

External Quality Assessment Scheme

Myocardial markers and CRP, low concentration Round 2, 2020

Specimens

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

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

Storage and use

The samples are analyzed in the same way as patient samples. They shall be analyzed as soon as the samples 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. The samples must not be frozen.

Result reporting

Please enter the results and methods via LabScala. If you can't find your instrument or reagent from the registry, please contact the coordinator.

S001: LQ738220021



S002: LQ738220022



S003: LQ738220023



2020-04-27

INSTRUCTIONS

Product no. 2540, 2541, 1541
LQ738220021-023/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 **May 14, 2020.**

Inquiries

EQA Coordinator
Päivi Ranta
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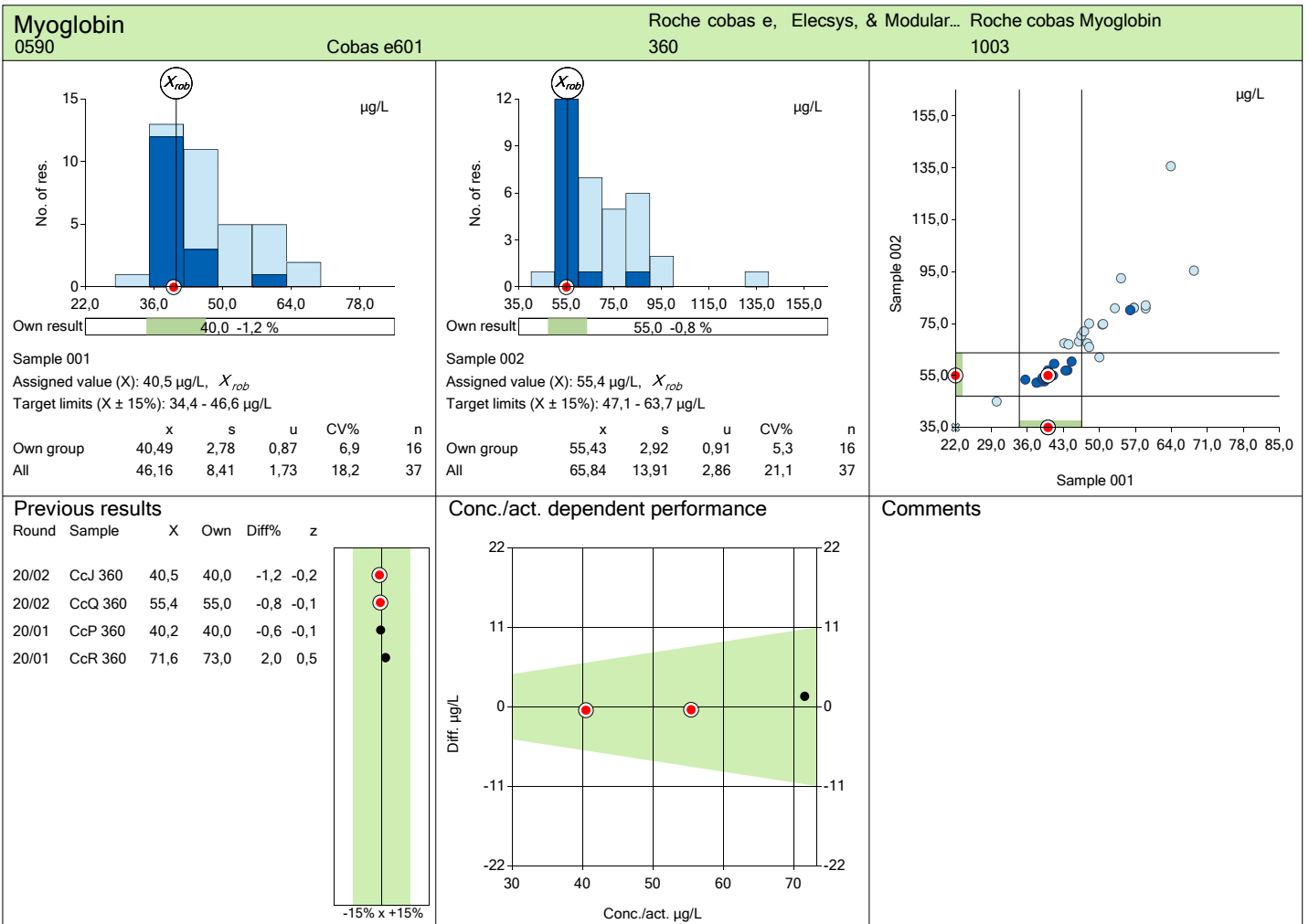
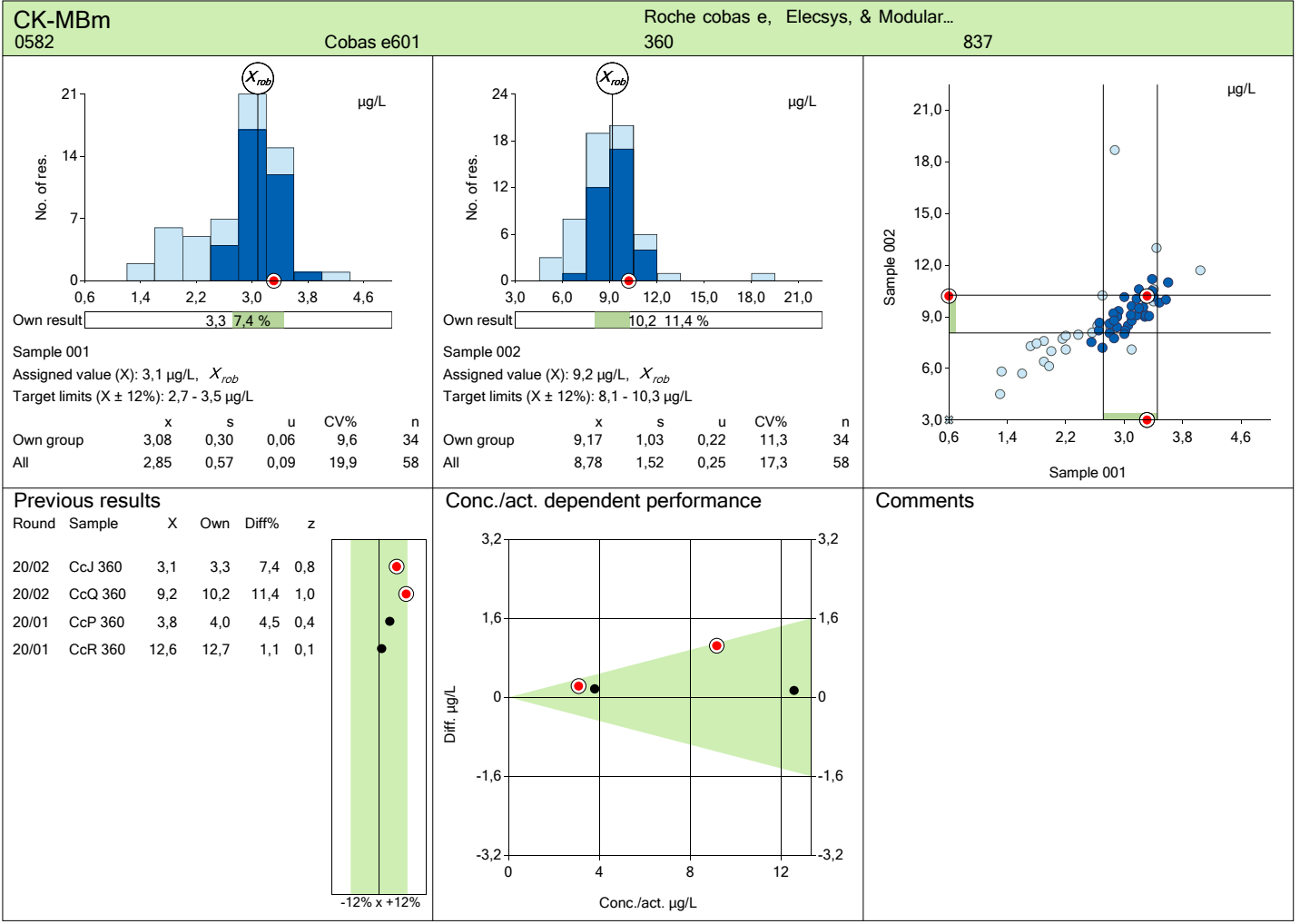
Labquality

