LABQUALITY

External Quality Assessment Scheme

Procalcitonin
Round 1, 2023

Specimens
Please find enclosed 2 lyophilized human serum samples S001 and S002.

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
Procalcitonin

Storage and use
After arrival store the specimens at +2 … 8 °C. Before analyzing add 0.5 mL distilled or deionized water and allow to stand for 5 min at room temperature. Please check that content is completely dissolved and homogenous by swirling gently at least 30 seconds. Avoid foam formation. Analyze immediately after reconstitution in the same way as patient specimens.

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.

We ask clients using Siemens Advia Centaur analyzers to inform the used lot number of the PCT reagents in the comment box of the LabScala result form.

S001

S002

2023-04-03

INSTRUCTIONS

Product no. 2280
LQ728023011-12/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 **April 27, 2023**.

Inquiries
EQA Coordinator
Liisa Ylitepsa
liisa.ylitepsa@labquality.fi

Labquality Oy
Kumpulantie 15
FI-00520 HELSINKI
Finland

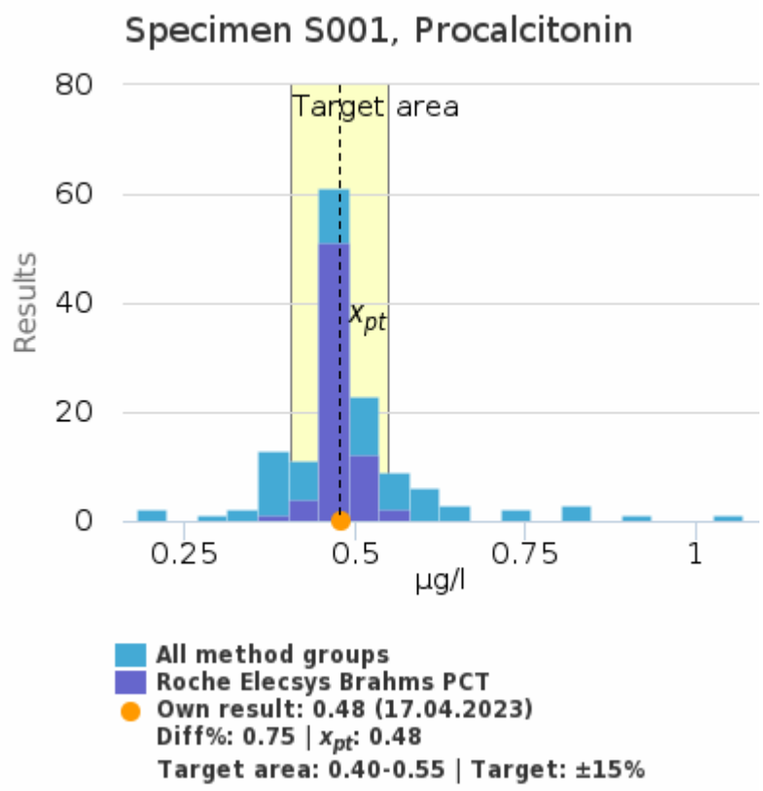
Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

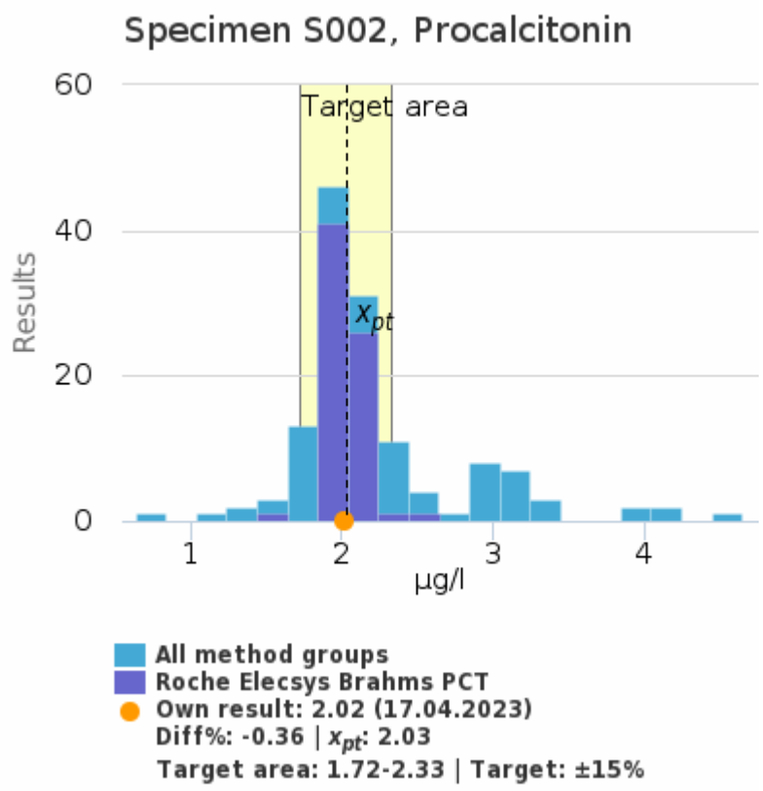
info@labquality.fi
www.labquality.com

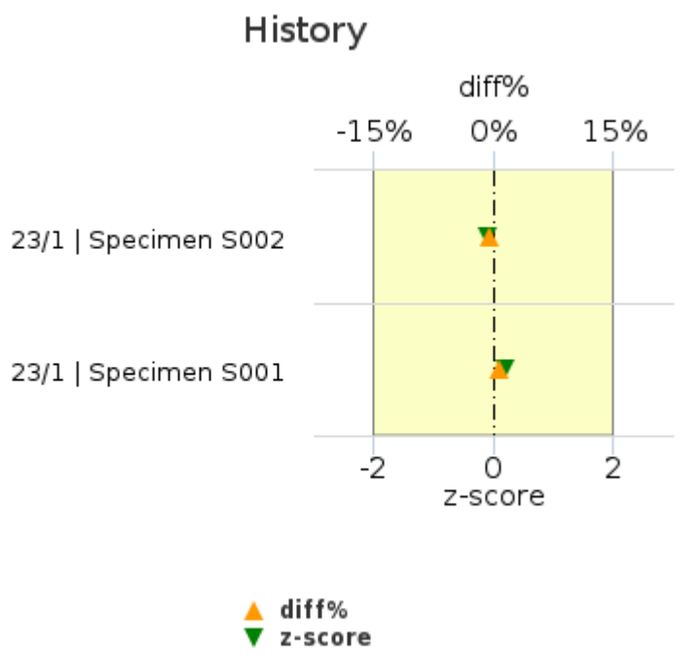
FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015

Procalcitonin |Cobas B







	x_{pt}	sd	SEM	CV%	n
Roche Elecsys Brahms PCT	0.48 µg/l	0.02	<0.01	4.2	70
All methods	0.48 µg/l	0.08	<0.01	16.2	138

	x_{pt}	sd	SEM	CV%	n
Roche Elecsys Brahms PCT	2.03 µg/l	0.08	<0.01	3.9	70
All methods	2.15 µg/l	0.45	0.04	21.1	136

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Specimen S002	2.03	2.02	-0.36%	-0.09
23/1	Specimen S001	0.48	0.48	0.75%	0.18

Report info

Participants

130 participants from 19 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).

