

External Quality Assessment Scheme

Myocardial markers and CRP, low concentration Round 1, 2023

Specimens

Please find enclosed 3 liquid commercial human serum samples S001, S002 and S003, each 1 mL. Sample S003 is only for low concentration CRP measurement.

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

CKMBm
Myoglobin
Troponin I
Troponin T
CRP low concentration

Storage and use

The samples are analyzed in the same way as patient samples. They shall be analyzed immediately when they arrive at the laboratory. If not done immediately, the samples can be stored at +2 ... +8 ° C, where they are stable until the round is closed. Mix the sample by gently inverting the vial several times to mix the liquid on the bottom and surface. Avoid foam formation. Careful mixing is very important to get a reliable result. The samples must not be frozen.

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.

S001



S002



S003



2023-02-21

INSTRUCTIONS

Product no. 2540, 2541, 1541
LQ738223011-013/DE, DK

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

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

Inquiries

EQA Coordinator
Päivi Ranta
paivi.ranta@labquality.fi

Labquality Oy

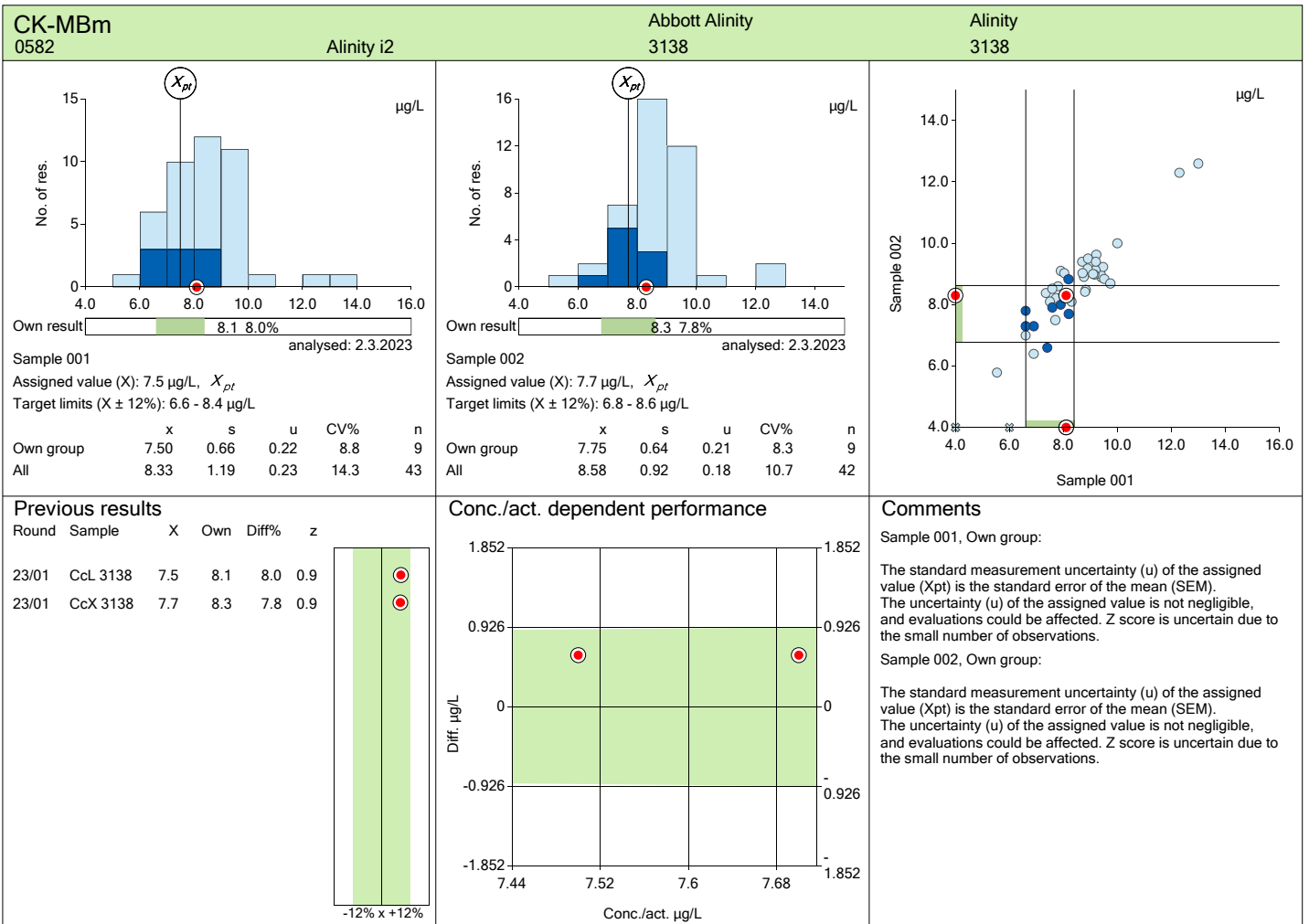
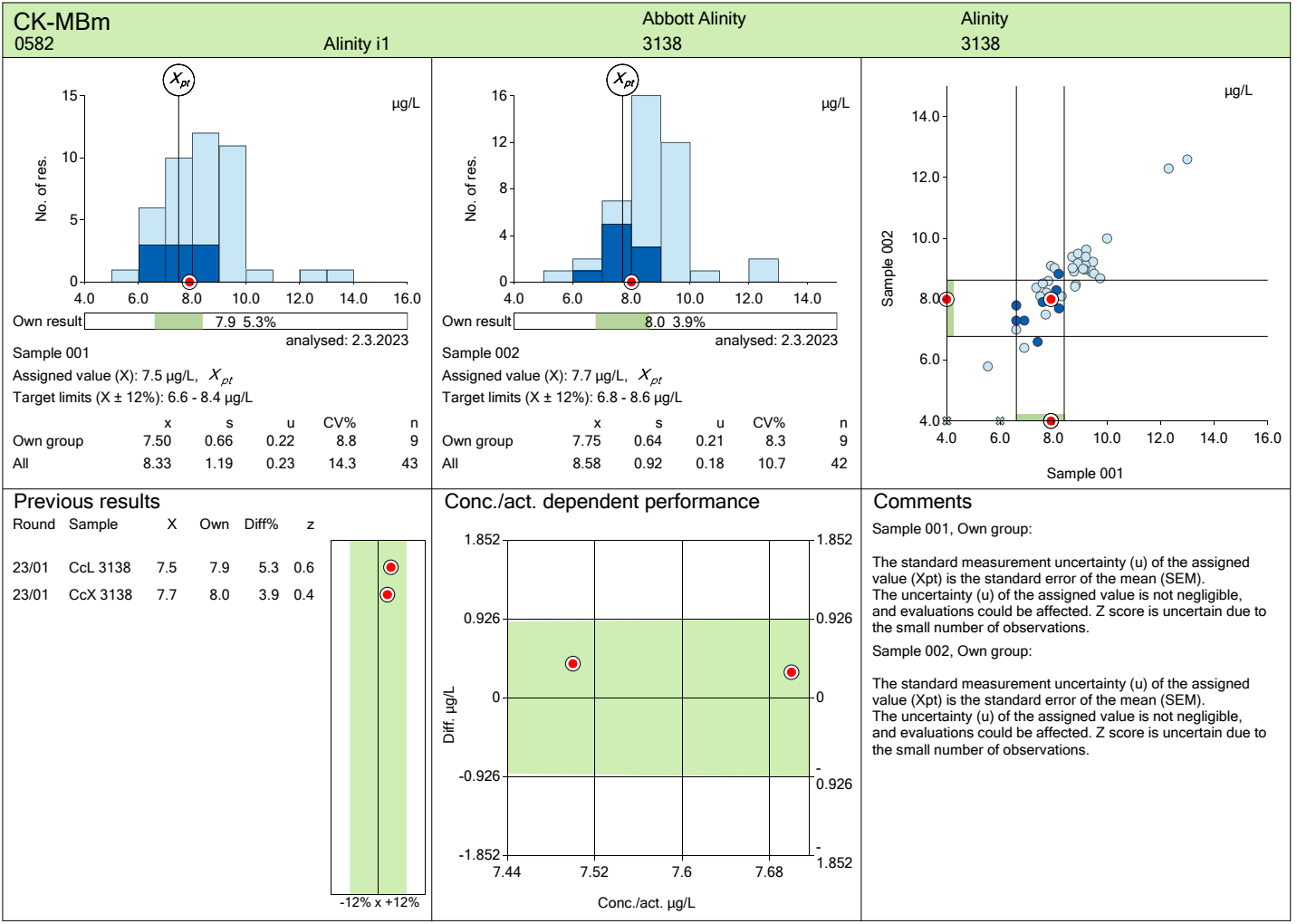
Kumpulantie 15
FI-00520 HELSINKI
Finland

