

External Quality Assessment Scheme

## Special Coagulation Round 1, 2023

### Specimens

Please find enclosed 2 lyophilized citrate plasma 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

Antithrombin III  
Protein C  
Protein S  
Factor VIII  
Thrombin Time

### Storage and use

After arrival store the unopened vials in a refrigerator (+2...8 °C). Open the vials carefully to prevent escape of dried material and reconstitute the contents in 1.0 mL of distilled water. Allow samples to stand for 15 minutes at room temperature. After that mix the samples gently by inverting the tubes several times. Avoid foam formation. Samples are stable for 4 hours after reconstitution. Analyse as a patient sample.

### 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



2023-02-06

### INSTRUCTIONS

Product no. 4386  
LQ708523011-012/AT

If the kit is incomplete or contains damaged specimens, please report immediately to [info@labquality.fi](mailto:info@labquality.fi)

The results should be reported no later than **February 21, 2023.**

### Inquiries

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[iida.silvo@labquality.fi](mailto:iida.silvo@labquality.fi)

### Labquality Oy

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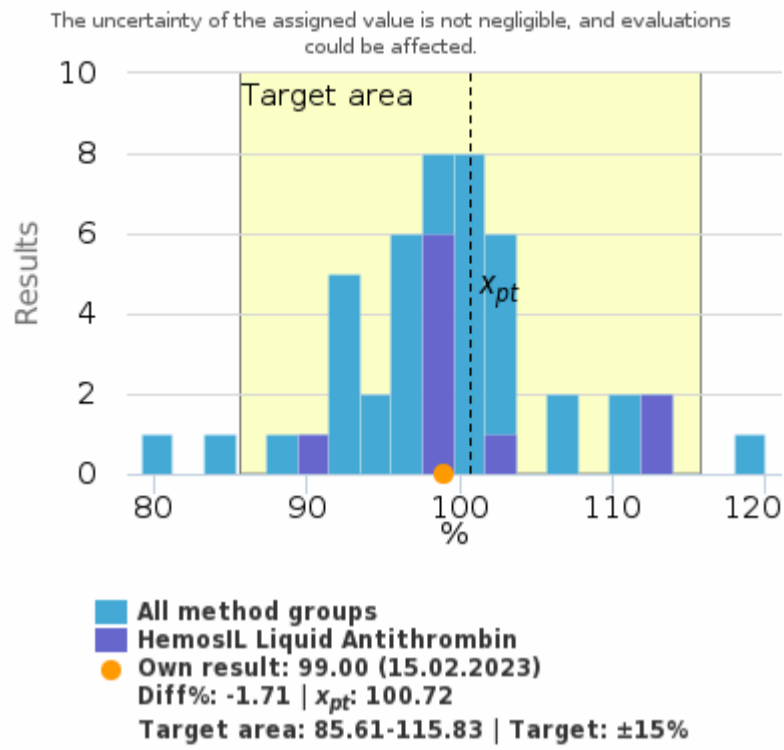
Tel. + 358 9 8566 8200  
Fax + 358 9 8566 8280

[info@labquality.fi](mailto:info@labquality.fi)  
[www.labquality.com](http://www.labquality.com)

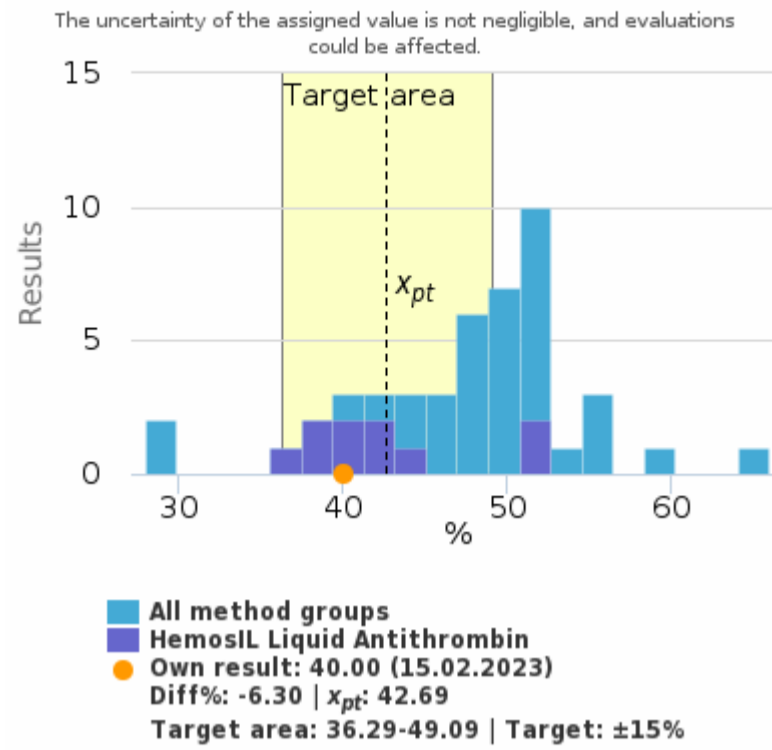


Antitrombin III |03

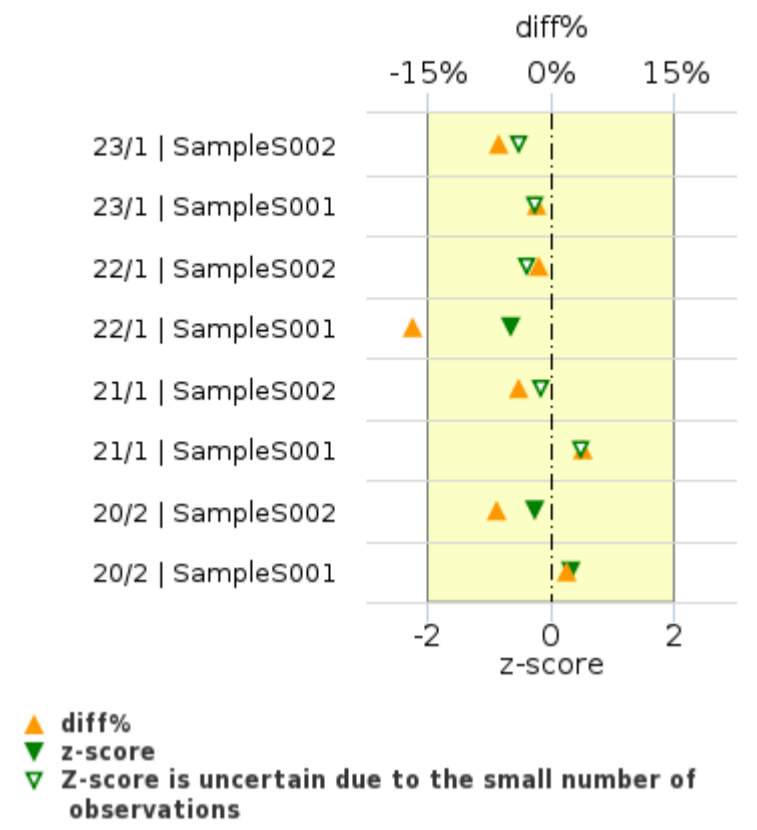
SampleS001, Antitrombin III



SampleS002, Antitrombin III



History

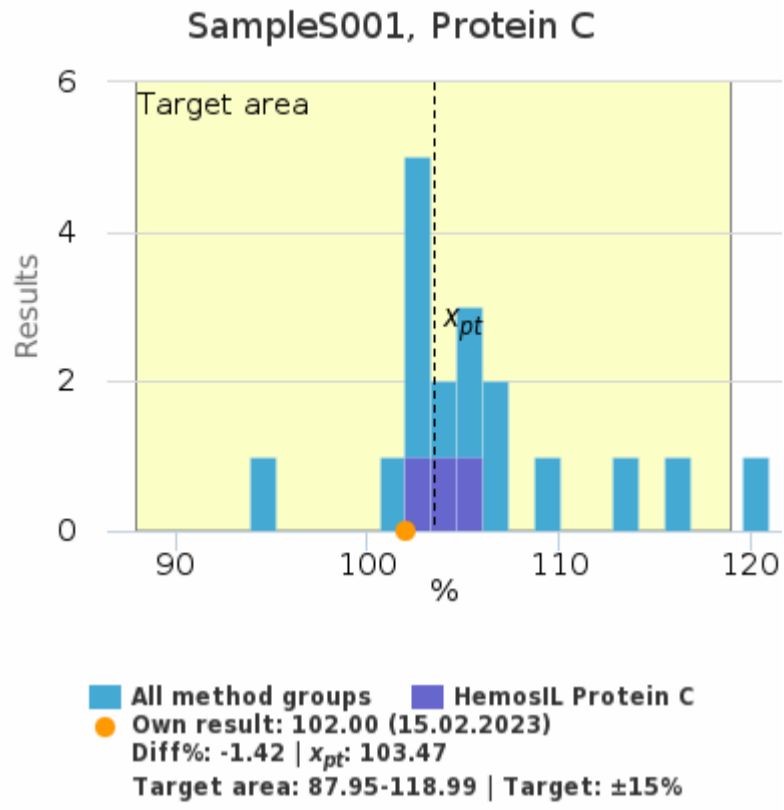


	$x_{pt}$	sd	SEM	CV%	n
HemosIL Liquid Antithrombin	100.72 %	6.95	2.20	6.9	10
All methods	99.10 %	7.27	1.07	7.3	46

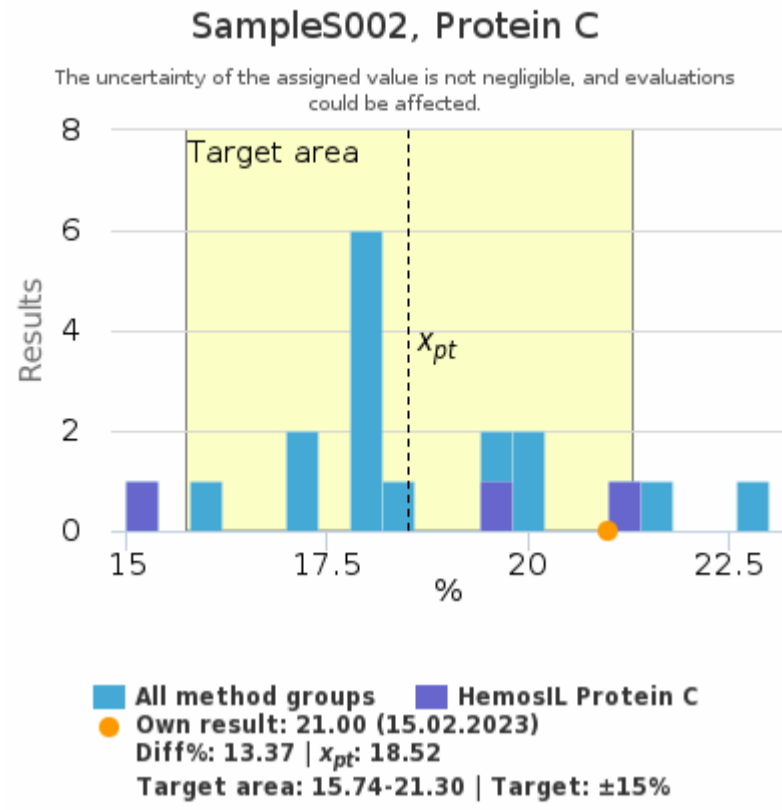
	$x_{pt}$	sd	SEM	CV%	n
HemosIL Liquid Antithrombin	42.69 %	5.07	1.60	11.9	10
All methods	47.53 %	7.03	1.04	14.8	46

Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Sample S002	42.69	40.00	-6.30%	-0.53
23/1	Sample S001	100.72	99.00	-1.71%	-0.25
22/1	Sample S002	96.45	95.00	-1.51%	-0.39
22/1	Sample S001	33.08	27.50	-16.86%	-0.64
21/1	Sample S002	27.78	26.66	-4.03%	-0.16
21/1	Sample S001	102.48	106.33	3.76%	0.49
20/2	Sample S002	27.84	26.00	-6.59%	-0.26
20/2	Sample S001	97.03	99.00	2.03%	0.32

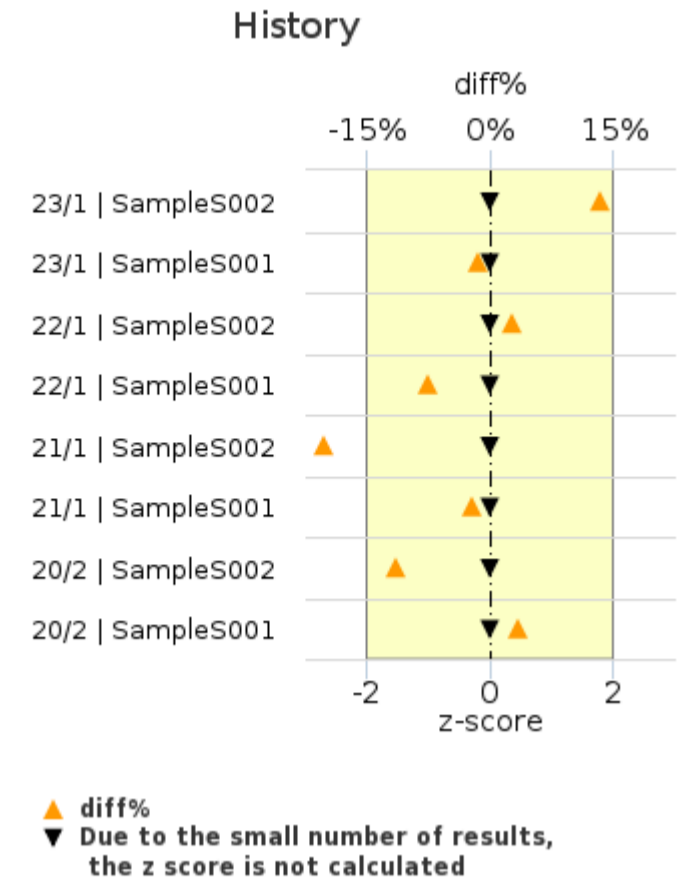
Protein C |03



	$x_{pt}$	sd	SEM	CV%	n
HemosIL Protein C	103.47 %	1.50	0.87	1.5	3
All methods	105.76 %	6.04	1.42	5.7	18



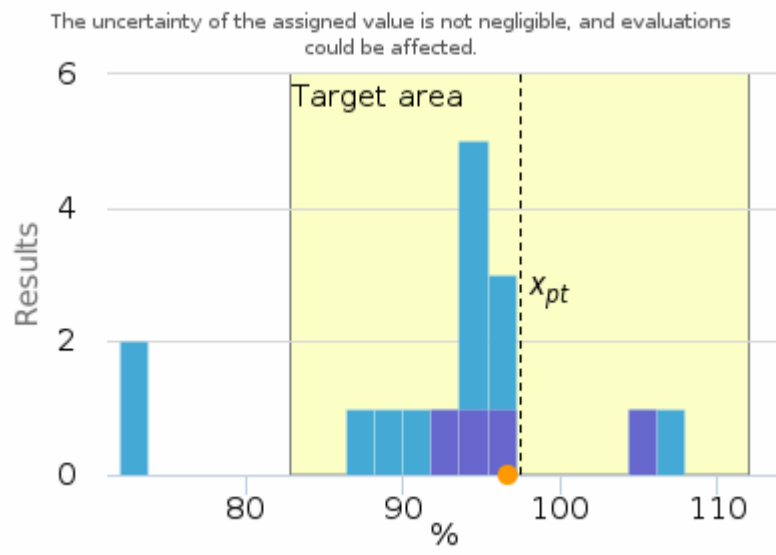
	$x_{pt}$	sd	SEM	CV%	n
HemosIL Protein C	18.52 %	3.13	1.81	16.9	3
All methods	18.68 %	1.99	0.47	10.6	18



Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Sample S002	18.52	21.00	13.37%	-
23/1	Sample S001	103.47	102.00	-1.42%	-
22/1	Sample S002	103.23	106.00	2.69%	-
22/1	Sample S001	14.05	13.00	-7.47%	-
21/1	Sample S002	15.01	12.00	-20.05%	-
21/1	Sample S001	110.22	107.66	-2.32%	-
20/2	Sample S002	12.77	11.30	-11.51%	-
20/2	Sample S001	98.70	102.00	3.34%	-

Protein S |03

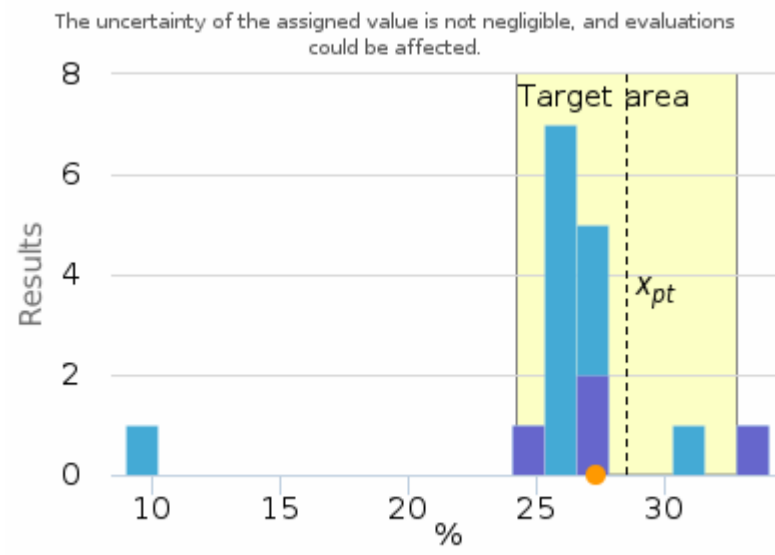
SampleS001, Protein S



■ All method groups    ■ HemosIL Free Protein S  
● Own result: 96.70 (15.02.2023)  
 Diff%: -0.74 |  $x_{pt}$ : 97.43  
 Target area: 82.81-112.04 | Target: ±15%

	$x_{pt}$	sd	SEM	CV%	n
HemosIL Free Protein S	97.43 %	5.93	2.96	6.1	4
All methods	92.65 %	9.40	2.35	10.1	16

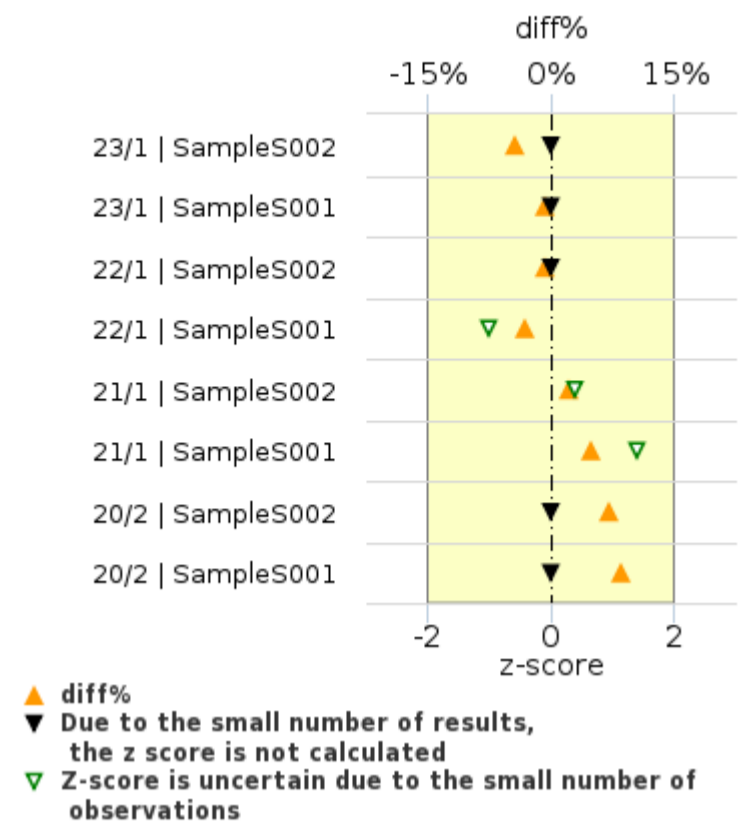
SampleS002, Protein S



■ All method groups    ■ HemosIL Free Protein S  
● Own result: 27.30 (15.02.2023)  
 Diff%: -4.38 |  $x_{pt}$ : 28.55  
 Target area: 24.27-32.83 | Target: ±15%

	$x_{pt}$	sd	SEM	CV%	n
HemosIL Free Protein S	28.55 %	3.90	1.95	13.6	4
All methods	27.22 %	2.36	0.61	8.7	16

History



Round	Sample	$x_{pt}$	Result	diff%	z-score
23/1	Sample S002	28.55	27.30	-4.38%	-
23/1	Sample S001	97.43	96.70	-0.74%	-
22/1	Sample S002	106.80	106.10	-0.66%	-
22/1	Sample S001	24.18	23.40	-3.23%	-0.99
21/1	Sample S002	20.43	20.85	2.06%	0.40
21/1	Sample S001	96.40	101.10	4.88%	1.39
20/2	Sample S002	20.53	22.00	7.14%	-
20/2	Sample S001	100.45	109.00	8.51%	-

**Report info****Participants**

42 participants from 12 countries.

**Report info**

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

Assigned values ( $x_p$ , target values) are means of the results where results deviating more than  $\pm 3$  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.

