

Report EurA1c 2022

*HbA1c Trial
EQA organisers*



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FINAL Version
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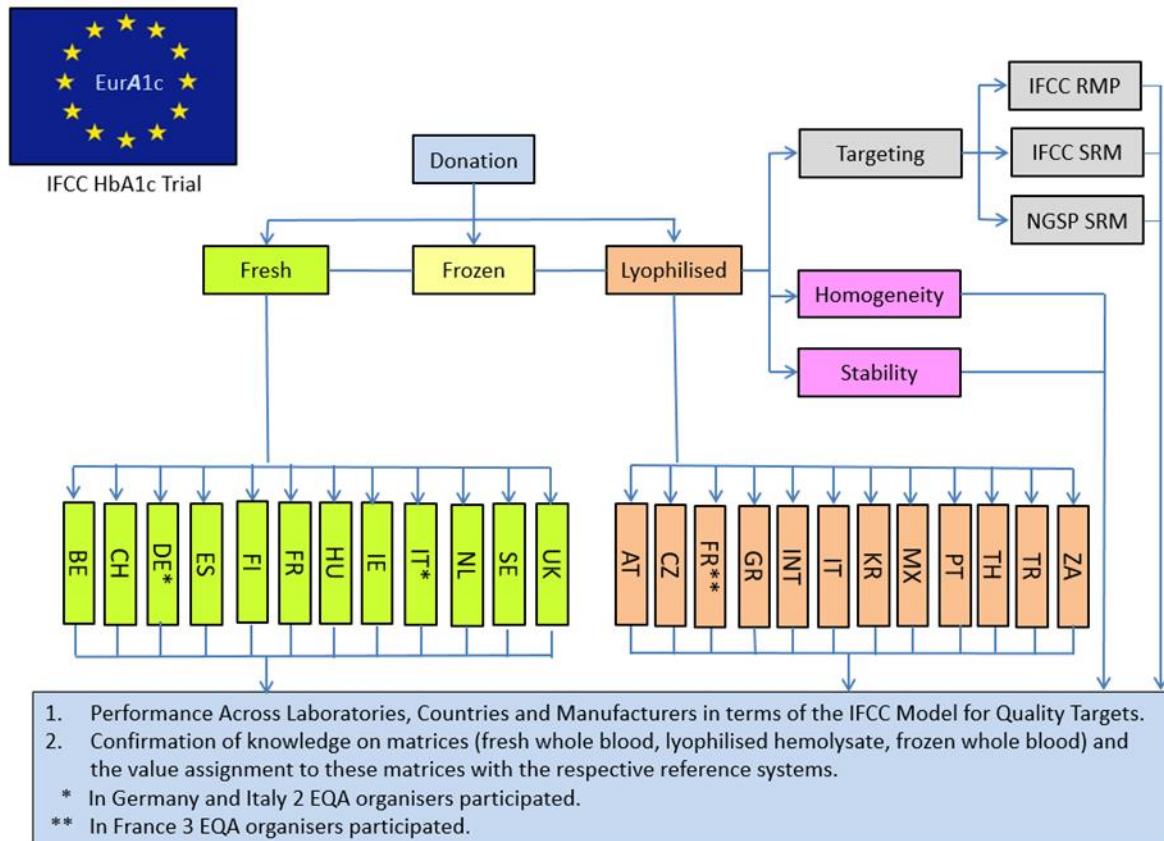
I Introduction and Overview of Results

Introduction

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

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

Figure 1. Design EurA1c Trial 2022



Confidentiality and Ownership

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

The time schedule is:

July 2023:

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

At the same time the invitation to participate in EurA1c 2023 is sent.

31 August 2023:

Deadline for comments and remarks.

30 September 2023:

Final report sent to all who are involved and published on the IFCC-HbA1c website (www.ifcchba1c.org).

By then all who are involved are free to share results with third parties.

Value Assignment

Five Approved IFCC Network Laboratories performed the value assignment with the IFCC Reference Measurement Procedure. For EurA1c 2022-1 the assigned value is 41.7 mmol/mol (expanded uncertainty 0.8 mmol/mol) and for EurA1c 2022-2 the assigned value is 58.2 mmol/mol (expanded uncertainty 1.2 mmol/mol). The values are the target values for both fresh whole blood and lyophilised samples.

Outliers

Outliers have been removed before calculation of the mean and between laboratory CV. Instead of using statistical criteria we only considered “blunders” as outliers. The criterion used was a difference exceeding 25% of the target values. In our opinion these results are a relevant picture of “real life”. In this way 18 results (0.6%) have been excluded from the database of the fresh whole blood samples and 12 results (0.8%) from the database of the lyophilised hemolysates.

Methods

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

Units

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

Summary of Results

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

Table 1. Results of EurA1c 2022

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

* n = the number of datasets.

** Individual laboratories of a number of countries

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

Differentiation of Results

Results are differentiated per sample and a) per country b) per manufacturer/method and c) per manufacturer/method per country in fresh whole blood (section II) and in lyophilised hemolysates (section III).

II Results EQA Fresh Whole Blood samples

Table 2 shows the results per EQA organiser for each sample. Tables 3 and 4 show the results per manufacturer/method for manufacturers/methods with 5 or more participants (table 3) and those with 5 or less participants (table 4).

Table 2. Results per EQA organiser for Fresh Whole Blood

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

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

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

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

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

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

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

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

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

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

III Results EQA Lyophilised Hemolysate samples

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

Table 6. Results per EQA organiser for Lyophilised Hemolysate

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

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

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

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

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

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

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

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

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

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

* Group of Individual laboratories of a number of countries

IV. Value Assignment (Targeting)

The samples in their respective matrices have been measured with the IFCC RMP, the IFCC SRLs, and the US NGSP SRLs. Table 12 shows the results.

