

# Report

# EurAAA1c 2019

*HbA1c Trial*  
*EQA organisers*



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Final Version  
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Carla Siebelder  
Cas Weykamp  
Eline van der Hagen

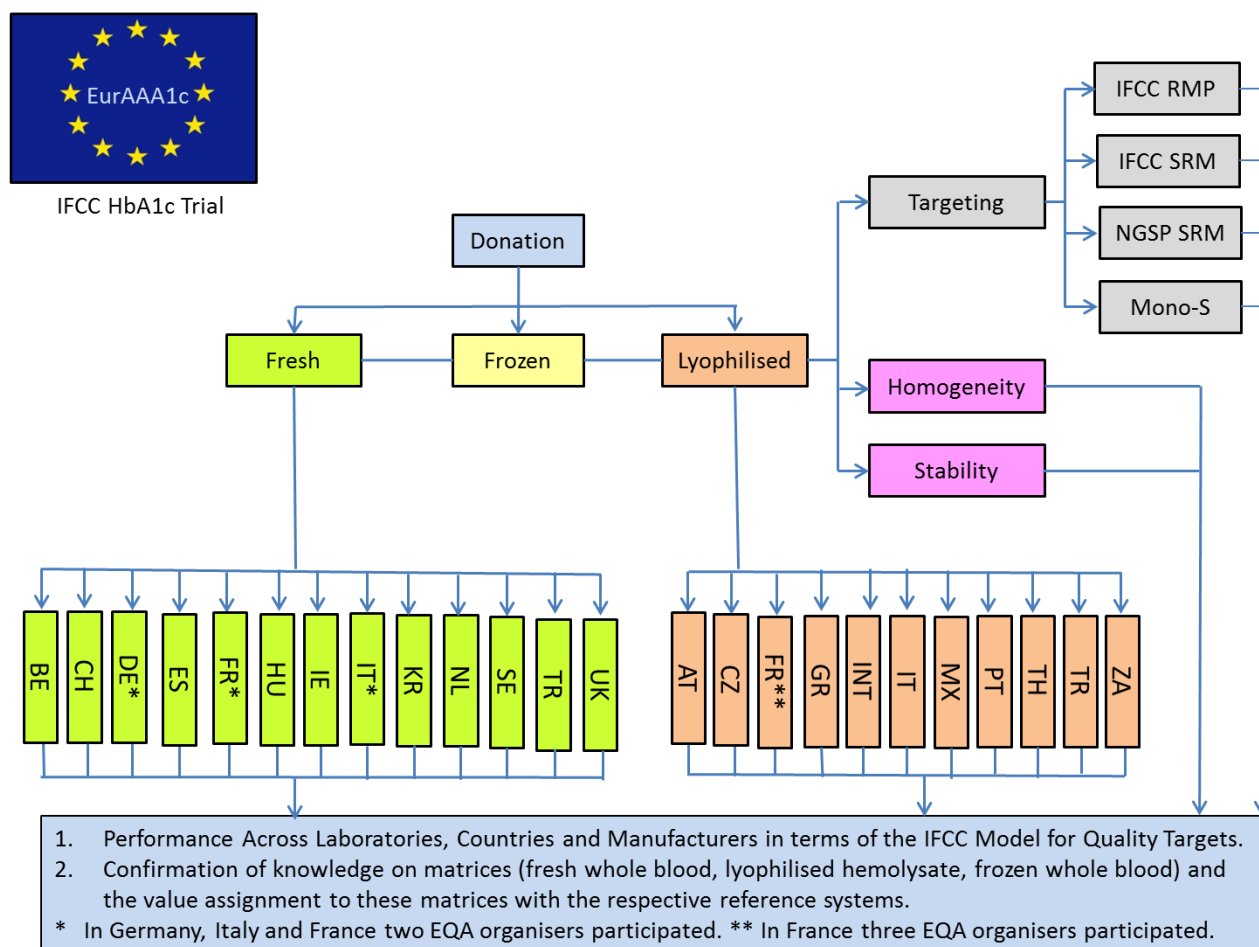
# I Introduction and Overview of Results

## Introduction

25 EQA organisers of 20 countries agreed to participate in the fourth “EurAAA1c” project. The design is shown in figure 1. The name and logo of the project have been changed to EurAAA1c to acknowledge the participation of EQA organisers in Asia, America and Africa.

16 EQA organisers used fresh whole blood samples and 13 organisers used lyophilised hemolysate samples (4 organisations used both fresh and lyophilised samples). In October 2019 the fresh whole blood samples were sent to the participants. From November 2019 up to April 2020 the lyophilised samples are assayed by the participants.

Figure 1. Design EurAAA1c Trial 2019



## Confidentiality and Ownership

The results of the EurAAA1c 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 2020: Draft report sent to all who are involved in EurAAA1c 2019. At the same time the invitation to participate in EurAAA1c 2020 is sent.
- 31 August 2020: Deadline for comments and remarks
- 30 September 2020: 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 EurAAA1c 2019-1 the assigned value is 70.1 mmol/mol (expanded uncertainty 1.1 mmol/mol) and for EurAAA1c 2019-2 the assigned value is 38.2 mmol/mol (expanded uncertainty 0.6 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 42 results (0.7%) have been excluded from the database of fresh whole blood samples and 35 results (2.5%) from the database of lyophilised hemolysates.

## Methods

This is a point of consideration. 96 of the laboratories did not report their method at all. Also a number of labs did not specify their method (Siemens and Abbott users not specifying whether they used the enzymatic or immunoassay; Roche users who did not specify instruments). For details see table 3 (fresh whole blood) and table 7 (lyophilized).

## 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 EurAAA1c 2019

| 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           |                   |                       |                       | 116                    | +1.0                  | 5.6%                  |
| Belgium           | 133               | +0.6                  | 3.5%                  |                        |                       |                       |
| Czech Republic    |                   |                       |                       | 195                    | +1.2                  | 5.1%                  |
| France Asqualab   |                   |                       |                       | 47                     | +1.4                  | 5.2%                  |
| France CTCB       | 177               | +0.4                  | 3.8%                  | 157                    | +1.4                  | 4.9%                  |
| France Probioqual | 361               | +0.7                  | 3.4%                  | 548                    | +1.0                  | 5.9%                  |
| Germany INSTAND   | 636               | +0.1                  | 5.2%                  |                        |                       |                       |
| Germany RfB       | 728               | +0.5                  | 4.6%                  |                        |                       |                       |
| Greece            |                   |                       |                       | 78                     | +1.2                  | 5.6%                  |
| Hungary           | 67                | +0.4                  | 6.1%                  |                        |                       |                       |
| International**   |                   |                       |                       | 43                     | +0.9                  | 3.9%                  |
| Ireland           | 37                | -0.3                  | 4.7%                  |                        |                       |                       |
| Italy CRB         | 56                | +0.7                  | 4.8%                  | 43                     | +1.2                  | 4.3%                  |
| Italy CRRVEQ      | 116               | +0.9                  | 4.9%                  |                        |                       |                       |
| Korea             | 74                | +0.6                  | 3.6%                  |                        |                       |                       |
| Mexico            |                   |                       |                       | 27                     | +1.6                  | 6.1%                  |
| Netherlands       | 119               | +0.4                  | 3.9%                  |                        |                       |                       |
| Portugal          |                   |                       |                       | 43                     | +1.2                  | 4.8%                  |
| South Africa      |                   |                       |                       | 5                      | +2.2                  | 3.5%                  |
| Spain             | 105               | +0.8                  | 3.7%                  |                        |                       |                       |
| Sweden            | 132               | -0.9                  | 4.0%                  |                        |                       |                       |
| Switzerland       | 67                | -0.2                  | 4.3%                  |                        |                       |                       |
| Thailand          |                   |                       |                       | 185                    | +0.5                  | 10.1%                 |
| Turkey            | 52                | +1.0                  | 5.8%                  | 50                     | +2.3                  | 7.2%                  |
| United Kingdom    | 178               | +0.1                  | 4.7%                  |                        |                       |                       |
| Overall           | 3038              | +0.4                  | 4.6%                  | 1537                   | +1.1                  | 6.2%                  |

\* n = the number of datasets.

\*\* Individual laboratories of a number of countries

In total 4575 datasets were submitted (3038 in fresh whole blood and 1537 in lyophilised hemolysate). The results are encouraging. The mean bias of all countries in the fresh whole blood programme is +0.4 mmol/mol and the between laboratory CV of 4.6% is also quite satisfying. In lyophilised hemolysate the mean bias of all laboratories is +1.1 mmol/mol and the between laboratory CV is 6.2%.