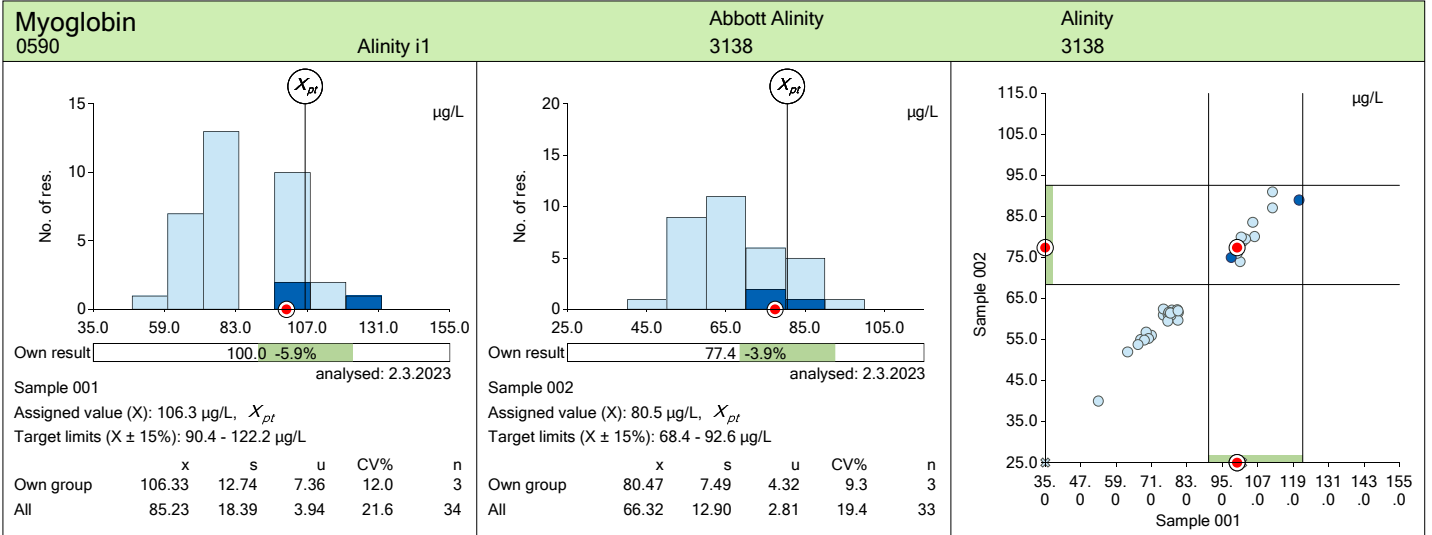
Tel. + 358 9 8566 8200

Fax + 358 9 8566 8280

info@labquality.fi
www.labquality.com

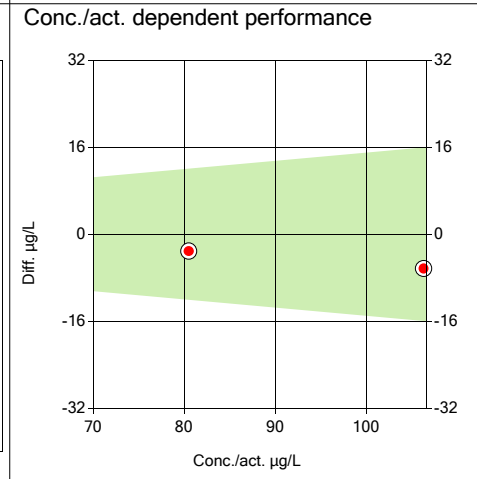