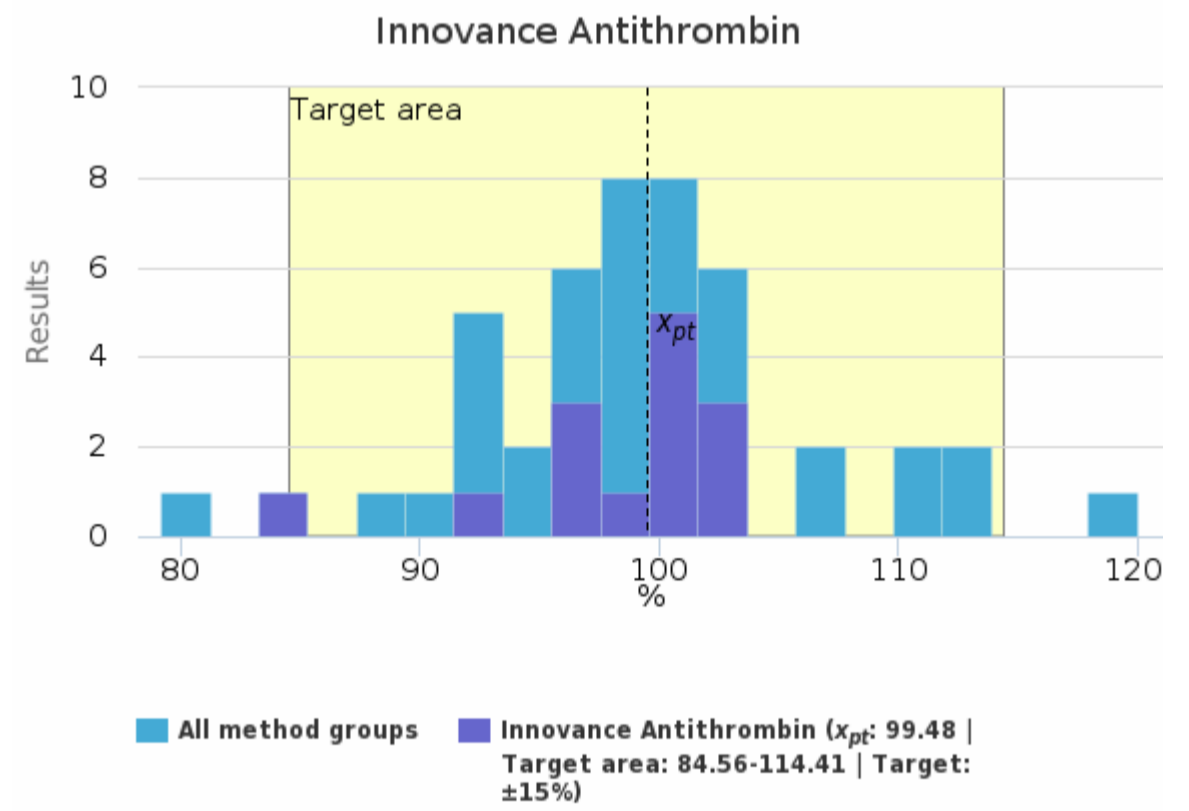
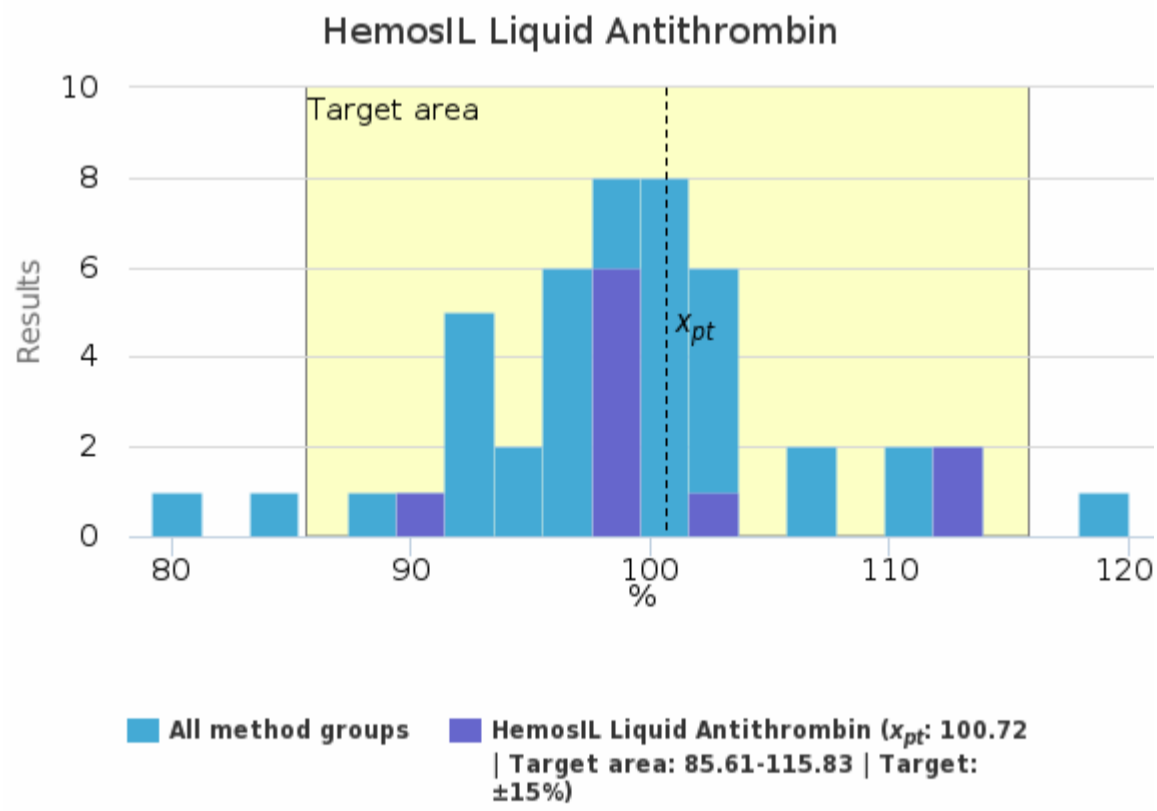
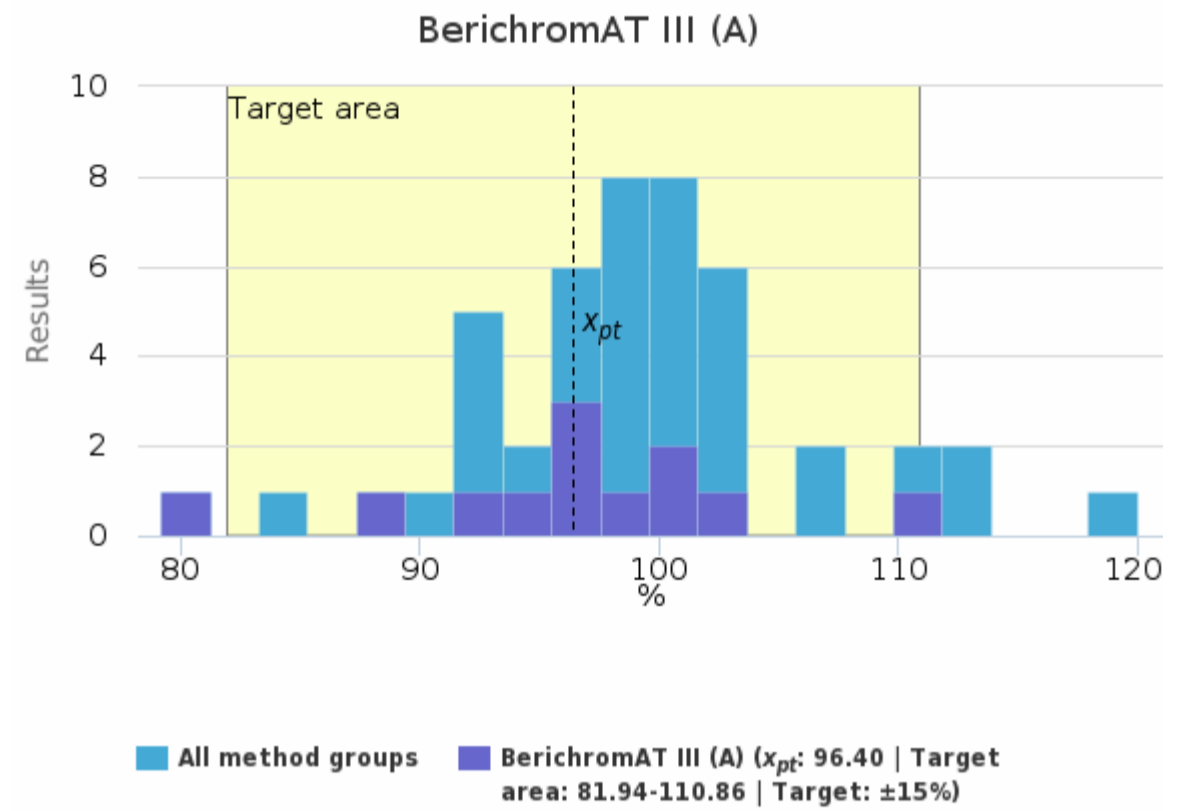
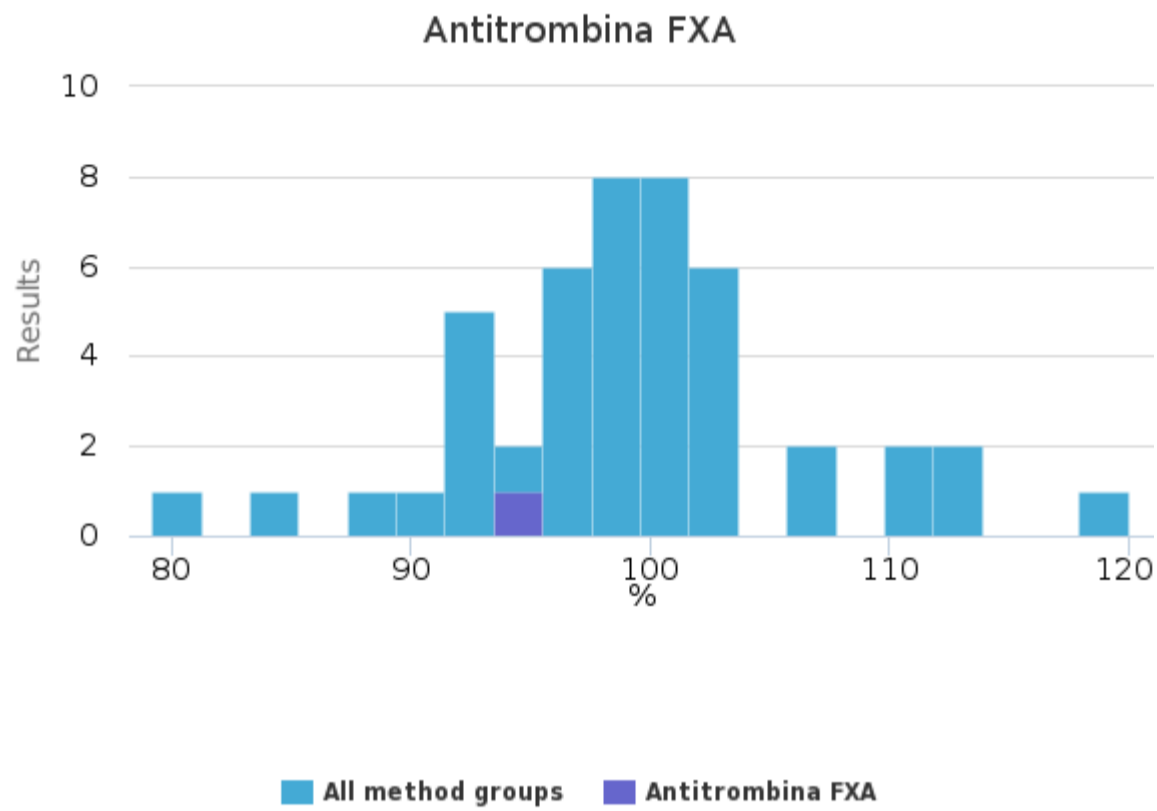
Results reported with  $<$  or  $>$  -signs cannot be included in the statistics.