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FI-00520 HELSINKI
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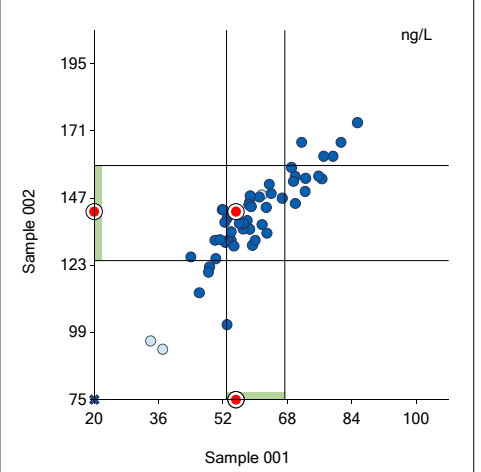
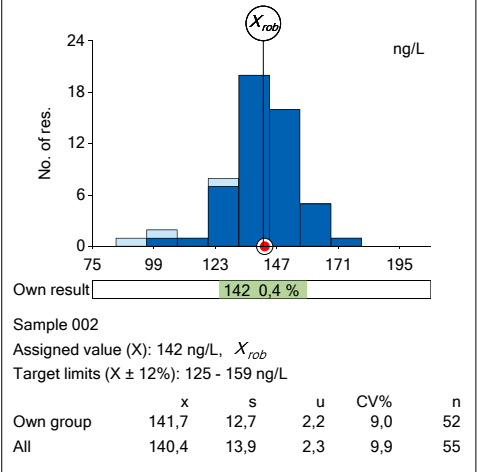
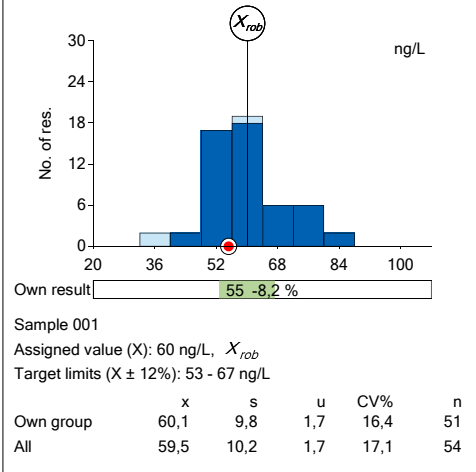
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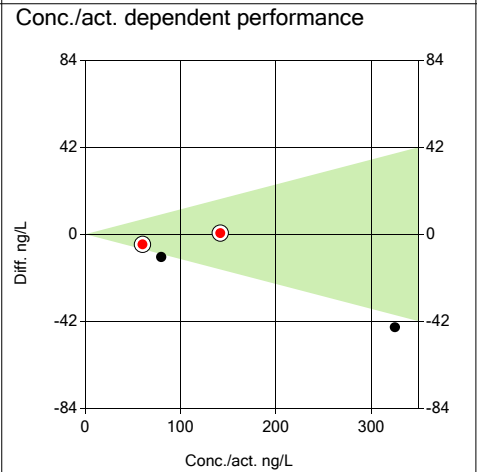


Troponin T 0599 **Cobas e601** **Roche Troponin T hs** 1015 **Roche Troponin T hs 5. gen** 853



Previous results

Round	Sample	X	Own	Diff%	z
20/02	CcJ 1015	60	55	-8,2	-0,5
20/02	CcQ 1015	142	142	0,4	0,0
20/01	CcP 1015	80	69	-13,7	-1,6
20/01	CcR 1015	325	280	-13,8	-1,9