Previous results

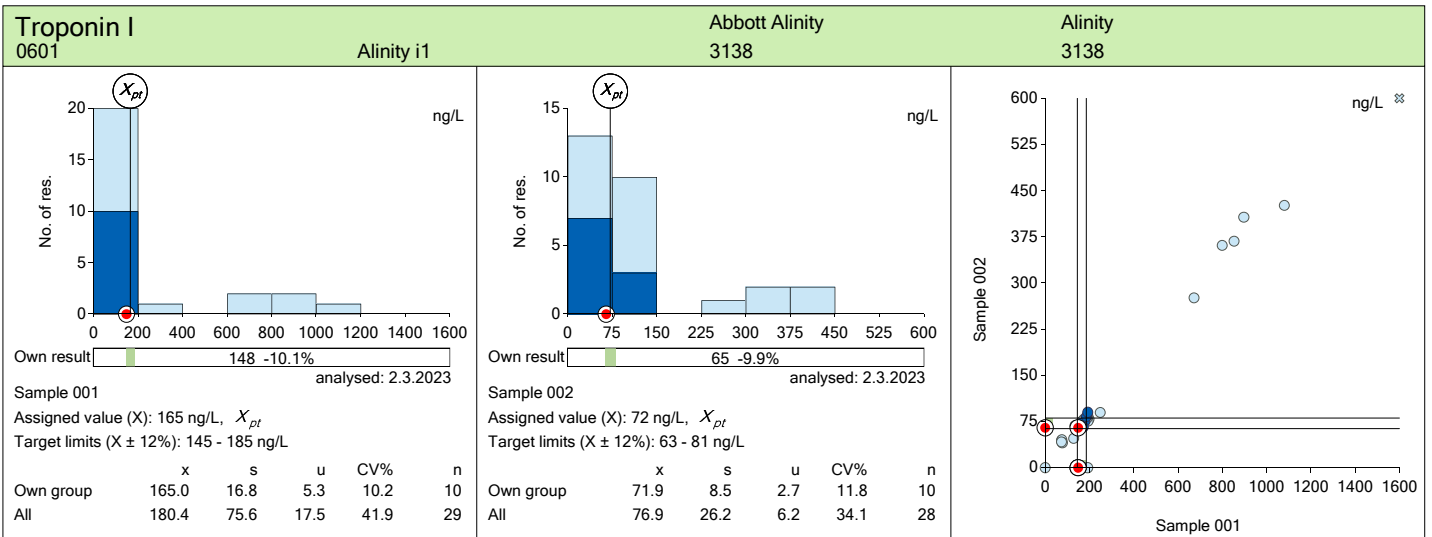
Round	Sample	X	Own	Diff%	z
23/01	CcL 3138	106.3	100.0	-5.9	-
23/01	CcX 3138	80.5	77.4	-3.9	-