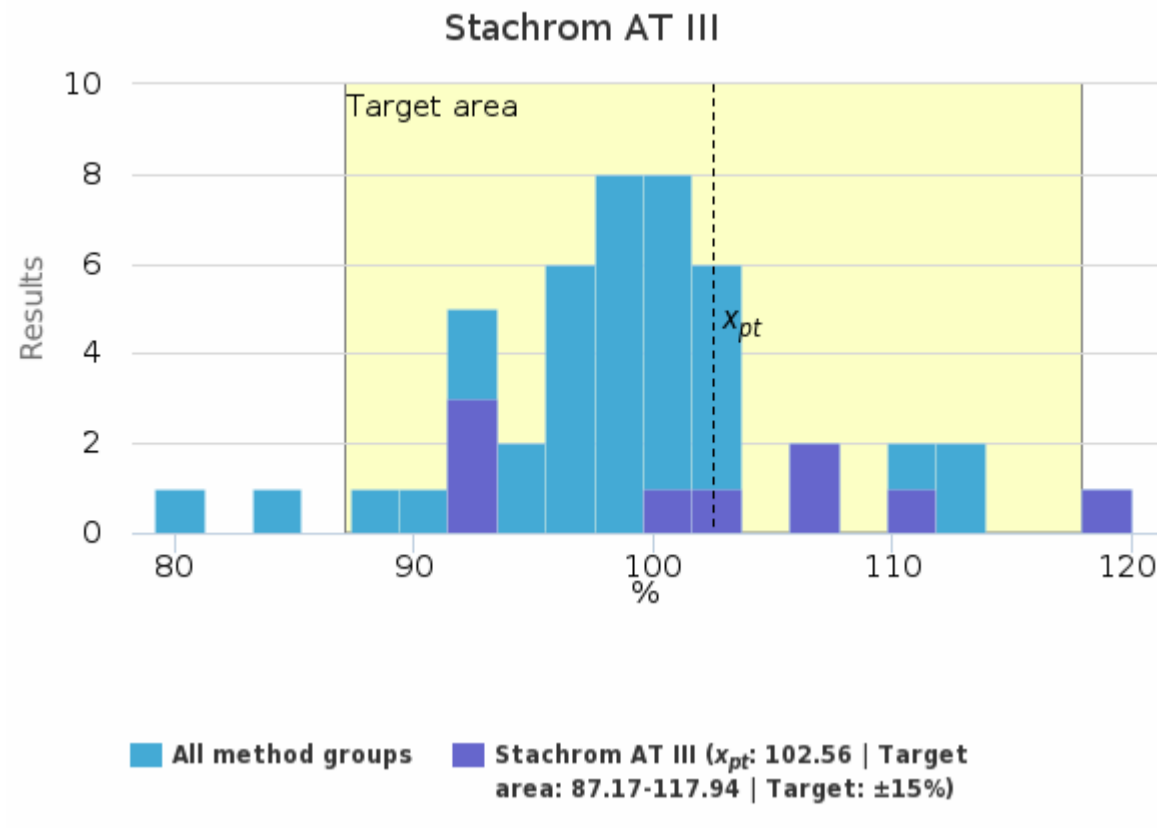
For information on report interpretation and performance evaluation, please see the "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

### Sample S001 | Antitrombin III, %

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Antitrombina FXA	-	-	-	-	-	94.90	94.90	-	1
BerichromAT III (A)	96.40	97.00	7.78	8.1	2.25	79.20	111.00	-	12
HemosIL Liquid Antithrombin	100.72	98.45	6.95	6.9	2.20	90.00	113.00	-	10
Innovance Antithrombin	99.48	100.50	2.77	2.8	0.77	93.00	102.70	1	14
Stachrom AT III	102.56	103.00	9.36	9.1	3.12	92.00	120.00	-	9
<b>All</b>	<b>99.10</b>	<b>98.45</b>	<b>7.27</b>	<b>7.3</b>	<b>1.07</b>	<b>79.20</b>	<b>120.00</b>	-	<b>46</b>

### Sample S001 | Antitrombin III, % | histogram summaries in LabScala

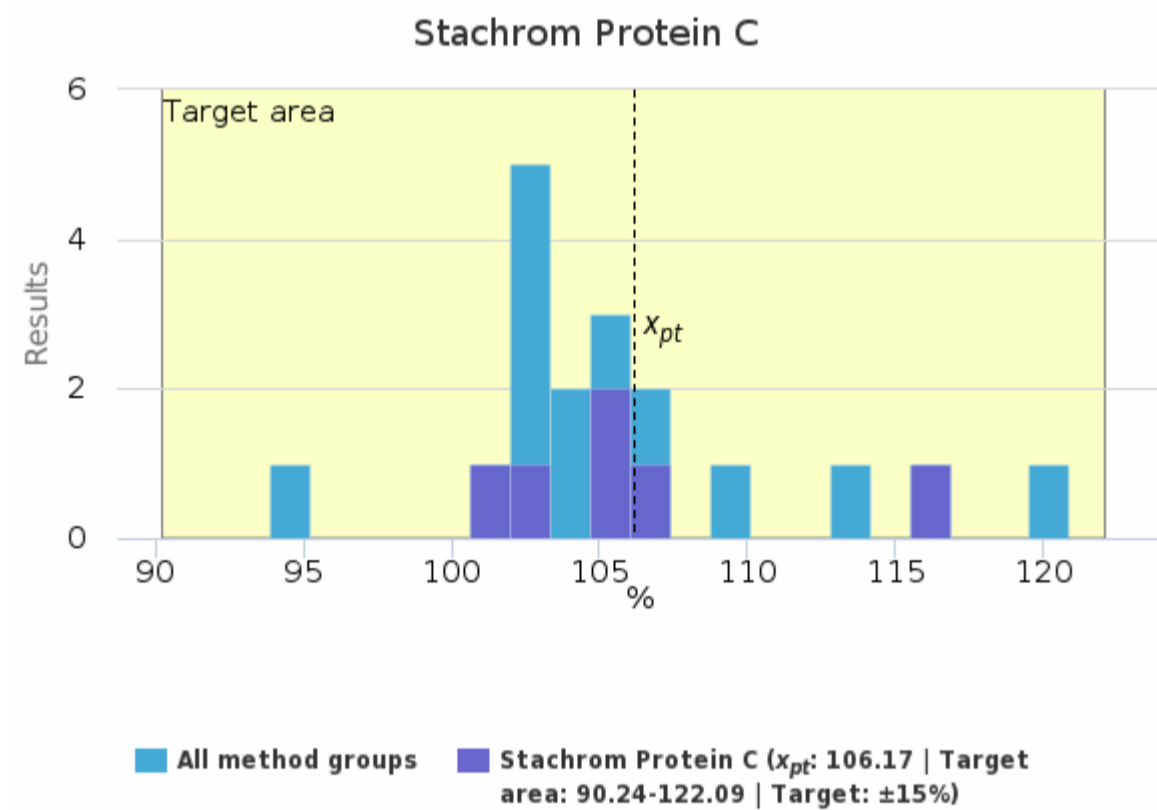
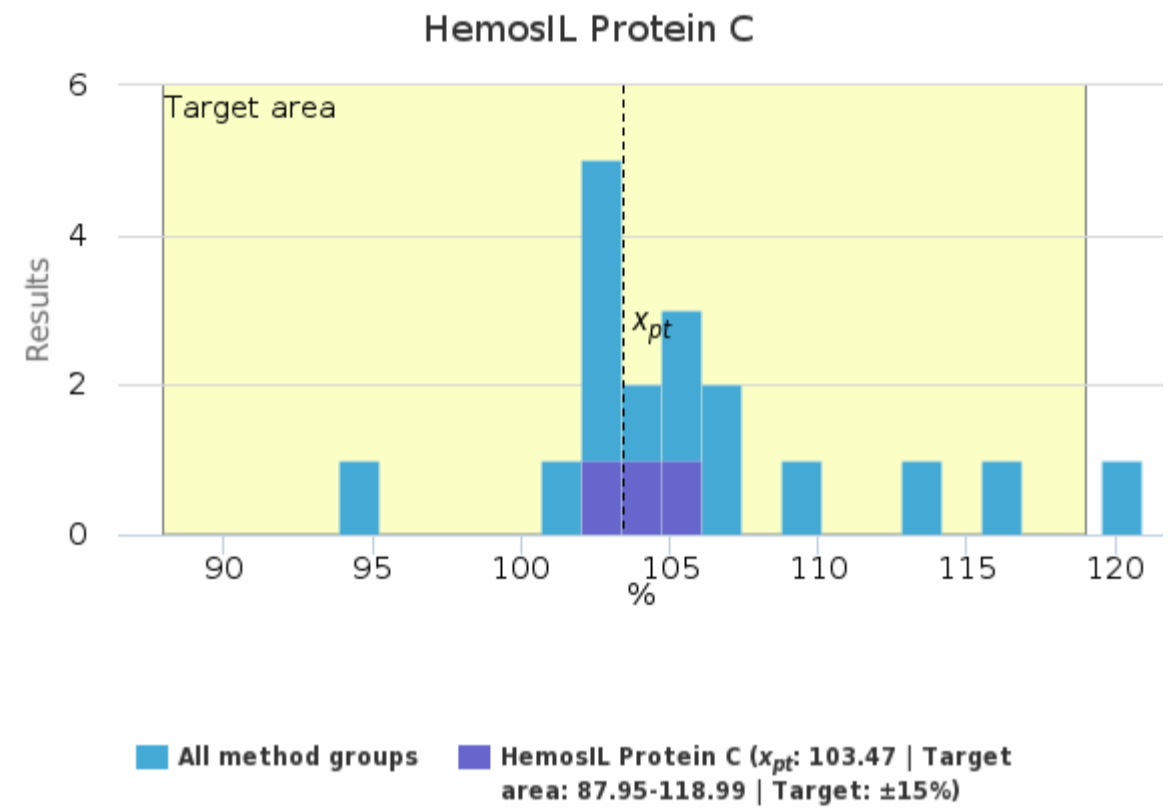
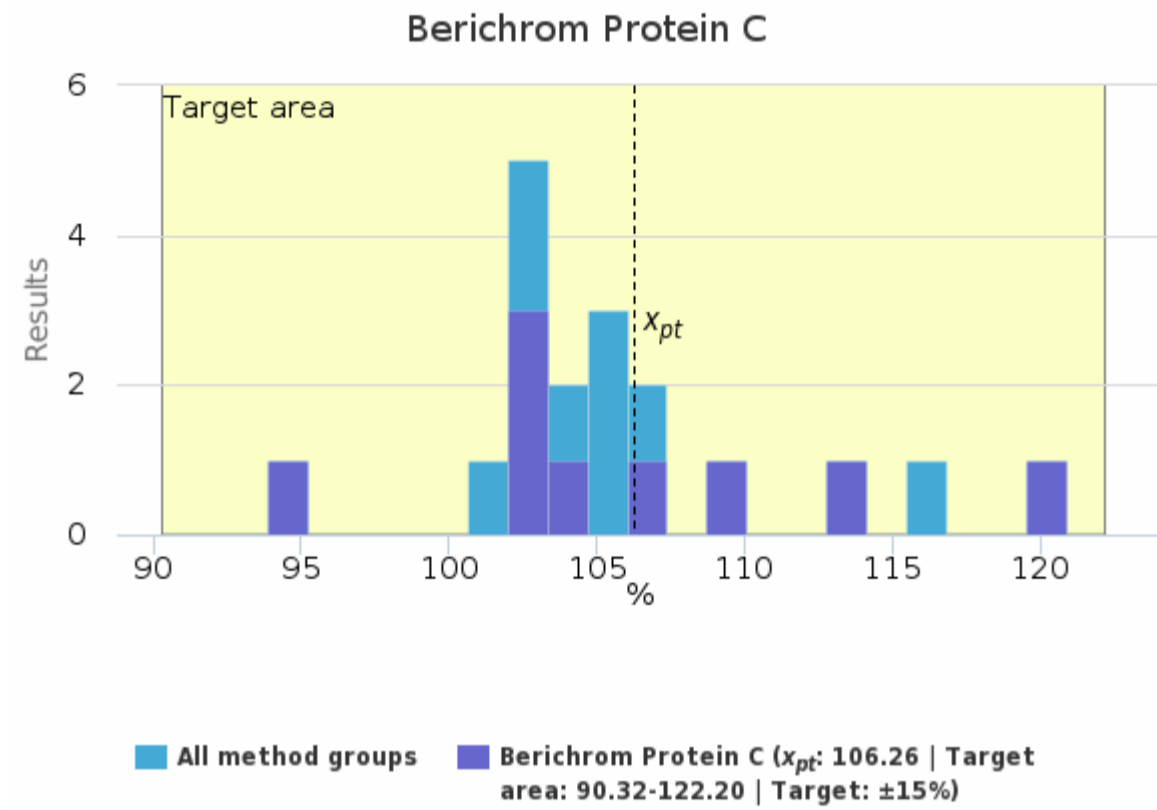




### Sample S001 | Protein C, %

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Berichrom Protein C	106.26	104.00	7.59	7.1	2.53	93.90	120.90	-	9
HemosIL Protein C	103.47	103.42	1.50	1.5	0.87	102.00	105.00	-	3
Stachrom Protein C	106.17	105.00	5.23	4.9	2.14	101.00	116.00	-	6
<b>All</b>	<b>105.76</b>	<b>104.50</b>	<b>6.04</b>	<b>5.7</b>	<b>1.42</b>	<b>93.90</b>	<b>120.90</b>	-	<b>18</b>