#### **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)

## 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           | EurAAA1c 2019-1<br>Target 70.1 mmol/mol |      |      |     | EurAAA1c 2019-2<br>Target 38.2 mmol/mol |      |      |     | Mean<br>2 Samples |     |
|-------------------|---|------|------|-----|---|------|------|-----|-------------------|-----|
|                   | n                                       | Mean | Bias | CV% | n                                       | Mean | Bias | CV% | Bias              | CV% |
| Belgium           | 133                                     | 71.3 | +1.2 | 2.9 | 133                                     | 38.3 | +0.1 | 4.0 | +0.6              | 3.5 |
| France CTGB       | 177                                     | 71.2 | +1.1 | 3.3 | 174                                     | 37.9 | -0.3 | 4.3 | +0.4              | 3.8 |
| France Probioqual | 361                                     | 71.4 | +1.3 | 3.1 | 358                                     | 38.3 | +0.1 | 3.8 | +0.7              | 3.4 |
| Germany INSTAND   | 636                                     | 70.5 | +0.4 | 4.8 | 632                                     | 38.0 | -0.2 | 5.6 | +0.1              | 5.2 |
| Germany RfB       | 728                                     | 71.2 | +1.1 | 4.1 | 727                                     | 38.2 | 0.0  | 5.1 | +0.5              | 4.6 |
| Hungary           | 67                                      | 71.0 | +0.9 | 5.8 | 66                                      | 38.2 | 0.0  | 6.3 | +0.4              | 6.1 |
| Ireland           | 37                                      | 70.6 | +0.5 | 4.1 | 36                                      | 37.1 | -1.1 | 5.2 | -0.3              | 4.7 |
| Italy CRB         | 56                                      | 71.5 | +1.4 | 4.1 | 54                                      | 38.3 | +0.1 | 5.4 | +0.7              | 4.8 |
| Italy CRRVEQ      | 115                                     | 71.4 | +1.3 | 4.5 | 116                                     | 38.6 | +0.4 | 5.3 | +0.9              | 4.9 |
| Korea             | 74                                      | 71.3 | +1.2 | 2.9 | 74                                      | 38.2 | 0.0  | 4.4 | +0.6              | 3.6 |
| Netherlands       | 119                                     | 71.0 | +0.9 | 3.3 | 119                                     | 38.2 | 0.0  | 4.4 | +0.4              | 3.9 |
| Spain             | 104                                     | 71.6 | +1.5 | 3.3 | 105                                     | 38.2 | 0.0  | 4.2 | +0.8              | 3.7 |
| Sweden            | 130                                     | 69.5 | -0.6 | 3.7 | 132                                     | 37.0 | -1.2 | 4.4 | -0.9              | 4.0 |
| Switzerland       | 67                                      | 70.3 | +0.2 | 4.3 | 67                                      | 37.6 | -0.6 | 4.4 | -0.2              | 4.3 |
| Turkey            | 51                                      | 71.9 | +1.8 | 4.9 | 52                                      | 38.4 | +0.2 | 6.7 | +1.0              | 5.8 |
| United Kingdom    | 176                                     | 70.9 | +0.8 | 3.8 | 178                                     | 37.6 | -0.6 | 5.7 | +0.1              | 4.7 |
| Overall           | 3031                                    | 71.0 | +0.9 | 4.1 | 3023                                    | 38.1 | -0.1 | 5.0 | +0.4              | 4.6 |

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

| Manufacturer   | EurAAA1c 2019-1<br>Target 70.1 mmol/mol |      |      |     | EurAAA1c 2019-2<br>Target 38.2 mmol/mol |      |      |      | Mean<br>2 Samples |     |
|--|---|------|------|-----|---|------|------|------|-------------------|-----|
|  | n                                       | Mean | Bias | CV% | n                                       | Mean | Bias | CV%  | Bias              | CV% |
| Abbott ARCHITECT (enzymatic)                                   | 24                                      | 71.9 | +1.8 | 1.9 | 24                                      | 38.1 | -0.1 | 3.1  | +0.9              | 2.5 |
| Abbott ARCHITECT not specified                                 | 24                                      | 71.2 | +1.1 | 3.9 | 24                                      | 37.6 | -0.6 | 4.0  | +0.3              | 3.9 |
| Abbott/Alere Afinion   | 142                                     | 68.4 | -1.7 | 2.7 | 141                                     | 36.6 | -1.6 | 5.1  | -1.6              | 3.9 |
| Beckman Coulter AU series                                      | 57                                      | 69.0 | -1.1 | 6.3 | 57                                      | 38.3 | +0.1 | 6.6  | -0.5              | 6.5 |
| Beckman Coulter Unicel DxC series                              | 19                                      | 70.6 | +0.5 | 3.3 | 19                                      | 37.7 | -0.5 | 3.2  | 0.0               | 3.2 |
| Bio-Rad D-10 series  | 91                                      | 73.7 | +3.6 | 3.4 | 92                                      | 39.2 | +1.0 | 4.3  | +2.3              | 3.8 |
| Bio-Rad D-100 series   | 124                                     | 69.0 | -1.1 | 2.8 | 123                                     | 36.1 | -2.1 | 3.6  | -1.6              | 3.2 |
| Bio-Rad Variant series   | 162                                     | 73.0 | +2.9 | 2.8 | 163                                     | 38.4 | +0.2 | 5.2  | +1.6              | 4.0 |
| EKF Diagnostics  | 11                                      | 71.4 | +1.3 | 3.0 | 11                                      | 39.4 | +1.2 | 5.4  | +1.3              | 4.2 |
| HemoCue HbA1c 501  | 14                                      | 68.4 | -1.7 | 4.3 | 14                                      | 35.4 | -2.8 | 8.9  | -2.2              | 6.6 |
| Menarini (ARKRAY) HA-8160 series                               | 74                                      | 70.7 | +0.6 | 3.2 | 73                                      | 37.6 | -0.6 | 4.4  | 0.0               | 3.8 |
| Menarini (ARKRAY) HA-8180 series                               | 214                                     | 71.0 | +0.9 | 2.8 | 213                                     | 38.1 | -0.1 | 3.8  | +0.4              | 3.3 |
| Not known  | 96                                      | 69.3 | -0.8 | 6.8 | 94                                      | 37.2 | -1.0 | 7.0  | -0.9              | 6.9 |
| Roche Diagnostics cobas b 101                                  | 6                                       | 71.9 | +1.8 | 3.8 | 6                                       | 40.3 | +2.1 | 4.1  | +2.0              | 3.9 |
| Roche Diagnostics cobas c 501/502<br>(part of cobas 6000/8000) | 387                                     | 71.6 | +1.5 | 3.5 | 387                                     | 38.1 | -0.1 | 4.0  | +0.7              | 3.7 |
| Roche Diagnostics cobas c 513                                  | 93                                      | 71.8 | +1.7 | 2.7 | 93                                      | 38.5 | +0.3 | 2.3  | +1.0              | 2.5 |
| Roche Diagnostics cobas c 311/c111                             | 20                                      | 71.4 | +1.3 | 3.6 | 20                                      | 37.7 | -0.5 | 5.4  | +0.4              | 4.5 |
| Roche Diagnostics cobas Integra                                | 98                                      | 71.7 | +1.6 | 3.3 | 98                                      | 37.9 | -0.3 | 3.5  | +0.7              | 3.4 |
| Roche Diagnostics not specified                                | 33                                      | 71.2 | +1.1 | 3.3 | 34                                      | 37.9 | -0.3 | 3.1  | +0.4              | 3.2 |
| Sebia CAPILLARYS 2   | 193                                     | 71.2 | +1.1 | 3.0 | 192                                     | 37.9 | -0.3 | 3.7  | +0.4              | 3.4 |
| Sebia CAPILLARYS 3   | 112                                     | 70.8 | +0.7 | 2.4 | 110                                     | 37.6 | -0.6 | 3.3  | +0.1              | 2.8 |
| Sebia MINICAP  | 23                                      | 70.0 | -0.1 | 2.8 | 23                                      | 37.3 | -0.9 | 3.1  | -0.5              | 3.0 |
| Siemens Advia (immunoassay)                                    | 7                                       | 72.5 | +2.4 | 6.7 | 7                                       | 39.2 | +1.0 | 5.2  | +1.7              | 5.9 |
| Siemens Advia not specified                                    | 8                                       | 73.4 | +3.3 | 6.1 | 8                                       | 39.3 | +1.1 | 11.0 | +2.2              | 8.6 |
| Siemens DCA 2000/Vantage                                       | 262                                     | 68.8 | -1.3 | 3.8 | 263                                     | 36.3 | -1.9 | 3.8  | -1.6              | 3.8 |
| Siemens Dimension series                                       | 102                                     | 68.2 | -1.9 | 2.9 | 102                                     | 39.3 | +1.1 | 4.6  | -0.4              | 3.8 |
| Tosoh G11  | 148                                     | 72.3 | +2.2 | 2.7 | 148                                     | 39.2 | +1.0 | 3.4  | +1.6              | 3.0 |
| Tosoh G7   | 19                                      | 69.8 | -0.3 | 6.6 | 19                                      | 38.2 | 0.0  | 7.1  | -0.1              | 6.8 |
| Tosoh G8   | 354                                     | 72.7 | +2.6 | 2.4 | 351                                     | 39.6 | +1.4 | 2.9  | +2.0              | 2.6 |
| Tosoh GX   | 22                                      | 72.8 | +2.7 | 3.9 | 22                                      | 39.8 | +1.6 | 2.6  | +2.1              | 3.2 |
| Trinity Biotech Premier Hb9210                                 | 29                                      | 71.1 | +1.0 | 2.4 | 28                                      | 38.5 | +0.3 | 5.4  | +0.7              | 3.9 |

