LABQUALITY

External Quality Assessment Scheme

Troponin I and troponin T, detection, POCT Round 1, 2023

Specimens
Please find enclosed 2 human serum pool samples S001 and S002, each 1 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
Troponin I
Troponin T

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. Hold the sample vial between your thumb and forefinger and invert the vial at least eight 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.

For troponin I and troponin T, qualitative results which gives a positive/negative result, fill the result to the field qualitative. Troponin I and troponin T results, where the device gives a number, fill in the result to the field quantitative. If the device marks < or > with the result, please fill it also in connection with the result in the quantitative field. We will handle these results in a round separately.

If you do not fill any result on row, you can leave it blank by deleting the measurement date from the row.

S001

S002

2023-02-21

INSTRUCTIONS

Product no. 2530
LQ738323011-012/DE

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
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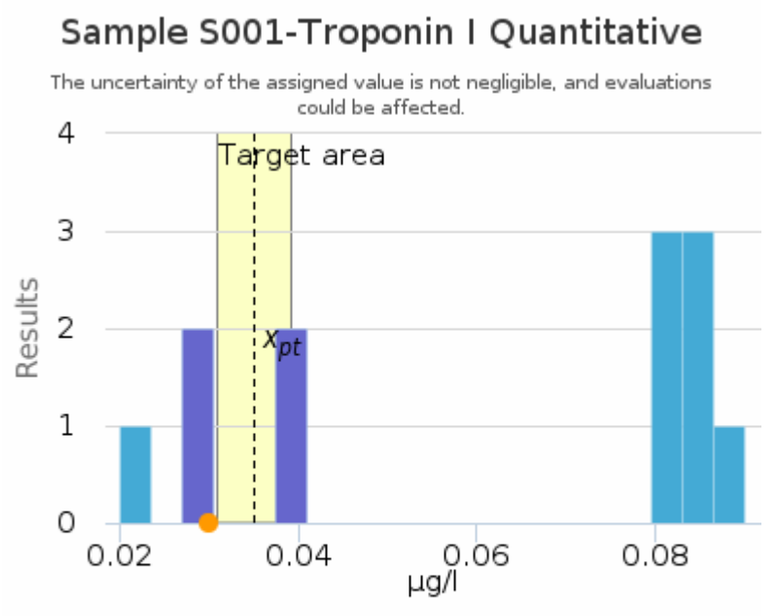
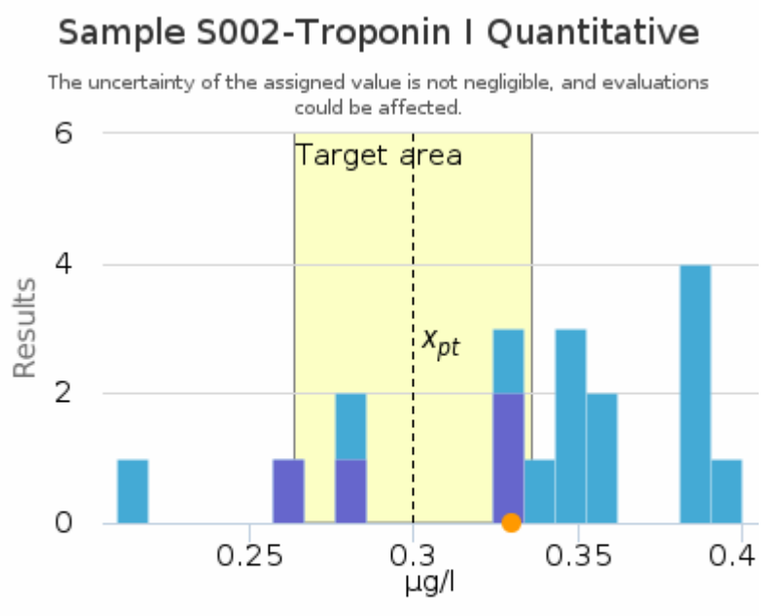
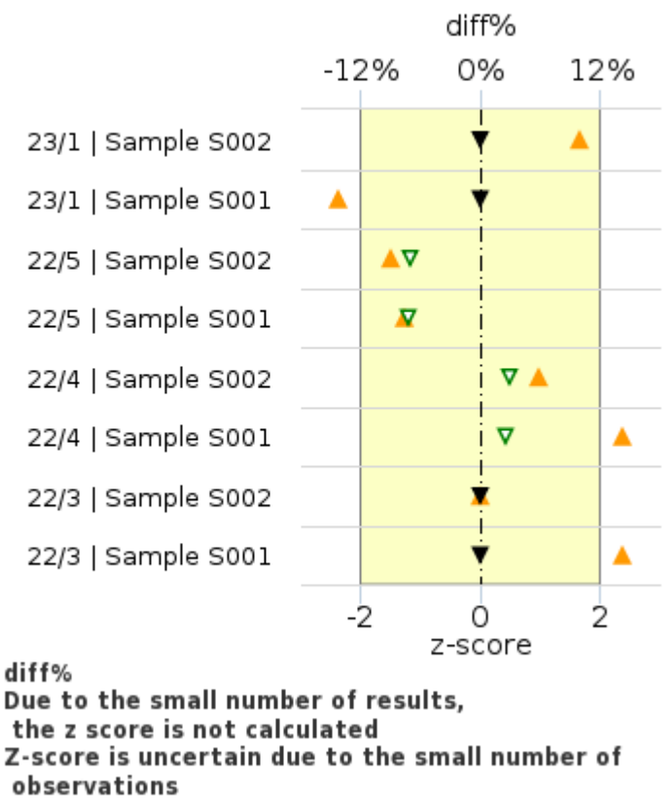
Troponin I Quantitative |I-Stat-H