### Sample S001 | Protein C, % | histogram summaries in LabScala

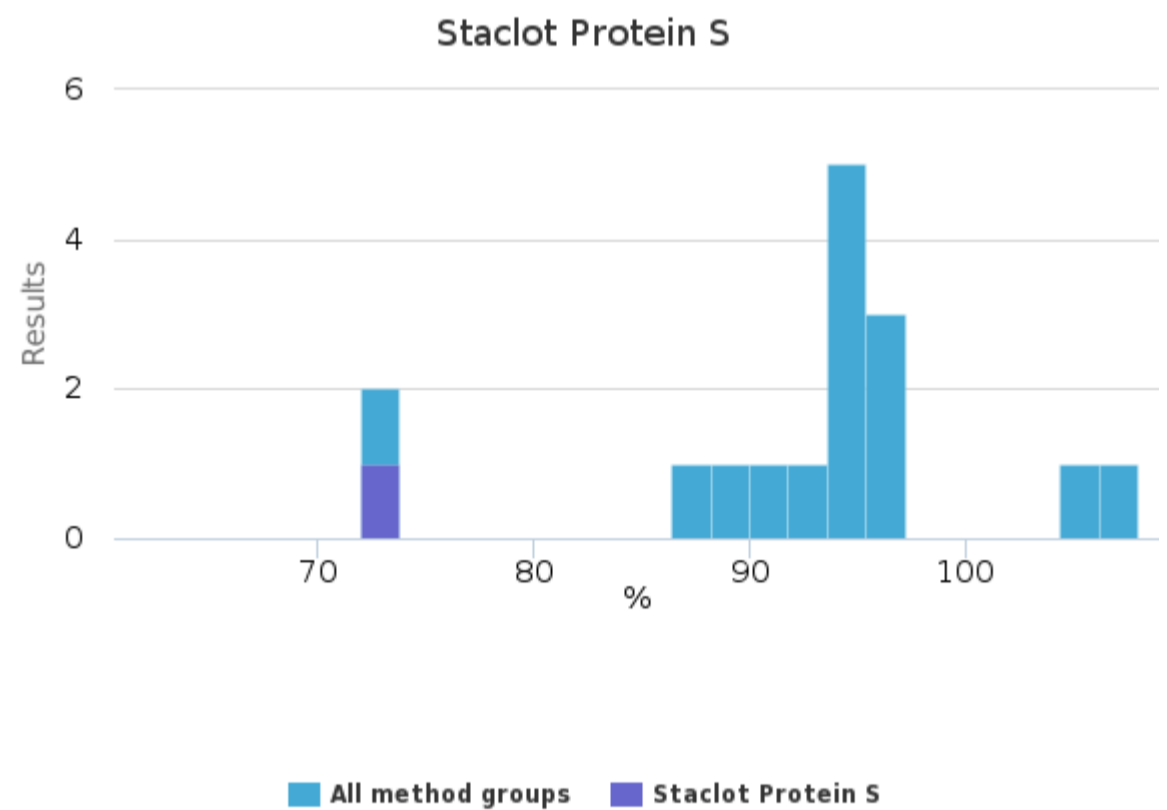
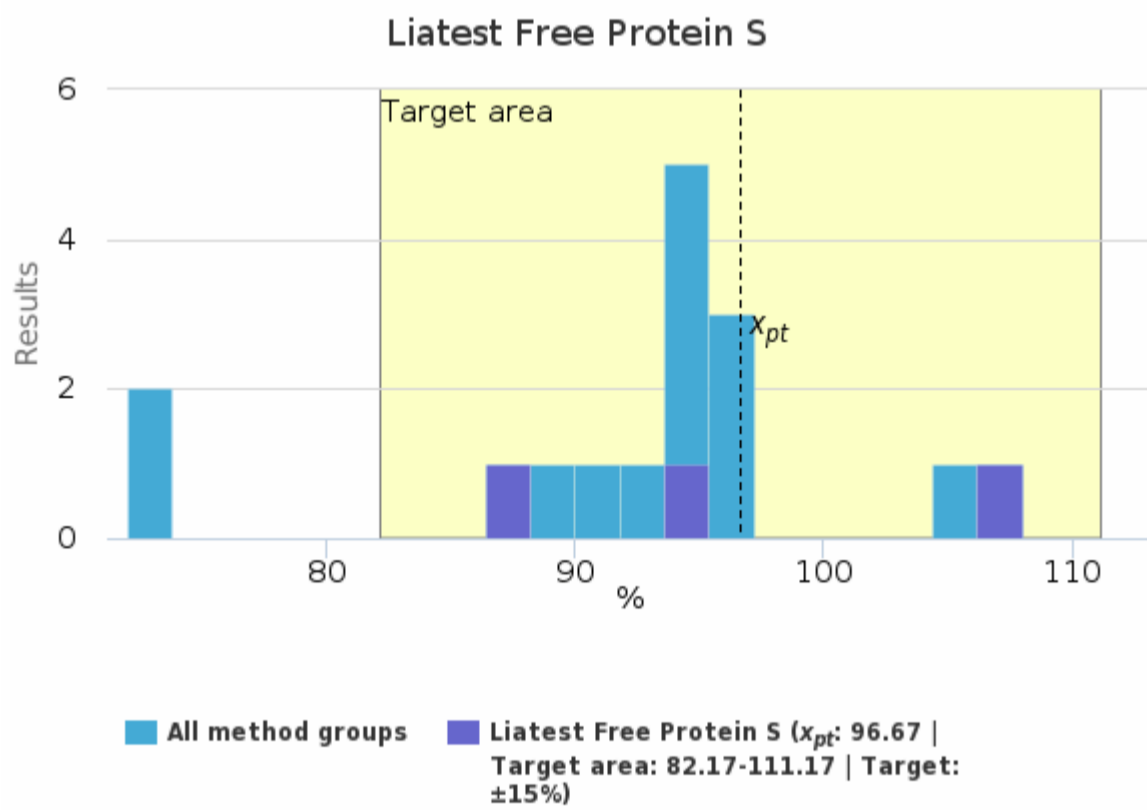
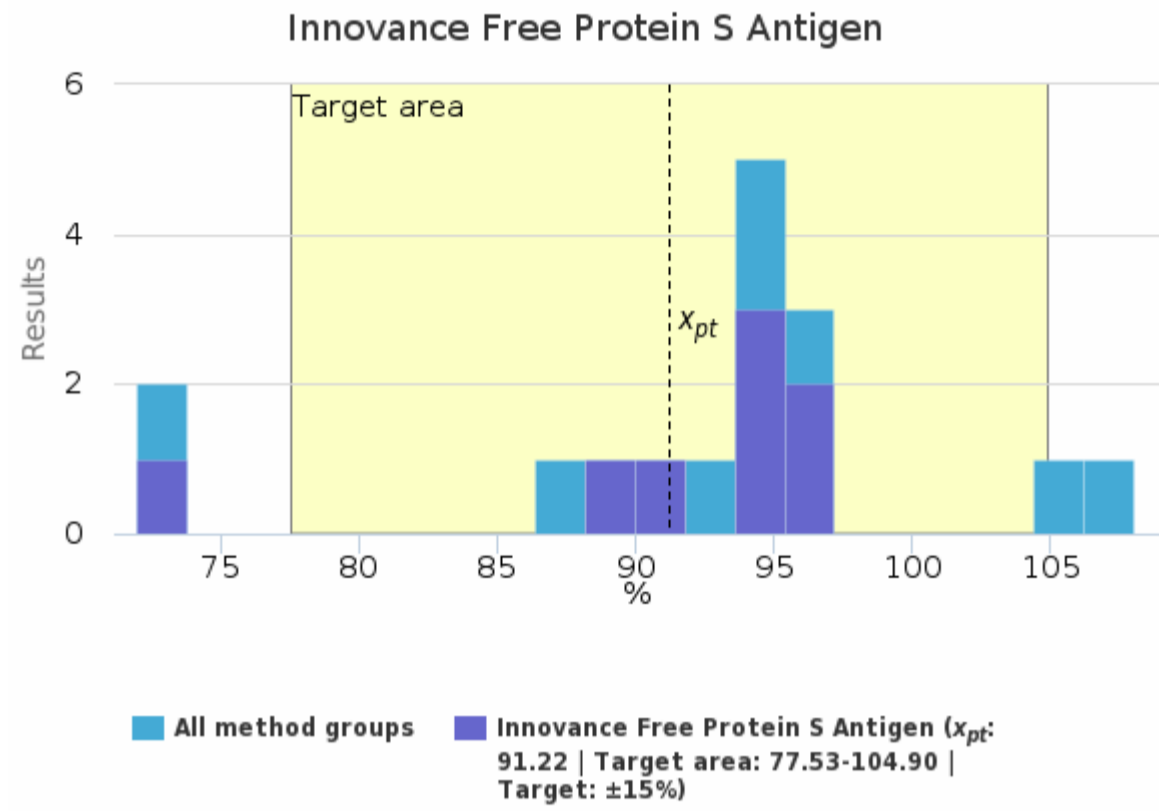
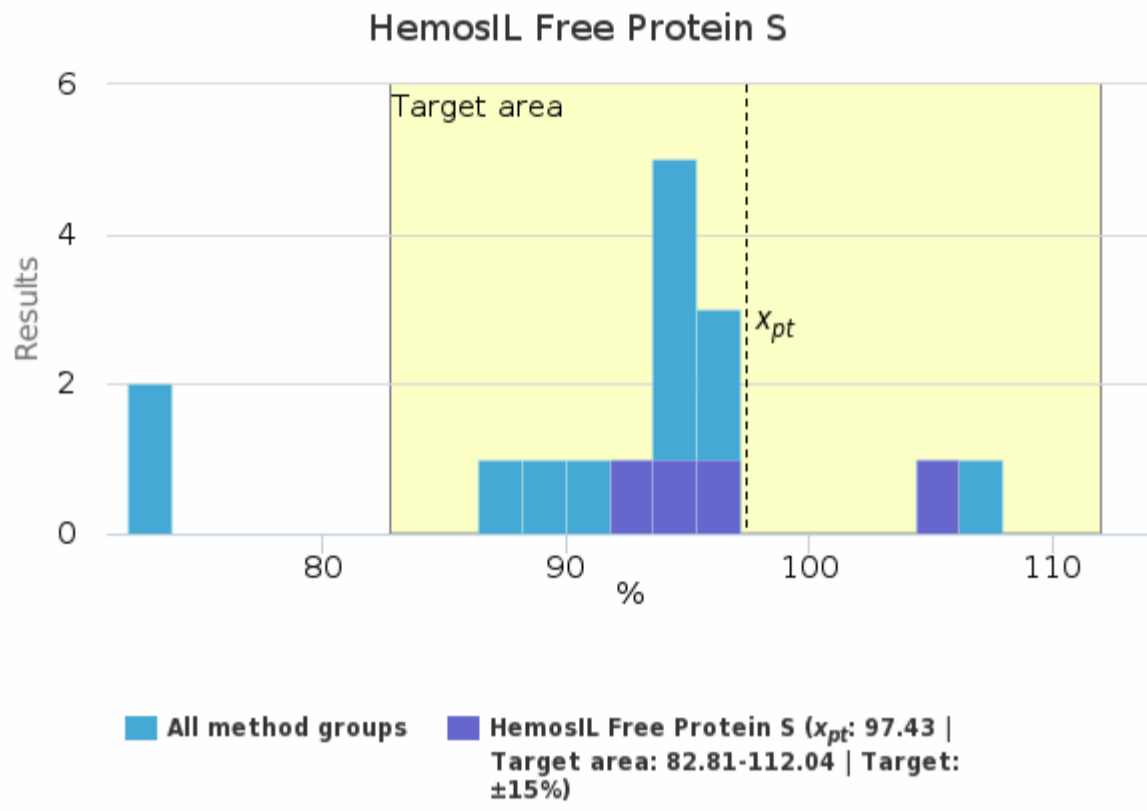