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

| Manufacturer                                 | EurAAA1c 2019-1<br>Target 70.1 mmol/mol |      |       |      | EurAAA1c 2019-2<br>Target 38.2 mmol/mol |      |      |      | Mean<br>2 Samples |      |
|--|---|------|-------|------|---|------|------|------|-------------------|------|
|  | n                                       | Mean | Bias  | CV%  | n                                       | Mean | Bias | CV%  | Bias              | CV%  |
| Abbott Alinity                               | 4                                       | 72.2 | +2.1  | 5.0  | 4                                       | 38.3 | 0.0  | 4.6  | +1.1              | 4.8  |
| Abbott ARCHITECT (immunoassay)               | 3                                       | 66.8 | -3.3  | 12.2 | 3                                       | 36.9 | -1.3 | 0.7  | -2.3              | 6.5  |
| Abbott AxSym                                 | 3                                       | 70.0 | -0.1  | 5.7  | 3                                       | 37.0 | -1.2 | 8.1  | -0.6              | 6.9  |
| Beckman Coulter not specified                | 2                                       | 69.2 | -0.9  | 5.8  | 2                                       | 37.4 | -0.8 | 6.1  | -0.9              | 6.0  |
| Bio-Rad not specified                        | 5                                       | 74.7 | +4.6  | 5.5  | 5                                       | 39.5 | +1.3 | 5.1  | +3.0              | 5.3  |
| Diasys InnovaStar                            | 1                                       | 80.8 | +10.7 |      | 1                                       | 46.5 | +8.3 |      | +9.5              |      |
| Eurolyser                                    | 2                                       | 68.0 | -2.2  |      | 2                                       | 34.4 | -3.7 |      | -2.9              |      |
| Hitado                                       | 2                                       | 64.2 | -5.9  | 0.5  | 2                                       | 34.6 | -3.6 | 10.7 | -4.7              | 5.6  |
| Horiba Pentra                                | 5                                       | 72.6 | +2.5  | 5.3  | 5                                       | 37.3 | -0.9 | 4.1  | +0.8              | 4.7  |
| ISE S.r.l. Hemo One ISE HbA1c                | 1                                       | 59.2 | -10.9 |      | 1                                       | 31.0 | -7.2 |      | -9.1              |      |
| Lifotronic                                   | 1                                       | 70.4 | +0.3  |      | 1                                       | 38.7 | +0.5 |      | +0.4              |      |
| Medinor NycoCard                             | 5                                       | 67.0 | -3.1  | 9.9  | 6                                       | 38.3 | +0.1 | 11.3 | -1.5              | 10.6 |
| Menarini (ARKRAY) HA-8140 series             | 2                                       | 71.3 | +1.2  | 1.5  | 2                                       | 39.0 | +0.8 | 0.0  | +1.0              | 0.7  |
| Menarini (ARKRAY) not specified              | 3                                       | 70.2 | +0.1  | 3.3  | 3                                       | 38.7 | +0.5 | 5.4  | +0.3              | 4.3  |
| MTD Diagnostics                              | 1                                       | 68.7 | -1.4  |      | 1                                       | 32.9 | -5.3 |      | -3.4              |      |
| Ortho Clinical Diagnostics Vitros series     | 1                                       | 70.0 | -0.1  |      | 1                                       | 35.0 | -3.2 |      | -1.7              |      |
| Randox RX series                             | 1                                       | 64.7 | -5.4  |      | 1                                       | 42.1 | +3.9 |      | -0.7              |      |
| Roche Diagnostics cobas c 503<br>(cobas pro) | 4                                       | 70.3 | +0.2  | 3.7  | 4                                       | 38.6 | +0.3 | 2.7  | +0.3              | 3.2  |
| Siemens Advia (enzymatic)                    | 3                                       | 71.8 | +1.7  | 3.7  | 3                                       | 39.2 | +1.0 | 4.3  | +1.4              | 4.0  |
| Siemens Atellica CH (immunoassay)            | 2                                       | 68.7 | -1.4  | 3.6  | 2                                       | 38.9 | +0.7 | 0.4  | -0.3              | 2.0  |
| Siemens Atellica CH not specified            | 2                                       | 75.0 | +4.9  | 0.0  | 2                                       | 41.5 | +3.3 | 1.7  | +4.1              | 0.9  |
| Siemens not specified                        | 1                                       | 68.0 | -2.1  |      | 1                                       | 37.0 | -1.2 |      | -1.7              |      |
| Siemens Other                                | 1                                       | 66.0 | -4.1  |      | 1                                       | 35.0 | -3.2 |      | -3.7              |      |
| Thermo Scientific                            | 5                                       | 67.0 | -3.1  | 5.1  | 5                                       | 39.5 | +1.3 | 4.6  | -0.9              | 4.8  |
| Tosoh not specified                          | 3                                       | 75.7 | +5.6  | 2.9  | 3                                       | 41.2 | +3.0 | 4.0  | +4.3              | 3.5  |

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   | EurAAA1c 2019-1<br>Target 70.1 mmol/mol |     | EurAAA1c 2019-2<br>Target 38.2 mmol/mol |     | Mean |     |
|---|-----|---|-----|---|-----|------|-----|
|   |     | Bias                                    | CV% | Bias                                    | CV% | Bias | CV% |
| <b>Abbott/Alere AFINION</b>             |     |   |     |   |     |      |     |
| Overall                                 | 142 | -1.7                                    | 2.7 | -1.6                                    | 5.1 | -1.6 | 3.9 |
| CH                                      | 19  | -2.1                                    | 2.1 | -1.5                                    | 2.4 | -1.8 | 2.2 |
| DE-INSTAND                              | 47  | -1.6                                    | 2.6 | -1.0                                    | 4.4 | -1.3 | 3.5 |
| DE-RfB                                  | 7   | -1.8                                    | 4.3 | -0.9                                    | 8.2 | -1.4 | 6.2 |
| IE                                      | 6   | +0.2                                    | 1.5 | -1.7                                    | 3.8 | -0.7 | 2.6 |
| NL                                      | 11  | -1.1                                    | 3.3 | -1.5                                    | 4.9 | -1.3 | 4.1 |
| SE                                      | 37  | -1.9                                    | 2.0 | -1.8                                    | 3.7 | -1.9 | 2.9 |
| UK                                      | 14  | -2.6                                    | 2.8 | -3.7                                    | 4.7 | -3.1 | 3.7 |
| <b>Beckman Coulter AU series</b>        |     |   |     |   |     |      |     |
| Overall                                 | 57  | -1.1                                    | 6.3 | +0.1                                    | 6.6 | -0.5 | 6.5 |
| DE-INSTAND                              | 22  | -0.2                                    | 6.0 | +0.6                                    | 8.2 | +0.2 | 7.1 |
| DE-RfB                                  | 25  | -1.0                                    | 6.3 | -0.3                                    | 4.1 | -0.6 | 5.2 |
| <b>Bio-Rad D-10 series</b>              |     |   |     |   |     |      |     |
| Overall                                 | 91  | +3.6                                    | 3.4 | +1.0                                    | 4.3 | +2.3 | 3.8 |
| DE-INSTAND                              | 22  | +3.6                                    | 3.5 | +1.0                                    | 3.9 | +2.3 | 3.7 |
| DE-RfB                                  | 31  | +3.7                                    | 3.1 | +0.8                                    | 4.4 | +2.2 | 3.8 |
| FR-CTCB                                 | 9   | +3.1                                    | 3.8 | +0.8                                    | 6.1 | +2.0 | 4.9 |
| FR-Probioqual                           | 14  | +3.9                                    | 3.1 | +1.6                                    | 2.7 | +2.8 | 2.9 |
| <b>Bio-Rad D-100 series</b>             |     |   |     |   |     |      |     |
| Overall                                 | 124 | -1.1                                    | 2.8 | -2.1                                    | 3.6 | -1.6 | 3.2 |
| BE                                      | 6   | -1.5                                    | 2.1 | -3.2                                    | 1.6 | -2.3 | 1.8 |
| DE-INSTAND                              | 13  | -1.2                                    | 6.6 | -1.0                                    | 5.6 | -1.1 | 6.1 |
| DE-RfB                                  | 30  | -1.2                                    | 1.5 | -2.5                                    | 3.7 | -1.8 | 2.6 |
| ES                                      | 12  | -1.0                                    | 3.1 | -2.1                                    | 3.4 | -1.6 | 3.2 |
| FR-Probioqual                           | 19  | -1.4                                    | 2.5 | -2.3                                    | 2.6 | -1.8 | 2.6 |
| KR                                      | 27  | -0.7                                    | 1.9 | -1.7                                    | 2.8 | -1.2 | 2.3 |
| <b>Bio-Rad Variant series</b>           |     |   |     |   |     |      |     |
| Overall                                 | 162 | +2.9                                    | 2.8 | +0.2                                    | 5.2 | +1.6 | 4.0 |
| DE-INSTAND                              | 21  | +2.0                                    | 3.8 | 0.0                                     | 6.1 | +1.0 | 4.9 |
| DE-RfB                                  | 43  | +2.6                                    | 2.4 | -0.3                                    | 5.8 | +1.2 | 4.1 |
| FR-CTCB                                 | 16  | +3.3                                    | 2.6 | -0.3                                    | 5.7 | +1.5 | 4.2 |
| FR-Probioqual                           | 31  | +3.3                                    | 2.0 | +0.5                                    | 3.6 | +1.9 | 2.8 |
| HU                                      | 8   | +2.8                                    | 4.0 | +1.1                                    | 4.5 | +1.9 | 4.3 |
| IT-CRRVEQ                               | 9   | +4.1                                    | 2.6 | +0.2                                    | 2.3 | +2.2 | 2.4 |
| SE                                      | 8   | +1.7                                    | 1.7 | +0.1                                    | 3.3 | +0.9 | 2.5 |
| TR                                      | 13  | +4.5                                    | 2.2 | +1.5                                    | 5.2 | +3.0 | 3.7 |
| <b>HemoCue HbA1c 501</b>                |     |   |     |   |     |      |     |
| Overall                                 | 14  | -1.7                                    | 4.3 | -2.8                                    | 8.9 | -2.2 | 6.6 |
| DE-INSTAND                              | 7   | -1.1                                    | 5.7 | -3.2                                    | 8.9 | -2.2 | 7.3 |
| DE-RfB                                  | 7   | -2.3                                    | 2.4 | -2.4                                    | 9.5 | -2.3 | 6.0 |
| <b>Menarini (ARKRAY) HA-8160 series</b> |     |   |     |   |     |      |     |
| Overall                                 | 74  | +0.6                                    | 3.2 | -0.6                                    | 4.4 | 0.0  | 3.8 |
| BE                                      | 21  | +0.7                                    | 2.5 | -0.7                                    | 2.7 | 0.0  | 2.6 |
| HU                                      | 21  | -0.2                                    | 4.3 | -0.7                                    | 5.4 | -0.5 | 4.9 |
| IT-CRB                                  | 12  | +1.9                                    | 2.4 | -0.1                                    | 6.2 | +0.9 | 4.3 |
| NL                                      | 9   | +1.1                                    | 2.0 | -0.2                                    | 3.9 | +0.5 | 3.0 |
| <b>Menarini (ARKRAY) HA-8180 series</b> |     |   |     |   |     |      |     |
| Overall                                 | 214 | +0.9                                    | 2.8 | -0.1                                    | 3.8 | +0.4 | 3.3 |
| BE                                      | 39  | +0.6                                    | 2.6 | -0.2                                    | 3.1 | +0.2 | 2.8 |
| CH                                      | 2   | -0.7                                    | 4.5 | -0.5                                    | 8.2 | -0.6 | 6.3 |
| DE-INSTAND                              | 20  | +1.3                                    | 2.3 | +0.4                                    | 3.2 | +0.8 | 2.7 |
| DE-RfB                                  | 26  | +0.4                                    | 4.2 | -0.7                                    | 6.4 | -0.2 | 5.3 |
| ES                                      | 47  | +1.4                                    | 2.9 | 0.0                                     | 3.3 | +0.7 | 3.1 |
| HU                                      | 6   | +1.2                                    | 2.7 | +0.6                                    | 3.8 | +0.9 | 3.2 |
| IE                                      | 7   | +1.8                                    | 2.6 | +0.4                                    | 2.9 | +1.1 | 2.8 |
| IT-CRB                                  | 8   | +1.8                                    | 1.7 | +0.4                                    | 2.4 | +1.1 | 2.1 |
| IT-CRRVEQ                               | 11  | +0.9                                    | 1.8 | -0.1                                    | 2.5 | +0.4 | 2.1 |
| KR                                      | 8   | +1.2                                    | 1.6 | +0.1                                    | 2.2 | +0.6 | 1.9 |
| NL                                      | 20  | +0.4                                    | 2.1 | -0.1                                    | 2.7 | +0.2 | 2.4 |
| TR                                      | 6   | +0.7                                    | 3.9 | -0.8                                    | 7.0 | -0.1 | 5.4 |
| UK                                      | 14  | +0.8                                    | 2.4 | -0.3                                    | 2.7 | +0.2 | 2.5 |