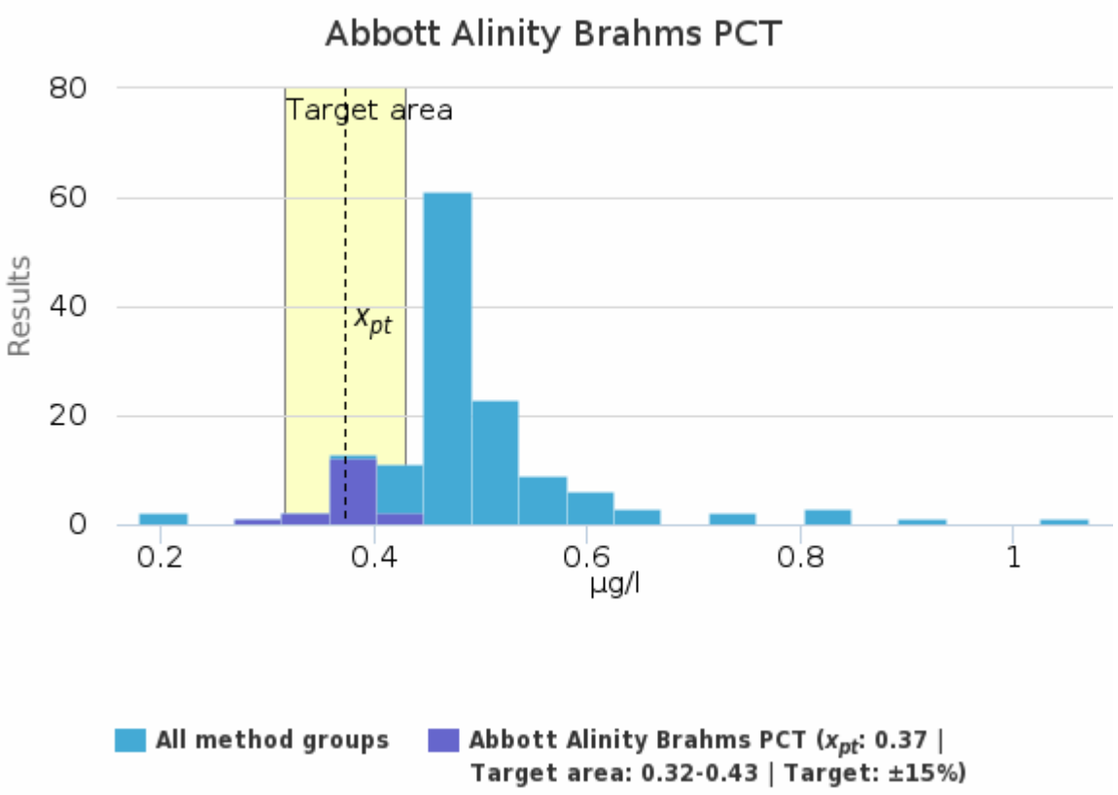
Procalcitonin, April, 1-2023

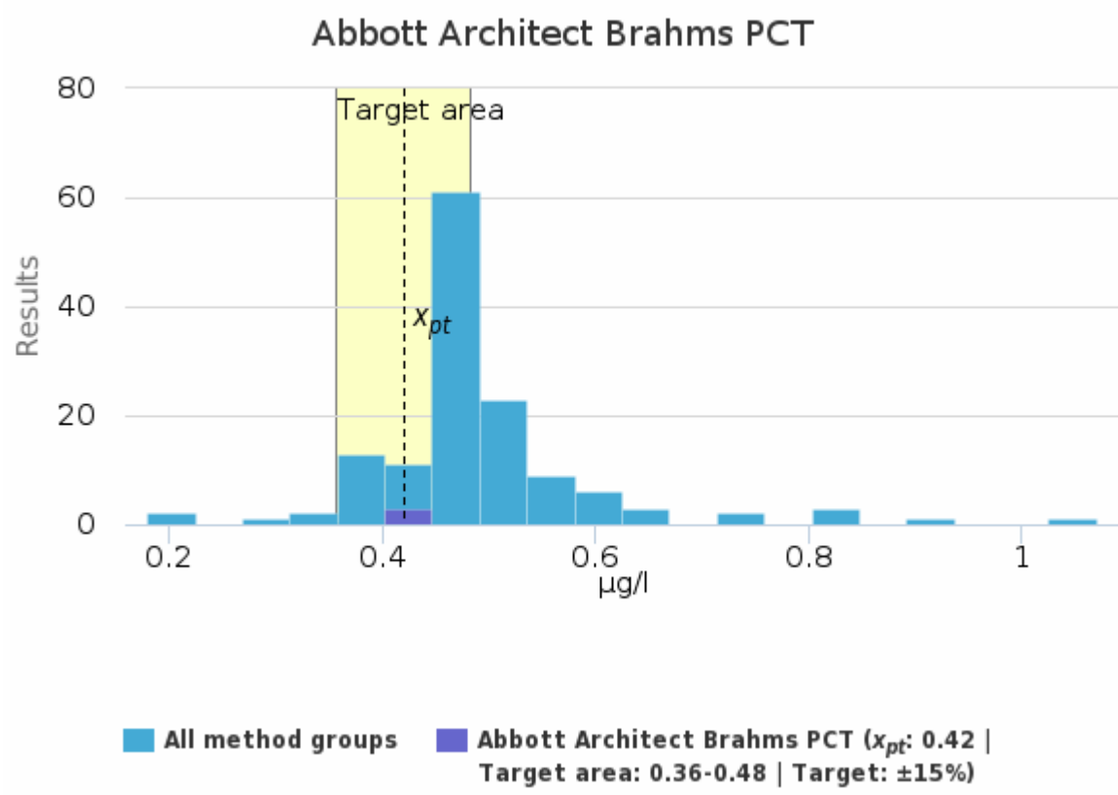
Quantitative report

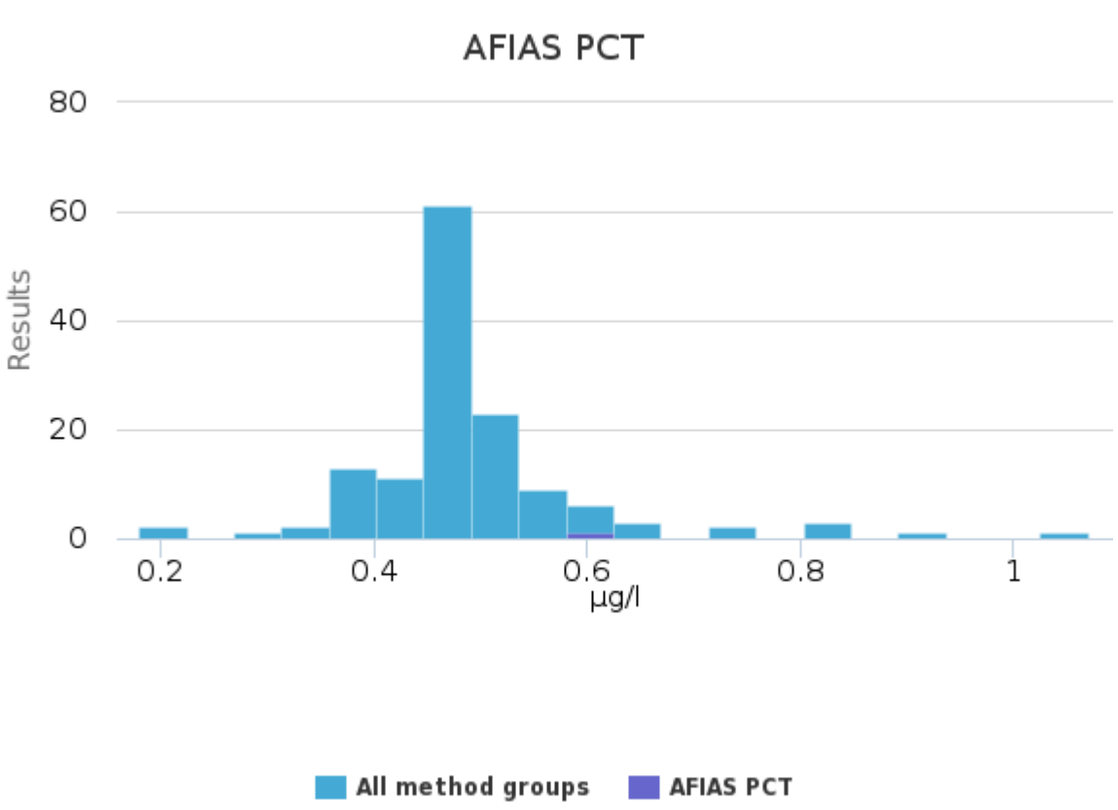
Specimen S001 | Procalcitonin, µg/l

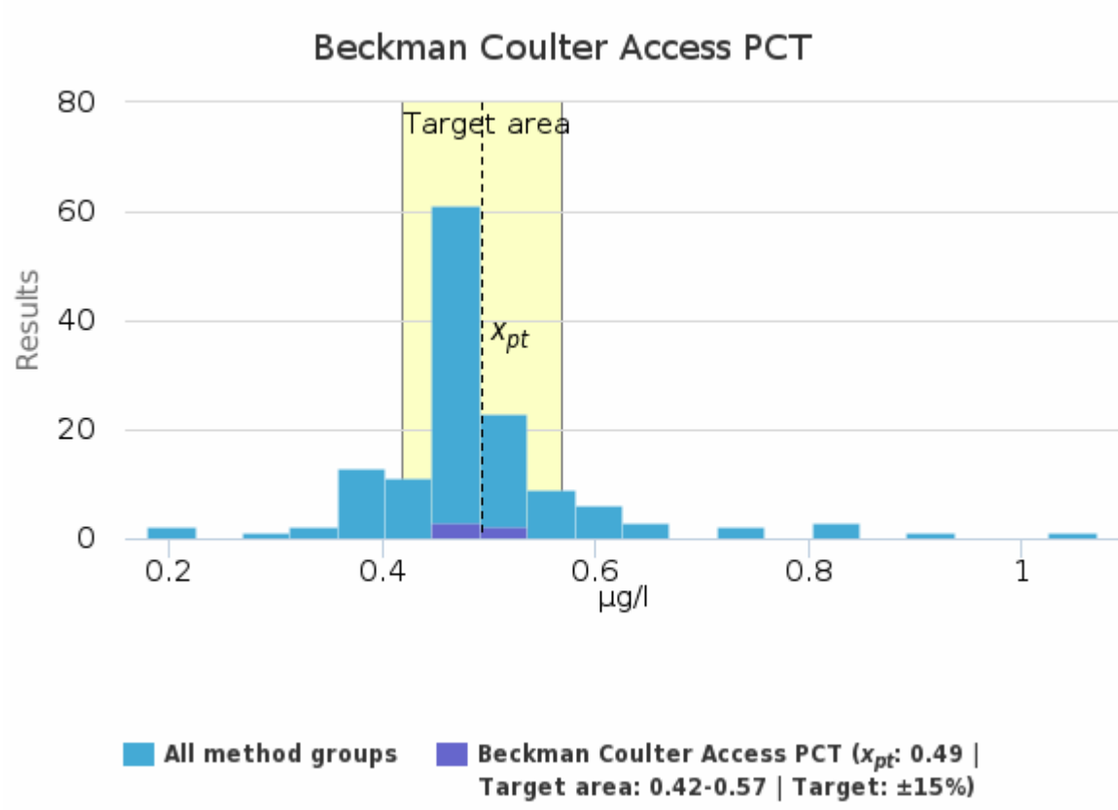
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott Alinity Brahms PCT	0.37	0.37	0.03	7.9	<0.01	0.30	0.42	-	17
Abbott Architect Brahms PCT	0.42	0.42	0.01	2.4	<0.01	0.41	0.43	-	3
AFIAS PCT	-	-	-	-	-	0.60	0.60	-	1
Beckman Coulter Access PCT	0.49	0.49	0.01	2.9	<0.01	0.48	0.52	-	5
Biomerieux Vidas Brahms PCT	0.57	0.58	0.04	7.5	0.01	0.51	0.64	-	18
Boditech ichroma PCT Plus	-	-	-	-	-	0.81	0.81	-	1
Boditech ichromax PCT	-	-	-	-	-	0.48	0.48	-	1
Cormay PCT	-	-	-	-	-	0.82	0.82	-	1
Diasorin Liaison Brahms PCT II gen	0.47	0.47	0.03	5.8	0.02	0.45	0.50	-	3
Diazyme Procalcitonin (PCT)	-	-	-	-	-	1.07	1.07	-	1
Getein one-step test for PCT	0.79	0.75	0.09	11.7	0.05	0.73	0.90	-	3
Radiometer AQT90 FLEX PCT	0.49	0.49	0.01	2.5	<0.01	0.48	0.50	-	2
Roche Elecsys Brahms PCT	0.48	0.48	0.02	4.2	<0.01	0.43	0.55	2	70
Siemens Advia Centaur Brahms PCT	-	-	-	-	-	0.51	0.51	-	1
Siemens Atellica Brahms PCT	0.50	0.48	0.06	12.7	0.03	0.44	0.59	-	5
Snibe Maglumi PCT	-	-	-	-	-	0.82	0.82	-	1
Thermo Scientific Brahms direct	-	-	-	-	-	0.52	0.52	-	1
Vitros Brahms PCT	0.48	0.48	<0.01	0.4	<0.01	0.48	0.49	-	2
Wuhan Easydiagnostics PCT	0.19	0.19	0.01	7.4	0.01	0.18	0.20	-	2
All	**0.48**	**0.48**	**0.08**	**16.2**	**<0.01**	**0.18**	**0.75**	**5**	**138**

