/4	1	54.0	-4.1		1	47.5	+5.3		+0.6	
TOSOH GX	4	57.1	-1.0	1.1	4	42.4	+0.2	1.0	-0.4	1.1
Trinity Biotech Ultra2	1	55.0	-3.1		1	45.0	+2.8		-0.2	

Table 9 shows results per manufacturer per country. Included are only manufacturers with 6 or more participants in at least 2 countries.
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	HbA1c High (2018-1)		HbA1c Low (2018-2)		Mean	
		Bias	CV%	Bias	CV%	Bias	CV%
Abbott Architect							
Overall	42	-3.5	6.1	-3.6	8.0	-3.5	7.1
AT	11	-2.9	2.1	-3.1	2.9	-3.0	2.5
FR	7	-4.5	1.6	-4.6	2.0	-4.6	1.8
GR	8	-0.6	5.3	-0.7	3.4	-0.7	4.4
TH	8	-7.1	2.3	-7.3	4.7	-7.2	3.5
Bio-Rad D10 series							
Overall	36	-1.1	4.9	-0.2	5.8	-0.6	5.4
CZ	7	-1.8	2.2	-0.4	3.3	-1.1	2.7
FR	9	+0.5	6.9	+0.7	8.6	+0.6	7.8
Bio-Rad D100 series							
Overall	28	-1.1	2.1	+0.2	2.8	-0.5	2.4
AT	7	-0.5	0.9	+0.5	1.8	0.0	1.3
ES	16	-1.3	2.3	-0.1	3.1	-0.7	2.7
Bio-Rad Variant series							
Overall	47	+4.0	4.7	+3.3	5.3	+3.7	5.0
ES	7	+3.3	2.1	+2.5	2.1	+2.9	2.1
FR	18	+5.1	4.1	+4.7	3.4	+4.9	3.7
TR	12	+4.8	3.5	+3.4	5.7	+4.1	4.6
Menarini (ARKRAY) HA 8160 series							
Overall	66	-0.5	4.2	-0.1	4.4	-0.3	4.3
AT	6	+0.6	1.4	+1.5	1.9	+1.0	1.6
ES	6	-1.1	1.1	-0.2	2.6	-0.7	1.9
GR	13	-0.8	2.6	+0.7	4.0	-0.1	3.3
IT-CRB	11	-0.6	4.1	-0.2	4.3	-0.4	4.2
PT	25	-0.1	5.3	-0.6	5.0	-0.4	5.1
Menarini (ARKRAY) HA 8180 series							
Overall	121	-1.0	4.5	-0.4	5.2	-0.7	4.8
AT	23	-0.8	2.3	+0.1	2.8	-0.4	2.6
ES	49	+0.1	3.3	+0.5	3.2	+0.3	3.3
IT-CRB	8	+0.8	1.1	+1.4	1.2	+1.1	1.1
INT*	14	-0.7	2.3	+0.4	2.5	-0.1	2.4
TH	14	-5.9	2.1	-4.6	2.0	-5.3	2.1
Roche Diagnostics							
Overall	239	+2.0	4.9	+1.1	5.4	+1.5	5.2
AT	67	+2.0	4.2	+0.6	4.5	+1.3	4.4
CZ	14	+1.6	4.2	+0.4	6.8	+1.0	5.5
ES	11	+2.4	6.0	+1.1	6.2	+1.8	6.1
FR	21	+2.5	3.1	+1.4	3.7	+1.9	3.4
GR	24	+1.4	5.8	+1.0	4.1	+1.2	4.9
PT	6	+0.3	2.9	+0.6	3.5	+0.5	3.2
TH	76	+2.2	4.1	+1.3	5.7	+1.8	4.9
TR	10	+3.8	5.0	+3.3	6.3	+3.6	5.6
Sebia Capillarys 2 flex-piercing							
Overall	56	+0.3	2.8	+0.2	3.9	+0.2	3.4
AT	6	+0.4	2.6	+0.3	3.2	+0.3	2.9
FR	34	0.0	2.8	+0.3	4.3	+0.2	3.6
INT*	7	-0.2	2.7	-0.4	1.8	-0.3	2.3
Siemens Dimension series							
Overall	23	+1.6	5.4	+4.4	4.8	+3.0	5.1
AT	6	+3.6	6.9	+4.1	5.0	+3.9	6.0
GR	8	+0.4	2.9	+3.9	4.7	+2.2	3.8
Tosoh G8							
Overall	98	-0.4	3.4	+1.4	4.6	+0.5	4.0
AT	8	-1.4	2.8	-0.2	1.8	-0.8	2.3
CZ	7	+1.0	3.7	+2.1	1.7	+1.6	2.7
ES	9	+1.0	3.0	+1.4	2.0	+1.2	2.5
FR	45	-0.9	2.9	+2.0	5.2	+0.6	4.1
IT-CRB	7	-0.2	3.4	+0.9	3.1	+0.3	3.2
INT*	10	-1.1	3.3	+0.5	4.6	-0.3	3.9
TR	6	-0.6	3.7	+1.3	6.3	+0.4	5.0

