

LABQUALITY

External Quality Assessment Scheme

Haemoglobin A1c Round 2, 2023

Specimens

Please find enclosed 2 commercial human blood samples S003 and S004, each 0.5 mL.

Caution

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations

HbA1c

Storage and use

We recommend analyzing the samples as soon as possible. If this is not possible, store in a refrigerator (+ 2... + 8 ° C). Do not freeze. The samples should be analyzed in the same way as patient samples. Allow the tube to stand at room temperature for about 15 minutes. Mix the sample by inverting the tube several times, until the suspension appears homogeneous. Do not mix too vigorously. Do not use mechanical blood mixers. Samples will be usable for 2 months from the date of this letter.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator.

S003:



S004:



2023-03-27

INSTRUCTIONS

Product no. 1261, 1263
LQ729423023-024/US

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi

The results should be reported no later than **April 13, 2023.**

Inquiries

EQA Coordinator
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Labquality Oy

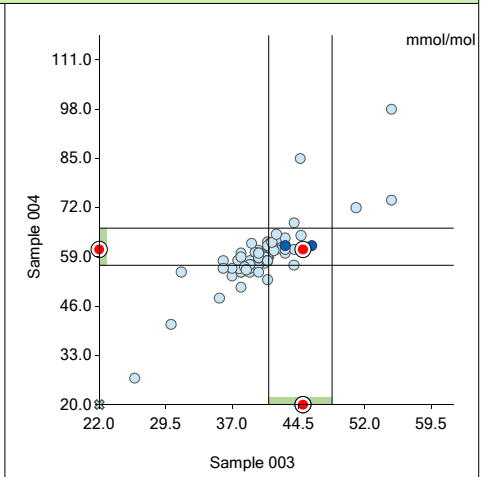
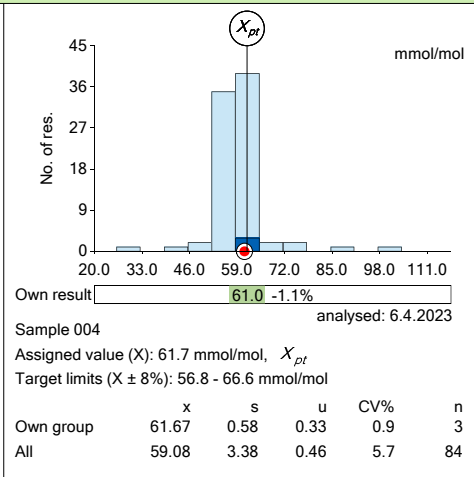
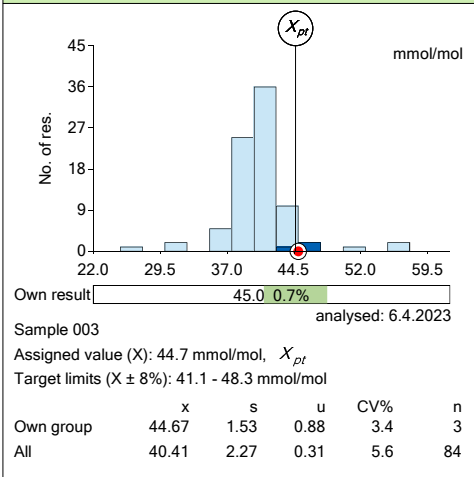
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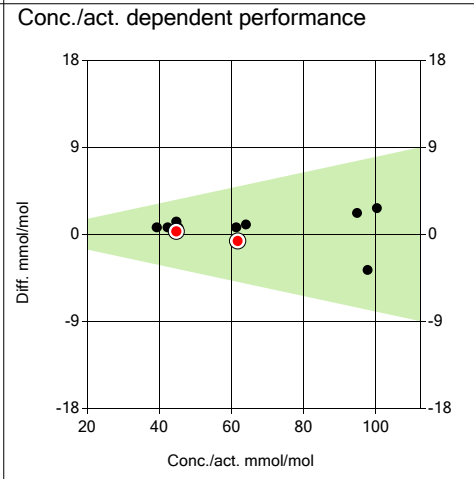