	x_{pt}	sd	SEM	CV%	n
CTnI Abbott	0.035 µg/l	0.006	0.003	16.5	4
All methods	0.062 µg/l	0.027	0.008	43.5	12

	x_{pt}	sd	SEM	CV%	n
CTnI Abbott	0.300 µg/l	0.036	0.018	11.9	4
All methods	0.337 µg/l	0.051	0.012	15.0	18

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	0.300	0.330	10.000%	-
23/1	Sample S001	0.035	0.030	-14.286%	-
22/5	Sample S002	0.726	0.660	-9.035%	-1.16
22/5	Sample S001	0.238	0.220	-7.477%	-1.20
22/4	Sample S002	0.264	0.280	5.882%	0.50
22/4	Sample S001	0.026	0.030	14.286%	0.41
22/3	Sample S002	0.190	0.190	0.000%	-
22/3	Sample S001	0.035	0.040	14.286%	-

Report info

Participants

278 participants from 11 countries.

Report info

Your own result should be compared to others using the same method.
Assigned values (x_{pt}, target values) 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 large an automatic text is printed on the report: “The uncertainty of the assigned value is not negligible, and evaluations could be affected.”
In case the client’s result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client’s own method group, the result can be compared to all method mean or to a group that is similar to the own method.
Results reported with < or > -signs cannot be included in the statistics.