Comments

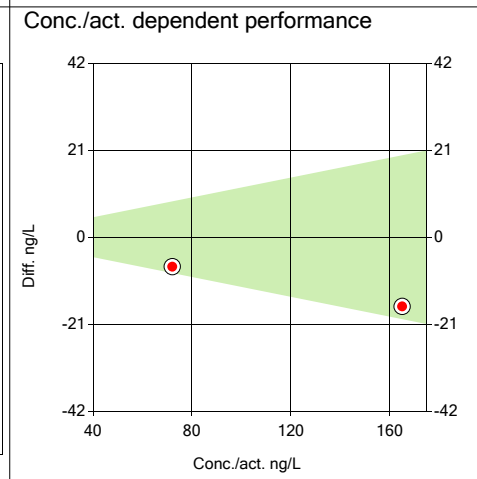
Sample 001, Own group:
The standard measurement uncertainty (u) of the assigned value (X_{pt}) is the standard error of the mean (SEM). The uncertainty (u) of the assigned value is not negligible, and evaluations could be affected. Due to the small number of results, the z score is not calculated.

Sample 002, 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 assigned value is not negligible, and evaluations could be affected. Due to the small number of results, the z score is not calculated.



Previous results

Round	Sample	X	Own	Diff%	z
23/01	CcL 3138	165	148	-10.1	-1.0
23/01	CcX 3138	72	65	-9.9	-0.8

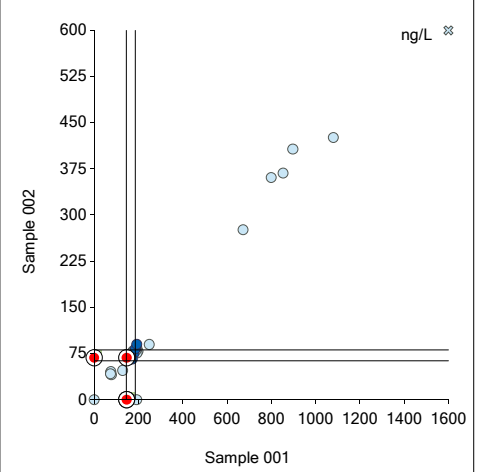
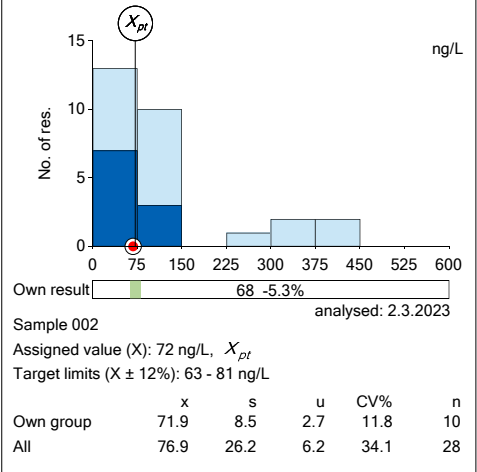
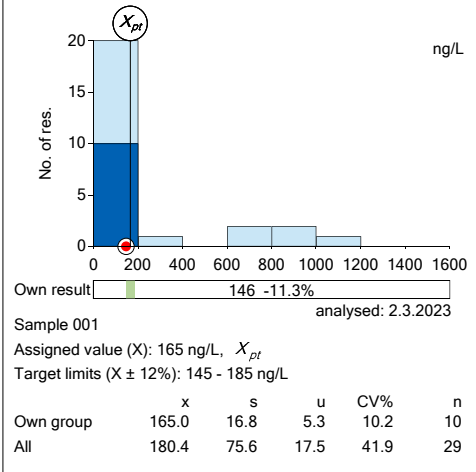