### Sample S001 | Protein S, %

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
HemosIL Free Protein S	97.43	95.35	5.93	6.1	2.96	93.00	106.00	-	4
Innovance Free Protein S Antigen	91.22	95.00	8.18	9.0	2.89	72.00	97.00	-	8
Liatest Free Protein S	96.67	94.00	10.26	10.6	5.93	88.00	108.00	-	3
Staclot Protein S	-	-	-	-	-	73.00	73.00	-	1
<b>All</b>	<b>92.65</b>	<b>94.50</b>	<b>9.40</b>	<b>10.1</b>	<b>2.35</b>	<b>72.00</b>	<b>108.00</b>	-	<b>16</b>

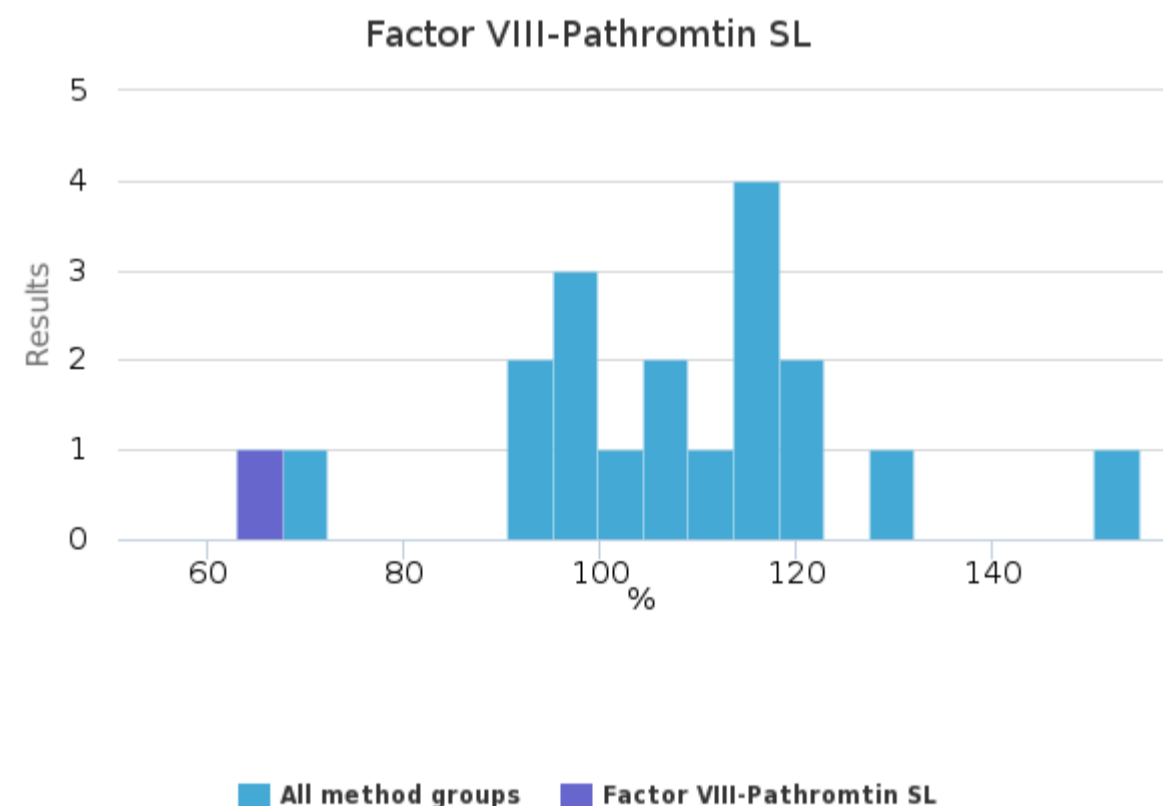
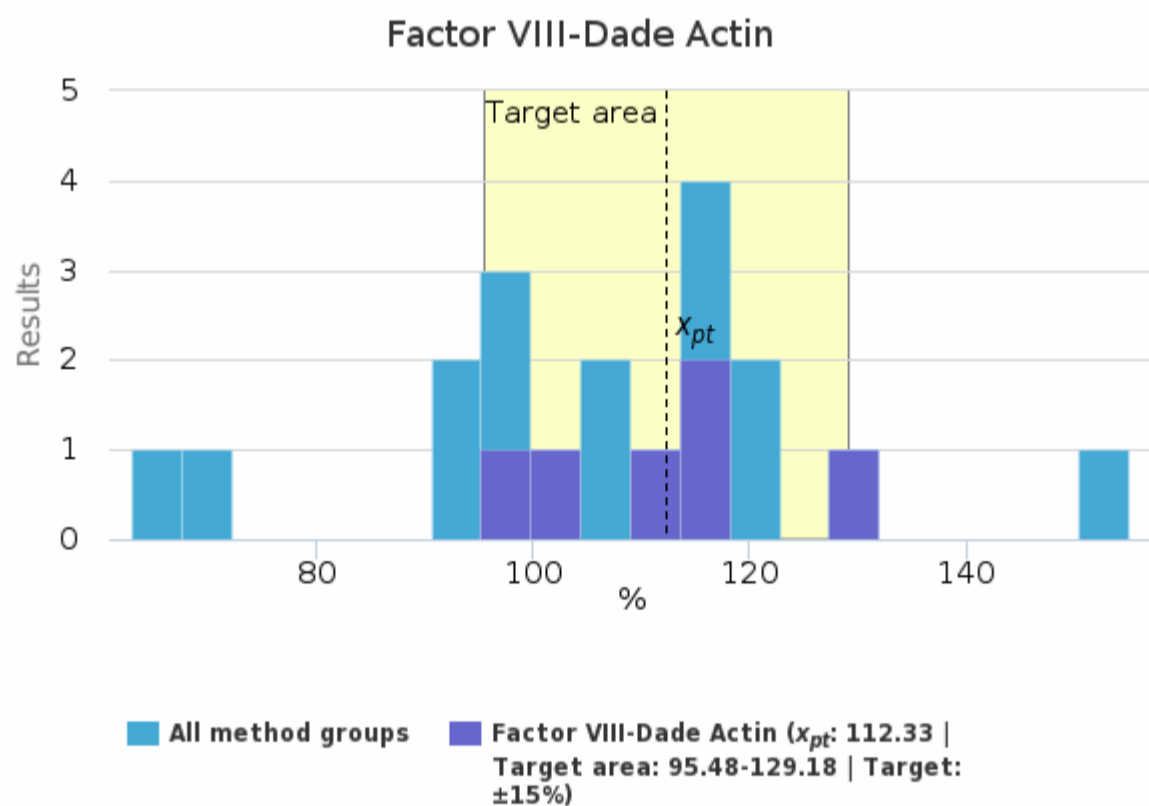
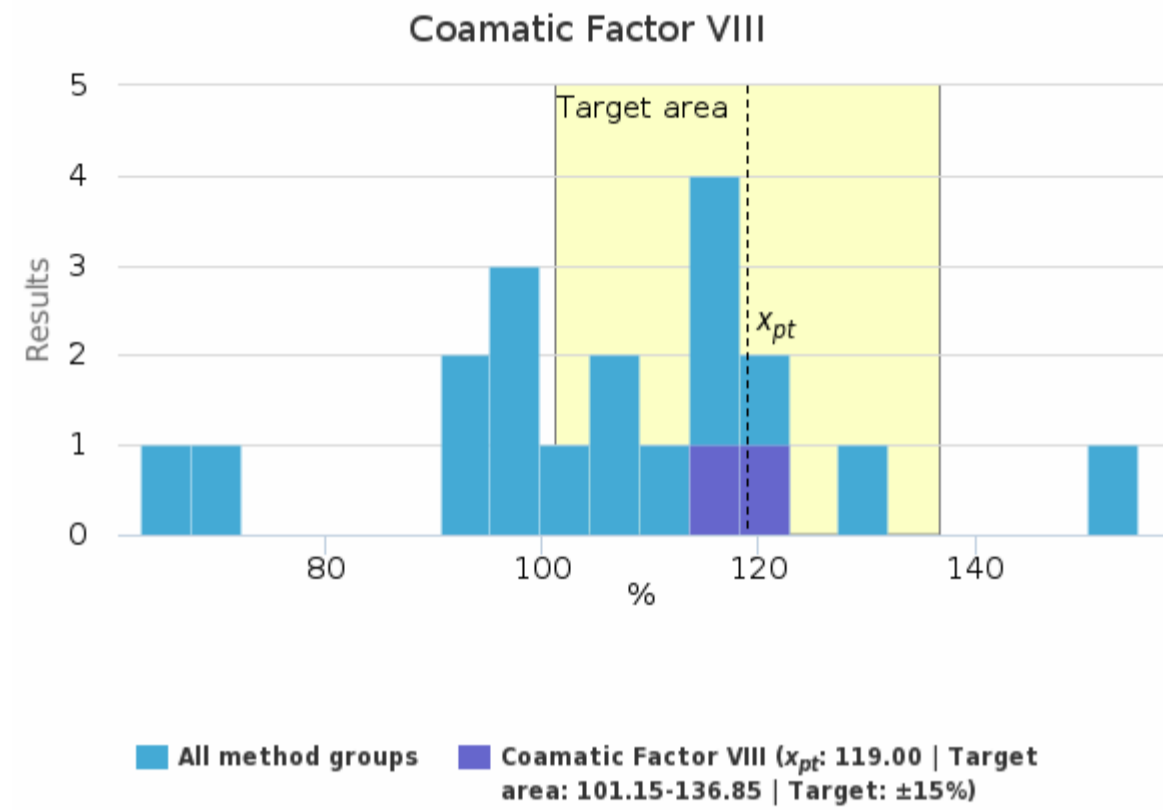
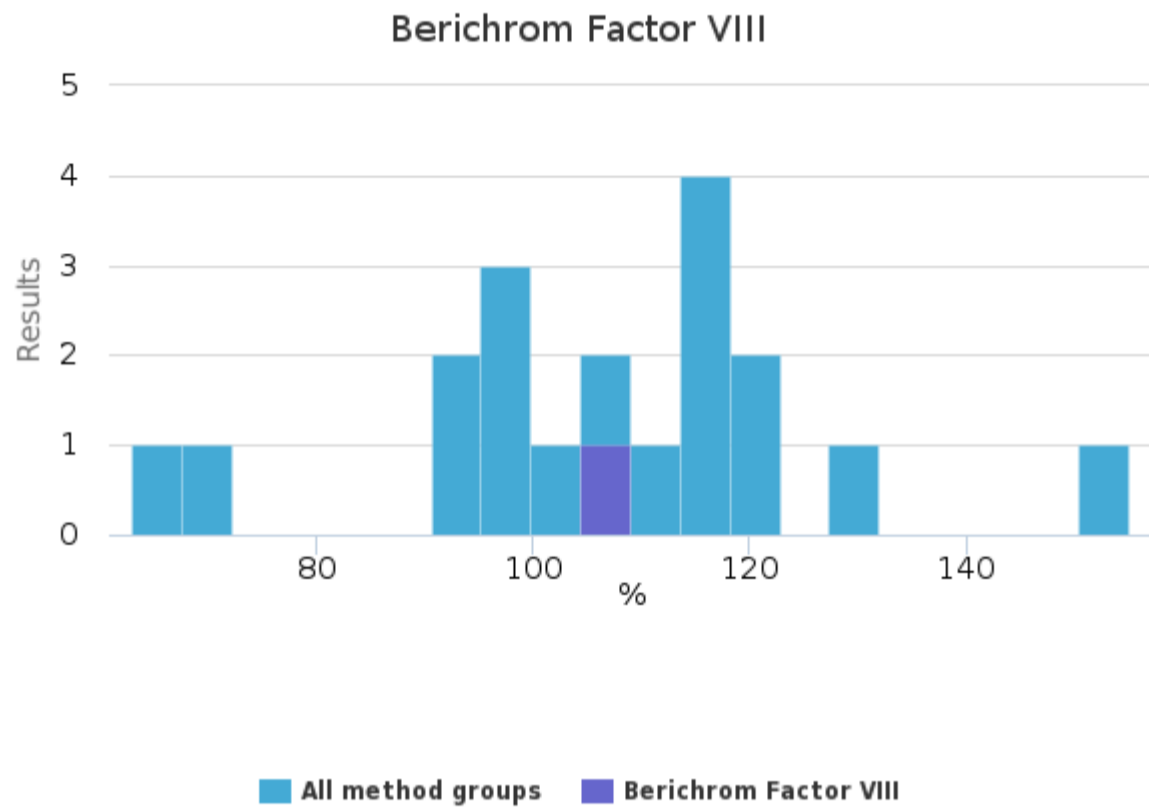
### Sample S001 | Protein S, % | histogram summaries in LabScala