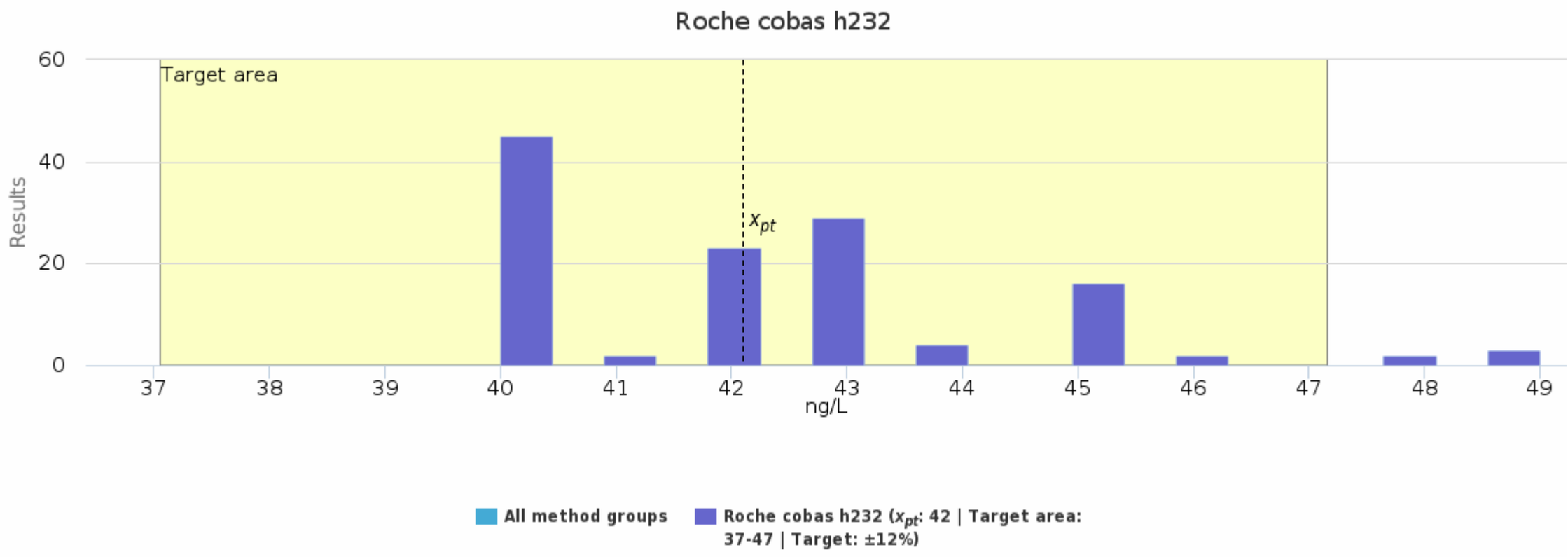
For information on report interpretation and performance evaluation, please see the " EQAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

Sample S001 | Troponin T Qualitative (pos/neg), --

Methodics	Negative	Total
Roche Troponin T sensitive	1	1
Total	**1**	**1**

Sample S001 | Troponin T Quantitative, ng/L

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Roche cobas h232	42	42	2	4.7	<1	40	48	3	126
All	**42**	**42**	**2**	**4.7**	**<1**	**40**	**48**	**3**	**126**