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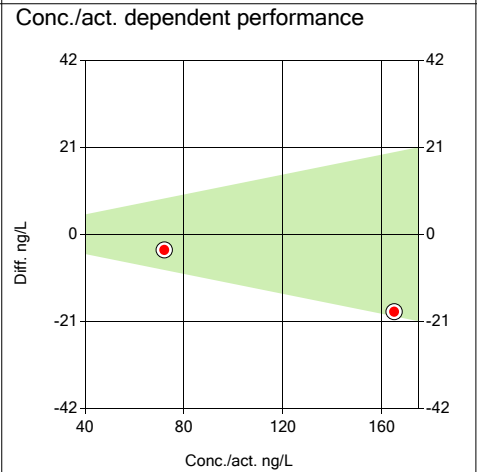
Sample 002, Own group:
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Troponin I 0601 **Alinity i2** **Abbott Alinity** 3138 **Alinity** 3138



Previous results

Round	Sample	X	Own	Diff%	z
23/01	CcL 3138	165	146	-11.3	-1.1
23/01	CcX 3138	72	68	-5.3	-0.4



Comments

Sample 001, 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 assigned value is not negligible, and evaluations could be affected. Z score is uncertain due to the small number of observations.

Sample 002, 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 assigned value is not negligible, and evaluations could be affected. Z score is uncertain due to the small number of observations.

Participants

78 participants from 13 countries.

Report info

Assigned value (target value) calculation and its uncertainty

Your own result should be compared to others using the same method.

The assigned values (X_{rob}) 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.

In case there are 2-12 results in a method group, the robust calculation is not used but assigned values (X_{pt}) are means of the results where results deviating more than $\pm 3 \times$ standard deviation from the median are removed. The standard uncertainty (u) of the assigned value is reported as standard error of the mean (SEM). Additionally, if the measurement uncertainty of the target value is too large ($u > 0.1 \times$ maximum allowable error) an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected."

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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 (top right corner ?Help link).

CRP low 0593	Alinity c1	Abbott Architect 344	854																														
<p>Own result: 2.99 -2.6%</p> <p>analysed: 2.3.2023</p> <p>Sample 003 Assigned value (X): 3.07 mg/L, X_{pt} Target limits ($X \pm 15\%$): 2.61 - 3.53 mg/L</p> <table border="1" style="font-size: small;"> <thead> <tr> <th></th> <th>x</th> <th>s</th> <th>u</th> <th>CV%</th> <th>n</th> </tr> </thead> <tbody> <tr> <td>Own group</td> <td>3.066</td> <td>0.632</td> <td>0.239</td> <td>20.6</td> <td>7</td> </tr> <tr> <td>All</td> <td>3.274</td> <td>0.374</td> <td>0.078</td> <td>11.4</td> <td>36</td> </tr> </tbody> </table>		x	s	u	CV%	n	Own group	3.066	0.632	0.239	20.6	7	All	3.274	0.374	0.078	11.4	36	<p>Previous results</p> <table border="1" style="font-size: small;"> <thead> <tr> <th>Round</th> <th>Sample</th> <th>X</th> <th>Own</th> <th>Diff%</th> <th>z</th> </tr> </thead> <tbody> <tr> <td>23/01</td> <td>C18 344</td> <td>3.07</td> <td>2.99</td> <td>-2.6</td> <td>-0.1</td> </tr> </tbody> </table>	Round	Sample	X	Own	Diff%	z	23/01	C18 344	3.07	2.99	-2.6	-0.1	<p>Comments</p> <p>Sample 003, Own group:</p> <p>The standard measurement uncertainty (u) of the assigned value (X_{pt}) is the standard error of the mean (SEM). The uncertainty (u) of the assigned value is not negligible, and evaluations could be affected. Z score is uncertain due to the small number of observations.</p>	
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NUMERICAL SUMMARY
Myocardial markers 2023/01