** 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, the US NGSP SRLs and the Swedish Mono S. Table 10 shows the results.

Table 10. Results of Reference Measurement Procedures

Matrix	**Low HbA1c (range 41.5 – 42.9 mmol/mol)**				**High HbA1c (range 57.2 – 59.0 mmol/mol)**			
	IFCC RMP	IFCC SRLs	US NGSP SRLs	Sweden Mono S	IFCC RMP	IFCC SRLs	US NGSP SRLs	Sweden Mono S
	n = 5	n = 8	n = 3	n = 1	n = 5	n = 8	n = 3	n = 1
Fresh Whole Blood	42.2	42.8	43.6	42.2	58.1	58.7	59.5	56.0
Lyophilised Hemolysate	41.9	42.2	42.5	41.7	57.9	58.0	57.9	55.7
Frozen Whole Blood	42.1	43.1	43.0	42.5	57.8	58.8	58.1	56.8

1) US-NGSP and Sweden Mono-S results in % are converted to SI (IFCC) units with the respective Master Equations
2) Expanded Uncertainty (k=2) of the IFCC RMP in fresh whole blood is 0.7 mmol/mol in the low and 0.9 in the high sample.

V. Homogeneity

Homogeneity testing of the samples EurA1c-2018-1, 3 and 5 is performed according to ISO 13528:2005 (Annex B) with the Menarini 8180V. The results in table 11 show that the samples are homogeneous.

Table 11. Homogeneity test of EurA1c 2018

Vial	**Fresh Whole Blood**				**Lyophilised Hemolysate**				**Frozen Whole Blood**			
	EurA1c 2018-1				**EurA1c 2018-3**				**EurA1c 2018-5**			
	1	2	mean	Δ	1	2	mean	Δ	1	2	mean	Δ
1	58.5	58.5	58.50	0.0	58.6	58.7	58.65	0.1	57.7	57.9	57.80	0.2
2	58.7	58.5	58.60	0.2	58.9	58.6	58.75	0.3	57.7	57.9	57.80	0.2
3	58.7	58.4	58.55	0.3	58.9	58.7	58.80	0.2	57.8	57.7	57.75	0.1
4	58.7	58.7	58.70	0.0	59.0	58.7	58.85	0.3	57.5	57.9	57.70	0.4
5	58.4	58.4	58.40	0.0	58.6	58.6	58.60	0.0	57.7	57.9	57.80	0.2
6	58.7	58.4	58.55	0.3	58.7	58.6	58.65	0.1	57.8	57.8	57.80	0.0
7	58.7	58.5	58.60	0.2	58.9	58.7	58.80	0.2	57.9	57.7	57.80	0.2
8	58.5	58.4	58.45	0.1	58.6	58.7	58.65	0.1	57.8	57.7	57.75	0.1
9	58.2	58.4	58.30	0.2	58.6	58.6	58.60	0.0	57.9	57.8	57.85	0.1
10	58.4	58.4	58.40	0.0	59.0	58.6	58.80	0.4	58.1	57.8	57.95	0.3
11	58.5	58.1	58.30	0.4	58.9	58.6	58.75	0.3	57.7	57.7	57.70	0.0
12	58.1	58.2	58.15	0.1	58.6	58.4	58.50	0.2	57.8	57.7	57.75	0.1
average			58.5				58.7				57.8	
SD		0.120	0.156	0.141		0.000	0.107	0.155		0.000	0.068	0.137
0.3 x SD_{RL}			0.306				0.306				0.306	
Criterion			-0.186				-0.306				-0.306	
Homogeneity:			**Pass**				**Pass**				**Pass**	