Specimen S001 | Procalcitonin, µg/l| histogram summaries in LabScala



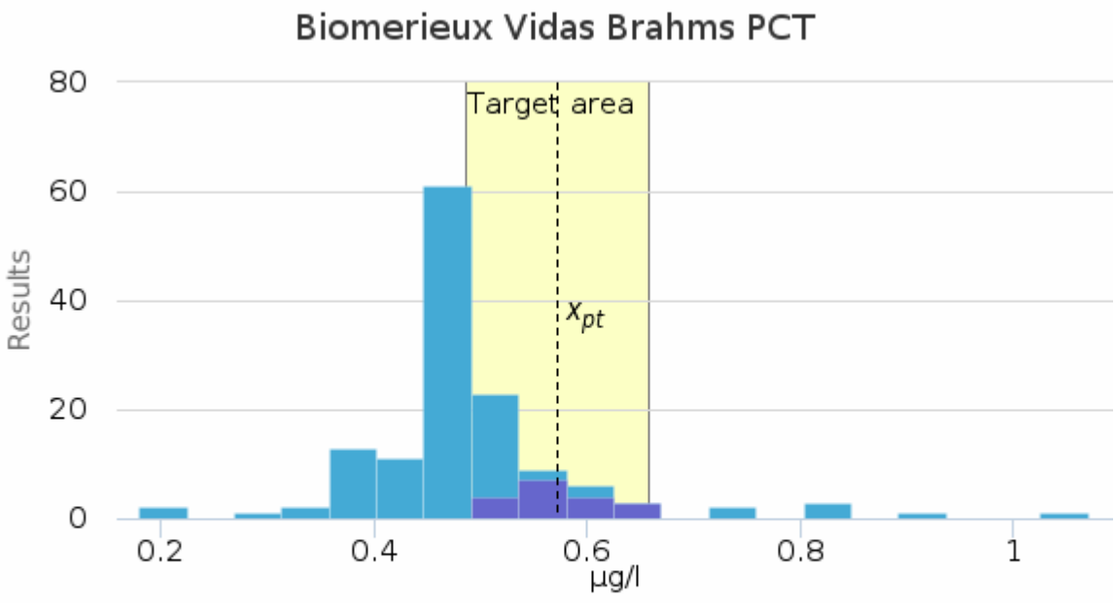


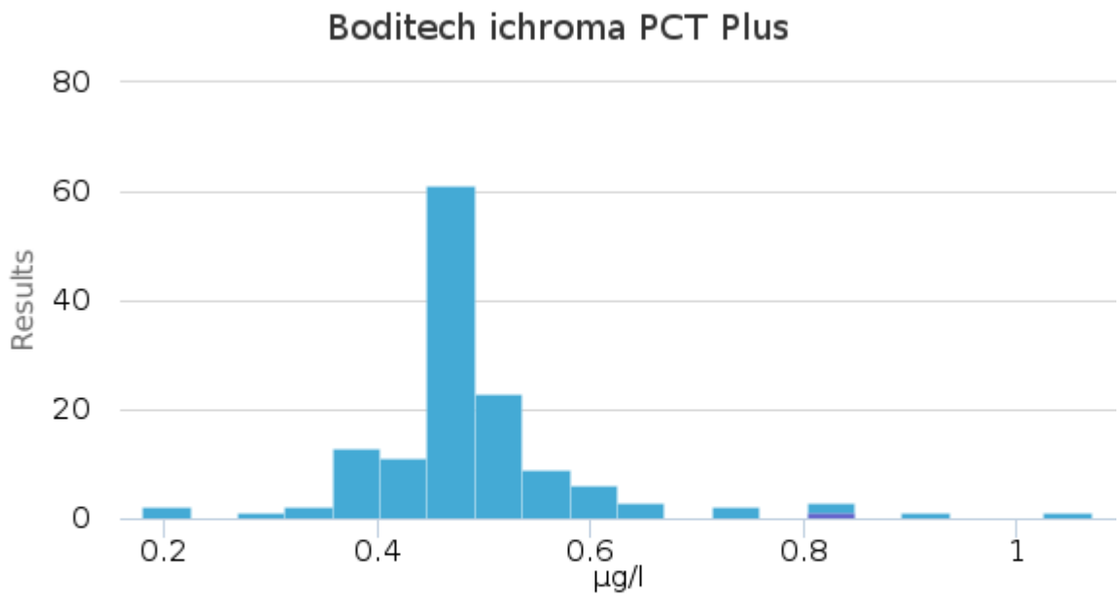


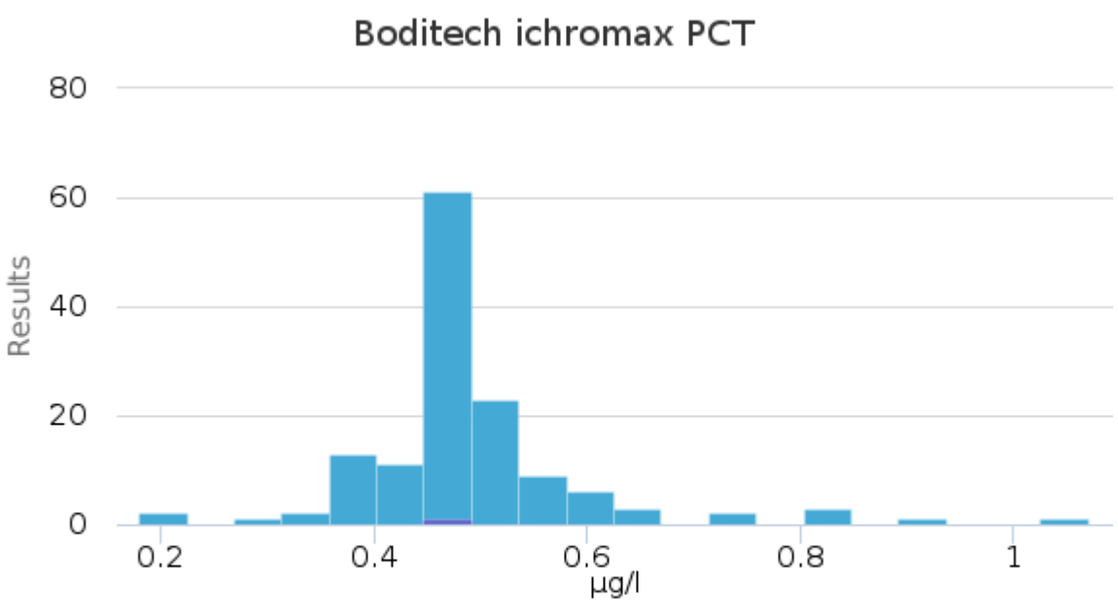


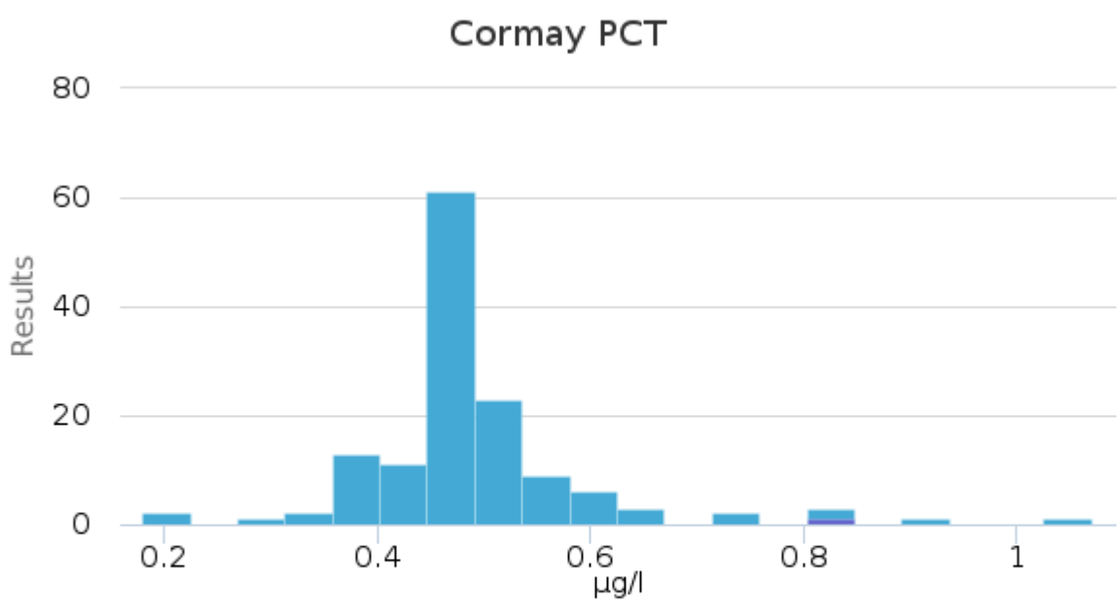
Procalcitonin, April, 1-2023

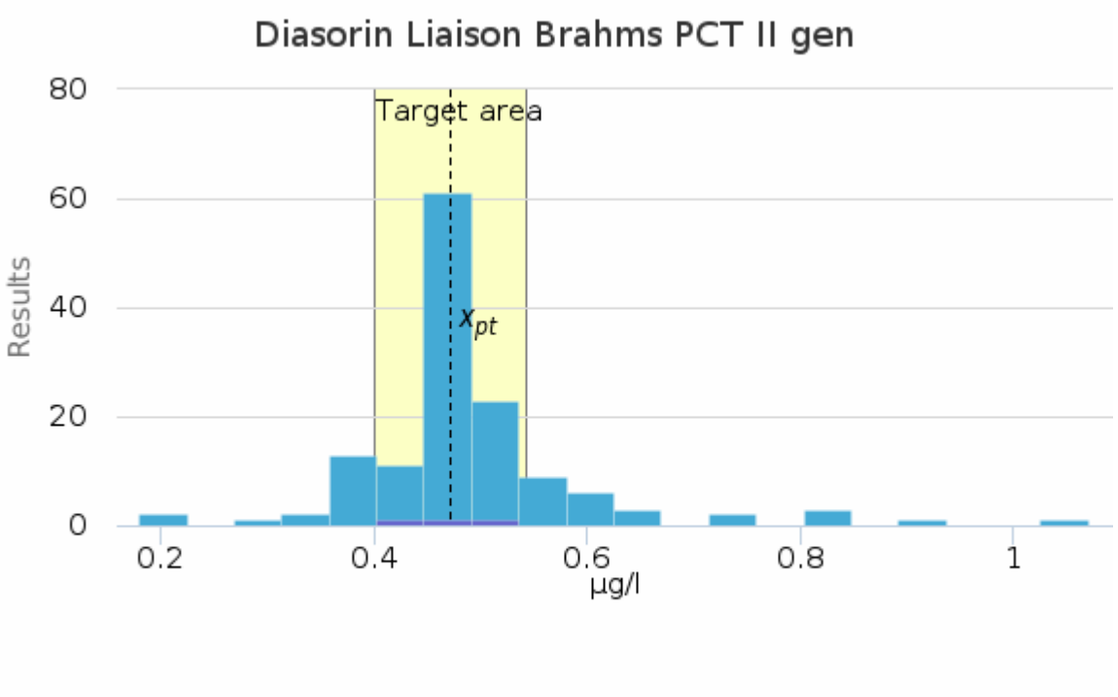
Quantitative report

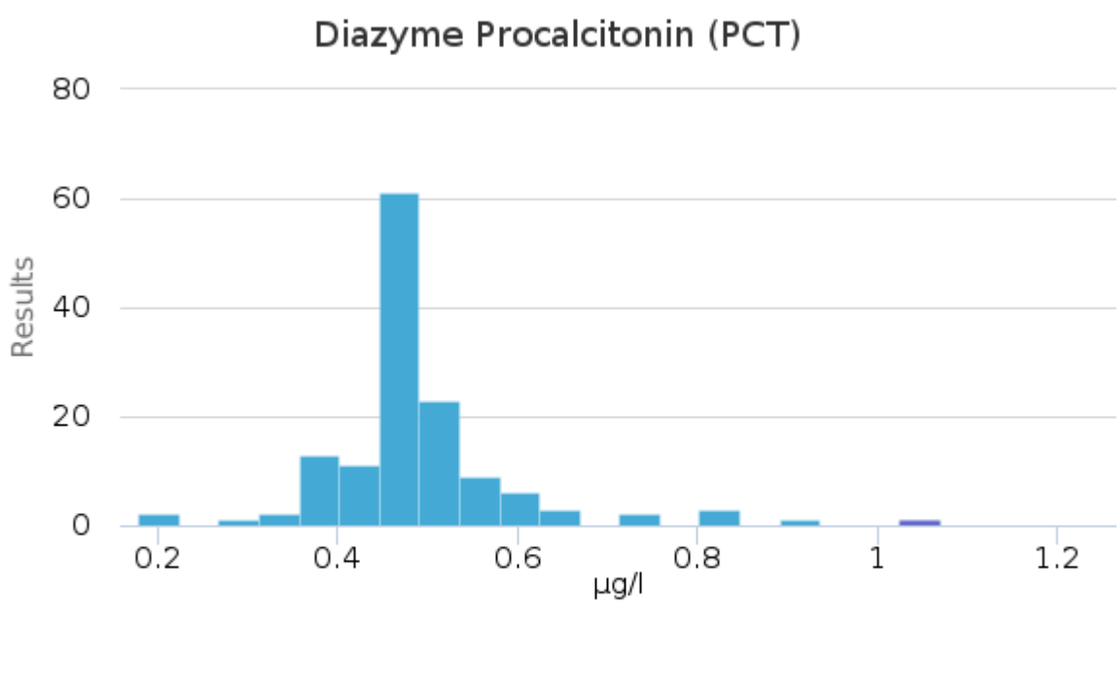








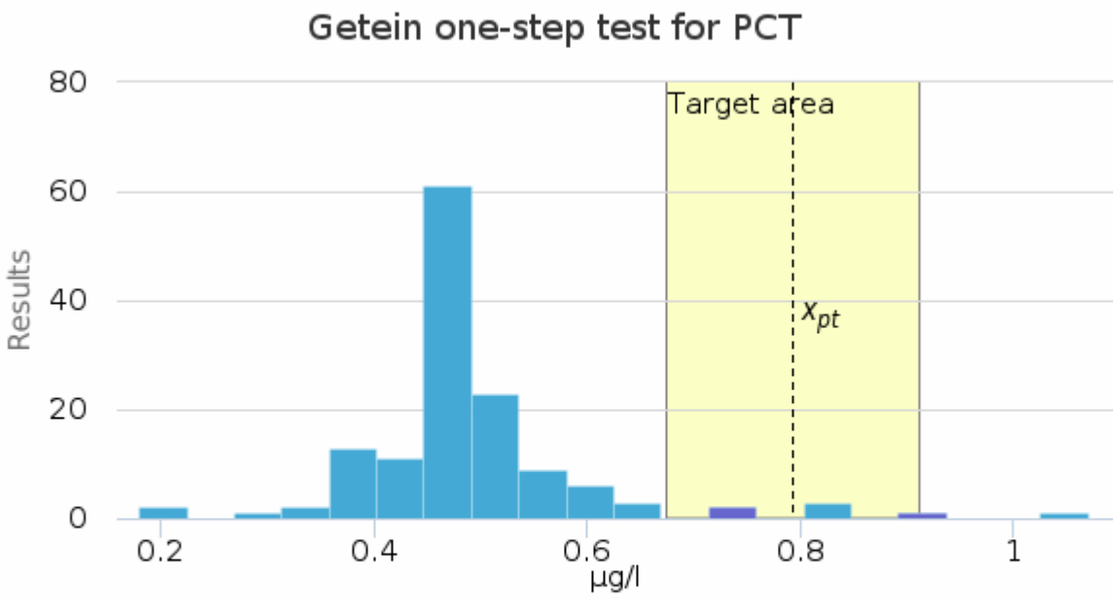


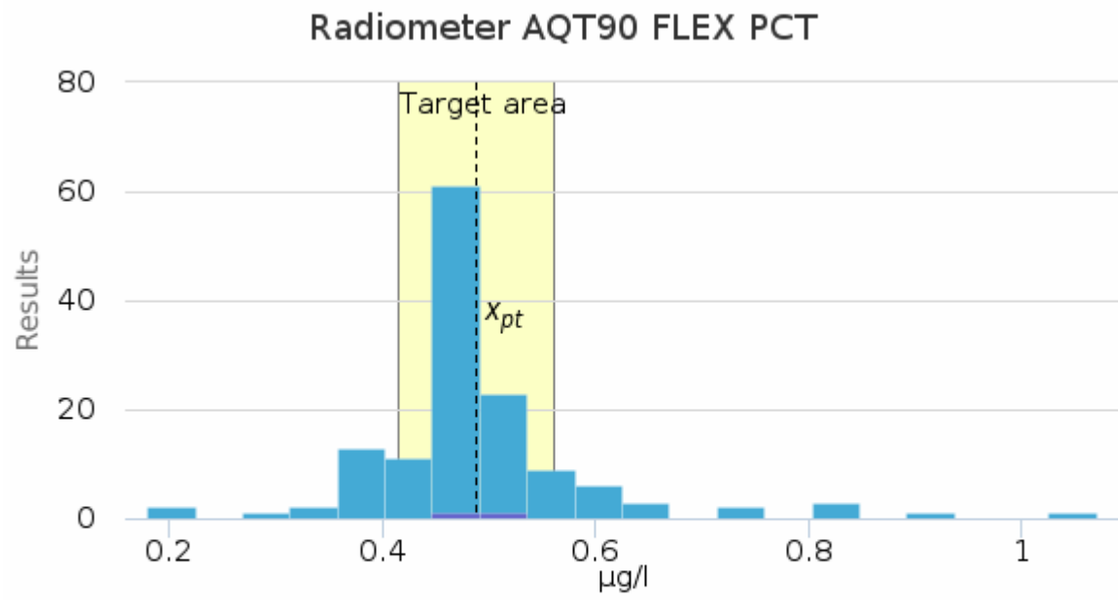


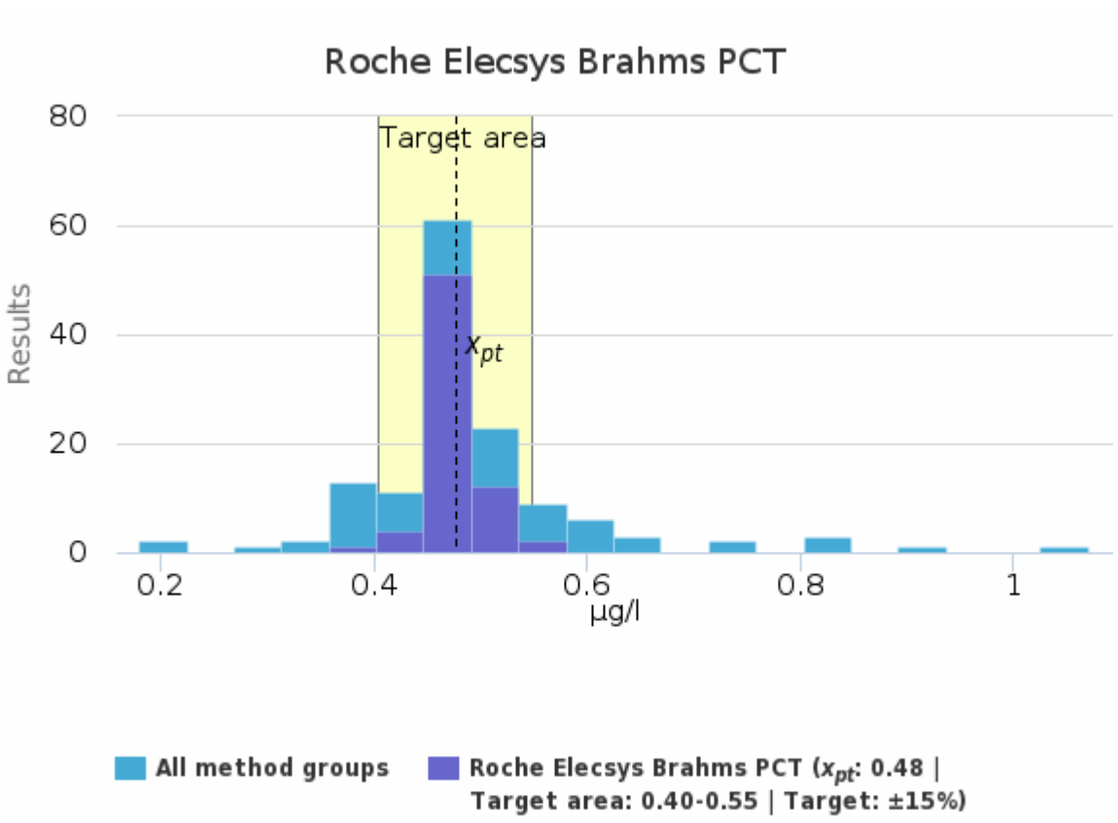
LABQUALITY

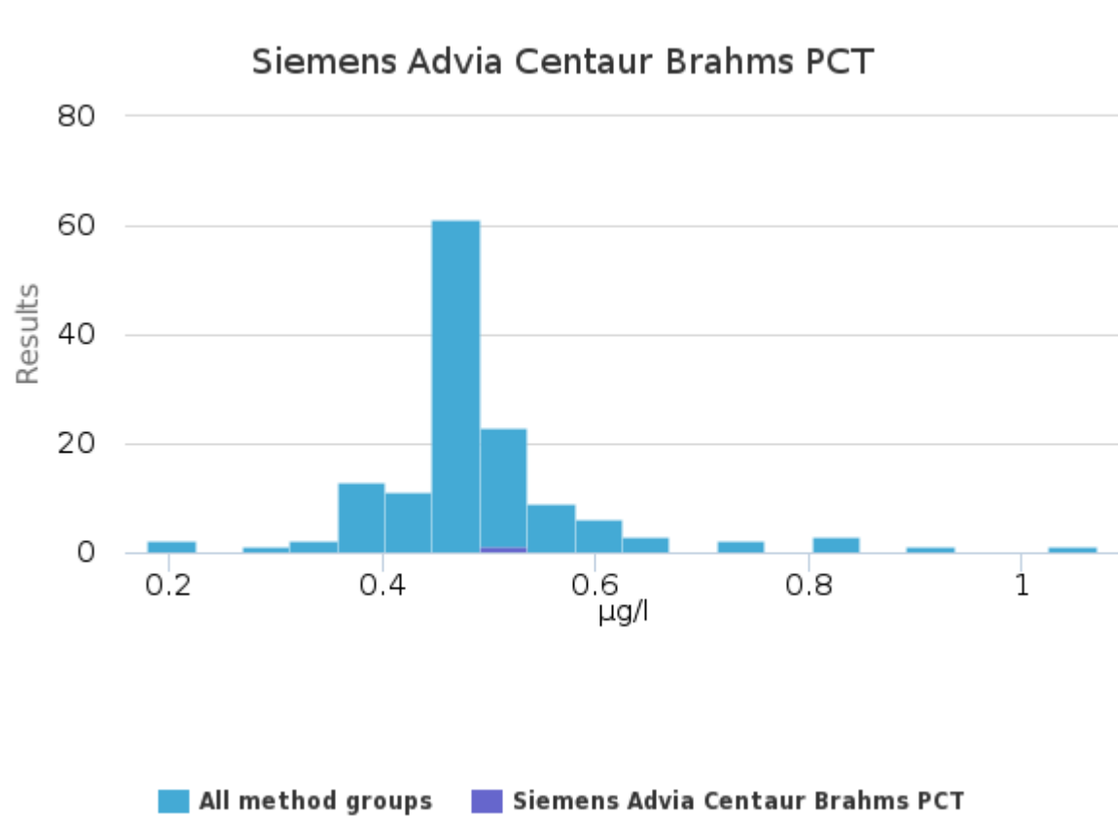