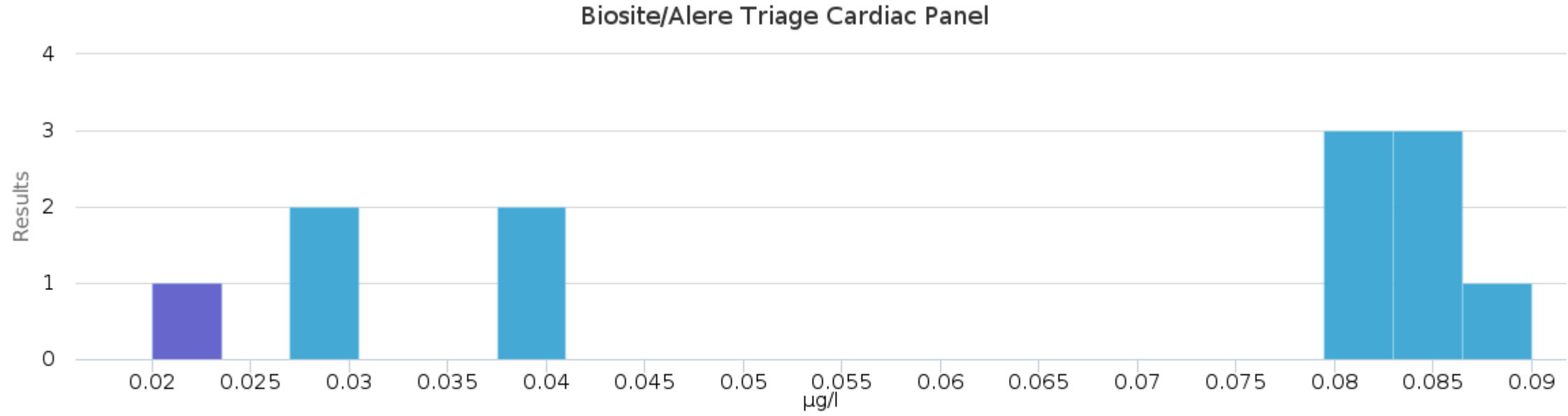


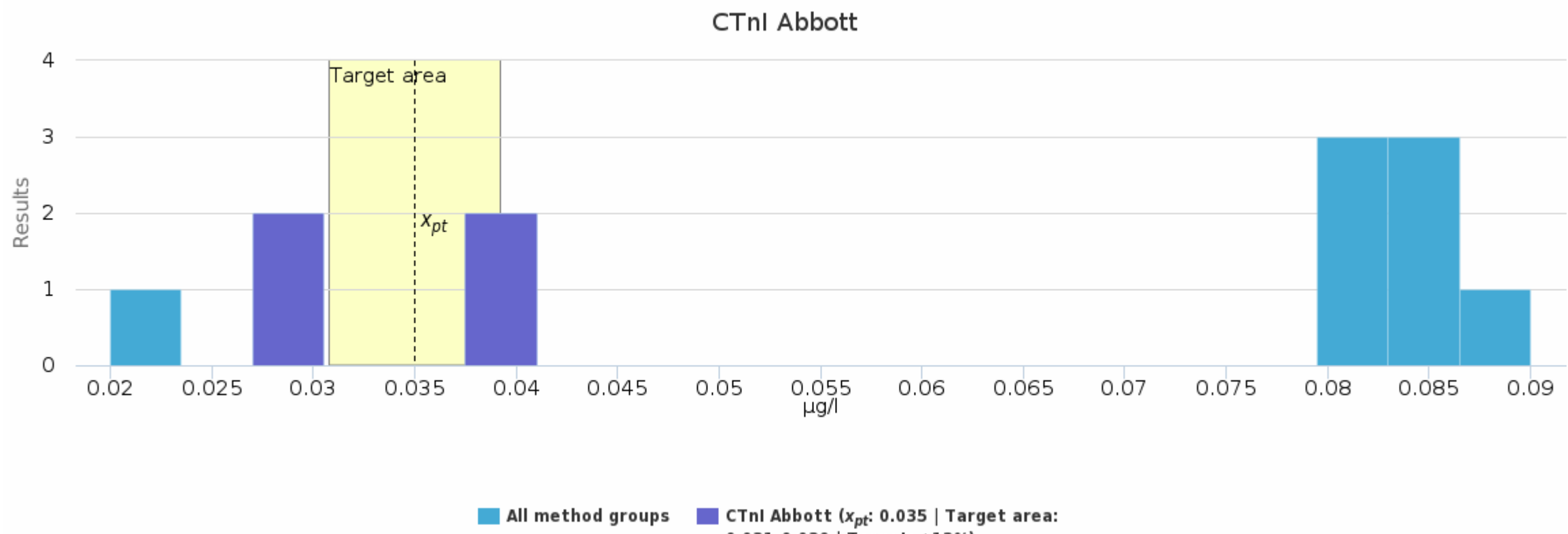
Sample S001 | Troponin I Qualitative (pos/neg), --

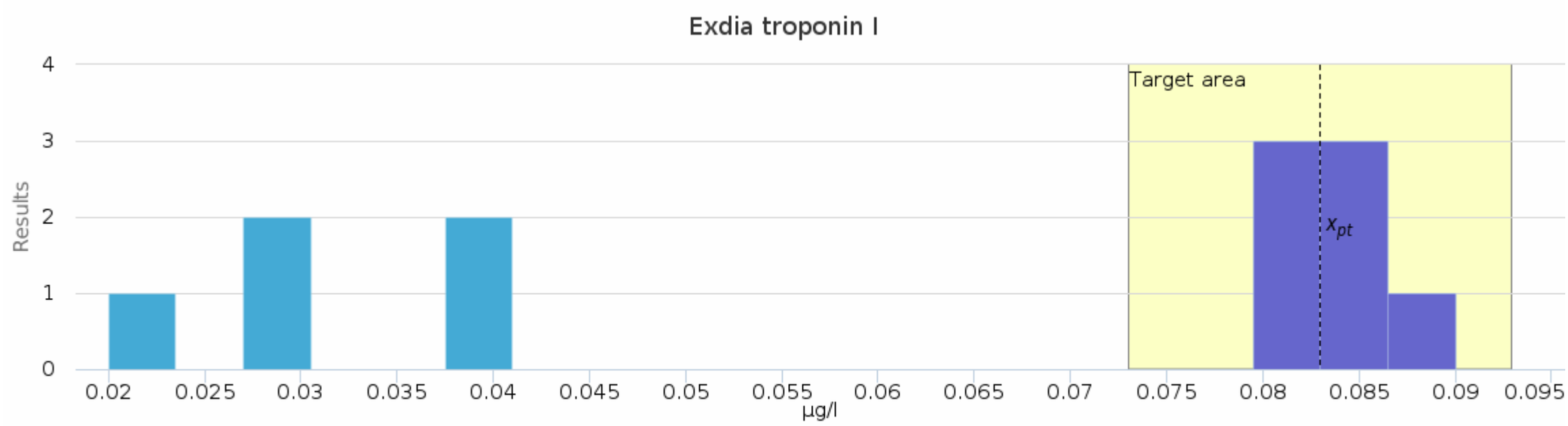
Methodics	Negative	Total
ALL DIAG reagents	1	1
Nal von Minden TnI	1	1
Total	**2**	**2**

