

External Quality Assessment Scheme

Haemoglobin A1c Round 1, 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 analysed 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:



2023-02-06

INSTRUCTIONS

Product no. 1261
LQ729423013-014/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 **February 23, 2023.**

Inquiries

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Labquality Oy

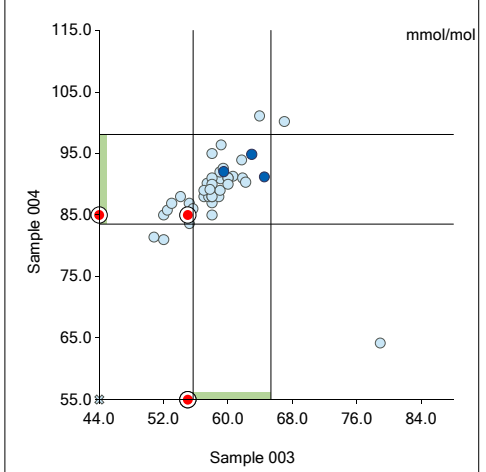
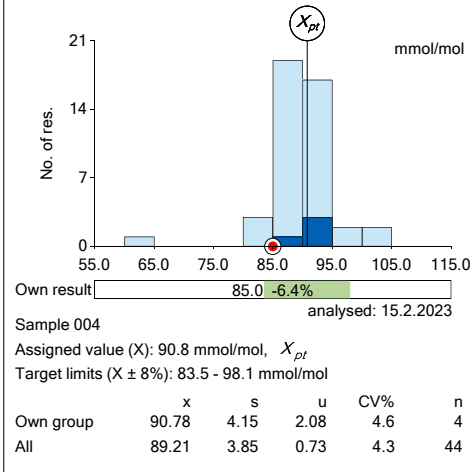
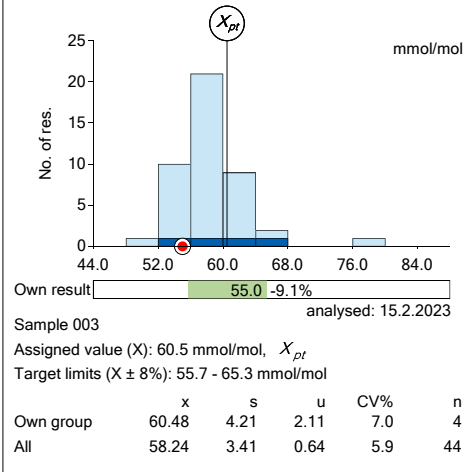
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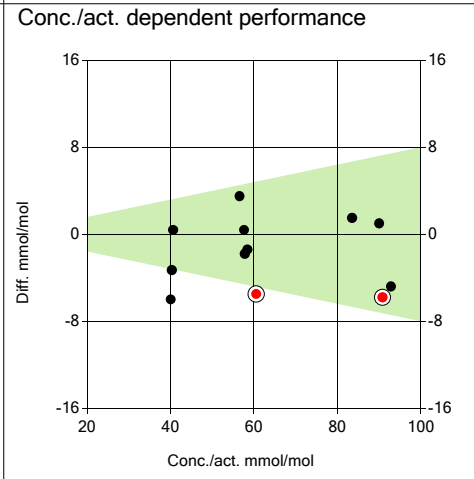


HbA1c 0199 Integra HbA1C Roche Cobas Integra 53



Previous results

Round	Sample	X	Own	Diff%	z
23/01	La25 53	60.5	55.0	-9.1	-
23/01	La24 53	90.8	85.0	-6.4	-
22/06	La22 53	40.3	37.0	-8.2	-
22/06	La23 53	58.4	57.0	-2.4	-
22/05	La22 53	40.0	34.0	-15.0	-1.5
22/05	La24 53	92.8	88.0	-5.2	-0.6
22/04	La21 53	57.8	56.0	-3.1	-0.7
22/04	La24 53	90.0	91.0	1.1	0.2
22/03	La21 53	57.6	58.0	0.7	0.1
22/03	La19 53	83.5	85.0	1.8	0.3
22/02	La21 53	56.5	60.0	6.2	1.6
22/02	La22 53	40.6	41.0	1.0	0.2
22/01	La21 53	59.6	56.0	-6.0	-0.9



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). 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.

Participants

101 participants from 15 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 $< tai >$ -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 2023/01