| Method   | n   | EurAAA1c 2019-1<br>Target 70.1 mmol/mol |     | EurAAA1c 2019-2<br>Target 38.2 mmol/mol |     | Mean |     |
|--|-----|---|-----|---|-----|------|-----|
|  |     | Bias                                    | CV% | Bias                                    | CV% | Bias | CV% |
| Roche Diagnostics cobas c 501/502<br>(part of cobas 6000/8000) |     |   |     |   |     |      |     |
| Overall  | 387 | +1.5                                    | 3.5 | -0.1                                    | 4.0 | +0.7 | 3.7 |
| CH   | 13  | +2.6                                    | 3.3 | +0.2                                    | 2.9 | +1.4 | 3.1 |
| DE-INSTAND   | 127 | +1.5                                    | 3.3 | -0.1                                    | 3.7 | +0.7 | 3.5 |
| DE-RfB   | 163 | +1.4                                    | 3.4 | -0.2                                    | 4.6 | +0.6 | 4.0 |
| ES   | 6   | +3.4                                    | 2.1 | -0.1                                    | 3.8 | +1.7 | 3.0 |
| FR-Probioqual  | 27  | +1.7                                    | 4.0 | -0.1                                    | 3.7 | +0.8 | 3.9 |
| NL   | 15  | +1.2                                    | 2.1 | +0.1                                    | 2.9 | +0.7 | 2.5 |
| SE   | 9   | +0.5                                    | 4.1 | -0.7                                    | 2.1 | -0.1 | 3.1 |
| TR   | 11  | +1.4                                    | 4.3 | 0.0                                     | 4.1 | +0.7 | 4.2 |
| Roche Diagnostics cobas c 513                                  |     |   |     |   |     |      |     |
| Overall  | 93  | +1.7                                    | 2.7 | +0.3                                    | 2.3 | +1.0 | 2.5 |
| DE-INSTAND   | 28  | +1.4                                    | 2.9 | +0.3                                    | 1.9 | +0.8 | 2.4 |
| DE-RfB   | 54  | +1.4                                    | 1.9 | +0.1                                    | 1.8 | +0.8 | 1.9 |
| Roche Diagnostics cobas Integra                                |     |   |     |   |     |      |     |
| Overall  | 98  | +1.6                                    | 3.3 | -0.3                                    | 3.5 | +0.7 | 3.4 |
| DE-INSTAND   | 45  | +1.4                                    | 3.4 | -0.7                                    | 3.5 | +0.4 | 3.4 |
| DE-RfB   | 46  | +1.6                                    | 3.4 | +0.2                                    | 3.1 | +0.9 | 3.3 |
| Roche Diagnostics not specified                                |     |   |     |   |     |      |     |
| Overall  | 33  | +1.1                                    | 3.3 | -0.3                                    | 3.1 | +0.4 | 3.2 |
| FR-CTCB  | 20  | +1.0                                    | 3.4 | -0.4                                    | 3.1 | +0.3 | 3.2 |
| KR   | 9   | +1.7                                    | 2.1 | +0.4                                    | 2.4 | +1.0 | 2.2 |
| Sebia CAPILLARYS 2   |     |   |     |   |     |      |     |
| Overall  | 193 | +1.1                                    | 3.0 | -0.3                                    | 3.7 | +0.4 | 3.4 |
| BE   | 9   | +0.7                                    | 4.3 | +0.5                                    | 3.2 | +0.6 | 3.7 |
| DE-INSTAND   | 9   | +0.8                                    | 3.0 | +0.4                                    | 1.9 | +0.6 | 2.5 |
| DE-RfB   | 42  | +1.7                                    | 3.1 | -0.1                                    | 4.7 | +0.8 | 3.9 |
| FR-CTCB  | 34  | -0.1                                    | 3.9 | -1.0                                    | 3.8 | -0.5 | 3.9 |
| FR-Probioqual  | 69  | +1.2                                    | 2.3 | -0.2                                    | 2.9 | +0.5 | 2.6 |
| IT-CRB   | 6   | +0.7                                    | 2.3 | 0.0                                     | 2.6 | +0.3 | 2.4 |
| IT-CRRVEQ  | 8   | +2.3                                    | 2.9 | +0.2                                    | 4.2 | +1.2 | 3.5 |
| UK   | 7   | +1.0                                    | 1.0 | -1.5                                    | 3.4 | -0.2 | 2.2 |
| Sebia CAPILLARYS 3   |     |   |     |   |     |      |     |
| Overall  | 112 | +0.7                                    | 2.4 | -0.6                                    | 3.3 | +0.1 | 2.8 |
| DE-RfB   | 6   | +0.7                                    | 2.7 | -0.4                                    | 3.9 | +0.2 | 3.3 |
| FR-CTCB  | 30  | +0.4                                    | 2.8 | -1.1                                    | 3.3 | -0.4 | 3.1 |
| FR-Probioqual  | 46  | +0.9                                    | 2.1 | -0.3                                    | 3.1 | +0.3 | 2.6 |
| IT-CRRVEQ  | 8   | +0.9                                    | 2.6 | -0.7                                    | 2.9 | +0.1 | 2.7 |
| SE   | 6   | +0.4                                    | 1.2 | -1.2                                    | 3.4 | -0.4 | 2.3 |
| UK   | 6   | +1.3                                    | 3.2 | -0.8                                    | 1.5 | +0.3 | 2.3 |
| Sebia MINICAP  |     |   |     |   |     |      |     |
| Overall  | 23  | -0.1                                    | 2.8 | -0.9                                    | 3.1 | -0.5 | 3.0 |
| BE   | 6   | -0.1                                    | 3.6 | -1.0                                    | 4.6 | -0.6 | 4.1 |
| FR-Probioqual  | 8   | 0.0                                     | 2.1 | -0.6                                    | 2.4 | -0.3 | 2.3 |
| Siemens DCA 2000/Vantage                                       |     |   |     |   |     |      |     |
| Overall  | 262 | -1.3                                    | 3.8 | -1.9                                    | 3.8 | -1.6 | 3.8 |
| CH   | 10  | -1.1                                    | 5.6 | -1.8                                    | 4.9 | -1.5 | 5.2 |
| DE-INSTAND   | 49  | -2.1                                    | 3.0 | -2.3                                    | 4.3 | -2.2 | 3.7 |
| DE-RfB   | 32  | -1.8                                    | 3.5 | -1.9                                    | 3.6 | -1.9 | 3.6 |
| FR-Probioqual  | 26  | -1.0                                    | 3.5 | -1.5                                    | 2.7 | -1.3 | 3.1 |
| IE   | 18  | -0.7                                    | 5.0 | -2.2                                    | 3.9 | -1.5 | 4.4 |
| NL   | 14  | -1.5                                    | 3.8 | -1.8                                    | 2.6 | -1.7 | 3.2 |
| SE   | 52  | -1.2                                    | 3.8 | -1.6                                    | 4.2 | -1.4 | 4.0 |
| UK   | 58  | -0.6                                    | 3.5 | -1.9                                    | 3.7 | -1.3 | 3.6 |
| Siemens Dimension series                                       |     |   |     |   |     |      |     |
| Overall  | 102 | -1.9                                    | 2.9 | +1.1                                    | 4.6 | -0.4 | 3.8 |
| DE-INSTAND   | 37  | -2.0                                    | 2.5 | +1.0                                    | 3.9 | -0.5 | 3.2 |
| DE-RfB   | 47  | -1.8                                    | 3.5 | +1.0                                    | 5.0 | -0.4 | 4.3 |
| FR-Probioqual  | 9   | -2.4                                    | 0.8 | +1.2                                    | 4.4 | -0.6 | 2.6 |