Comments

CRP low 0593	cobas c501	Roche Tina-quant CRP (latex) HS 412	847																																			
<p>Own result: 4.00 3.4%</p> <p>Sample 003 Assigned value (X): 3.87 mg/L, X_{pt} Target limits ($X \pm 15\%$): 3.29 - 4.45 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>3,866</td> <td>0,572</td> <td>0,256</td> <td>14,8</td> <td>5</td> </tr> <tr> <td>All</td> <td>3,966</td> <td>0,365</td> <td>0,088</td> <td>9,2</td> <td>27</td> </tr> </tbody> </table>		x	s	u	CV%	n	Own group	3,866	0,572	0,256	14,8	5	All	3,966	0,365	0,088	9,2	27	<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>20/02</td> <td>C14 412</td> <td>3,87</td> <td>4,00</td> <td>3,4</td> <td>0,2</td> </tr> <tr> <td>20/01</td> <td>C14 412</td> <td>4,92</td> <td>5,00</td> <td>1,6</td> <td>0,2</td> </tr> </tbody> </table>	Round	Sample	X	Own	Diff%	z	20/02	C14 412	3,87	4,00	3,4	0,2	20/01	C14 412	4,92	5,00	1,6	0,2	<p>Comments</p> <p>Sample 003, Own group: 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 2020/02

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
Sample 001									
CK-MBm, µg/L									
	Abbott Alinity	2,39	2,4	0,48	20,2	0,22	1,9	3,1	5
	Abbott Architect	1,99	2,0	0,20	9,9	0,09	1,7	2,2	5
	bioMerieux Vidas	4,04	4,0	-	-	-	-	-	1
	cobas h232	2,63	2,6	-	-	-	-	-	1
	FIA Getein	3,16	3,2	0,40	12,8	0,28	2,9	3,4	2
	Roche cobas e, Elecsys, & Modular E	3,08	3,1	0,30	9,6	0,06	2,6	3,6	34
	Roche Tina-quant	2,06	2,1	1,07	52,0	0,76	1,3	2,8	2
	Siemens Advia Centaur & Atellica	3,10	3,2	0,36	11,5	0,18	2,7	3,4	4
	Siemens Dimension & Vista	1,73	1,7	0,37	21,4	0,19	1,3	2,2	4
	All	2,85	2,9	0,57	19,9	0,07	1,3	4,0	58
Myoglobin, µg/L									
	Abbott Architect	58,81	57,9	5,19	8,8	2,12	53,0	68,4	6
	bioMerieux Vidas	30,00	30,0	-	-	-	-	-	1
	cobas h232	50,00	50,0	-	-	-	-	-	1
	FIA Getein	59,05	59,1	6,86	11,6	4,85	54,2	63,9	2
	Roche cobas e, Elecsys, & Modular E	40,49	39,7	2,78	6,9	0,87	35,6	56,0	16
	Roche Tina-quant	43,25	43,3	6,72	15,5	4,75	38,5	48,0	2
	Siemens Advia Centaur & Atellica	46,47	46,5	2,47	5,3	0,93	43,2	50,6	7
	Siemens Dimension & Vista	50,70	50,7	-	-	-	-	-	1
	Vitros Systems	47,66	47,7	-	-	-	-	-	1
	All	46,16	44,6	8,41	18,2	1,38	30,0	68,4	37
Troponin I, ng/L									
	Abbott Alinity	26,4	26	0,7	2,5	0,3	26	27	5
	Abbott Architect hs STAT	29,1	30	3,5	12,0	1,3	23	45	12
	Atellica Solution High-Sensitivity TnI (TnIH)	102,7	106	17,7	17,2	7,9	85	128	5
	Beckman Coulter Access & Unicel	13,9	14	4,0	29,1	2,9	11	17	2
	bioMerieux Vidas	7,7	8	2,4	31,8	1,2	6	10	4
	FIA Getein	450,0	450	-	-	-	-	-	1
	Radiometer AQT 90 FLEX	24,1	24	2,8	11,5	2,0	22	26	2
	Roche cobas e, Elecsys, & Modular E	196,0	196	-	-	-	-	-	1
	Siemens Advia Centaur & Atellica	102,7	111	38,9	37,9	17,4	39	141	5
	Siemens Dimension & Vista	161,4	160	10,5	6,5	4,7	147	175	5
	VIDAS High sensitive Troponin I	6,3	6	1,6	25,4	0,7	4	8	5
	Vitros Systems	12,0	12	-	-	-	-	-	1
	All	55,6	29	58,3	104,8	8,4	4	450	48
Troponin T, ng/L									
	Radiometer AQT 90 FLEX	35,5	36	2,1	6,0	1,5	34	37	2
	Roche Tina-quant	61,6	62	-	-	-	-	-	1
	Roche Troponin T hs	60,1	59	9,8	16,4	1,7	44	85	51
	All	59,5	58	10,2	17,1	1,4	34	85	54
Sample 002									
CK-MBm, µg/L									
	Abbott Alinity	7,55	7,6	0,49	6,5	0,22	7,0	8,1	5
	Abbott Architect	6,93	7,1	0,65	9,4	0,29	6,1	7,7	5
	bioMerieux Vidas	11,70	11,7	-	-	-	-	-	1
	cobas h232	8,48	8,5	-	-	-	-	-	1
	FIA Getein	15,85	15,9	4,03	25,4	2,85	13,0	18,7	2
	Roche cobas e, Elecsys, & Modular E	9,17	9,1	1,03	11,3	0,22	7,2	11,2	34