Sample S001 | Troponin I Quantitative, µg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Biosite/Alere Triage Cardiac Panel	-	-	-	-	-	0.020	0.020	-	1
CTnI Abbott	0.035	0.035	0.006	16.5	0.003	0.030	0.040	-	4
Exdia troponin I	0.083	0.083	0.004	4.4	0.001	0.080	0.090	-	7
All	**0.062**	**0.080**	**0.027**	**43.5**	**0.008**	**0.020**	**0.090**	**-**	**12**

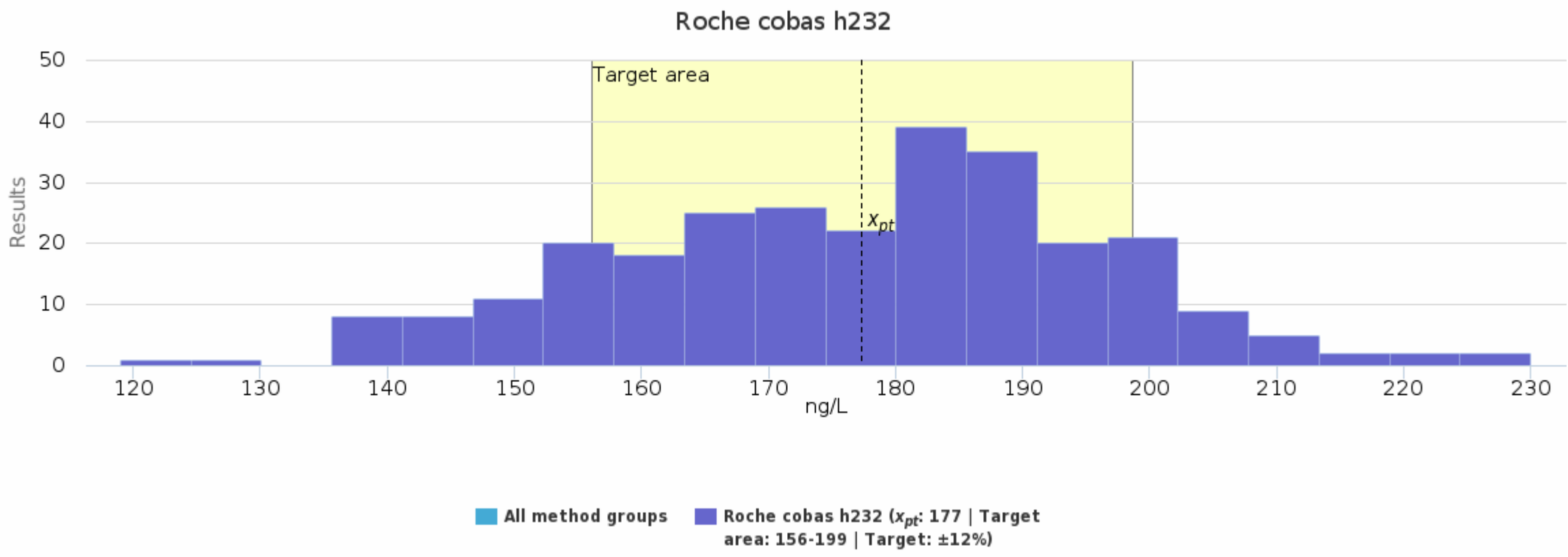






Sample S002 | Troponin T Quantitative, ng/L

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Roche cobas h232	177	180	19	10.6	1	128	230	1	275
All	**177**	**180**	**19**	**10.6**	**1**	**128**	**230**	**1**	**275**