VI. Stability

Fresh Whole Blood

Fresh whole blood samples EurA1c 2018-1 (HbA1c 42.2 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 12). Differences of 2 mmol/mol and higher are flagged amber. Differences seen on day 2 and 3 with Roche are considered not significant because no differences are seen on days 4 and 5. 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 12. 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	0	0	-1	-3
Sebia Capillarys 2	0	+1	+1	-1	-1	-2
Roche Cobas c513	0	+2	+2	+1	0	+1
Abbott Architect C4000	0	0	0	0	0	0
Tosoh G8	0	0	0	0	0	-1
Trinity Premier Hb9210	0	0	-1	-1	-1	-3
Storage Refrigerator						
Menarini/ARKRAY HA 8180V	0	0	0	0	0	-1
Sebia Capillarys 2	0	+1	0	-1	0	0
Roche Cobas c513	0	0	0	+1	-1	+1
Abbott Architect C4000	0	0	0	0	0	0
Tosoh G8	0	-1	0	0	0	0
Trinity Premier Hb9210	0	0	0	0	0	0

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

Lyophilised Hemolysate

Lyophilised hemolysate samples EurA1c 2016-1 (HbA1c 42.3 mmol/mol) were stored in the refrigerator at 2-8°C and in the freezer at -20°C and measured after 6, 18 and 24 months. Results are shown in table 13. It can be seen that the results of the Abbott Architect enzymatic assay start to show differences after 6 months. This is a remarkable and unexpected result of this new test. This may explain why a negative bias is observed in the EurA1c trial in some countries. Further investigation of this is scheduled.

Table 13. Stability of Lyophilised Hemolysate in Refrigerator and Freezer -20°C*

Method	0 month	6 months	18 months	24 months
Storage Refrigerator				
Menarini/ARKRAY HA 8180V	0	-1	-1	-1
Sebia Capillarys 2	0	-1	-1	-1
Roche Cobas c513	0	0	0	0
Abbott Architect C4000	0	-4	-6	-7
Tosoh G8	0	+1	+1	+3
Trinity Premier Hb9210	0	-1	-1	-2
Storage Freezer -20°C				
Menarini/ARKRAY HA 8180V	0	-1	0	0
Sebia Capillarys 2	0	-1	-1	-1
Roche Cobas c513	0	+1	0	0
Abbott Architect C4000	0	0	+1	+1
Tosoh G8	0	0	+1	0
Trinity Premier Hb9210	0	+1	0	0

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

Frozen Whole Blood

Frozen whole blood samples EurA1c 2016-1 (HbA1c 42.3 mmol/mol) were stored in freezers at -20°C and -70°C and measured after 6, 18 and 24 months (results of EurA1c 2016 samples are chosen to show stability because of these samples long-term results are available).

Results are shown in table 14. It can be seen that on storage at -20°C results start to differ from the originally measured HbA1c concentration, starting from 18 months.

Table 14. Stability of Frozen Whole Blood in Freezer -20°C and Freezer -70°C*

Method	0 month	6 months	18 months	24 months
Storage Freeze -20°C				
Menarini/ARKRAY HA 8180V	0	0	+3	n.m**
Sebia Capillarys 2	0	0	+1	-18
Roche Cobas c513	0	0	0	+1
Abbott Architect C4000	0	0	+2	+2
Tosoh G8	0	0	-2	-2
Trinity Premier Hb9210	0	-2	-4	-4
Storage Freezer -70°C				
Menarini/ARKRAY HA 8180V	0	0	0	0
Sebia Capillarys 2	0	0	-1	+1
Roche Cobas c513	0	0	+1	0
Abbott Architect C4000	0	0	0	0
Tosoh G8	0	0	0	0
Trinity Premier Hb9210	0	0	-1	-1