| Method           | n   | EurAAA1c 2019-1<br>Target 70.1 mmol/mol |     | EurAAA1c 2019-2<br>Target 38.2 mmol/mol |     | Mean |     |
|------------------|-----|---|-----|---|-----|------|-----|
|                  |     | Bias                                    | CV% | Bias                                    | CV% | Bias | CV% |
| <b>Tosoh G8</b>  |     |   |     |   |     |      |     |
| Overall          | 354 | +2.6                                    | 2.4 | +1.4                                    | 2.9 | +2.0 | 2.6 |
| BE               | 35  | +2.3                                    | 2.1 | +1.6                                    | 2.4 | +1.9 | 2.2 |
| DE-INSTAND       | 23  | +2.8                                    | 2.7 | +1.6                                    | 3.2 | +2.2 | 3.0 |
| DE-RfB           | 59  | +2.9                                    | 2.2 | +1.6                                    | 2.6 | +2.2 | 2.4 |
| ES               | 13  | +2.9                                    | 2.4 | +1.6                                    | 3.2 | +2.3 | 2.8 |
| FR-CTCB          | 39  | +1.3                                    | 1.7 | +0.5                                    | 2.0 | +0.9 | 1.9 |
| FR-Probioqual    | 56  | +2.4                                    | 1.7 | +1.2                                    | 2.1 | +1.8 | 1.9 |
| IT-CRB           | 6   | +4.2                                    | 2.2 | +2.1                                    | 3.0 | +3.2 | 2.6 |
| IT-CRRVEQ        | 28  | +2.4                                    | 3.4 | +1.3                                    | 3.1 | +1.8 | 3.3 |
| KR               | 11  | +3.2                                    | 1.7 | +1.9                                    | 2.4 | +2.5 | 2.0 |
| NL               | 26  | +2.5                                    | 2.6 | +1.5                                    | 3.2 | +2.0 | 2.9 |
| SE               | 11  | +2.1                                    | 2.5 | +0.7                                    | 3.6 | +1.4 | 3.1 |
| TR               | 7   | +2.9                                    | 3.3 | +0.6                                    | 5.7 | +1.8 | 4.5 |
| UK               | 37  | +3.7                                    | 1.9 | +1.9                                    | 2.5 | +2.8 | 2.2 |
| <b>Tosoh G11</b> |     |   |     |   |     |      |     |
| Overall          | 148 | +2.2                                    | 2.7 | +1.0                                    | 3.4 | +1.6 | 3.0 |
| DE-INSTAND       | 19  | +2.8                                    | 3.2 | +1.4                                    | 3.5 | +2.1 | 3.4 |
| DE-RfB           | 40  | +2.9                                    | 3.7 | +1.1                                    | 5.1 | +2.0 | 4.4 |
| FR-Probioqual    | 37  | +1.4                                    | 1.2 | +0.9                                    | 1.6 | +1.1 | 1.4 |
| IT-CRRVEQ        | 9   | +1.7                                    | 1.9 | +0.9                                    | 2.9 | +1.3 | 2.4 |
| KR               | 18  | +2.6                                    | 1.8 | +1.1                                    | 1.7 | +1.8 | 1.7 |
| UK               | 8   | +1.7                                    | 1.2 | +0.7                                    | 2.1 | +1.2 | 1.7 |

### 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 2019-1<br>Target 70.1 mmol/mol |      |      |     | EurA1c 2019-2<br>Target 38.2 mmol/mol |      |      |      | Mean<br>2 Samples |      |
|-------------------|---------------------------------------|------|------|-----|---------------------------------------|------|------|------|-------------------|------|
|                   | n                                     | Mean | Bias | CV% | n                                     | Mean | Bias | CV%  | Bias              | CV%  |
| Austria           | 116                                   | 72.0 | +1.9 | 5.4 | 117                                   | 38.3 | +0.1 | 5.8  | +1.0              | 5.6  |
| Czech Republic    | 195                                   | 72.3 | +2.2 | 5.1 | 197                                   | 38.5 | +0.3 | 5.2  | +1.2              | 5.1  |
| France Asqualab   | 47                                    | 71.9 | +1.8 | 4.6 | 46                                    | 39.1 | +0.9 | 5.8  | +1.4              | 5.2  |
| France CTCB       | 157                                   | 72.4 | +2.3 | 4.8 | 157                                   | 38.7 | +0.5 | 5.0  | +1.4              | 4.9  |
| France Probioqual | 548                                   | 71.8 | +1.7 | 5.1 | 539                                   | 38.5 | +0.3 | 6.7  | +1.0              | 5.9  |
| Greece            | 78                                    | 72.1 | +2.0 | 4.7 | 86                                    | 38.6 | +0.4 | 6.4  | +1.2              | 5.6  |
| International*    | 43                                    | 71.5 | +1.4 | 4.4 | 56                                    | 38.5 | +0.3 | 3.5  | +0.9              | 3.9  |
| Italy CRB         | 43                                    | 72.1 | +2.0 | 3.2 | 42                                    | 38.7 | +0.5 | 5.3  | +1.2              | 4.3  |
| Mexico            | 27                                    | 72.4 | +2.3 | 5.8 | 27                                    | 39.1 | +0.9 | 6.5  | +1.6              | 6.1  |
| Portugal          | 43                                    | 72.2 | +2.1 | 4.5 | 43                                    | 38.6 | +0.4 | 5.2  | +1.2              | 4.8  |
| South Africa      | 5                                     | 73.6 | +3.5 | 3.9 | 5                                     | 39.0 | +0.8 | 3.1  | +2.2              | 3.5  |
| Thailand          | 185                                   | 71.1 | +1.0 | 9.5 | 184                                   | 38.1 | -0.1 | 10.6 | +0.5              | 10.1 |
| Turkey            | 50                                    | 73.4 | +3.3 | 7.0 | 50                                    | 39.4 | +1.2 | 7.4  | +2.3              | 7.2  |
| Overall           | 1537                                  | 71.9 | +1.8 | 5.8 | 1549                                  | 38.5 | +0.3 | 6.7  | +1.1              | 6.2  |

\* Individual laboratories of a number of countries

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

| Manufacturer   | EurA1c 2019-1<br>Target 70.1 mmol/mol |      |      |      | EurA1c 2019-2<br>Target 38.2 mmol/mol |      |      |      | Mean<br>2 Samples |      |
|--|---------------------------------------|------|------|------|---------------------------------------|------|------|------|-------------------|------|
|  | n                                     | Mean | Bias | CV%  | n                                     | Mean | Bias | CV%  | Bias              | CV%  |
| Abbott ARCHITECT (enzymatic)                                   | 39                                    | 69.3 | -0.8 | 4.0  | 39                                    | 36.7 | -1.5 | 6.2  | -1.2              | 5.1  |
| Abbott ARCHITECT not specified                                 | 17                                    | 64.1 | -6.0 | 7.3  | 17                                    | 32.8 | -5.4 | 10.4 | -5.7              | 8.9  |
| Beckman Coulter AU series                                      | 13                                    | 76.6 | +6.5 | 5.6  | 14                                    | 41.7 | +3.5 | 6.6  | +5.0              | 6.1  |
| BioMajesty JCA-BM6010  | 7                                     | 64.1 | -6.0 | 6.9  | 6                                     | 35.1 | -3.1 | 7.6  | -4.5              | 7.3  |
| Bio-Rad D-10 series  | 106                                   | 73.4 | +3.3 | 5.2  | 107                                   | 38.4 | +0.2 | 6.6  | +1.8              | 5.9  |
| Bio-Rad D-100 series   | 49                                    | 71.4 | +1.3 | 2.3  | 49                                    | 37.8 | -0.4 | 3.6  | +0.4              | 2.9  |
| Bio-Rad Variant series   | 66                                    | 73.1 | +3.0 | 5.3  | 67                                    | 38.6 | +0.4 | 8.9  | +1.7              | 7.1  |
| Menarini (ARKRAY) HA-8160 series                               | 59                                    | 70.8 | +0.7 | 3.6  | 62                                    | 37.8 | -0.4 | 5.1  | +0.2              | 4.4  |
| Menarini (ARKRAY) HA-8180 series                               | 99                                    | 68.0 | -2.1 | 5.7  | 102                                   | 37.2 | -1.0 | 5.4  | -1.5              | 5.5  |
| Menarini (ARKRAY) not specified                                | 24                                    | 69.7 | -0.4 | 4.6  | 24                                    | 37.1 | -1.1 | 3.9  | -0.7              | 4.3  |
| Not known  | 11                                    | 71.5 | +1.4 | 4.6  | 13                                    | 37.5 | -0.7 | 8.7  | +0.4              | 6.7  |
| Ortho Clinical Diagnostics Vitros series                       | 7                                     | 74.6 | +4.5 | 4.8  | 7                                     | 40.6 | +2.4 | 5.0  | +3.5              | 4.9  |
| Roche Diagnostics cobas c 501/502<br>(part of cobas 6000/8000) | 203                                   | 75.2 | +5.1 | 3.7  | 199                                   | 39.3 | +1.1 | 6.1  | +3.1              | 4.9  |
| Roche Diagnostics cobas c 513                                  | 10                                    | 74.0 | +3.9 | 2.7  | 10                                    | 40.6 | +2.4 | 4.6  | +3.2              | 3.7  |
| Roche Diagnostics cobas c311/c111                              | 12                                    | 74.5 | +4.4 | 6.3  | 13                                    | 38.1 | -0.1 | 10.3 | +2.1              | 8.3  |
| Roche Diagnostics cobas Integra                                | 39                                    | 74.5 | +4.4 | 3.3  | 39                                    | 39.3 | +1.1 | 7.0  | +2.7              | 5.2  |
| Roche Diagnostics not specified                                | 22                                    | 74.3 | +4.2 | 3.9  | 23                                    | 39.9 | +1.7 | 4.0  | +3.0              | 4.0  |
| Sebia CAPILLARYS 2   | 131                                   | 70.1 | 0.0  | 2.4  | 135                                   | 37.9 | -0.3 | 3.8  | -0.2              | 3.1  |
| Sebia CAPILLARYS 3   | 101                                   | 70.8 | +0.7 | 2.6  | 104                                   | 38.4 | +0.2 | 2.9  | +0.5              | 2.8  |
| Sebia MINICAP  | 23                                    | 70.2 | +0.1 | 3.2  | 20                                    | 38.0 | -0.2 | 3.8  | 0.0               | 3.5  |
| Sebia not specified  | 10                                    | 71.2 | +1.1 | 2.9  | 10                                    | 38.0 | -0.2 | 4.1  | +0.5              | 3.5  |
| Siemens DCA 2000/Vantage                                       | 61                                    | 75.9 | +5.8 | 4.4  | 58                                    | 42.6 | +4.4 | 5.2  | +5.1              | 4.8  |
| Siemens Dimension series                                       | 32                                    | 75.3 | +5.2 | 8.5  | 33                                    | 41.4 | +3.2 | 7.1  | +4.2              | 7.8  |
| Sysmex bx-3010   | 8                                     | 63.2 | -6.9 | 10.8 | 8                                     | 34.0 | -4.2 | 13.0 | -5.6              | 11.9 |