NUMERICAL SUMMARY
Myocardial markers 2020/02, Sample 002

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
CK-MBm, µg/L									
Roche Tina-quant		6,42	6,4	2,72	42,3	1,92	4,5	8,3	2
Siemens Advia Centaur & Atellica		9,94	10,1	0,69	6,9	0,34	9,0	10,6	4
Siemens Dimension & Vista		6,72	6,6	1,12	16,7	0,56	5,7	7,9	4
All		8,78	8,8	1,52	17,3	0,20	4,5	18,7	58
Myoglobin, µg/L									
Abbott Architect		83,53	81,1	5,83	7,0	2,38	80,8	95,4	6
bioMerieux Vidas		45,00	45,0	-	-	-	-	-	1
cobas h232		62,00	62,0	-	-	-	-	-	1
FIA Getein		114,03	114,0	30,51	26,8	21,57	92,5	135,6	2
Roche cobas e, Elecsys, & Modular E		55,43	54,6	2,92	5,3	0,91	52,2	80,2	16
Roche Tina-quant		59,25	59,3	9,55	16,1	6,75	52,5	66,0	2
Siemens Advia Centaur & Atellica		70,66	70,5	3,33	4,7	1,26	67,0	75,0	7
Siemens Dimension & Vista		74,80	74,8	-	-	-	-	-	1
Vitros Systems		67,39	67,4	-	-	-	-	-	1
All		65,84	66,0	13,91	21,1	2,29	45,0	135,6	37
Troponin I, ng/L									
Abbott Alinity		88,7	92	5,7	6,4	2,5	81	94	5
Abbott Architect hs STAT		90,4	88	11,5	12,7	4,1	77	106	12
Atellica Solution High-Sensitivity TnI (TnIH)		190,5	181	40,0	21,0	17,9	157	260	5
Beckman Coulter Access & Unicel		34,5	35	9,2	26,7	6,5	28	41	2
bioMerieux Vidas		47,4	40	22,9	48,4	11,5	30	80	4
FIA Getein		450,0	450	-	-	-	-	-	1
Radiometer AQT 90 FLEX		55,5	56	6,4	11,5	4,5	51	60	2
Roche cobas e, Elecsys, & Modular E		214,7	215	187,1	87,1	132,3	82	347	2
Siemens Advia Centaur & Atellica		219,4	212	52,0	23,7	23,3	154	284	5
Siemens Dimension & Vista		249,5	243	35,0	14,0	15,7	225	310	5
VIDAS High sensitive Troponin I		37,9	39	3,1	8,3	1,4	35	41	5
Vitros Systems		12,0	12	-	-	-	-	-	1
All		120,2	92	88,9	74,0	12,7	12	450	49
Troponin T, ng/L									
Radiometer AQT 90 FLEX		94,5	95	2,1	2,2	1,5	93	96	2
Roche Tina-quant		125,4	125	-	-	-	-	-	1
Roche Troponin T hs		141,7	142	12,7	9,0	2,2	0	174	52
All		140,4	140	13,9	9,9	1,9	0	174	55
Sample 003									
CRP low, mg/L									
Abbott Architect		4,100	4,17	0,240	5,8	0,098	3,70	4,38	6
Beckman Coulter AU-laitteet CRP latex		3,775	3,78	0,163	4,3	0,115	3,66	3,89	2
Mindray		4,140	4,14	-	-	-	-	-	1
Orion Diagnostica		3,200	3,20	0,283	8,8	0,200	3,00	3,40	2
Roche cobas CRPL3		3,545	3,58	0,073	2,1	0,030	3,43	3,60	6
Roche Tina-quant		3,931	3,81	0,252	6,4	0,095	3,66	4,27	7
Roche Tina-quant CRP (latex) HS		3,866	3,90	0,572	14,8	0,256	3,07	4,66	5
Siemens Advia Centaur & Atellica		4,088	4,09	-	-	-	-	-	1
Siemens CardioPhase hsCRP		3,865	3,83	0,255	6,6	0,127	3,60	4,20	4
Siemens Dimension & Vista		3,840	4,00	0,277	7,2	0,160	3,52	4,00	3
Thermo Fisher Scientific, CRP high sensitivity		4,715	4,72	0,120	2,5	0,085	4,63	4,80	2
All		3,873	3,89	0,367	9,5	0,059	3,00	4,80	39