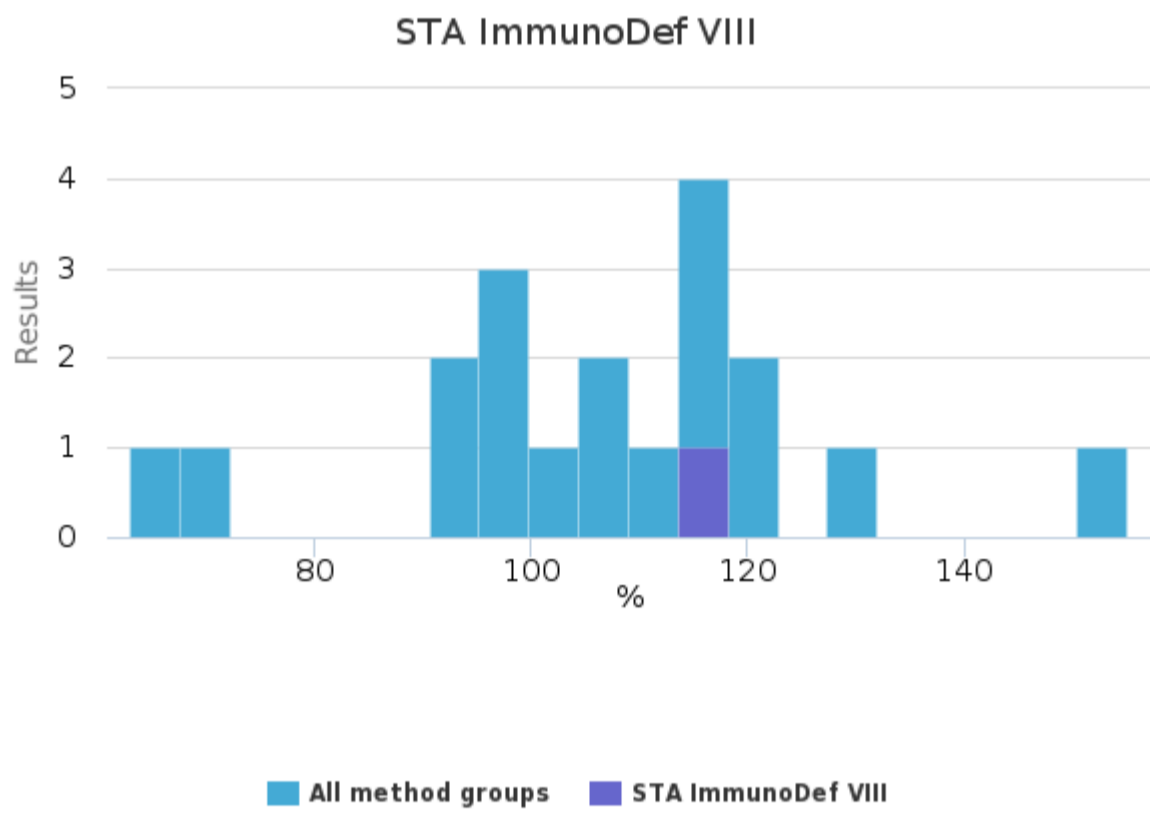
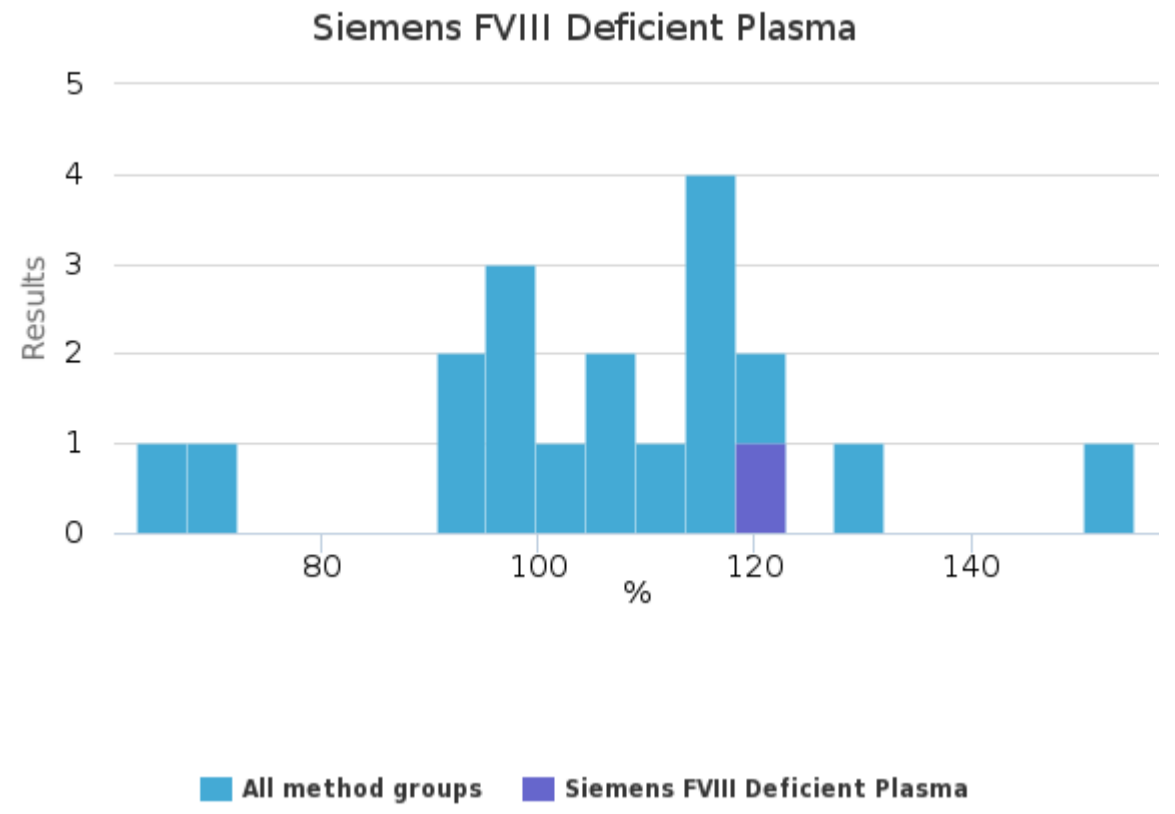
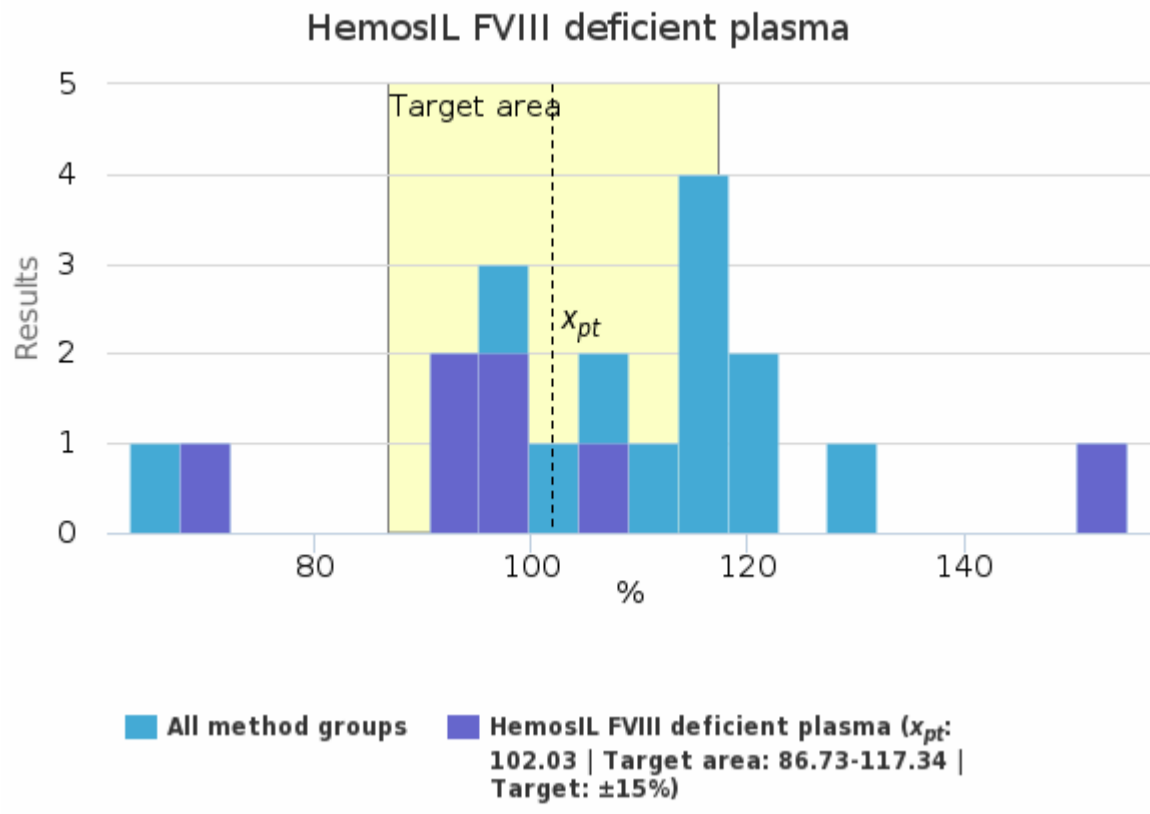


### Sample S001 | Factor VIII, %

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Berichrom Factor VIII	-	-	-	-	-	106.00	106.00	-	1
Coamatic Factor VIII	119.00	119.00	2.83	2.4	2.00	117.00	121.00	-	2
Factor VIII-Dade Actin	112.33	113.35	12.00	10.7	4.90	98.00	131.00	-	6
Factor VIII-Pathromtin SL	-	-	-	-	-	63.00	63.00	-	1
HemosIL FVIII deficient plasma	102.03	98.70	25.76	25.3	9.74	72.03	155.00	-	7
Siemens FVIII Deficient Plasma	-	-	-	-	-	121.35	121.35	-	1
STA ImmunoDef VIII	-	-	-	-	-	117.00	117.00	-	1
<b>All</b>	<b>107.03</b>	<b>107.00</b>	<b>20.53</b>	<b>19.2</b>	<b>4.71</b>	<b>63.00</b>	<b>155.00</b>	-	<b>19</b>