| Manufacturer                   | EurA1c 2019-1<br>Target 70.1 mmol/mol |      |      |     | EurA1c 2019-2<br>Target 38.2 mmol/mol |      |      |     | Mean<br>2 Samples |     |
|--------------------------------|---------------------------------------|------|------|-----|---------------------------------------|------|------|-----|-------------------|-----|
|                                | n                                     | Mean | Bias | CV% | n                                     | Mean | Bias | CV% | Bias              | CV% |
| Tosoh G11                      | 64                                    | 73.6 | +3.5 | 4.8 | 64                                    | 38.6 | +0.4 | 3.7 | +2.0              | 4.2 |
| Tosoh G7                       | 41                                    | 72.1 | +2.0 | 2.7 | 42                                    | 39.4 | +1.2 | 3.6 | +1.6              | 3.2 |
| Tosoh G8                       | 180                                   | 70.9 | +0.8 | 3.8 | 182                                   | 38.8 | +0.6 | 3.4 | +0.7              | 3.6 |
| Tosoh GX                       | 18                                    | 70.3 | +0.2 | 5.0 | 18                                    | 38.0 | -0.2 | 4.3 | 0.0               | 4.7 |
| Tosoh not specified            | 9                                     | 70.8 | +0.7 | 4.5 | 11                                    | 38.8 | +0.6 | 6.0 | +0.7              | 5.2 |
| Trinity Biotech Premier Hb9210 | 16                                    | 70.7 | +0.6 | 4.3 | 16                                    | 38.8 | +0.6 | 5.9 | +0.6              | 5.1 |

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 2019-1<br>Target 70.1 mmol/mol |      |      |      | EurA1c 2019-2<br>Target 38.2 mmol/mol |      |      |      | Mean<br>2 Samples |      |
|---|---------------------------------------|------|------|------|---------------------------------------|------|------|------|-------------------|------|
|   | n                                     | Mean | Bias | CV%  | n                                     | Mean | Bias | CV%  | Bias              | CV%  |
| Abbott Alinity                            | 4                                     | 62.9 | -7.2 | 7.4  | 4                                     | 31.7 | -6.5 | 10.7 | -6.9              | 9.0  |
| Abbott ARCHITECT (immunoassay)            | 3                                     | 73.6 | +3.5 | 8.2  | 2                                     | 36.3 | -1.9 | 5.2  | +0.8              | 6.7  |
| Abbott not specified                      | 2                                     | 76.4 | +6.3 | 4.0  | 2                                     | 40.5 | +2.3 | 0.5  | +4.3              | 2.2  |
| Abbott Other                              | 2                                     | 72.5 | +2.4 | 6.8  | 1                                     | 39.0 | +0.8 |      | +1.6              |      |
| Beckman Coulter AU series                 | 2                                     | 80.0 | +9.9 | 7.1  | 2                                     | 39.5 | +1.3 | 1.6  | +5.6              | 4.3  |
| Beckman Coulter P/ACE MDQ                 | 1                                     | 68.0 | -2.1 |      | 1                                     | 37.0 | -1.2 |      | -1.7              |      |
| Beckman Coulter Unicel DxC series         | 1                                     | 76.0 | +5.9 |      | 1                                     | 42.0 | +3.8 |      | +4.9              |      |
| BioHermes A1c Check Pro                   | 1                                     | 68.3 | -1.8 |      | 1                                     | 37.7 | -0.5 |      | -1.2              |      |
| Bio-Rad not specified                     | 5                                     | 76.0 | +5.9 | 4.8  | 4                                     | 39.2 | +1.0 | 3.2  | +3.5              | 4.0  |
| Bio-Rad Other                             | 1                                     | 73.0 | +2.9 |      | 1                                     | 39.0 | +0.8 |      | +1.9              |      |
| BioSystems BA400                          |                                       |      |      |      | 1                                     | 37.7 | -0.5 |      | -0.5              |      |
| Ceragem LabonaCheck A1c                   | 1                                     | 69.0 | -1.1 |      | 1                                     | 37.0 | -1.2 |      | -1.2              |      |
| Ceragem Medisys CERA-STAT 4000            | 1                                     | 70.5 | +0.4 |      |                                       |      |      |      |                   |      |
| Furuno CA-800                             | 1                                     | 73.8 | +3.7 |      | 1                                     | 43.2 | +5.0 |      | +4.4              |      |
| ISE S.r.l. Hemo One ISE HbA1c             | 1                                     | 69.1 | -1.0 |      | 1                                     | 36.8 | -1.4 |      | -1.2              |      |
| Lifotronic                                | 2                                     | 68.5 | -1.6 | 9.3  | 2                                     | 38.5 | +0.3 | 9.2  | -0.6              | 9.2  |
| Medconn MQ-2000PT                         | 2                                     | 68.9 | -1.3 | 1.1  | 2                                     | 38.8 | +0.5 | 7.8  | -0.4              | 4.5  |
| Menarini (ARKRAY) HA-8140 series          | 3                                     | 74.3 | +4.2 | 1.6  | 3                                     | 38.3 | +0.1 | 3.0  | +2.2              | 2.3  |
| Mindray bs series                         | 3                                     | 62.8 | -7.3 | 6.9  | 2                                     | 31.7 | -6.5 | 12.0 | -6.9              | 9.5  |
| Other                                     | 2                                     | 65.4 | -4.7 | 22.2 | 2                                     | 34.1 | -4.1 | 10.3 | -4.4              | 16.3 |
| Randox RX series                          | 4                                     | 63.0 | -7.1 | 9.6  | 5                                     | 37.7 | -0.5 | 11.5 | -3.8              | 10.5 |
| Roche Diagnostics cobas b 101             | 2                                     | 62.9 | -7.2 | 2.5  | 2                                     | 32.6 | -5.6 | 1.7  | -6.4              | 2.1  |
| Roche Diagnostics cobas c 503 (cobas pro) | 4                                     | 77.1 | +7.0 | 4.9  | 4                                     | 41.7 | +3.5 | 4.4  | +5.3              | 4.7  |
| Sekisui CS T240                           | 1                                     | 69.0 | -1.1 |      | 1                                     | 37.0 | -1.2 |      | -1.2              |      |
| Siemens Advia not specified               | 1                                     | 67.0 | -3.1 |      | 1                                     | 36.0 | -2.2 |      | -2.7              |      |
| Siemens Atellica CH not specified         | 3                                     | 68.4 | -1.7 | 11.1 | 3                                     | 35.7 | -2.5 | 15.6 | -2.1              | 13.3 |
| Spinreact Spinlab 200E                    | 2                                     | 76.0 | +5.9 | 5.6  | 2                                     | 40.0 | +1.8 | 3.5  | +3.9              | 4.6  |
| Sysmex not specified                      | 2                                     | 68.3 | -1.8 | 8.7  | 2                                     | 36.5 | -1.8 | 11.4 | -1.8              | 10.1 |
| Wondfo Finecare™ FIA Meter                | 2                                     | 64.5 | -5.6 | 10.7 | 2                                     | 42.6 | +4.4 | 9.3  | -0.6              | 10.0 |
| Zepnurhealth Audicom AC6600               | 1                                     | 70.6 | +0.5 |      | 1                                     | 30.1 | -8.1 |      | -3.8              |      |

