LABQUALITY

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

LQ738220021

S002: LQ738220022

LQ738220022

S003: LQ738220023

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**.

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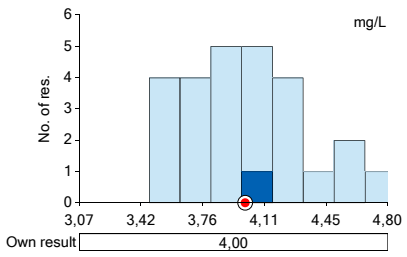
info@labquality.fi
www.labquality.fi

FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015

CRP low

0593	Vista	Siemens Dimension & Vista 816	Siemens Dimension Vista System 805

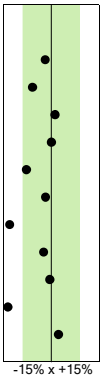


Sample 003

	x	s	u	CV%	n
Own group	-	-	-	-	1
All	3,966	0,365	0,088	9,2	27

Previous results

Round	Sample	X	Own	Diff%	z
20/02	C14 816	-	4,00	-	-
20/01	C14 816	4,34	4,20	-3,2	-
19/05	C14 816	8,10	7,30	-9,9	-
19/04	C17 816	2,06	2,10	1,9	-
19/03	C12 816	2,05	2,05	0,0	-
19/02	C13 500	2,30	2,00	-13,0	-
19/01	C12 816	4,25	4,12	-3,1	-
18/05	C1 816	2,43	1,90	-21,8	-
18/04	C11 816	2,21	2,12	-4,1	-
18/03	C9 816	4,84	4,80	-0,8	-
18/02	C1 816	2,33	1,80	-22,7	-0,4
18/01	C9 816	5,11	5,30	3,7	0,7
17/05	C9 816	5,10	5,10	-0,1	0,0



Comments

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 (Xrob) 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 (Xpt) 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 * 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 < 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).

LABQUALITY

External Quality Assessment Scheme

Myocardial markers and CRP, low concentration Round 2, 2020

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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FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015

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.

TnI and TnT
Troponin levels were elevated in both samples, which indicates a possible myocardial infarction. In sample 001, TnI 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%). TnI 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%s 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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