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
Sample 001									
HbA1c, mmol/mol									
	Abbott Alinity	51.43	51.5	0.39	0.8	0.23	51.0	51.8	3
	Abbott Architect enzymatic	50.58	50.8	0.53	1.0	0.30	50.0	51.0	3
	HPLC Bio-Rad D-10	53.00	53.0	0.00	0.0	0.00	53.0	53.0	2
	HPLC Tosoh	52.46	52.5	0.98	1.9	0.21	50.8	54.3	34
	Roche cobas c Tina-quant	52.60	53.0	1.05	2.0	0.38	33.3	54.0	12
	Sebia Capillary electrophoresis	51.00	51.0	1.41	2.8	1.00	50.0	52.0	2
	Siemens Advia Analysers	57.08	57.1	-	-	-	-	-	1
	Siemens Advia Centaur & Atellica	51.43	51.5	1.20	2.3	0.43	49.1	53.3	8
	Siemens DCA 2000+ & Vantage	51.75	51.0	2.76	5.3	0.87	47.0	56.0	10
	Thermo Scientific Konelab	50.77	51.0	2.02	4.0	0.61	48.0	54.0	11
	All	52.04	52.0	1.39	2.7	0.15	33.3	57.1	86
Sample 002									
HbA1c, mmol/mol									
	Abbott Alinity	31.72	31.9	0.64	2.0	0.37	31.0	32.2	3
	Abbott Architect enzymatic	32.30	32.1	0.43	1.3	0.25	32.0	32.8	3
	HPLC Bio-Rad D-10	32.50	32.5	0.71	2.2	0.50	32.0	33.0	2
	HPLC Tosoh	34.33	34.3	0.89	2.6	0.19	31.9	36.6	34
	Roche cobas c Tina-quant	33.93	34.0	1.36	4.0	0.49	32.0	53.0	12
	Sebia Capillary electrophoresis	34.00	34.0	0.00	0.0	0.00	34.0	34.0	2
	Siemens Advia Analysers	38.02	38.0	-	-	-	-	-	1
	Siemens Advia Centaur & Atellica	32.24	32.5	1.23	3.8	0.43	30.0	33.8	8
	Siemens DCA 2000+ & Vantage	34.25	34.0	1.51	4.4	0.48	32.0	37.5	10
	Thermo Scientific Konelab	35.33	34.7	2.98	8.4	0.90	31.0	42.0	11
	All	33.93	34.0	1.45	4.3	0.16	30.0	53.0	86
Sample 003									
HbA1c, mmol/mol									
	Abbott Alinity	57.79	57.8	0.28	0.5	0.20	57.6	58.0	2
	Abbott Architect enzymatic	60.75	59.1	3.87	6.4	1.73	57.0	67.0	5
	Akay Adams A1c	55.20	55.2	-	-	-	-	-	1
	Beckman Coulter	56.20	57.0	3.86	6.9	2.23	52.0	59.6	3
	Beckman Coulter AU instruments	53.15	52.5	1.62	3.0	0.93	52.0	55.0	3
	HPLC Bio-Rad D-10	51.90	51.9	1.56	3.0	1.10	50.8	53.0	2
	HPLC Tosoh	61.20	61.2	0.85	1.4	0.60	60.6	61.8	2
	Instrumentation laboratory	78.90	78.9	-	-	-	-	-	1
	Quo-Lab & Quo-Test HbA1c	63.04	63.0	1.21	1.9	0.86	62.2	63.9	2
	Roche cobas c Tina-quant	58.55	58.0	1.04	1.8	0.36	54.1	60.0	13
	Roche Cobas Integra	60.48	61.2	4.21	7.0	2.11	55.0	64.5	4
	Siemens Advia Centaur & ACS	58.00	58.0	-	-	-	-	-	1
	Siemens Advia Centaur & Atellica	56.07	55.6	1.16	2.1	0.67	55.2	57.4	3
	Siemens Dimension & Vista	60.00	60.0	-	-	-	-	-	1
	Thermo Scientific Konelab	58.00	58.0	-	-	-	-	-	1
	All	58.24	58.0	3.41	5.9	0.51	50.8	78.9	44
Sample 004									
HbA1c, mmol/mol									
	Abbott Alinity	88.63	88.6	0.95	1.1	0.68	88.0	89.3	2
	Abbott Architect enzymatic	93.20	92.0	4.30	4.6	1.92	89.0	100.2	5
	Akay Adams A1c	83.60	83.6	-	-	-	-	-	1
	Beckman Coulter	86.77	88.0	5.26	6.1	3.04	81.0	91.3	3
	Beckman Coulter AU instruments	85.26	85.0	0.46	0.5	0.26	85.0	85.8	3
	HPLC Bio-Rad D-10	84.15	84.2	3.89	4.6	2.75	81.4	86.9	2
	HPLC Tosoh	91.15	91.2	0.21	0.2	0.15	91.0	91.3	2

NUMERICAL SUMMARY
HbA1c 2023/01, Sample 004

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
HbA1c, mmol/mol									
	Instrumentation laboratory	64.20	64.2	-	-	-	-	-	1
	Quo-Lab & Quo-Test HbA1c	95.71	95.7	7.62	8.0	5.39	90.3	101.1	2
	Roche cobas c Tina-quant	90.30	90.0	2.54	2.8	0.88	88.0	96.4	13
	Roche Cobas Integra	90.78	91.6	4.15	4.6	2.08	85.0	94.9	4
	Siemens Advia Centaur & ACS	85.00	85.0	-	-	-	-	-	1
	Siemens Advia Centaur & Atellica	87.69	86.9	2.19	2.5	1.26	86.0	90.2	3
	Siemens Dimension & Vista	90.00	90.0	-	-	-	-	-	1
	Thermo Scientific Konelab	87.00	87.0	-	-	-	-	-	1
All		89.21	89.2	3.85	4.3	0.58	64.2	101.1	44

Participants

101 participants from 15 countries.

Report info

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LABQUALITY

External Quality Assessment Scheme

Haemoglobin A1c, liquid samples Round 1, 2023

Specimens

Sample S003 (LQ729423013) and sample S004 (LQ729423014) 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

The level of sample S003 was elevated and level of sample S004 was high. The mean of all results was 58.24 mmol/mol for sample S003 and 89.21 mmol/mol for sample S004.

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 1/2023 both samples S003 and S004 were higher than the diagnostic limit of ADA (48 mmol/mol). The mean (all results) of HbA1c samples S003 and S004 were 58.24 and 89.21 mmol/mol, respectively. None of method groups differed significantly from the mean values. The total variation was 5.9% for the sample S003 and 4.3% for the sample S004. The CV% of the samples were low and better than in the previous round.

End of report

2023-03-14

FINAL REPORT

Product no. 1261

Samples sent	2023-02-06
Round closed	2023-02-23
Final report	2023-03-14

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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