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
Sample 001									
CK-MBm, µg/L									
	Abbott Alinity	7.50	7.6	0.66	8.8	0.22	6.6	8.2	9
	Abbott Architect	6.91	7.0	0.76	11.0	0.38	6.0	7.7	4
	Beckman Coulter Access & Unicel	10.00	10.0	-	-	-	-	-	1
	Radiometer AQT 90 FLEX	12.65	12.7	0.49	3.9	0.35	12.3	13.0	2
	Roche cobas e, Elecsys, & Modular E	8.68	8.8	0.77	8.9	0.19	5.5	9.7	25
	Siemens Advia Centaur & Atellica	9.40	9.4	-	-	-	-	-	1
	Siemens Dimension & Vista	6.90	6.9	-	-	-	-	-	1
	All	8.33	8.3	1.19	14.3	0.18	5.5	13.0	43
Myoglobin, µg/L									
	Abbott Alinity	106.33	100.0	12.74	12.0	7.36	98.0	121.0	3
	Abbott Architect	106.85	106.9	7.28	6.8	5.15	101.7	112.0	2
	bioMerieux Vidas	53.00	53.0	-	-	-	-	-	1
	Radiometer AQT 90 FLEX	112.00	112.0	-	-	-	-	-	1
	Roche cobas e, Elecsys, & Modular E	74.12	76.5	5.51	7.4	1.58	62.9	80.1	19
	Roche Tina-quant	80.00	80.0	-	-	-	-	-	1
	Siemens Advia Centaur & Atellica	103.07	102.4	2.06	2.0	0.84	101.0	105.9	6
	Siemens Dimension & Vista	100.00	100.0	-	-	-	-	-	1
	All	85.23	78.8	18.39	21.6	3.15	53.0	121.0	34
Troponin I, ng/L									
	Abbott Alinity	165.0	164	16.8	10.2	5.3	145	192	10
	Abbott Architect hs STAT	187.5	191	29.9	16.0	10.0	135	248	9
	Access hsTnI (High Sensitivity Troponin I)	75.1	75	1.9	2.5	1.1	73	77	3
	Atellica Solution High-Sensitivity TnI (TnIH)	672.0	672	-	-	-	-	-	1
	Beckman Coulter Access & Unicel	73.0	73	-	-	-	-	-	1
	Radiometer AQT 90 FLEX	128.0	128	-	-	-	-	-	1
	Roche cobas e, Elecsys, & Modular E	1,080.0	1,080	-	-	-	-	-	1
	Siemens Dimension & Vista	849.7	853	49.1	5.8	28.3	799	897	3
	All	180.4	175	75.6	41.9	14.0	73	1,080	29
Troponin T, ng/L									
	Radiometer AQT 90 FLEX	224.0	224	41.0	18.3	29.0	195	253	2
	Roche Troponin T hs	255.9	253	21.4	8.4	4.3	180	326	38
	All	254.9	253	21.8	8.6	3.4	180	326	40
Sample 002									
CK-MBm, µg/L									
	Abbott Alinity	7.75	7.8	0.64	8.3	0.21	6.6	8.8	9
	Abbott Architect	7.63	7.5	0.70	9.2	0.40	7.0	8.4	3
	Beckman Coulter Access & Unicel	10.00	10.0	-	-	-	-	-	1
	Radiometer AQT 90 FLEX	12.45	12.5	0.21	1.7	0.15	12.3	12.6	2
	Roche cobas e, Elecsys, & Modular E	8.87	9.0	0.51	5.7	0.13	5.8	9.6	25
	Siemens Advia Centaur & Atellica	8.90	8.9	-	-	-	-	-	1
	Siemens Dimension & Vista	6.40	6.4	-	-	-	-	-	1
	All	8.58	8.8	0.92	10.7	0.14	5.8	12.6	42
Myoglobin, µg/L									
	Abbott Alinity	80.47	77.4	7.49	9.3	4.32	75.0	89.0	3
	Abbott Architect	91.00	91.0	-	-	-	-	-	1
	bioMerieux Vidas	40.00	40.0	-	-	-	-	-	1
	Radiometer AQT 90 FLEX	87.10	87.1	-	-	-	-	-	1