HbA1c 006 Siemens DCA 2000+ & Vantage 576



Previous results

Round	Sample	X	Own	Diff%	z
23/02	La26 576	44.7	45.0	0.7	-
23/02	La27 576	61.7	61.0	-1.1	-
22/05	La22 576	45.3	46.0	1.5	-
22/05	La24 576	97.7	94.0	-3.8	-
22/02	La21 576	61.3	62.0	1.1	-
22/02	La22 576	42.3	43.0	1.7	-
21/05	La20 576	44.4	45.0	1.4	0.2
21/05	La22 576	94.8	97.0	2.3	0.7
21/02	La20 576	44.7	46.0	2.9	0.3
21/02	La22 576	100.3	103.0	2.7	0.6
20/05	La18 576	64.0	65.0	1.6	-
20/05	La17 576	39.3	40.0	1.8	-
20/02	La17 576	39.5	39.0	-1.3	-



Comments

Sample 003, Own group:
The standard measurement uncertainty (u) of the assigned value (X_{pt}) is the standard error of the mean (SEM). The uncertainty (u) of the mean and the assigned value (X_{pt}) is not negligible, and evaluations could be affected. When a reference method value is used as assigned value (X_{ref}), its uncertainty is mentioned in the report letter. Due to the small number of results, the z score is not calculated.

Sample 004, Own group:
The standard measurement uncertainty (u) of the assigned value (X_{pt}) is the standard error of the mean (SEM). Due to the small number of results, the z score is not calculated.

Participants

306 participants from 13 countries.

Report info

Your own result should be compared to the given target value which can be reference method value (X_{ref}) or the mean of the own method group (X_{pt} or X_{rob}). The reference method value, its uncertainty and measurement method given in the report letter.

The assigned values are calculated according to the robust procedure described in the standard ISO 13528 (Statistical methods for use in proficiency testing by interlaboratory comparisons, Annex C, Algorithm A). The standard uncertainty of the assigned value is expressed as $1.25 \times$ the standard error of mean (SEM) and marked as "u" in numerical summary. Due to its iterative mode algorithm A adds the uncertainty of the assigned value and with this factor we want to adjust uncertainty accordingly. Please notice also that for groups that have only 1 result only the client's own result is shown. No target value (except for reference method values or transferred values) is calculated, no target areas are shown. In case there are 2-12 results in a method group, the robust calculation is not used but a calculation where results deviating more than ± 3 standard deviation SD from the median are removed. Additionally, if the measurement uncertainty of the target value is too large ($(u(x_{pt}) < 0.1dE)$) an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected." In case there are 2-5 results in a method group, no z-score is calculated, and a text is printed on the report: "Due to the small number of results, the z score is not calculated." In case there are 6-12 results, the report has a text: "Z score is uncertain due to the small number of observations."

Results reported with $< \text{tai} >$ -signs cannot be included in the statistics.

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions.