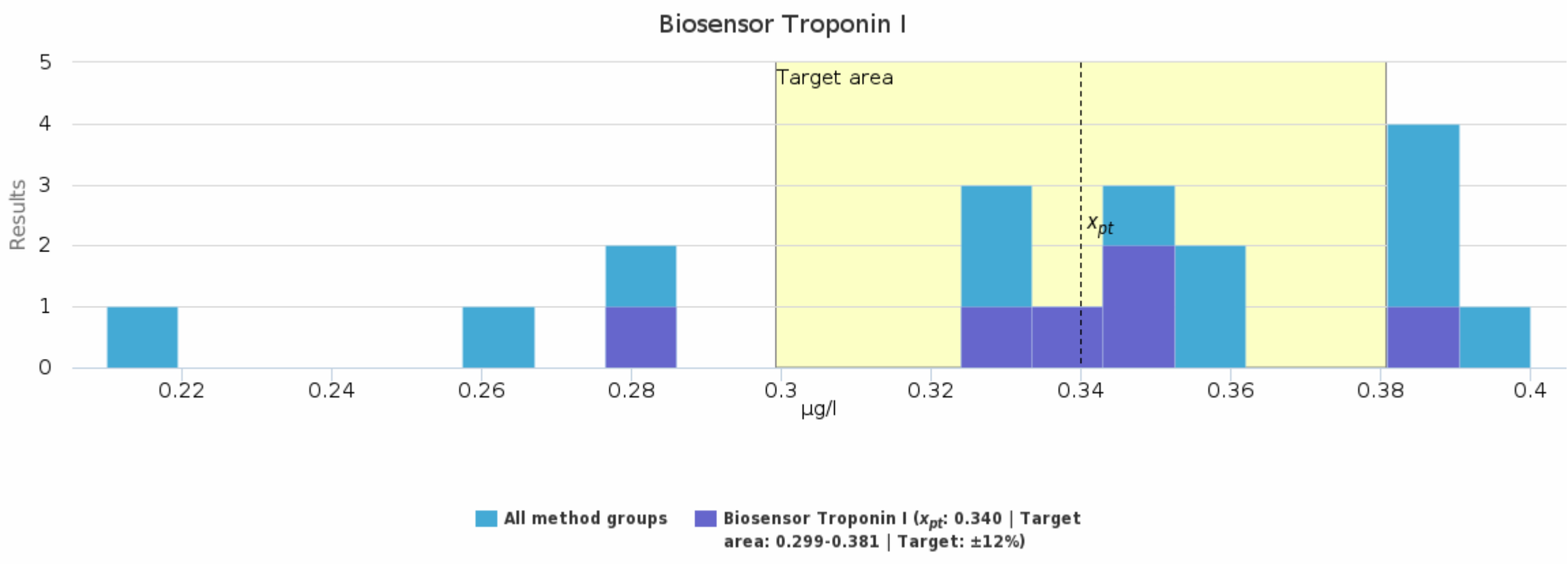


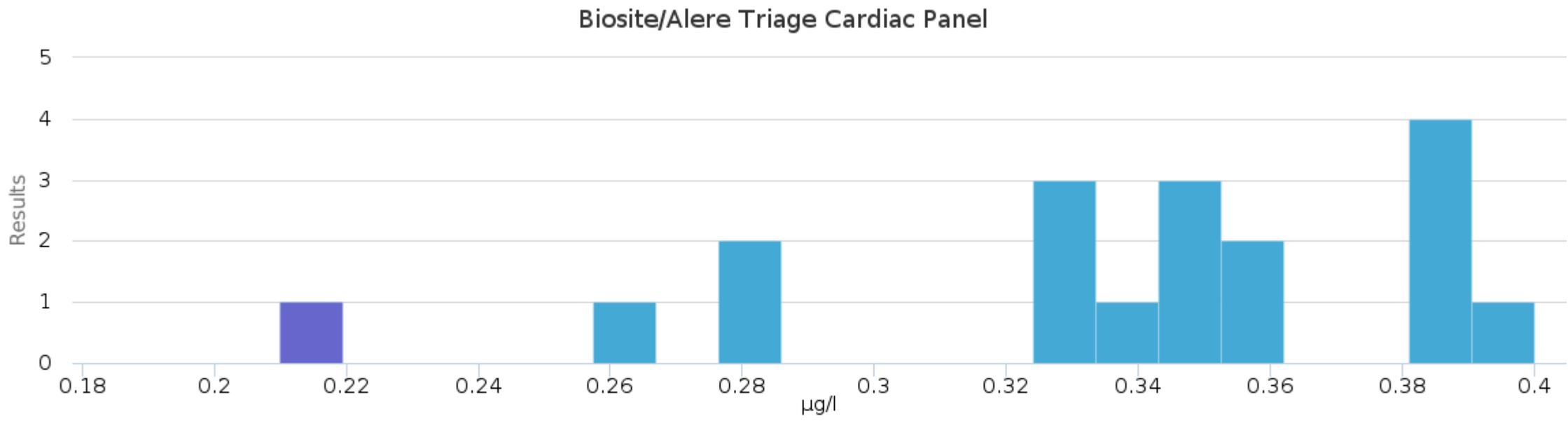
Sample S002 | Troponin I Qualitative (pos/neg), --