NUMERICAL SUMMARY

Myocardial markers 2020/02, Sample 003

Analyte	Method group	x	med	s	CV%	u	Min	Max	Number
CRP low, mg/L									

Participants

103 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 x 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 ± 3 * 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 ($u > 0.1 * \text{maximum allowable error}$) an automatic text is printed on the report: “The uncertainty of the assigned value is not negligible, and evaluations could be affected.”

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) is calculated, no target areas are shown.

Z score

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 (top right corner ?Help link).

External Quality Assessment Scheme

Myocardial markers and CRP, low concentration Round 2, 2020

Specimens

Sample S001 (LQ738220021), sample S002 (LQ738220022) and sample S003 (LQ738220023) 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.

Comments

It is important to read the Final report first, because it contains important information of the samples and results in each round.

CKMBm

In sample 001, CKMBm level was low - below the lower reference limit with all method groups. The reported results of all groups varied between 2.51-3.19 µg/l, while the CV% was 19.9%. In sample 002, the level was elevated, which indicates a possible myocardial infarction. The average level of all method groups was 8,78 µg/l. Depending on the method, the level varied between 7.73-9.83 µg/l, while the CV% was 17.3%.

Myoglobin

In sample 001, myoglobin level was within the reference range, and in sample 002 either within the upper limit of the reference range, or slightly elevated. Total CV% were 18.2% and 21,1%. Within method groups the CV% were mainly acceptable. Only slightly elevated myoglobin level indicates a possible cardiac event but does not necessarily clearly point towards a myocardial infarction.

Tnl and TnT

Troponin levels were elevated in both samples, which indicates a possible myocardial infarction. In sample 001, Tnl level varied between 49.0-62.3 ng/l (CV% 104.8%) between all methods, and in sample 002 between 105.7-134.6 ng/l (CV% 74.0%). Tnl level varies a lot depending on the method used. TnT level varied between 52.4-66.7 ng/l (CV% 17.1%) in sample 001, and between 123.6-157.3 ng/l (CV% 9.9%) in sample 002.

CRP

In sample 003, the high-sensitivity CRP (hs-CRP) level was in the risk area, the limit of which is 3mg/l. All method groups' reported results were between 3.29-4.45 mg/l and the total CV% was 9.5%, which is acceptable.

There were variations in the CV% of all myocardial markers. In some method groups the CV% were clearly larger than objectives. This might be highlighted if there are only a few participants in the group. Regardless, laboratories should ensure the functionality of their method, if its result differs from the group's average.

End of report

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2020-06-02

FINAL REPORT

Product no. 2540, 2541, 1541

Samples sent	2020-04-27
Round closed	2020-05-14
Final report	2020-06-02

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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