NUMERICAL SUMMARY
HbA1c 2023/02

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
Sample 001									
HbA1c, mmol/mol									
	Abbott Alinity	49.23	49.6	1.13	2.3	0.65	48.0	50.1	3
	Abbott Architect enzymatic	49.80	49.8	1.20	2.4	0.85	49.0	50.7	2
	Afinion	49.74	49.5	1.75	3.5	0.38	43.0	56.0	34
	Biosurfit Spinit	49.70	49.7	1.27	2.6	0.90	48.8	50.6	2
	cobas b101	49.50	49.5	1.52	3.1	0.62	48.0	52.0	6
	Hemocue	48.29	48.0	4.31	8.9	1.63	44.0	57.0	7
	HPLC Bio-Rad D-10	50.67	50.0	2.08	4.1	1.20	49.0	53.0	3
	HPLC Tosoh	50.69	50.4	0.85	1.7	0.18	48.4	52.4	33
	i-Chroma HbA1c	54.00	54.0	-	-	-	-	-	1
	Infopia Clover A1c	50.00	50.0	-	-	-	-	-	1
	QuikRead	50.68	51.0	2.29	4.5	0.31	44.0	58.0	88
	Quo-Lab & Quo-Test HbA1c	52.10	51.8	1.20	2.3	0.60	51.0	53.8	4
	Roche cobas c Tina-quant	50.92	50.9	1.39	2.7	0.50	36.6	52.7	12
	SD Biosensor Standard F200	52.28	53.0	2.51	4.8	0.56	47.4	56.3	31
	Sebia Capillary electrophoresis	50.00	50.0	1.00	2.0	0.58	49.0	51.0	3
	Siemens Advia Centaur & Atellica	50.07	50.2	1.09	2.2	0.34	47.9	51.4	10
	Siemens DCA 2000+ & Vantage	50.40	51.0	1.37	2.7	0.32	45.0	54.0	28
	Thermo Scientific Konelab	49.39	49.0	4.19	8.5	1.26	44.0	59.0	11
	Vedalab	22.00	22.0	-	-	-	-	-	1
	Wellion Bona HbA1c	51.28	52.9	5.11	10.0	2.09	44.5	57.5	6
	All	50.53	50.6	2.09	4.1	0.12	22.0	59.0	286
Sample 002									
HbA1c, mmol/mol									
	Abbott Alinity	37.35	37.6	0.81	2.2	0.47	36.5	38.0	3
	Abbott Architect enzymatic	38.05	38.1	0.81	2.1	0.57	37.5	38.6	2
	Afinion	38.93	39.0	1.23	3.1	0.26	36.0	62.0	36
	Biosurfit Spinit	40.55	40.6	1.48	3.7	1.05	39.5	41.6	2
	cobas b101	38.00	38.0	0.63	1.7	0.26	37.0	39.0	6
	Hemocue	43.57	43.0	3.74	8.6	1.41	39.0	49.0	7
	HPLC Bio-Rad D-10	39.00	38.0	2.65	6.8	1.53	37.0	42.0	3
	HPLC Tosoh	39.58	39.4	0.79	2.0	0.17	37.9	41.5	33
	i-Chroma HbA1c	36.70	36.7	-	-	-	-	-	1
	Infopia Clover A1c	39.00	39.0	-	-	-	-	-	1
	QuikRead	39.80	40.0	1.89	4.8	0.25	35.0	45.0	88
	Quo-Lab & Quo-Test HbA1c	41.13	41.3	0.88	2.1	0.44	39.9	42.0	4
	Roche cobas c Tina-quant	38.78	38.8	0.77	2.0	0.28	38.0	48.6	12
	Roche Tina-quant	39.00	39.0	-	-	-	-	-	1
	SD Biosensor Standard F200	38.97	38.9	1.74	4.5	0.39	34.4	42.1	31
	Sebia Capillary electrophoresis	38.00	38.0	0.00	0.0	0.00	38.0	38.0	3
	Siemens Advia Centaur & Atellica	37.70	38.2	1.11	2.9	0.35	36.0	39.3	10
	Siemens DCA 2000+ & Vantage	38.87	39.0	1.46	3.8	0.36	37.0	41.0	26
	Thermo Scientific Konelab	38.65	39.0	3.15	8.2	4.05	34.0	78.0	9
	Vedalab	36.30	36.3	-	-	-	-	-	1
	Wellion Bona HbA1c	40.62	40.1	3.35	8.2	1.37	36.9	46.0	6
	All	39.26	39.0	1.67	4.3	0.10	34.0	78.0	286
Sample 003									
HbA1c, mmol/mol									
	Abbott Alinity	39.59	39.6	0.86	2.2	0.30	38.0	41.0	8
	Abbott Architect enzymatic	40.61	41.0	0.62	1.5	0.25	39.7	41.0	6
	AFIAS HbA1c	30.10	30.1	-	-	-	-	-	1
	Beckman Coulter AU instruments	40.40	41.0	1.52	3.8	0.68	38.0	42.0	5
	Biosurfit Spinit	44.70	44.7	-	-	-	-	-	1
	Biosystems reagents	39.76	39.2	1.53	3.8	0.88	38.6	41.5	3

NUMERICAL SUMMARY
HbA1c 2023/02, Sample 003

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
HbA1c, mmol/mol									
	cobas b101	37.00	37.0	-	-	-	-	-	1
	Diasys reagents	42.55	42.6	0.64	1.5	0.45	42.1	43.0	2
	EuroLyser Smart 700/340	55.00	55.0	-	-	-	-	-	1
	FIA Getein	26.00	26.0	-	-	-	-	-	1
	HPLC Bio-Rad D-10	41.00	41.0	-	-	-	-	-	1
	HPLC Tosoh	41.04	41.2	0.66	1.6	0.25	39.6	41.6	7
	i-Chroma HbA1c	35.56	35.6	-	-	-	-	-	1
	Nycocard (GHbA1c)	49.50	49.5	7.78	15.7	5.50	44.0	55.0	2
	Roche cobas c Tina-quant	39.81	40.0	2.54	6.4	0.73	36.0	44.0	19
	Roche Cobas Integra	40.24	40.0	1.97	4.9	0.60	31.3	44.8	17
	Sebia Capillary electrophoresis	38.00	38.0	-	-	-	-	-	1
	Siemens DCA 2000+ & Vantage	44.67	45.0	1.53	3.4	0.88	43.0	46.0	3
	Siemens Dimension & Vista	40.00	40.0	-	-	-	-	-	1
	skyla Hi	51.00	51.0	-	-	-	-	-	1
	Thermo Scientific Konelab	38.00	38.0	-	-	-	-	-	1
	Others	42.00	42.0	-	-	-	-	-	1
	All	40.41	40.0	2.27	5.6	0.25	26.0	55.0	84