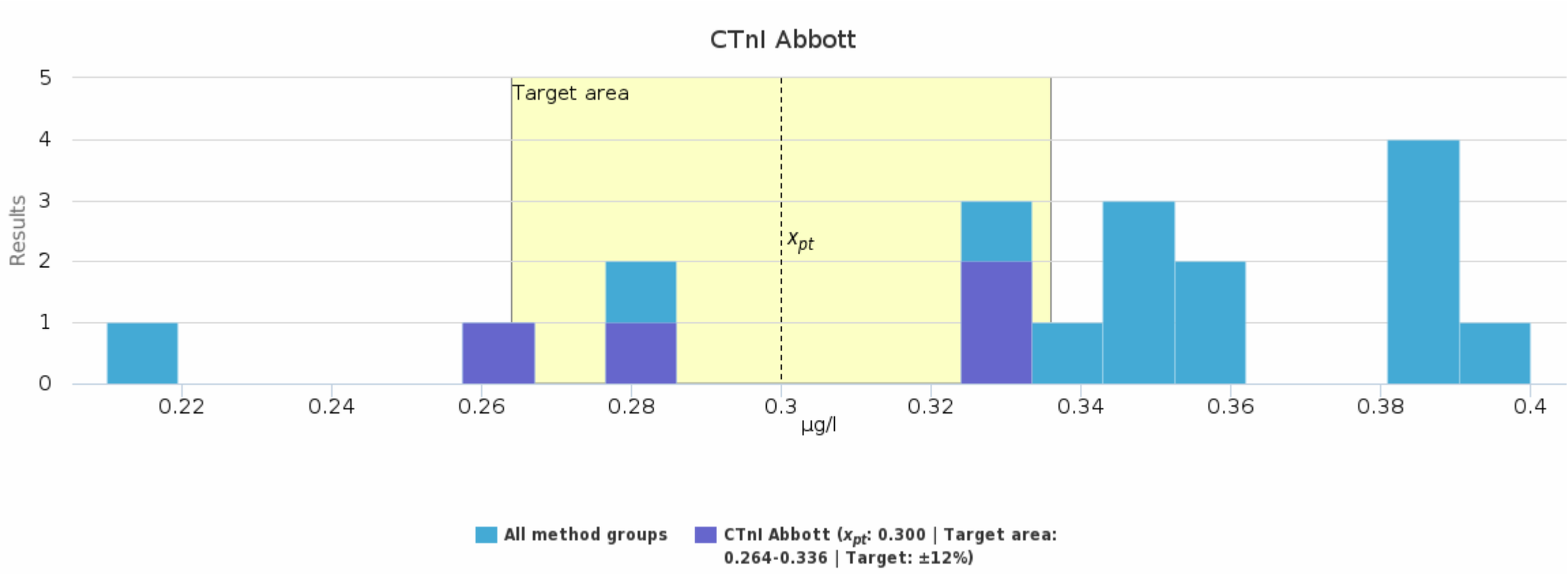
Methodics	Negative	Weak positive	Total
ALL DIAG reagents	-	1	1
Nal von Minden TnI	1	-	1
Total	**1**	**1**	**2**