Procalcitonin, April, 1-2023

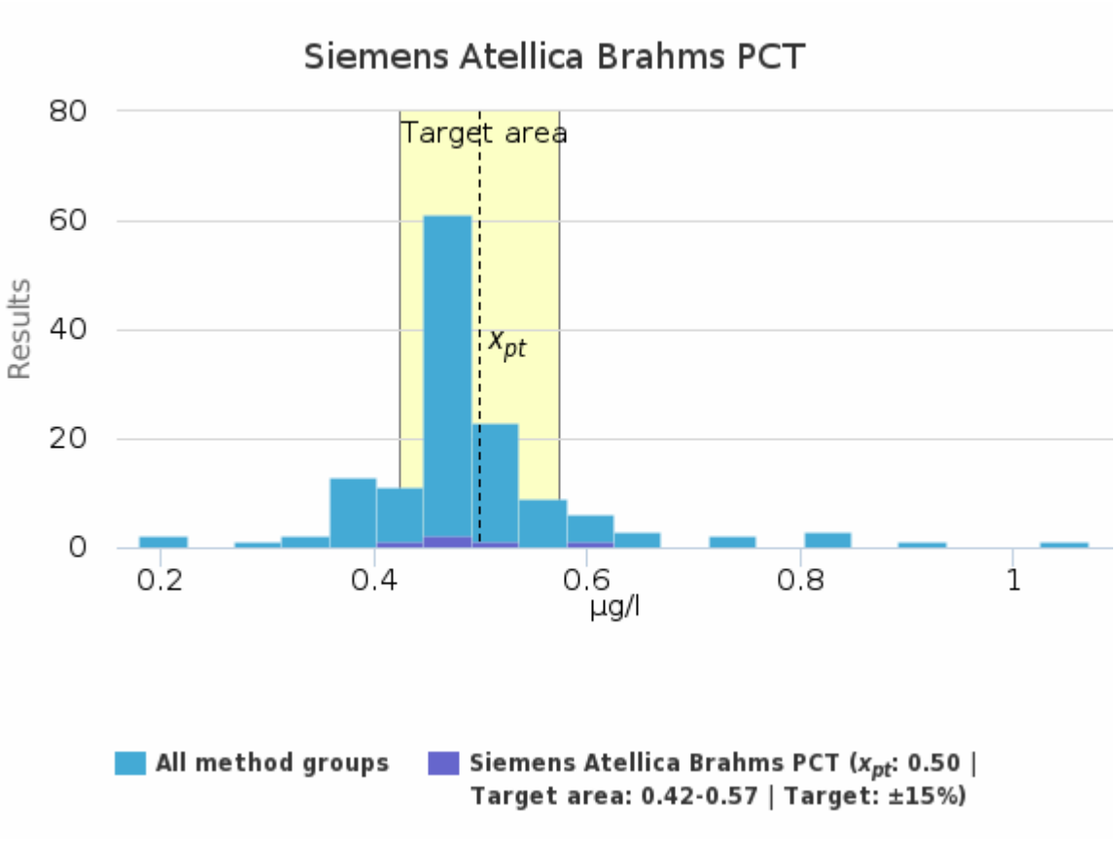
Quantitative report

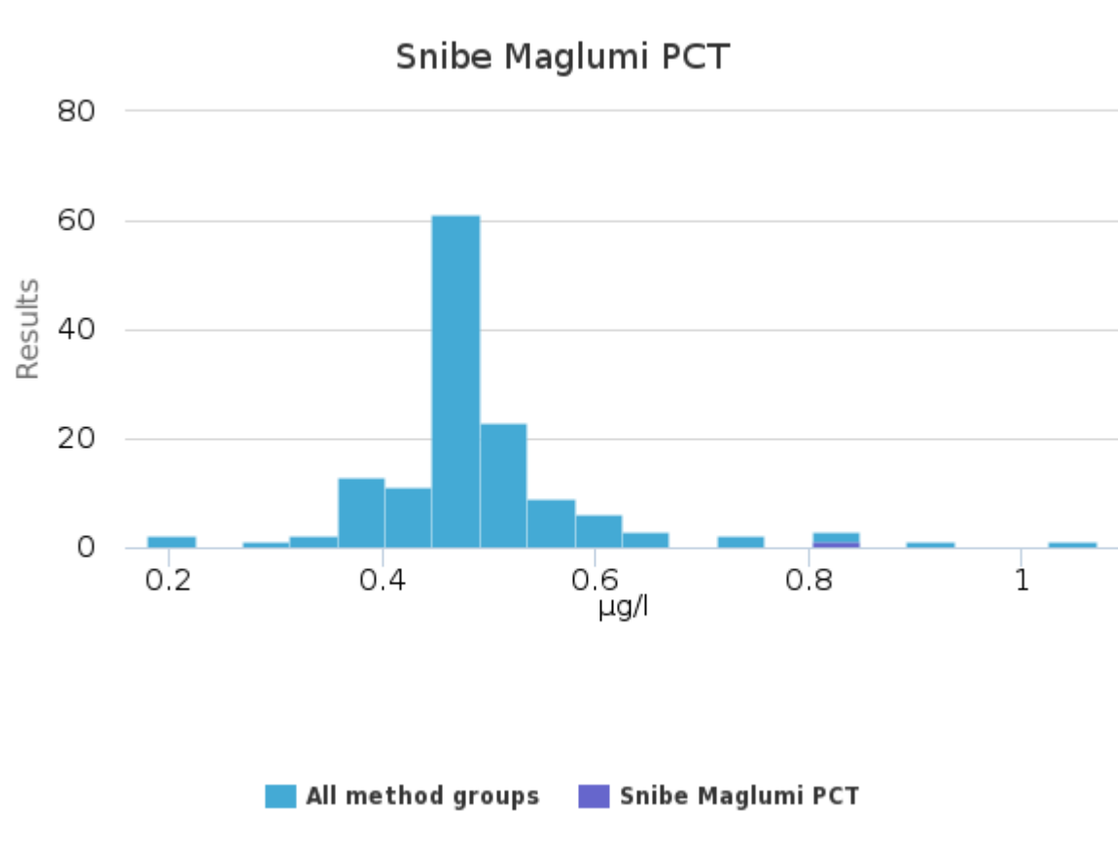






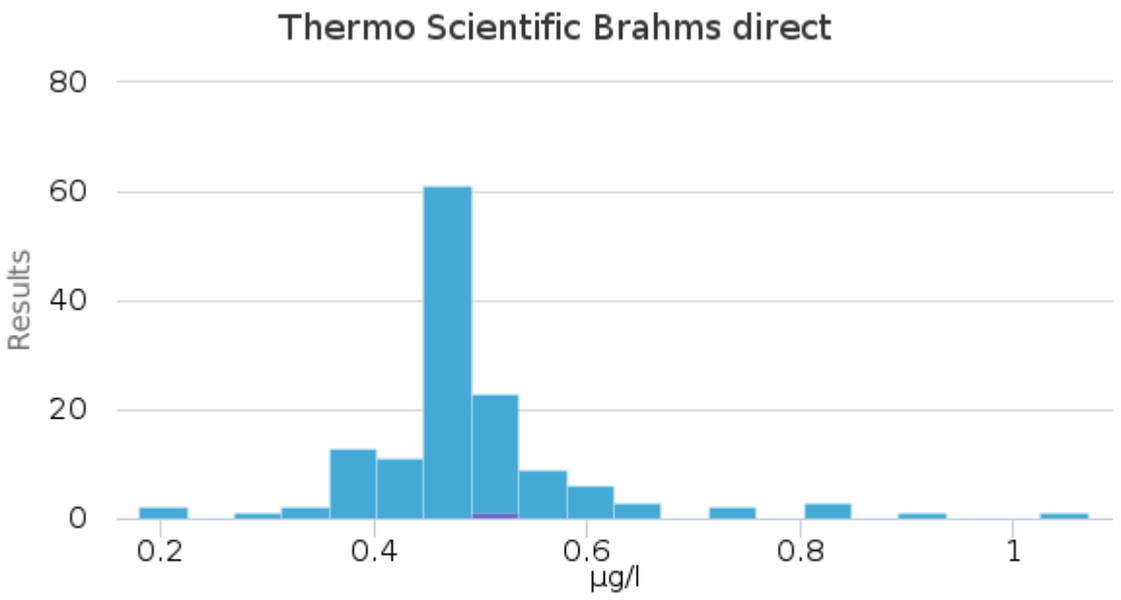


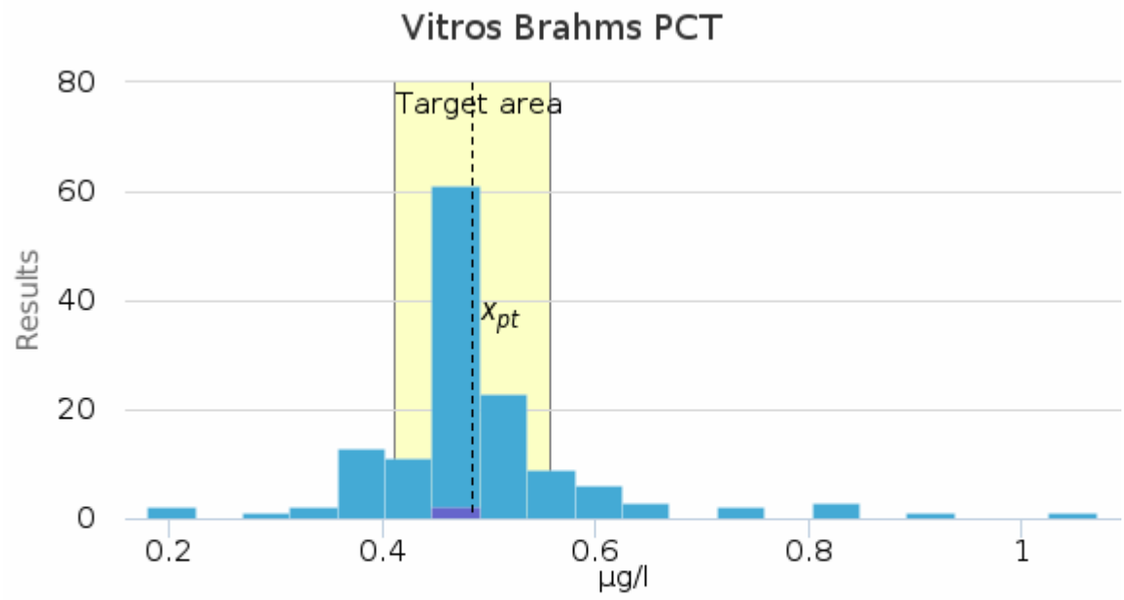


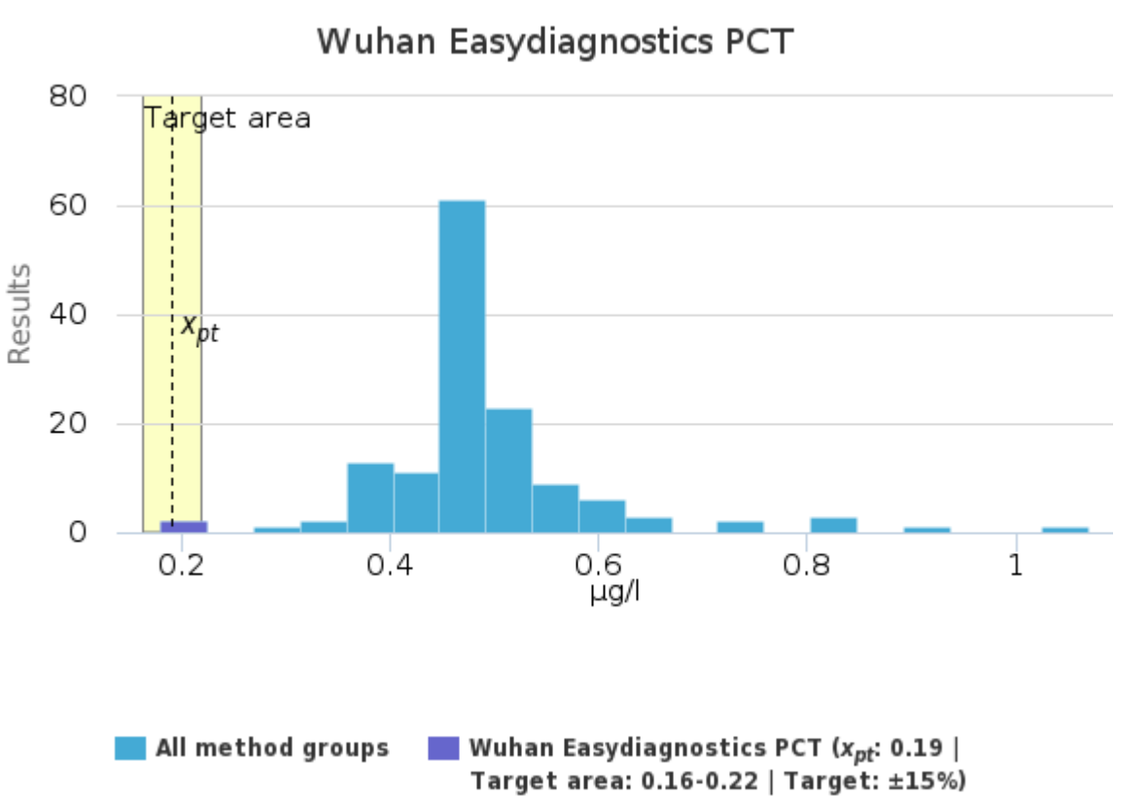


Procalcitonin, April, 1-2023

Quantitative report







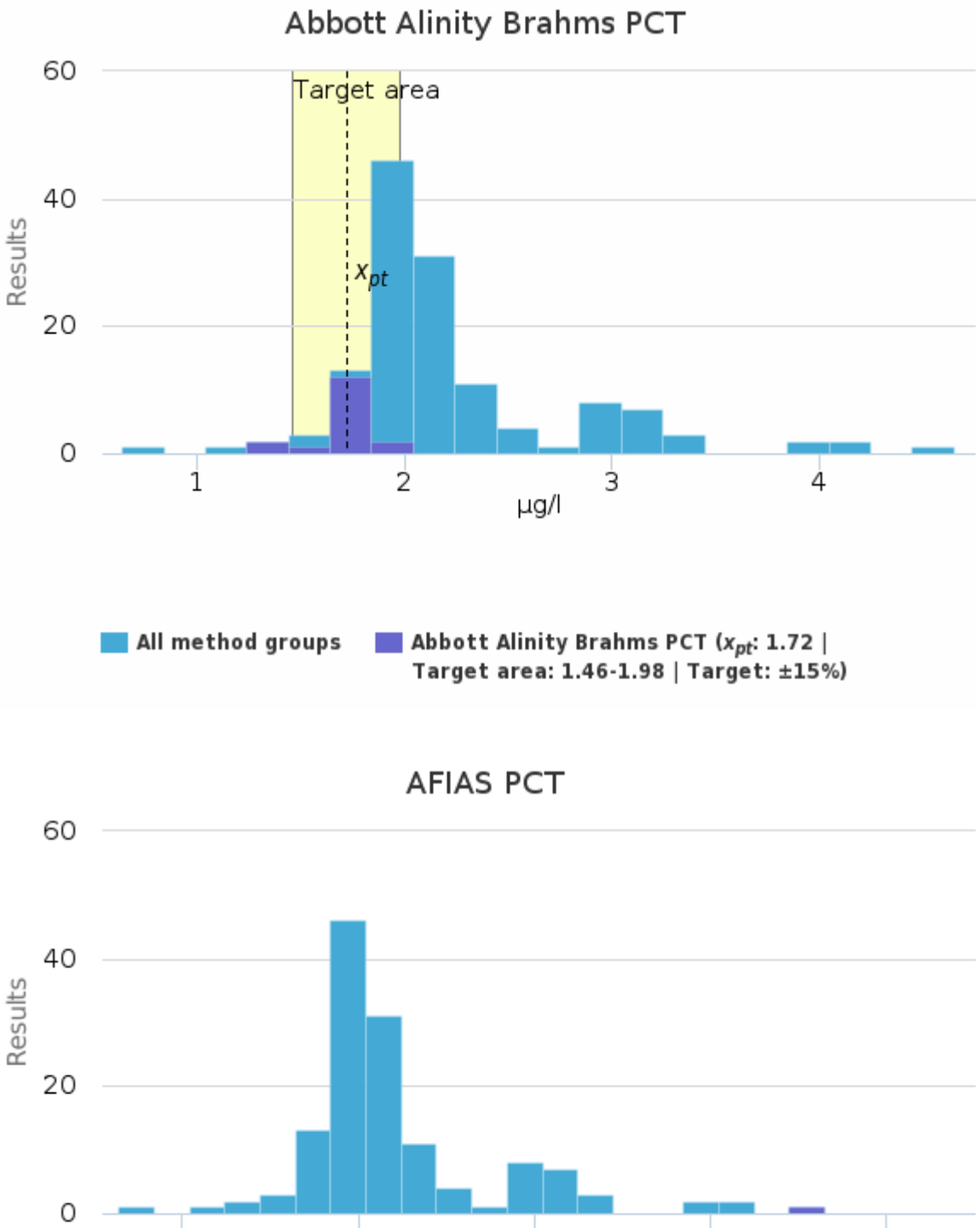
Procalcitonin, April, 1-2023

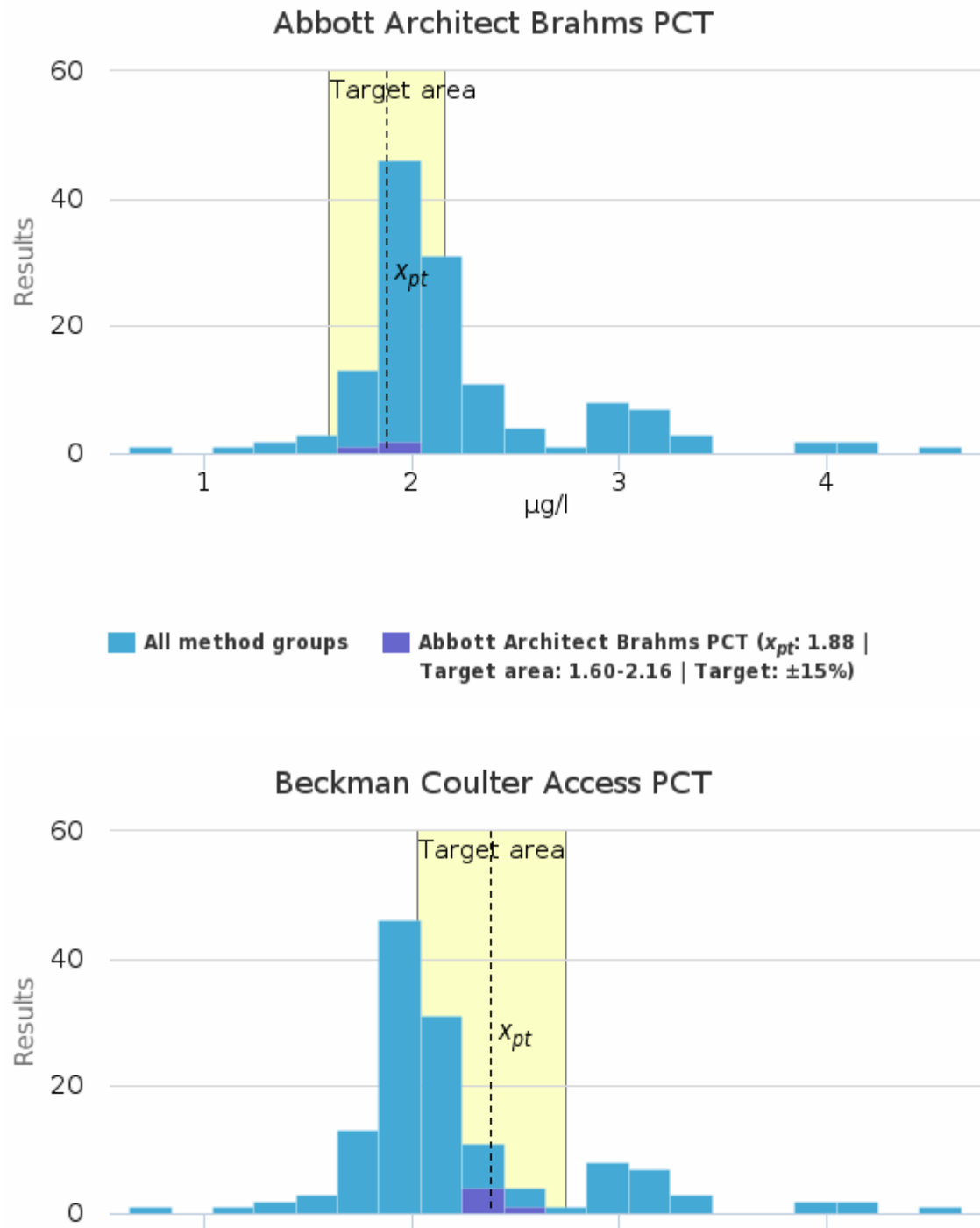
Quantitative report

Specimen S002 | Procalcitonin, µg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Abbott Alinity Brahms PCT	1.72	1.78	0.14	8.3	0.03	1.41	1.93	-	17