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 (2019-1) |     | HbA1c Low (2019-2) |      | Mean |     |
|---|-----|---------------------|-----|--------------------|------|------|-----|
|   |     | Bias                | CV% | Bias               | CV%  | Bias | CV% |
| Abbott ARCHITECT (enzymatic)                                |     |                     |     |                    |      |      |     |
| Overall   | 39  | -0.8                | 4.0 | -1.5               | 6.2  | -1.2 | 5.1 |
| AT  | 11  | -2.8                | 1.9 | -3.2               | 2.9  | -3.0 | 2.4 |
| FR-Probioqual   | 13  | -0.6                | 3.0 | -1.5               | 5.7  | -1.1 | 4.3 |
| GR  | 8   | +0.2                | 3.8 | -0.3               | 2.2  | -0.1 | 3.0 |
| Bio-Rad D-10 series   |     |                     |     |                    |      |      |     |
| Overall   | 106 | +3.3                | 5.2 | +0.2               | 6.6  | +1.8 | 5.9 |
| CZ  | 36  | +4.7                | 3.3 | +0.4               | 4.6  | +2.6 | 4.0 |
| FR-CTCB   | 12  | +3.8                | 6.3 | +0.3               | 5.6  | +2.0 | 5.9 |
| FR-Probioqual   | 32  | +1.6                | 5.5 | -0.3               | 7.7  | +0.6 | 6.6 |
| MX  | 7   | +2.3                | 4.9 | +0.8               | 6.5  | +1.6 | 5.7 |
| Bio-Rad D-100 series  |     |                     |     |                    |      |      |     |
| Overall   | 49  | +1.3                | 2.3 | -0.4               | 3.6  | +0.4 | 2.9 |
| AT  | 10  | +1.5                | 2.3 | -0.5               | 3.8  | +0.5 | 3.0 |
| FR-Probioqual   | 28  | +1.5                | 2.0 | -0.3               | 3.3  | +0.6 | 2.7 |
| Bio-Rad Variant series                                      |     |                     |     |                    |      |      |     |
| Overall   | 66  | +3.0                | 5.3 | +0.4               | 8.9  | +1.7 | 7.1 |
| FR-CTCB   | 12  | +4.3                | 3.7 | +1.6               | 6.7  | +2.9 | 5.2 |
| FR-Probioqual   | 36  | +2.0                | 5.5 | -0.5               | 10.0 | +0.7 | 7.8 |
| Menarini (ARKRAY) HA-8160 series                            |     |                     |     |                    |      |      |     |
| Overall   | 59  | +0.7                | 3.6 | -0.4               | 5.1  | +0.2 | 4.4 |
| CZ  | 8   | +0.3                | 6.1 | -1.3               | 7.7  | -0.5 | 6.9 |
| GR  | 13  | +1.7                | 3.6 | +0.1               | 4.8  | +0.9 | 4.2 |
| IT  | 8   | +1.1                | 1.9 | -1.0               | 6.9  | 0.0  | 4.4 |
| PT  | 24  | +0.6                | 3.3 | -0.5               | 3.9  | +0.1 | 3.6 |
| Menarini (ARKRAY) HA-8180 series                            |     |                     |     |                    |      |      |     |
| Overall   | 99  | -2.1                | 5.7 | -1.0               | 5.4  | -1.5 | 5.5 |
| AT  | 23  | -0.8                | 2.6 | +0.1               | 3.2  | -0.3 | 2.9 |
| CZ  | 29  | -1.1                | 2.3 | -1.1               | 2.5  | -1.1 | 2.4 |
| IT  | 7   | +2.0                | 2.5 | +1.2               | 3.5  | +1.6 | 3.0 |
| International*  | 9   | +0.3                | 3.0 | +0.2               | 1.7  | +0.3 | 2.4 |
| TH  | 20  | -8.6                | 2.8 | -4.1               | 3.2  | -6.4 | 3.0 |
| Roche Diagnostics cobas c 501/502 (part of cobas 6000/8000) |     |                     |     |                    |      |      |     |
| Overall   | 203 | +5.1                | 3.7 | +1.1               | 6.1  | +3.1 | 4.9 |
| AT  | 34  | +4.8                | 3.3 | +1.5               | 5.0  | +3.1 | 4.2 |
| FR-Probioqual   | 52  | +4.1                | 3.9 | -1.1               | 6.0  | +1.5 | 4.9 |
| GR  | 10  | +3.5                | 4.8 | +1.0               | 6.5  | +2.3 | 5.6 |
| TH  | 77  | +6.0                | 3.2 | +1.8               | 4.9  | +3.9 | 4.0 |
| TR  | 12  | +6.5                | 3.6 | +2.0               | 5.1  | +4.3 | 4.3 |
| Roche Diagnostics cobas Integra                             |     |                     |     |                    |      |      |     |
| Overall   | 39  | +4.4                | 3.3 | +1.1               | 7.0  | +2.7 | 5.2 |
| CZ  | 6   | +5.4                | 2.0 | +0.8               | 12.0 | +3.1 | 7.0 |
| GR  | 6   | +4.4                | 2.8 | +1.5               | 4.7  | +2.9 | 3.7 |
| TH  | 16  | +4.3                | 4.0 | +1.5               | 6.5  | +2.9 | 5.3 |
| Sebia CAPILLARYS 2  |     |                     |     |                    |      |      |     |
| Overall   | 131 | 0.0                 | 2.4 | -0.3               | 3.8  | -0.2 | 3.1 |
| FR-CTCB   | 25  | +1.4                | 2.3 | 0.0                | 2.8  | +0.7 | 2.5 |
| FR-Probioqual   | 90  | -0.4                | 2.1 | -0.5               | 4.2  | -0.5 | 3.2 |
| International*  | 6   | +0.2                | 1.5 | +0.3               | 2.8  | +0.3 | 2.1 |
| Sebia CAPILLARYS 3  |     |                     |     |                    |      |      |     |
| Overall   | 101 | +0.7                | 2.6 | +0.2               | 2.9  | +0.5 | 2.8 |
| FR-CTCB   | 29  | +1.4                | 2.6 | +0.3               | 2.3  | +0.9 | 2.5 |
| FR-Probioqual   | 66  | +0.3                | 2.5 | +0.2               | 3.3  | +0.2 | 2.9 |
| Siemens DCA 2000/Vantage                                    |     |                     |     |                    |      |      |     |
| Overall   | 61  | +5.8                | 4.4 | +4.4               | 5.2  | +5.1 | 4.8 |
| FR-Asqualab   | 6   | +6.1                | 6.2 | +3.4               | 4.7  | +4.7 | 5.5 |
| FR-Probioqual   | 46  | +5.3                | 3.9 | +4.9               | 4.9  | +5.1 | 4.4 |
| Siemens Dimension series                                    |     |                     |     |                    |      |      |     |
| Overall   | 32  | +5.2                | 8.5 | +3.2               | 7.1  | +4.2 | 7.8 |
| FR-Probioqual   | 14  | +11.2               | 5.3 | +3.0               | 8.8  | +7.1 | 7.1 |
| GR  | 6   | -0.1                | 2.4 | +3.7               | 6.1  | +1.8 | 4.2 |
| Tosoh G11   |     |                     |     |                    |      |      |     |
| Overall   | 64  | +3.5                | 4.8 | +0.4               | 3.7  | +2.0 | 4.2 |
| FR-CTCB   | 8   | +4.6                | 5.0 | +1.6               | 4.7  | +3.1 | 4.8 |
| FR-Probioqual   | 45  | +3.1                | 4.2 | +0.2               | 2.7  | +1.7 | 3.5 |

| Method        | n   | HbA1c High (2019-1) |     | HbA1c Low (2019-2) |     | Mean |     |
|---------------|-----|---------------------|-----|--------------------|-----|------|-----|
|               |     | Bias                | CV% | Bias               | CV% | Bias | CV% |
| Tosoh G8      |     |                     |     |                    |     |      |     |
| Overall       | 180 | +0.8                | 3.8 | +0.6               | 3.4 | +0.7 | 3.6 |
| AT            | 8   | +1.4                | 5.3 | -0.5               | 2.7 | +0.5 | 4.0 |
| CZ            | 19  | +2.1                | 1.6 | +1.2               | 2.5 | +1.6 | 2.0 |
| FR-Asqualab   | 13  | +0.7                | 2.2 | +0.8               | 3.0 | +0.8 | 2.6 |
| FR-CTCB       | 30  | +2.6                | 4.9 | +0.1               | 4.1 | +1.4 | 4.5 |
| FR-Probioqual | 83  | -0.6                | 3.0 | +0.4               | 2.9 | -0.1 | 2.9 |
| IT            | 6   | +3.6                | 2.2 | +2.0               | 2.7 | +2.8 | 2.5 |
| TR            | 9   | +1.8                | 3.5 | +1.2               | 4.9 | +1.5 | 4.2 |

\* 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. The assigned values are the values assigned with the IFCC RMP. Values of the SRLs are for comparison and information.

Table 10. Results of Reference Measurement Procedures

| Matrix                 | Low HbA1c<br>(range 37.6 – 38.8 mmol/mol) |           |              |               | High HbA1c<br>(range 69.0 – 71.2 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      | 38.2                                      | 38.6      | 5.63         | 4.48          | 70.1                                       | 70.7      | 8.58         | 7.37          |
| Lyophilised Hemolysate | 38.2                                      | 38.2      | 5.67         | 4.55          | 70.3                                       | 69.9      | 8.55         | 7.44          |
| Frozen Whole Blood     | 37.9                                      | 39.1      | 5.70         | 4.64          | 70.3                                       | 71.7      | 8.68         | 7.57          |

- 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 0.6 mmol/mol in the low and 1.1 in the high sample.

## V. Homogeneity

Homogeneity testing of the samples EurAAA1c-2019-2. 4 and 6 is performed according to ISO 13528:2005 (Annex B) with the Menarini (ARKRAY) HA- 8180V. The results in table 11 show that the samples are homogeneous.