Sample 004

HbA1c, mmol/mol									
	Abbott Alinity	57.17	57.0	1.83	3.2	0.65	55.0	60.7	8
	Abbott Architect enzymatic	58.67	58.0	2.25	3.8	0.92	57.0	63.0	6
	AFIAS HbA1c	41.20	41.2	-	-	-	-	-	1
	Beckman Coulter AU instruments	59.08	60.0	2.52	4.3	1.13	55.0	61.0	5
	Biosurfit Spinit	85.00	85.0	-	-	-	-	-	1
	Biosystems reagents	60.35	62.6	4.11	6.8	2.37	55.6	62.8	3
	cobas b101	54.00	54.0	-	-	-	-	-	1
	Diasys reagents	63.95	64.0	0.07	0.1	0.05	63.9	64.0	2
	EuroLyser Smart 700/340	98.00	98.0	-	-	-	-	-	1
	FIA Getein	27.00	27.0	-	-	-	-	-	1
	HPLC Bio-Rad D-10	53.00	53.0	-	-	-	-	-	1
	HPLC Tosoh	61.49	61.5	0.78	1.3	0.29	60.2	62.7	7
	i-Chroma HbA1c	48.14	48.1	-	-	-	-	-	1
	Nycocard (GHbA1c)	71.00	71.0	4.24	6.0	3.00	68.0	74.0	2
	Roche cobas c Tina-quant	58.76	58.7	1.96	3.3	0.56	56.0	62.0	19
	Roche Cobas Integra	58.23	58.0	2.28	3.9	0.69	55.0	64.6	17
	Sebia Capillary electrophoresis	51.00	51.0	-	-	-	-	-	1
	Siemens DCA 2000+ & Vantage	61.67	62.0	0.58	0.9	0.33	61.0	62.0	3
	Siemens Dimension & Vista	55.00	55.0	-	-	-	-	-	1
	skyla Hi	72.00	72.0	-	-	-	-	-	1
	Thermo Scientific Konelab	60.00	60.0	-	-	-	-	-	1
	Others	65.00	65.0	-	-	-	-	-	1
	All	59.08	58.9	3.38	5.7	0.37	27.0	98.0	84

NUMERICAL SUMMARY

HbA1c 2023/02, Sample 004

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
HbA1c, mmol/mol									

Participants

306 participants from 13 countries.

Report info

Your own result should be compared to the given target value which can be reference method value (Xref) or the mean of the own method group (Xpt or Xrob). The reference method value, its uncertainty and measurement method given in the report letter.

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LABQUALITY

External Quality Assessment Scheme

Haemoglobin A1c, liquid samples Round 2, 2023

Specimens

Sample S003 (LQ729423023) and sample S004 (LQ729423024) were human blood samples.

Based on the previous tests and the results of this round, the samples are homogeneous, stable and suitable for the external quality assessment scheme.

The materials were sent without temperature control packaging.

Report info

Please see the description of the data analysis on the last page of the laboratory-specific histogram and Global report. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments – EQA coordinator

There were some results reported as %. If the instruments give the results as % it can be converted to mmol/mol by a converter.

If any extra peaks are found, they may be caused by the denatured hemoglobin which may occur in chromatographic methods. But in these findings may reveal many system errors shown only in chromatographic runs.

Comments – Expert

HbA1c round 2/2023 the sample S003 was at the normal level and the sample S004 was higher than the diagnostic limit of ADA (48 mmol/mol). The mean (all results) of HbA1c samples S003 and S004 were 40.41 and 59.08 mmol/mol, respectively. There was a lot of variation between the method groups and several method groups differed significantly from the mean. The number of participants in round 2/2023 was significantly higher than in the previous round. The total variation was 5.6% for the sample S003 and 5.7% for the sample S004. However, the CV% of the samples were adequate.

End of report

2023-05-02

FINAL REPORT

Product no. 1261, 1263

Samples sent	2023-03-27
Round closed	2023-04-13
Final report	2023-05-02

Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by

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