NUMERICAL SUMMARY
Myocardial markers 2023/01, Sample 002

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
Myoglobin, µg/L									
Roche cobas e, Elecsys, & Modular E		58.93	60.6	3.66	6.2	1.05	52.0	62.5	19
Roche Tina-quant		62.00	62.0	-	-	-	-	-	1
Siemens Advia Centaur & Atellica		79.36	79.8	3.08	3.9	1.26	74.0	83.6	6
Siemens Dimension & Vista		76.00	76.0	-	-	-	-	-	1
All		66.32	61.6	12.90	19.4	2.25	40.0	91.0	33
Troponin I, ng/L									
Abbott Alinity		71.9	68	8.5	11.8	2.7	65	90	10
Abbott Architect hs STAT		79.1	79	6.3	8.0	2.2	68	90	8
Access hsTnl (High Sensitivity Troponin I)		43.3	44	2.5	5.9	1.5	41	46	3
Atellica Solution High-Sensitivity Tnl (TnlH)		276.0	276	-	-	-	-	-	1
Beckman Coulter Access & Unicel		42.0	42	-	-	-	-	-	1
Radiometer AQT 90 FLEX		47.5	48	-	-	-	-	-	1
Roche cobas e, Elecsys, & Modular E		426.0	426	-	-	-	-	-	1
Siemens Dimension & Vista		378.7	368	24.8	6.5	14.3	361	407	3
All		76.9	76	26.2	34.1	4.9	41	426	28
Troponin T, ng/L									
Radiometer AQT 90 FLEX		89.7	90	2.8	3.2	2.0	88	92	2
Roche Troponin T hs		147.5	146	11.0	7.5	2.2	122	325	38
All		146.5	146	12.0	8.2	1.9	88	325	40

Sample 003
CRP low, mg/L

Abbott Architect		3.066	3.30	0.632	20.6	0.239	1.70	3.60	7
Orion Diagnostica		2.500	2.50	-	-	-	-	-	1
Roche cobas CRPL3		3.054	2.93	0.274	9.0	0.097	2.83	3.52	8
Roche Tina-quant		3.400	3.40	-	-	-	-	-	1
Roche Tina-quant CRP (latex) HS		3.335	3.23	0.362	10.9	0.148	3.08	4.05	6
Siemens Advia Centaur & Atellica		3.210	3.20	0.121	3.8	0.054	3.02	3.33	5
Siemens CardioPhase hsCRP		3.200	3.20	-	-	-	-	-	1
Siemens Dimension & Vista		3.350	3.35	0.212	6.3	0.150	3.20	3.50	2
Siemens Immulite hs CRP		4.590	4.59	-	-	-	-	-	1
Thermo Fisher Scientific, CRP high sensitivity		3.998	3.97	0.246	6.1	0.123	3.76	4.30	4
All		3.274	3.25	0.374	11.4	0.062	1.70	4.59	36

NUMERICAL SUMMARY

Myocardial markers 2023/01, Sample 003

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CRP low, mg/L									

Participants

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External Quality Assessment Scheme

Myocardial markers and CRP, low concentration Round 1, 2023

Specimens

Sample S001 (LQ738223011), sample S002 (LQ738223012) and sample S003 (LQ738223013) were commercial liquid human serum 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

CKMBm, Myoglobin, Troponin I and Troponin T

In both samples, the concentrations of all analytes were elevated, indicating a possible cardiac event.

Troponin I result levels vary a lot between different method groups, with Roche representing the highest level (N=1) and Beckman Coulter Access the lowest level (N=3) in both samples. The overall CV% was high, being 41.9% for sample S001 and 34.1% for sample S002. However, CV%s within the method groups were lower than 20% in those groups with N≥2.

hsCRP

In sample 003, the concentration of sensitive CRP (hsCRP) was in the risk area above 3 mg/L.

End of report

2023-03-15

FINAL REPORT

Product no. 2540, 2541, 1541

Samples sent	2023-02-21
Round closed	2023-03-13
Final report	2023-03-15

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

EQA Coordinator
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