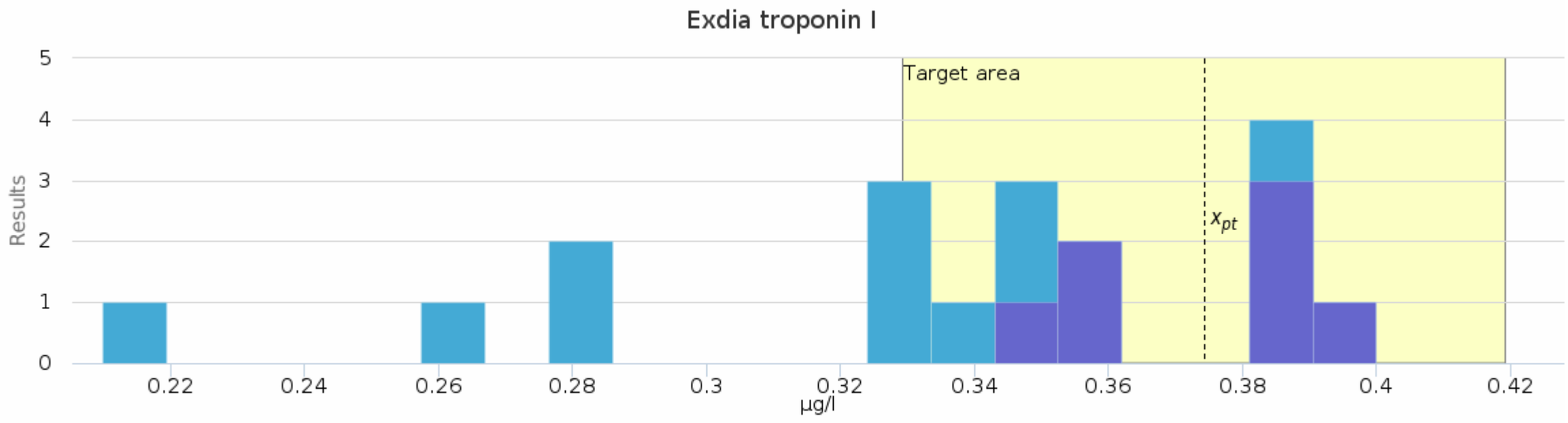
Sample S002 | Troponin I Quantitative, µg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Biosensor Troponin I	0.340	0.345	0.036	10.5	0.015	0.280	0.390	-	6
Biosite/Alere Triage Cardiac Panel	-	-	-	-	-	0.210	0.210	-	1
CTnI Abbott	0.300	0.305	0.036	11.9	0.018	0.260	0.330	-	4
Exdia troponin I	0.374	0.382	0.018	4.8	0.007	0.350	0.400	-	7
All	**0.337**	**0.350**	**0.051**	**15.0**	**0.012**	**0.210**	**0.400**	**-**	**18**









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External Quality Assessment Scheme

Troponin I and troponin T, detection, POCT Round 1, 2023

Specimens
Sample S001 (LQ738323011) and sample S002 (LQ738323012) were 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
One negative troponin T qualitative result was reported from sample S001 using Roche Troponin T sensitive test and it can be considered correct based on it's cut off value 100 ng/L and the mean of quantitative results. The mean of the quantitative results obtained with the Cobas h 232 device was 42 ng/L, N=126. In addition, 144 results <40 ng/L and three results <50 ng/L were reported. All troponin T results obtained are consistent with each other. For sample S002, only quantitative results were reported with the Cobas h232 device, and the mean of the results was 177 ng/l, N=275.

Sample S001 had one negative result for troponin I with the qualitative tests of Nal von Minden and ALL DIAG. Sample S002 had one negative result with the Nal von Minden qualitative test and one weak positive result with the ALL DIAG qualitative test. Customers should compare their results with the sensitivity limit of the method and the average of the quantitative results obtained for troponin I. In quantitative results, troponin I levels varied between different method groups. Six results <0.05 µg/L were reported for sample S001 using the Biosensor Troponin I method. The results are consistent with each other. The Biosensor results of sample S001 are not in the numerical summary.

Overall, the round went very well.

End of report

2023-03-15

FINAL REPORT

Product no. 2530

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
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