Abbott Architect Brahms PCT	1.88	1.87	0.06	3.0	0.03	1.83	1.94	-	3
AFIAS PCT	-	-	-	-	-	4.65	4.65	-	1
Beckman Coulter Access PCT	2.38	2.38	0.08	3.5	0.04	2.30	2.52	-	5
Biomerieux Vidas Brahms PCT	3.08	3.08	0.15	4.7	0.03	2.83	3.31	-	18
Cormay PCT	-	-	-	-	-	4.05	4.05	-	1
Diasorin Liaison Brahms PCT II gen	2.14	2.14	0.25	11.7	0.14	1.89	2.39	-	3
Diazyme Procalcitonin (PCT)	-	-	-	-	-	4.04	4.04	-	1
Getein one-step test for PCT	3.99	3.99	0.18	4.4	0.13	3.86	4.11	-	2
Radiometer AQT90 FLEX PCT	2.33	2.33	0.04	1.5	0.03	2.30	2.35	-	2
Roche Elecsys Brahms PCT	2.03	2.02	0.08	3.9	<0.01	1.89	2.31	2	70
Siemens Advia Centaur Brahms PCT	-	-	-	-	-	2.41	2.41	-	1
Siemens Atellica Brahms PCT	2.25	2.18	0.18	7.8	0.08	2.05	2.50	-	5
Snibe Maglumi PCT	-	-	-	-	-	2.47	2.47	-	1
Thermo Scientific Brahms direct	1.97	1.97	1.30	66.0	0.92	1.05	2.89	-	2
Vitros Brahms PCT	2.23	2.23	0.04	1.9	0.03	2.20	2.26	-	2
Wuhan Easydiagnostics PCT	1.07	1.07	0.61	56.8	0.43	0.64	1.50	-	2
All	**2.15**	**2.03**	**0.45**	**21.1**	**0.04**	**0.64**	**3.31**	**5**	**136**

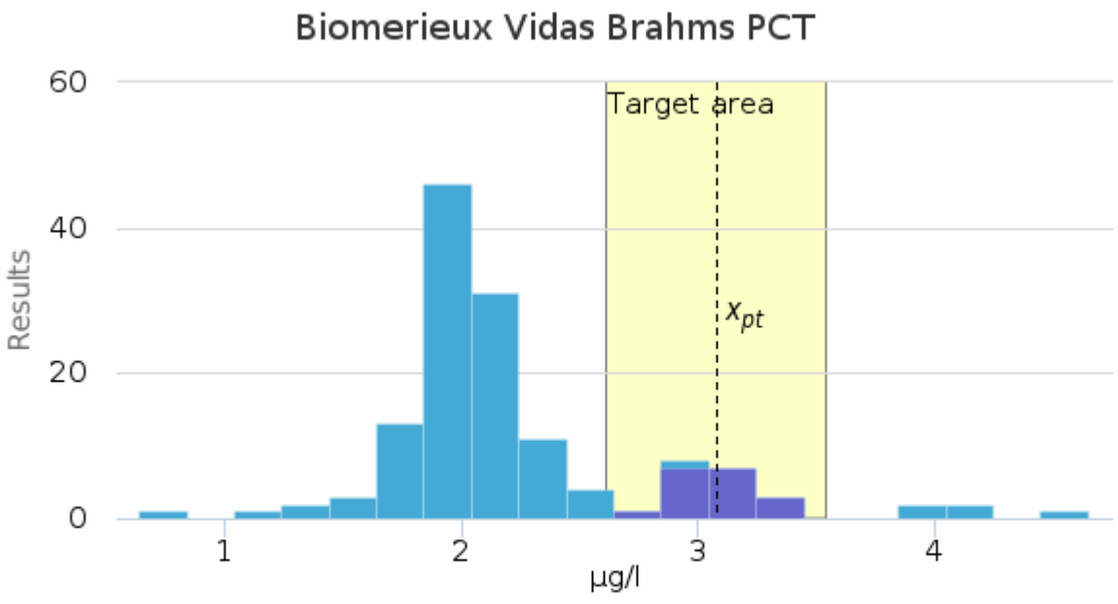
Specimen S002 | Procalcitonin, µg/l| histogram summaries in LabScala