Table 11. Homogeneity test of EurAAA1c 2019

| Vial                   | Fresh Whole Blood |       |             |          | Lyophilised Hemolysate |       |             |          | Frozen Whole Blood |       |             |          |
|------------------------|-------------------|-------|-------------|----------|------------------------|-------|-------------|----------|--------------------|-------|-------------|----------|
|                        | EurAAA1c 2019-2   |       |             |          | EurAAA1c 2019-4        |       |             |          | EurAAA1c 2019-6    |       |             |          |
|                        | 1                 | 2     | mean        | $\Delta$ | 1                      | 2     | mean        | $\Delta$ | 1                  | 2     | mean        | $\Delta$ |
| 1                      | 38.8              | 38.7  | 38.75       | 0.1      | 38.6                   | 38.8  | 38.70       | 0.2      | 38.2               | 38.1  | 38.15       | 0.1      |
| 2                      | 38.8              | 38.7  | 38.75       | 0.1      | 38.9                   | 38.9  | 38.90       | 0.0      | 38.2               | 38.1  | 38.15       | 0.1      |
| 3                      | 38.8              | 38.7  | 38.75       | 0.1      | 38.6                   | 38.8  | 38.70       | 0.2      | 38.2               | 38.1  | 38.15       | 0.1      |
| 4                      | 38.8              | 38.7  | 38.75       | 0.1      | 38.8                   | 38.8  | 38.80       | 0.0      | 38.1               | 38.1  | 38.10       | 0.0      |
| 5                      | 38.7              | 38.7  | 38.70       | 0.0      | 38.8                   | 38.9  | 38.85       | 0.1      | 38.1               | 38.2  | 38.15       | 0.1      |
| 6                      | 38.7              | 38.7  | 38.70       | 0.0      | 38.8                   | 38.9  | 38.85       | 0.1      | 38.1               | 38.1  | 38.10       | 0.0      |
| 7                      | 38.8              | 38.7  | 38.75       | 0.1      | 38.9                   | 38.9  | 38.90       | 0.0      | 38.1               | 38.1  | 38.10       | 0.0      |
| 8                      | 38.8              | 38.8  | 38.80       | 0.0      | 38.8                   | 38.9  | 38.85       | 0.1      | 38.1               | 38.1  | 38.10       | 0.0      |
| 9                      | 38.7              | 38.7  | 38.70       | 0.0      | 38.6                   | 38.8  | 38.70       | 0.2      | 38.1               | 38.0  | 38.05       | 0.1      |
| 10                     | 38.7              | 38.7  | 38.70       | 0.0      | 38.9                   | 38.8  | 38.85       | 0.1      | 38.1               | 38.1  | 38.10       | 0.0      |
| 11                     | 38.7              | 38.7  | 38.70       | 0.0      | 38.6                   | 38.8  | 38.70       | 0.2      | 38.2               | 38.1  | 38.15       | 0.1      |
| 12                     | 39.0              | 38.7  | 38.85       | 0.3      | 38.8                   | 38.9  | 38.85       | 0.1      | 38.1               | 38.1  | 38.10       | 0.0      |
| average                |                   |       | 38.7        |          |                        |       | 38.8        |          |                    |       | 38.1        |          |
| SD                     |                   | 0.000 | 0.047       | 0.076    |                        | 0.047 | 0.081       | 0.094    |                    | 0.000 | 0.033       | 0.050    |
| 0.3 x SD <sub>RL</sub> |                   |       | 0.306       |          |                        |       | 0.306       |          |                    |       | 0.306       |          |
| Criterion              |                   |       | -0.306      |          |                        |       | -0.259      |          |                    |       | -0.306      |          |
| <b>Homogeneity:</b>    |                   |       | <b>Pass</b> |          |                        |       | <b>Pass</b> |          |                    |       | <b>Pass</b> |          |

## VI. Stability

### Fresh Whole Blood

Fresh whole blood samples EurAAA1c 2019-2 (HbA1c 38.2 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. 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     | 0     | 0     | 0     | -1    | -2    |
| Sebia CAPILLARYS 3 Octa        | 0     | -2    | -1    | 0     | 0     | +2    |
| Roche Cobas c 513              | 0     | 0     | 0     | 0     | 0     | 0     |
| Abbott ARCHITECT C4000         | 0     | +1    | +1    | +1    | +1    | 0     |
| Tosoh G8                       | 0     | 0     | 0     | 0     | 0     | -1    |
| Trinity Biotech Premier Hb9210 | 0     | 0     | 0     | +1    | +1    | +2    |
| Storage Refrigerator           |       |       |       |       |       |       |
| Menarini/ARKRAY HA-8180V       | 0     | -1    | 0     | 0     | 0     | 0     |
| Sebia CAPILLARYS 3 Octa        | 0     | 0     | 0     | 0     | 0     | 0     |
| Roche Cobas c 513              | 0     | 0     | 0     | 0     | 0     | 0     |
| Abbott ARCHITECT C4000         | 0     | 1     | 0     | 0     | 0     | 0     |
| Tosoh G8                       | 0     | 0     | 0     | 0     | 0     | 0     |
| Trinity Biotech Premier Hb9210 | 0     | -1    | -1    | -1    | 0     | 0     |

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

### 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 and measured after 6, 13, 18 and 25 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 in the refrigerator. 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.

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

| Method                         | 0 month | 6 months | 13 months | 18 months | 25 months |
|--------------------------------|---------|----------|-----------|-----------|-----------|
| Storage Refrigerator           |         |          |           |           |           |
| Menarini/ARKRAY HA-8180V       | 0       | 0        | -1        | 0         | -1        |
| Sebia CAPILLARYS 3 Octa**      | 0       | -2       | +1        | 0         | -1        |
| Roche Cobas c513               | 0       | 0        | 0         | +1        | +1        |
| Abbott ARCHITECT C4000         | 0       | -3       | -5        | -5        | -8        |
| Tosoh G8                       | 0       | -1       | +1        | -2        | -2        |
| Trinity Biotech Premier Hb9210 | 0       | 0        | 0         | -1        | 0         |
| Storage Freezer -20°C          |         |          |           |           |           |
| Menarini/ARKRAY HA-8180V       | 0       | +1       | 0         | 0         | +1        |
| Sebia CAPILLARYS 3 Octa**      | 0       | -1       | +1        | +1        | -1        |
| Roche Cobas c 513              | 0       | +1       | 0         | 0         | +1        |
| Abbott ARCHITECT C4000         | 0       | +2       | +2        | +2        | 0         |
| Tosoh G8                       | 0       | +1       | +1        | +1        | +1        |
| Trinity Biotech Premier Hb9210 | 0       | +1       | +1        | +1        | +2        |

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

\*\*Initial measurement (0 month) on Sebia CapillaryS 2 FP)



### 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 and 25 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 14. 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 14. Stability\* of Frozen Whole Blood in Freezer -20°C and Freezer -70°C

| Method                         | 0 month | 6 months | 13 months | 18 months | 25 months |
|--------------------------------|---------|----------|-----------|-----------|-----------|
| Storage Freeze -20°C           |         |          |           |           |           |
| Menarini/ARKRAY HA-8180V       | 0       | 0        | -5        | n.m***    | n.m***    |
| Sebia CAPILLARYS 3 Octa**      | 0       | +2       | +3        | n.m***    | n.m***    |
| Roche Cobas c513               | 0       | +1       | 0         | +1        | +1        |
| Abbott ARCHITECT C4000         | 0       | +1       | +2        | +2        | +2        |
| Tosoh G8                       | 0       | -3       | -2        | -1        | -1        |
| Trinity Biotech Premier Hb9210 | 0       | -5       | -11       | -3        | -3        |
| Storage Freezer <-70°C         |         |          |           |           |           |
| Menarini/ARKRAY HA-8180V       | 0       | 0        | 0         | -1        | -1        |
| Sebia CAPILLARYS 3 Octa**      | 0       | 0        | +1        | +2        | +2        |
| Roche Cobas c513               | 0       | 1        | -1        | 0         | 0         |
| Abbott ARCHITECT C4000         | 0       | 1        | 1         | 0         | 0         |
| Tosoh G8                       | 0       | 1        | 1         | 1         | 1         |
| Trinity Biotech Premier Hb9210 | 0       | 0        | +2        | 0         | 0         |

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

\*\* initial measurement (0 month) on Sebia CapillaryS 2 FP

\*\*\* not measurable

## VII Organisations and Persons Involved

| Country  | Organisation  | Person   |
|--|---|--|
| <b>EQA Organisers</b>                            |   |  |
| AT   | ÖQUASTA   | Christoph Buchta. Mathias M. Mueller   |
| BE   | Sciensano   | Yolande Lenga  |
| CH   | CSCQ  | Dagmar Kessler. Pierre-Alain Morandi. Xavier Albe                                      |
| CZ   | SEKK s.r.o.   | Marek Budina. Josef Kratochvila. Bedrich Friedecky                                     |
| DE   | INSTAND   | Patricia Kaiser  |
| DE   | Reference Institute for Bioanalytics                      | Anja Kessler   |
| ES   | SEQC <sup>ML</sup>  | Montserrat Ventura Alemany. M <sup>a</sup> Carmen González Gómez. Carmen Perich Alsina |
| FR   | CTCB  | Erick Sanchez. Marie-Christine Onderbeke   |
| FR   | PROBIOQUAL  | Philippe Joly  |
| FR   | ASQUALAB  | Anne Vassault  |
| GR   | ESEAP/General Hospital                                    | Alexander Haliassos. Konstantinos Makris. Otto Panagiotakis                            |
| HU   | QualiCont Nonprofit Kft.                                  | Virag Gyongyosi. Erika Sarkany   |
| IE   | IEQAS   | Hazel Graham. Anne Kane. Thomas P. Smith. Ned Barrett                                  |
| INT  | ERL   | Cas Weykamp, Eline van der Hagen   |
| 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, Eline van der Hagen   |
| 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  |
| <b>IFCC Network Laboratories</b>                 |   |  |
| 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 Sloodstra                          |
| NL   | Queen Beatrix Hospital                                    | Carla Siebelder. Sanne Leppink   |
| <b>IFCC Secondary Reference Laboratories</b>     |   |  |
| IT   | CIRME   | Andrea Mosca. Renata Paleari   |
| NL   | Isala   | Erna Lenters. Robbert Slingerland. Janine Sloodstra                                    |
| NL   | Queen Beatrix Hospital                                    | Carla Siebelder. Sanne Leppink   |
| <b>NGSP Network Laboratories</b>                 |   |  |
| US   | University of Missouri                                    | Randie R. Little. Shawn M. Connolly  |
| US   | University of Minnesota                                   | Vicky Makky, Maren Nowicki   |
| <b>Mono S Laboratory</b>                         |   |  |
| SE   | SU/Sahlgrenska  | Anders Elmgren. Magnus Axelsson  |
| <b>Oversight Committee (members IFCC C-EUBD)</b> |   |  |
| 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)  |
| <b>Trial Management</b>                          |   |  |
| NL   | Overview  | Cas Weykamp, Eline van der Hagen   |
| NL   | Coordination  | Carla Siebelder  |
| NL   | Quality Assurance   | Liesbeth Schröer   |
| NL   | Data Processing   | Irene de Graaf   |
| NL   | Sample Logistics  | Marieke te Winkel  |