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

*** not measurable*

VII Organisations and Persons Involved

Country	Organisation	Person
EQA Organisers		
AT	ÖQUASTA	Christoph Buchta, Mathias M. Mueller
BE	Sciensano	Yolande Lenga
CH	CSCQ	Dagmar Kesseler, Pierre-Alain Morandi, Xavier Albe
CZ	SEKK s.r.o.	Marek Budina, Marie Uhlirova, Josef Kratochvila, Bedrich Friedecky
DE	INSTAND	Patricia Kaiser
DE	Reference Institute for Bioanalytics	Anja Kessler
ES	SEQC^{ML}	Montserrat Ventura Alemany, M^{a} Carmen González Gómez, Carmen Perich Alsina
FI	Labquality	Päivi Ranta
FR	Biologie Prospective	Jean-Pascal Siest
GR	ESEAP/General Hospital	Alexander Haliassos, Konstantinos Makris, Otto Panagiotakis
GH	Medlab Ghana Limited	Rosemary Keatley
HU	QualiCont Nonprofit Kft.	Virag Gyongyosi, Erika Sarkany
IE	IEQAS	Hazel Graham, Anne Kane, Thomas P. Smith, Ned Barrett
INT	ERL	Cas Weykamp
IT	Centro di Ricerca Biomedica	Laura Sciacovelli, Mario Plebani
IT	Italy CRRVEQ	Massimo Quercioli, Francesca Masi
KR	Korean Association of External Quality Assessment Service	Junghan Song, Sail Chun, Prof. Kyunghoon Lee
MX	Laboratorios Biomedicos Panuco	Eduardo Rojano Rodriguez
NL	SKML	Cas Weykamp
PT	Inst. Nac. de Saude Dr. Ricardo Jorge	Ana Andrade Faria, Ana Cardoso, Helena Correia
SE	EQUALIS	Gunnar Nordin, Håkan Lund
TH	National Institute of Health	Supaporn Suparak
UK	WEQAS	Annette Thomas, Samantha Jones, Gareth Davies
TR	TUBITAK UME / Pamukkale University	Fatma Akcadag, Müslüm Akgöz, Diler Aslan
ZA	NHLS/Stellenbosch University	Annalise Zemlin, Rajiv T. Erasmus
IFCC Network Laboratories		
FR	CHU Reims	Philippe Gillery, Stéphane Jaisson
DE	INSTAND	Patricia Kaiser
IT	CIRME	Andrea Mosca, Renata Paleari
NL	Isala	Erna Lenters-Westra, Robbert J. Slingerland, Janine Slootstra
NL	Queen Beatrix Hospital	Carla Siebelder, Sanne Leppink
IFCC Secondary Reference Laboratories		
IT	CIRME	Andrea Mosca, Renata Paleari
NL	Isala	Erna Lenters, Robbert Slingerland, Janine Slootstra
NL	Queen Beatrix Hospital	Carla Siebelder, Sanne Leppink
NGSP Network Laboratories		
US	University of Missouri	Randie R. Little, Shawn M. Connolly
US	University of Minnesota	Maren Nowicki, Vicky Makky
Mono S Laboratory		
SE	SU/Sahlgrenska	Anders Elmgren, Magnus Axelsson
Oversight Committee (members IFCC C-EUBD)		
JP	Tokyo Women's Medical Hospital	Asako Sato
UK	Norfolk and Norwich University Hosp.	W. Garry John
UK	University of East Anglia	Emma English
US	National Institutes of Health	David B. Sacks
NL	Queen Beatrix Hospital	Cas Weykamp
NL	Isala	Erna Lenters (consultant Point of Care)
Trial Management		
NL	Overview	Cas Weykamp
NL	Coordination	Carla Siebelder
NL	Quality Assurance	Liesbeth Schröer
NL	Data Processing	Irene de Graaf
NL	Sample Logistics	Marieke te Winkel