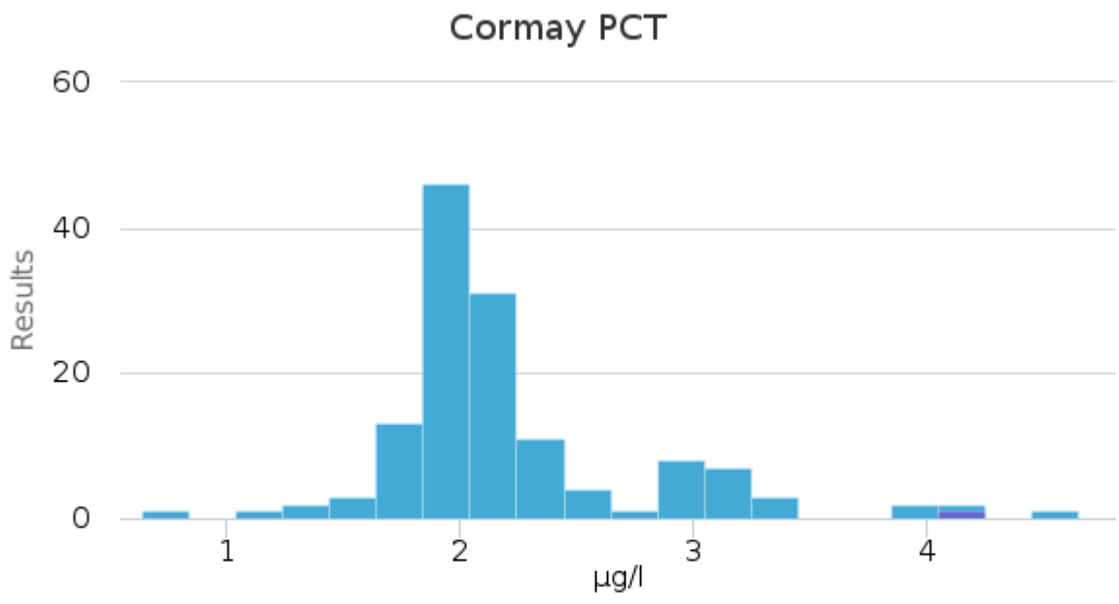


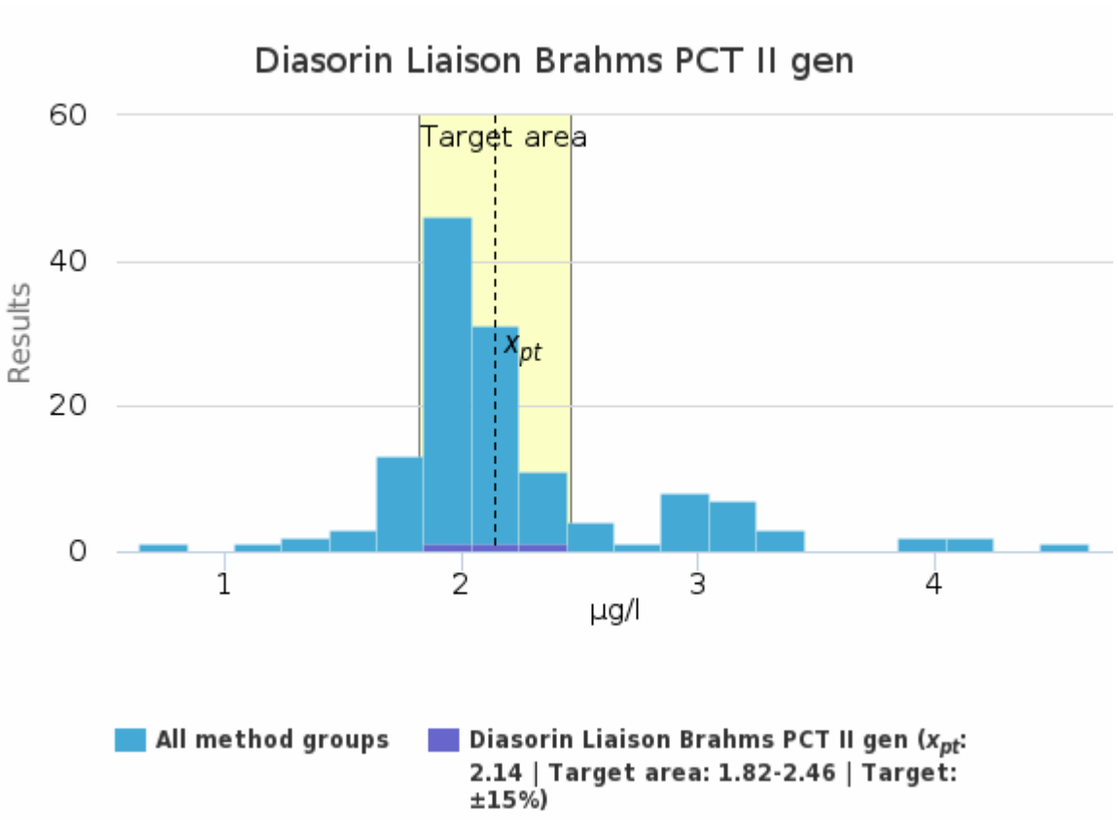


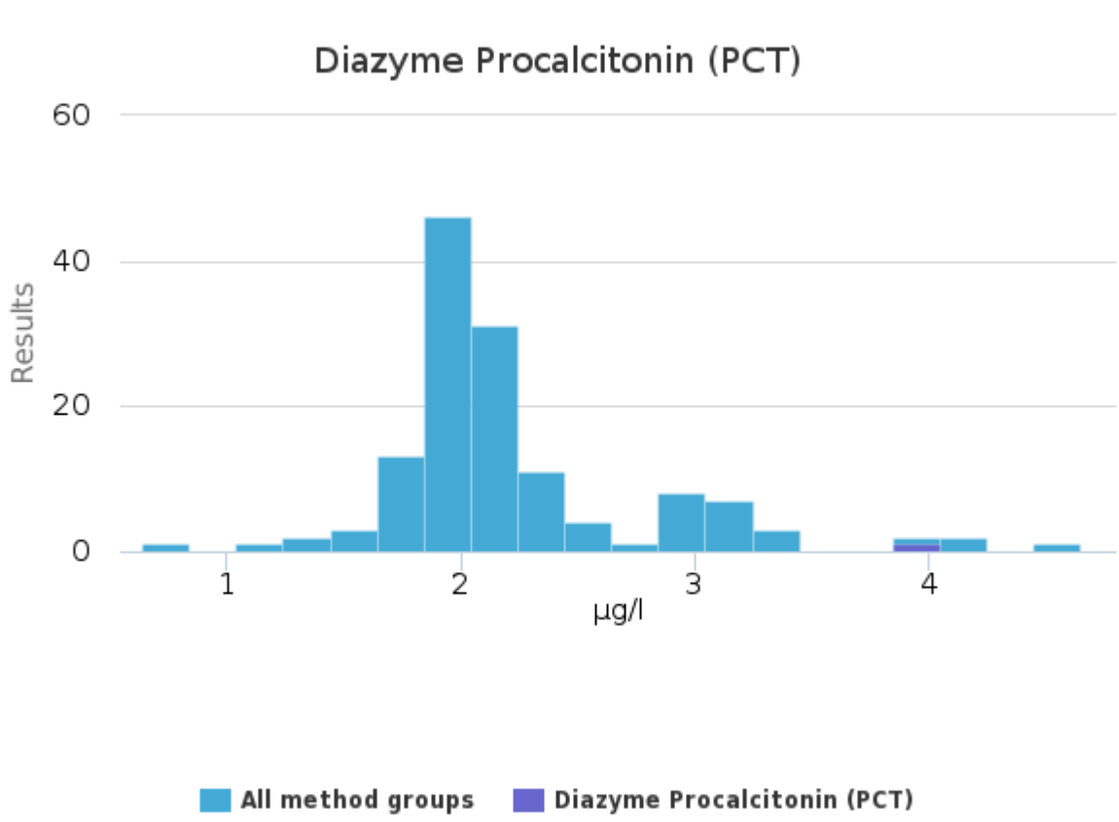
Procalcitonin, April, 1-2023

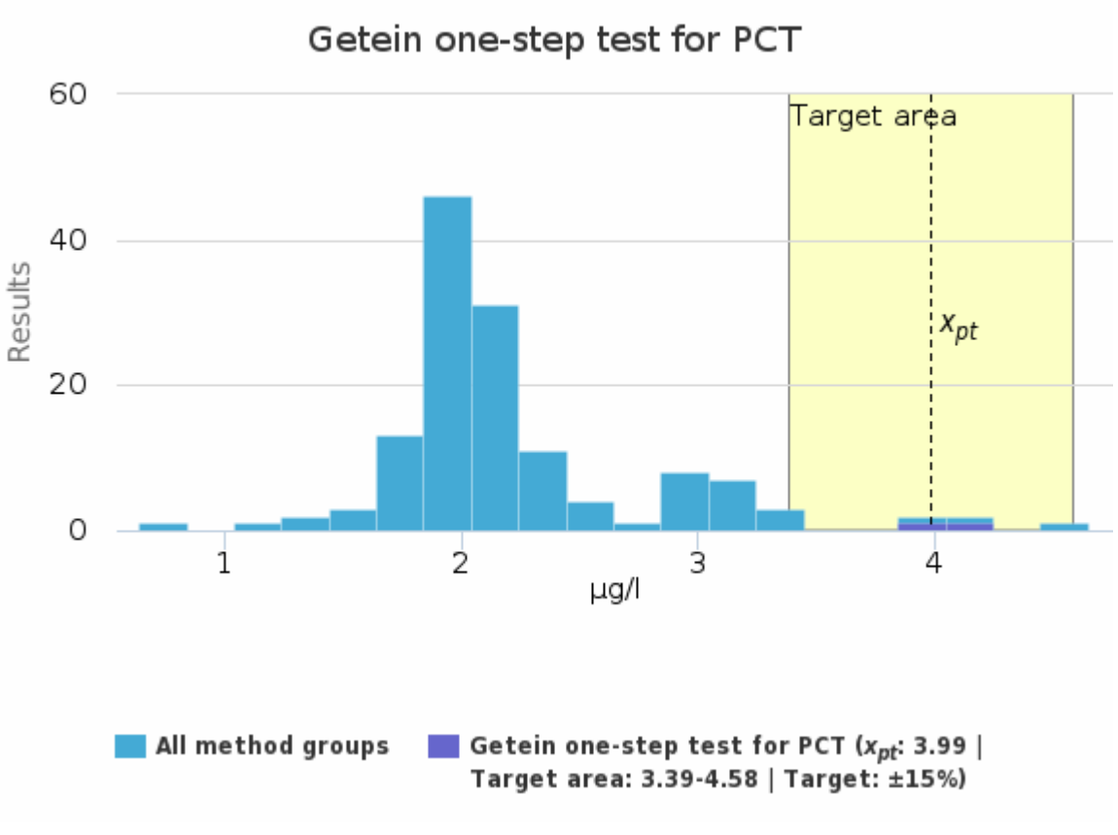
Quantitative report

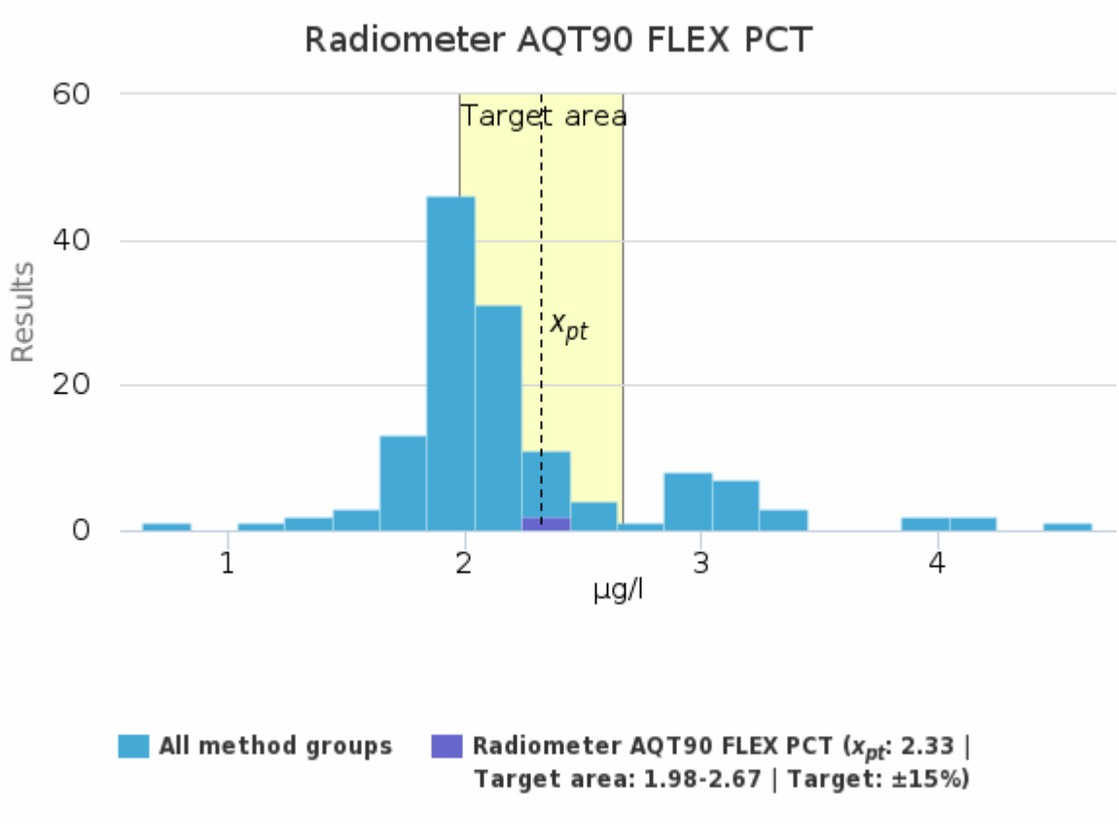






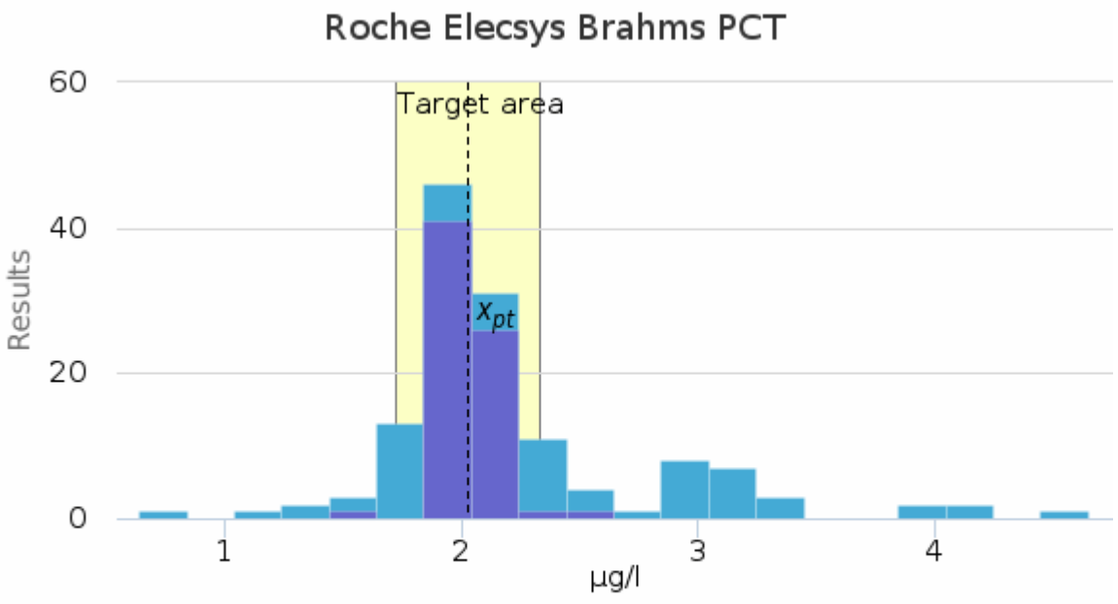


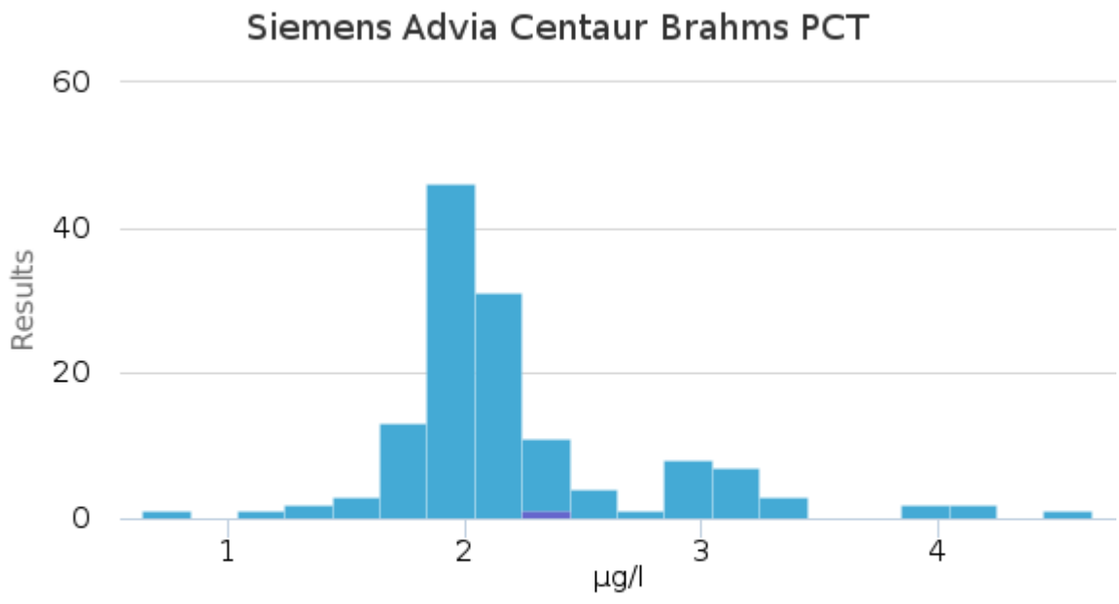


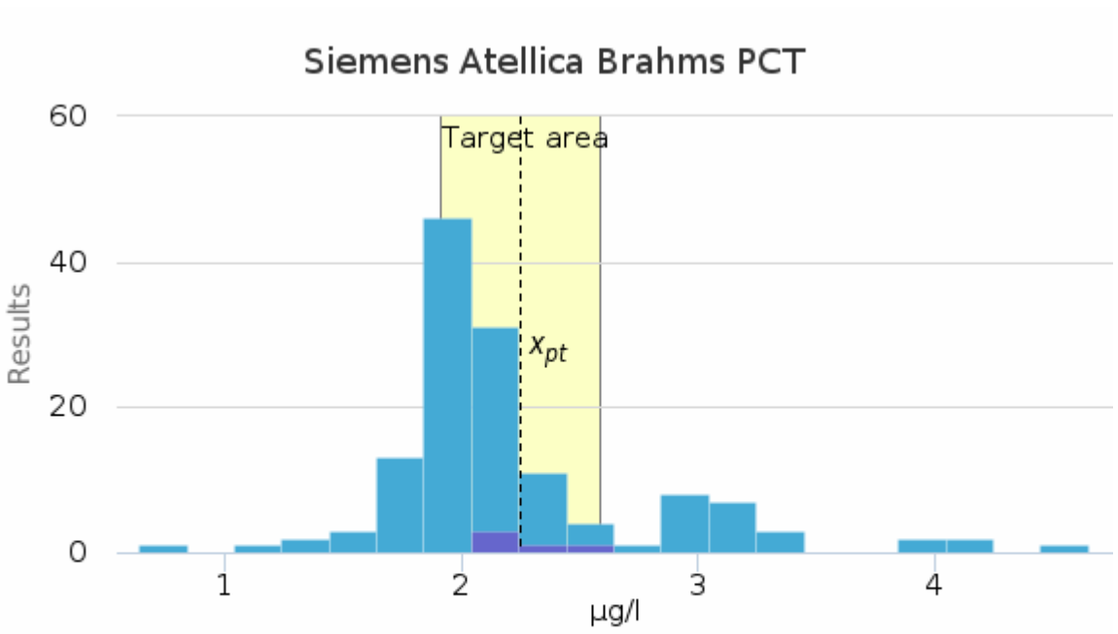


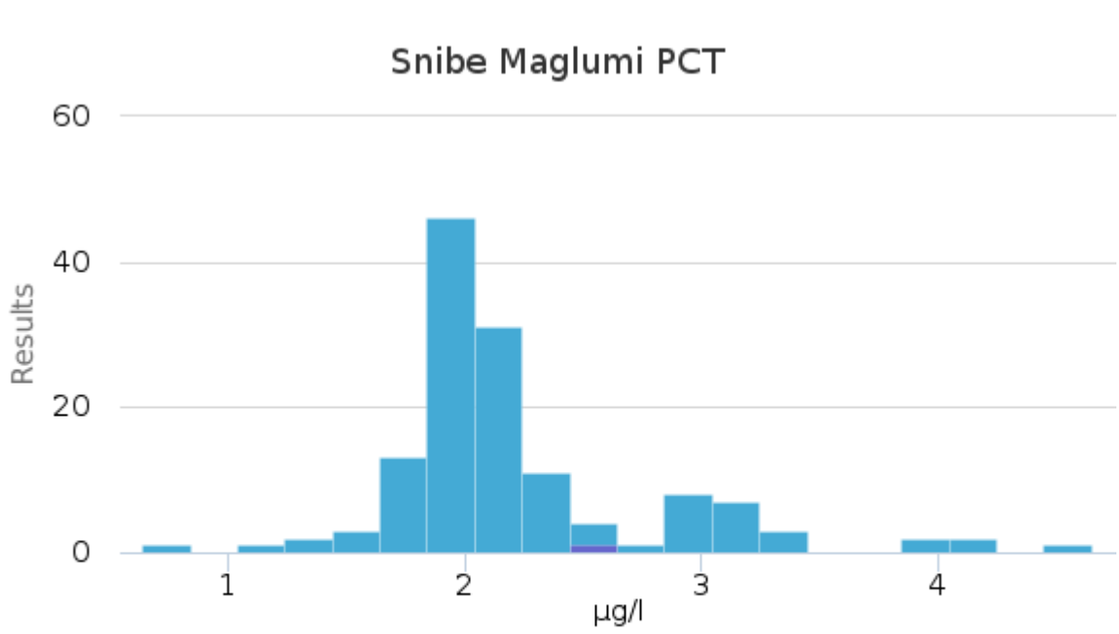
Procalcitonin, April, 1-2023

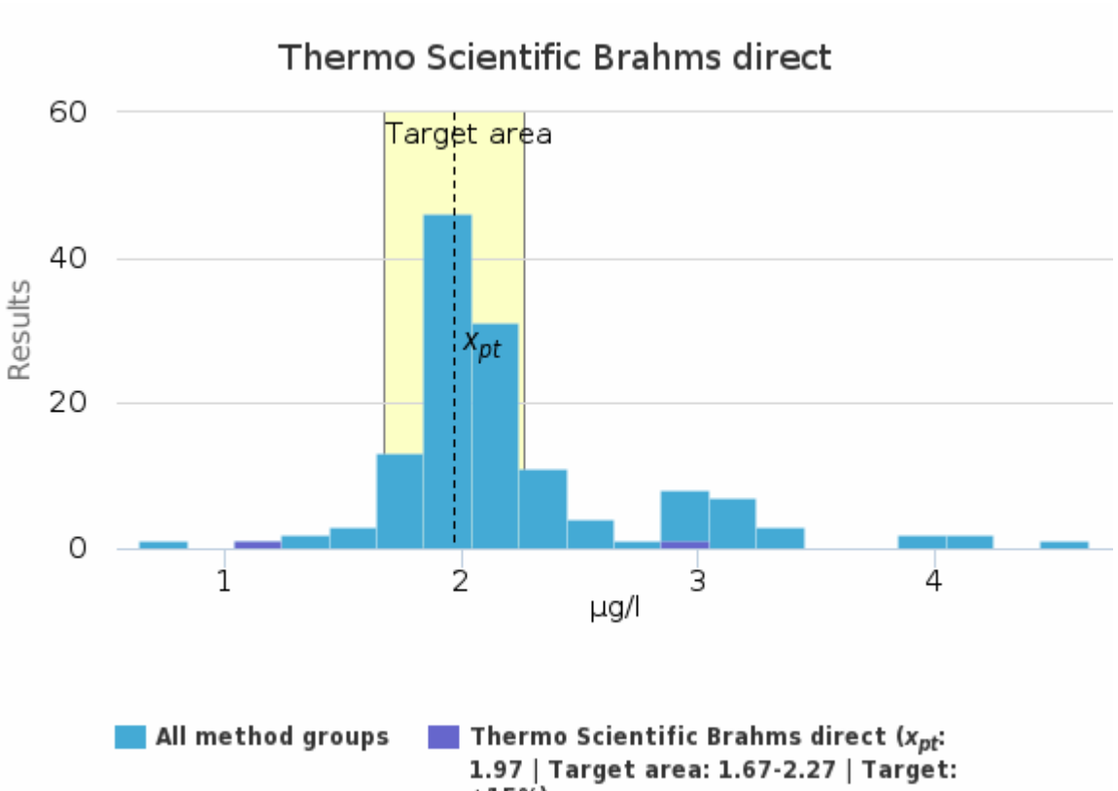
Quantitative report

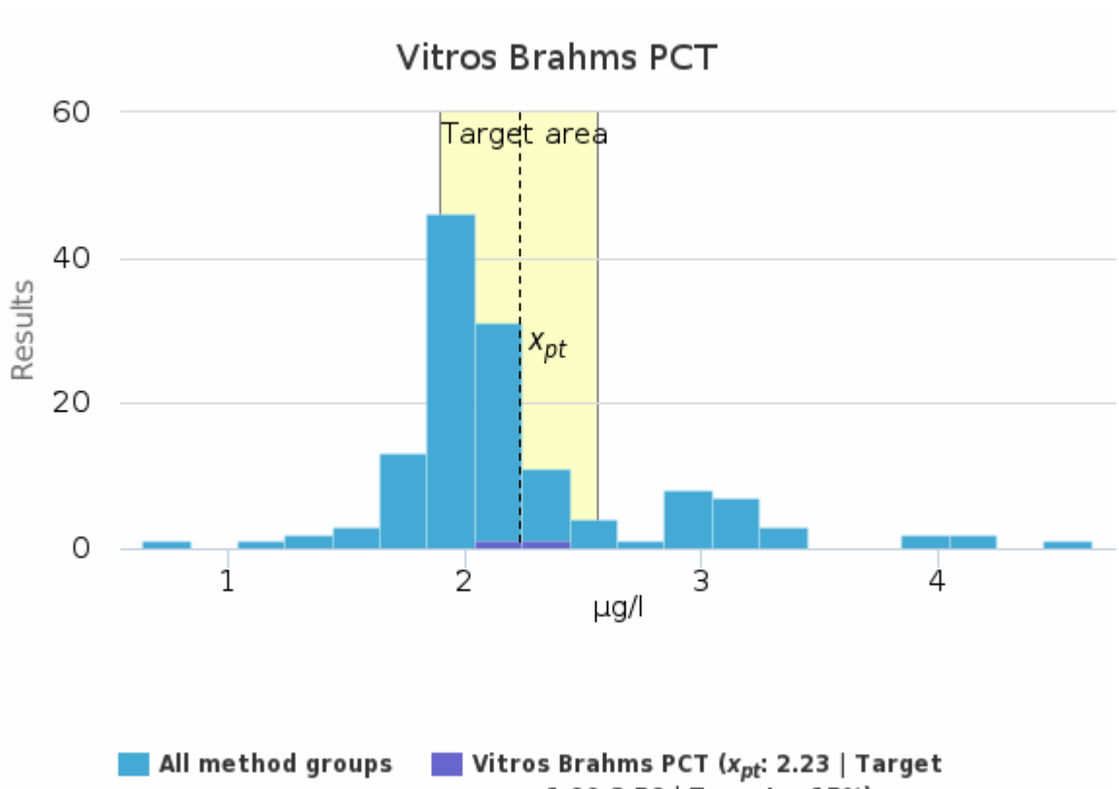






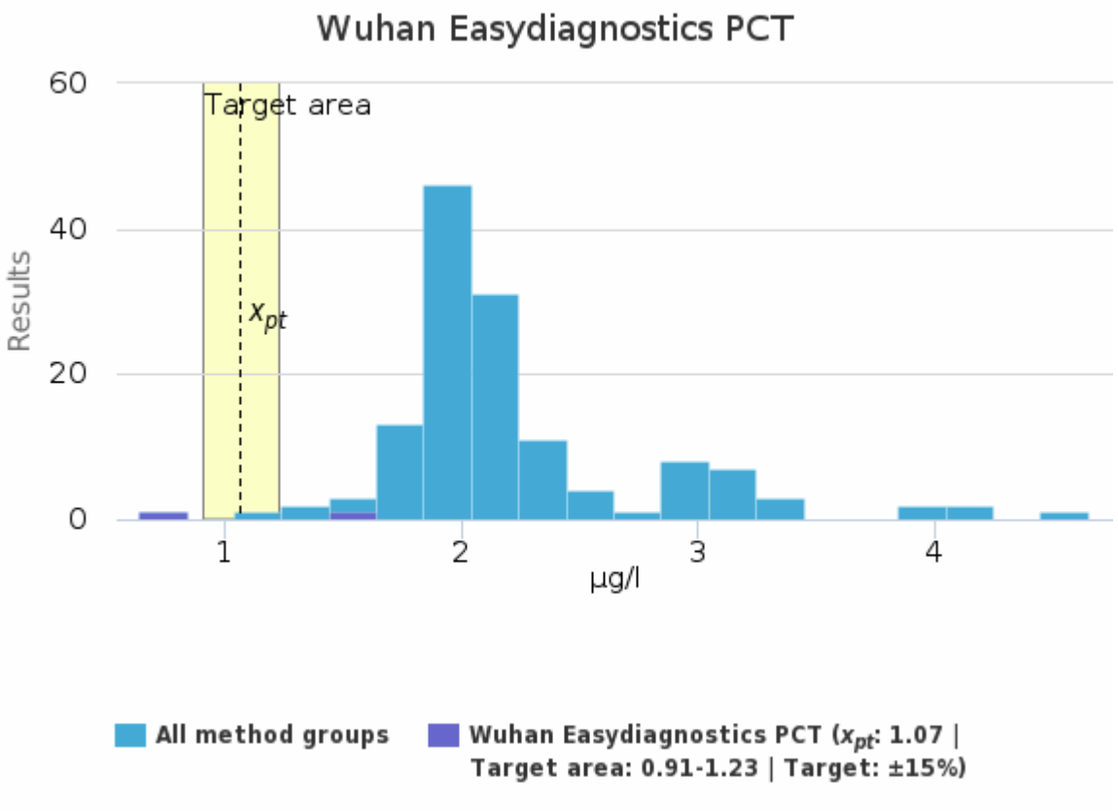






Procalcitonin, April, 1-2023

Quantitative report



Procalcitonin, April, 1-2023

Quantitative report

Report info

Participants

130 participants from 19 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).

LABQUALITY

External Quality Assessment Scheme

Procalcitonin
Round 1, 2023

Specimens
Sample S001 (LQ728023011) and Sample S002 (LQ728023012) were lyophilized human serum samples.

Based on the previous tests and the results of this round, the samples were 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 histograms and Numerical Summary reports. 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 samples S001 and S002 of this round were produced by a commercial manufacturer. The samples were human serum preparations into which pure human procalcitonin (human PCT recombinant) was added. The concentrations of procalcitonin confirmed by the manufacturer were as follows:

Sample S001: PCT	0.47 µg/L (±3SD limits: 0.45 – 0.50 µg/L)
Sample S002: PCT	2.21 µg/L (±3SD limits: 2.16 –2.27 µg/L)

Comments – Expert
At the concentration level of PCT in sample S001 sepsis is rather unlikely, whereas the concentration of PCT in sample S002 refers to possible sepsis.

In the present round there were 130 participants from 19 countries. Some laboratories reported results from several analyzers and the final statistical analysis included 138/136 results (sample S001/S002). Four/six (sample S001/ S002) results were disqualified as outliers from the statistical analysis.