The assigned values are the values assigned with the IFCC RMP as measured in fresh whole blood. Values of the other matrixes and other methods are for comparison and information.

Table 12. Results of Reference Measurement Procedures

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

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

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

V. Homogeneity

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

Table 13. Homogeneity test of EurA1c 2022

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

VI. Stability

Fresh Whole Blood

Fresh whole blood samples EurA1c 2022-1 (HbA1c 41.7 mmol/mol) were stored at room temperature and in the refrigerator at 2-8°C and measured after 1,2,3,4,5 and 8 days after storage. Results are expressed as the difference in measured HbA1c on day X and day 1 (table 14). Differences of 2 mmol/mol and higher are flagged amber. It can be seen that on storage at room temperature results of three methods start to show differences on day 8. It can be concluded that at room temperature samples are stable for 5 and in the refrigerator for at least 8 days.

Table 14. Stability* of Fresh Whole Blood at Room Temperature and in the Refrigerator

| Method | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 8 |
|--------------------------------|-------|-------|-------|-------|-------|-------|
| Storage at Room Temperature | | | | | | |
| ARKRAY HA-8180V | 0 | 0 | 0 | 0 | -1 | -2 |
| Sebia CAPILLARYS 3 Octa | 0 | +1 | 0 | 0 | -1 | -2 |
| Roche cobas c 513 | 0 | +1 | 0 | +1 | 0 | +1 |
| Abbott enzymatic Alinity | 0 | 0 | 0 | 0 | 0 | 0 |
| Tosoh G11 | 0 | +1 | 0 | +1 | 0 | +1 |
| Trinity Biotech Premier Hb9210 | 0 | 0 | 0 | +1 | -1 | -2 |
| Storage Refrigerator | | | | | | |
| ARKRAY HA-8180V | 0 | 0 | 0 | 0 | -1 | 0 |
| Sebia CAPILLARYS 3 Octa | 0 | 0 | +1 | +1 | 0 | 0 |
| Roche cobas c 513 | 0 | 0 | 0 | -1 | 0 | 0 |
| Abbott enzymatic Alinity | 0 | 0 | +1 | +1 | 0 | 0 |
| Tosoh G11 | 0 | 0 | 0 | 0 | 0 | 0 |
| Trinity Biotech Premier Hb9210 | 0 | 0 | 0 | 0 | 0 | 0 |

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

Frozen Whole Blood

Frozen whole blood is used only for RMP measurements. Frozen whole blood samples EurA1c 2017-2 (HbA1c 58.0 mmol/mol) were stored in freezers at -20°C and -70°C and measured after 6, 13, 18, 25, 37, 49 and 61 months (results of EurA1c 2017 samples are chosen to show stability because of these samples long-term results are available).

Results are shown in table 15. It can be seen that on storage at -20°C results start to differ from the originally measured HbA1c concentration, starting from 6 months.

Table 15. Stability* of Frozen Whole Blood in Freezer -20°C and Freezer -70°C

| Method | months | | | | | | | |
|--------------------------------|--------|----|-----|--------|--------|--------|--------|--------|
| | 0 | 6 | 13 | 18 | 25 | 37 | 49 | 61 |
| Storage Freeze -20°C | | | | | | | | |
| ARKRAY HA-8180V | 0 | 0 | -5 | n.m.** | n.m.** | -1 | +3 | -5 |
| Sebia CAPILLARYS 3 Octa*** | 0 | +2 | +3 | n.m.** | n.m.** | n.m.** | n.m.** | n.m.** |
| Roche Cobas c 513 | 0 | +1 | 0 | +1 | +1 | +3 | +2 | +2 |
| Abbott enzymatic Alinity**** | 0 | +1 | +2 | +2 | +2 | +4 | +5 | +6 |
| Tosoh G11***** | 0 | -3 | -2 | -1 | -1 | -3 | -5 | -15 |
| Trinity Biotech Premier Hb9210 | 0 | -5 | -11 | -3 | -3 | +8 | -1 | n.m.** |
| Storage Freezer <-70°C | | | | | | | | |
| ARKRAY HA-8180V | 0 | 0 | 0 | -1 | -1 | 0 | 0 | -1 |
| Sebia CAPILLARYS 3 Octa*** | 0 | 0 | +1 | +2 | +2 | +2 | +3 | +3 |
| Roche Cobas c 513 | 0 | 1 | -1 | 0 | 0 | +2 | 0 | +1 |
| Abbott enzymatic Alinity**** | 0 | 1 | 1 | 0 | 0 | +1 | +1 | +1 |
| Tosoh G11***** | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| Trinity Biotech Premier Hb9210 | 0 | 0 | +2 | 0 | 0 | +1 | -1 | 0 |

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

*** initial measurement (0 month) on Sebia CAPILLARYS 2 FP

***** until 49 months on Tosoh G8

** 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, 49 and 61 months. Results are shown in table 16. It can be seen that the results of the Abbott enzymatic assay start to show differences after 6 months.

Table 16. Stability* of Lyophilised Hemolysate in Refrigerator and Freezer -20°C and Freezer -70°C

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

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

**Initial measurement (0 month) on Sebia CAPILLARYS 2 FP

*** until 18 months on Abbott ARCHITECT C4000

***** until 49 months on Tosoh G8

VII Organisations and Persons Involved

| Country | Organisation | Person |
|--|--|---|
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