In this round the total number of assay methods was nineteen, but fourteen of these methods were used by 1-4 laboratories only. The following five automated methods were used by 5-70 laboratories: Roche Elecsys (70), Biomerieux Vidas (18), Abbott Alinity (17), Beckman Coulter (5) and Siemens Atellica (5).

The results by these five methods cover more than 83 per cent of all results given in this round. The method-based variation by these methods was relatively small (CV 3-8%), with the exception of S001 in Siemens Atellica group (CV 13%). Smallest variation was seen in Beckman Coulter group, and biggest in Siemens Atellica and Abbott Alinity groups. These variation figures can mainly be regarded as a good result.

Method-based differences in concentration were observed (total CV 16-21%), and in both samples the histogram is very wide and shows a biphasic distribution in sample S002, which is due to method-based numerical differences between Roche and Biomerieux groups. Roche Elecsys and Siemens Atellica groups (sample S001 and S002, respectively) were the closest to the concentration of procalcitonin confirmed by the manufacturer

2023-05-08

FINAL REPORT

Product no. 2280

Samples sent	2023-03-28
Round closed	2023-04-27
Final report	2023-05-08

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
Liisa Ylitepsa
liisa.ylitepsa@labquality.fi

Expert
PhD, Clinical Biochemist
Titta Salopuro
HUS Diagnostic Center
Helsinki, Finland

Labquality Oy
Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

info@labquality.fi
www.labquality.com

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in both samples. The biggest differences from the manufacturer's concentration were in Diazyme, Wuhan Easydiagnostics, AFIAS, Cormay and Getein groups. Especially Wuhan Easydiagnostics showed very low concentrations in both samples, which might lead to misclassification of sepsis in patient samples.

End of report