### Sample S001 | Factor VIII, %| histogram summaries in LabScala

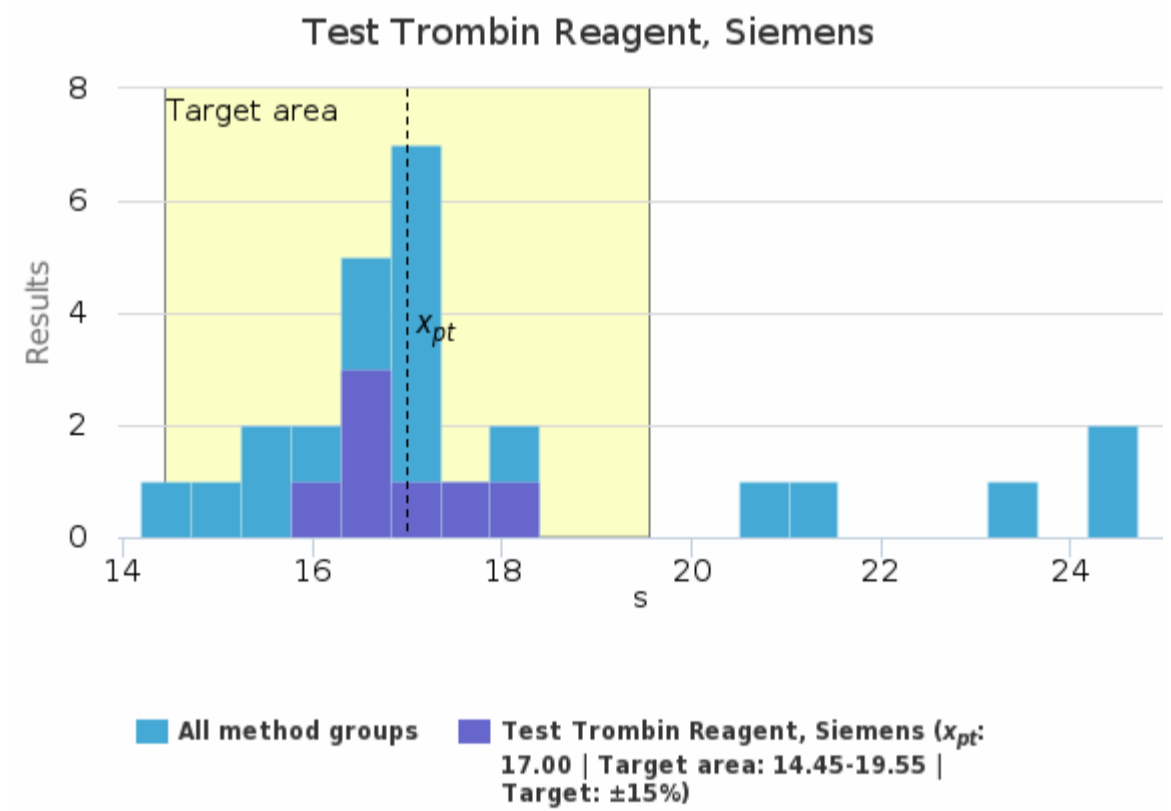
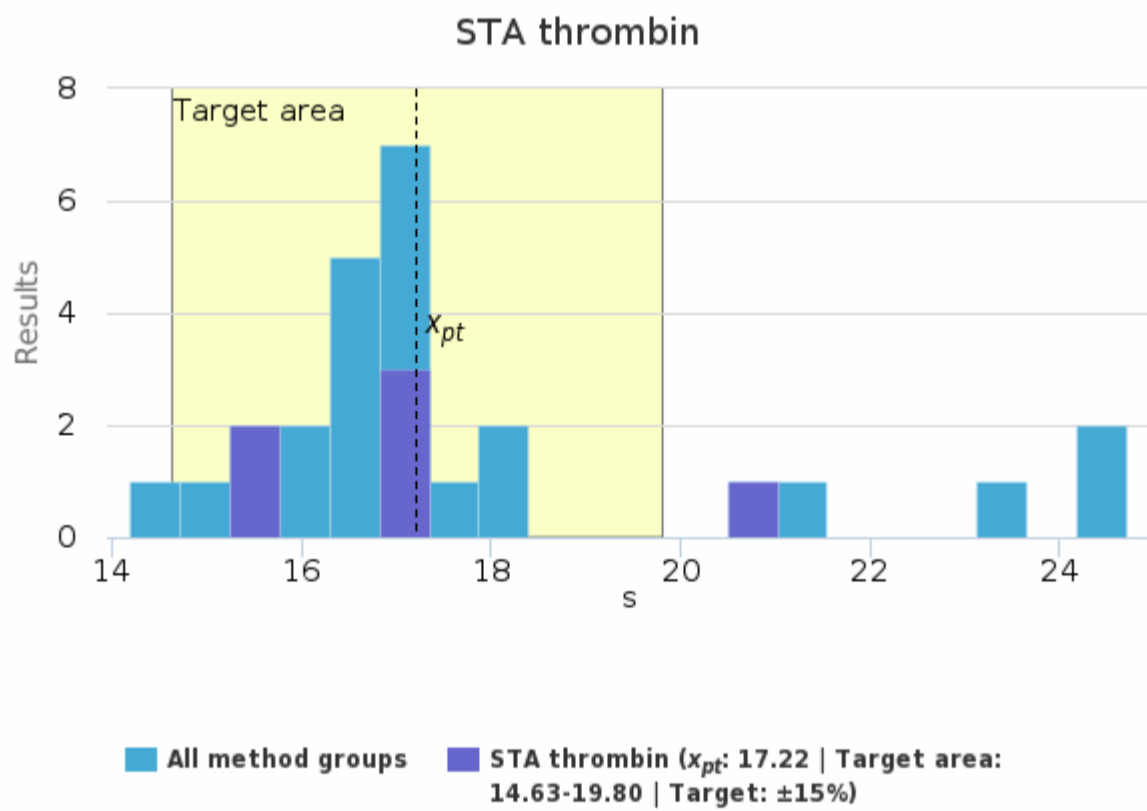
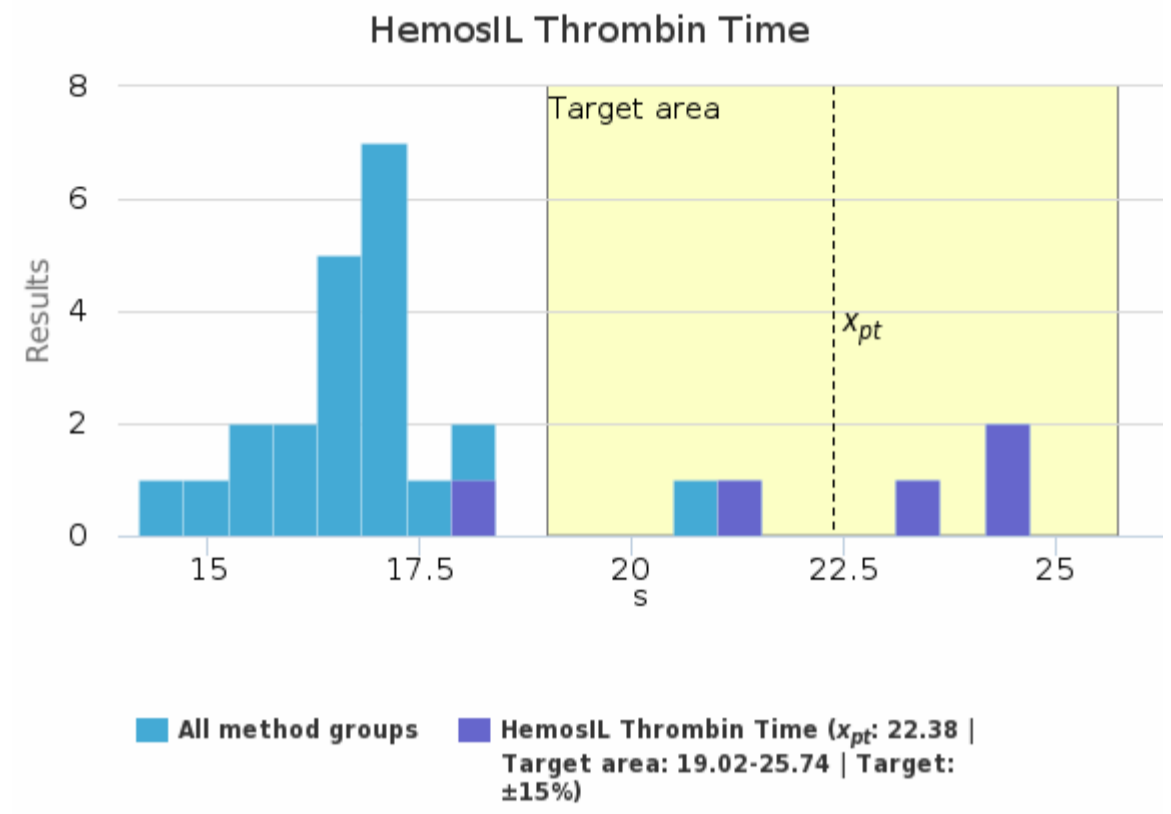
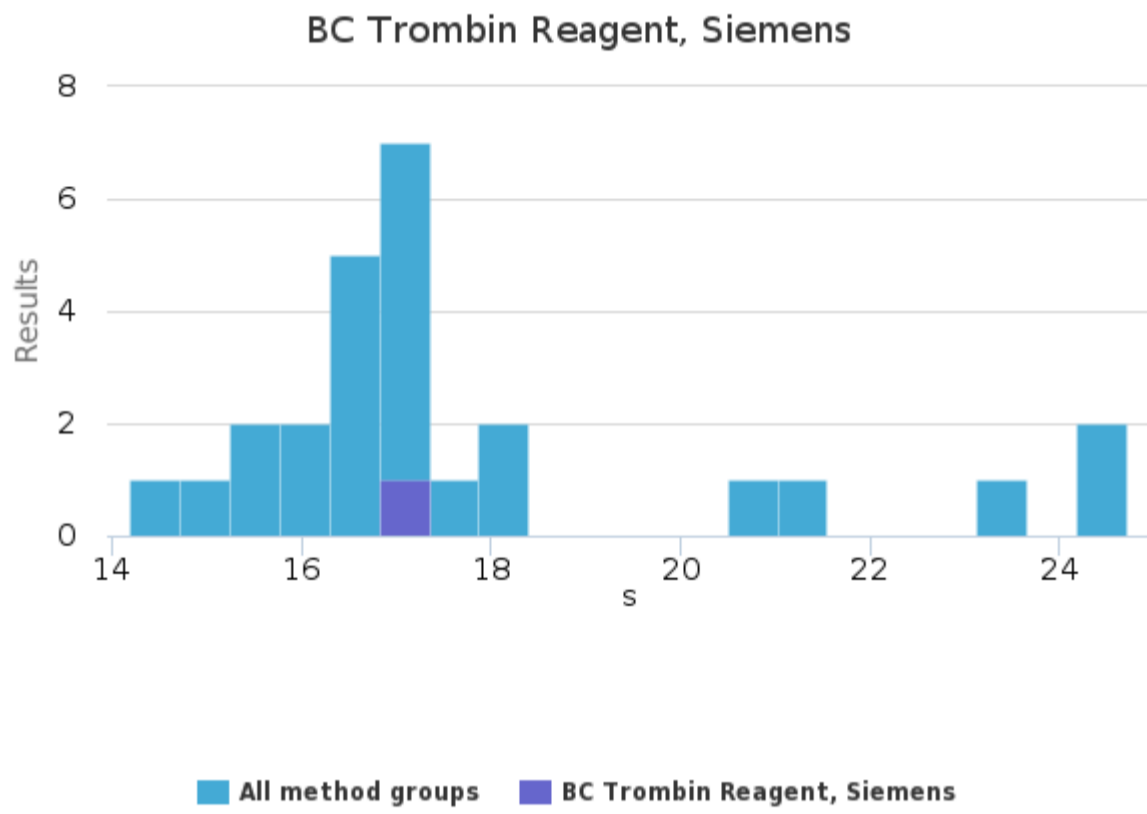


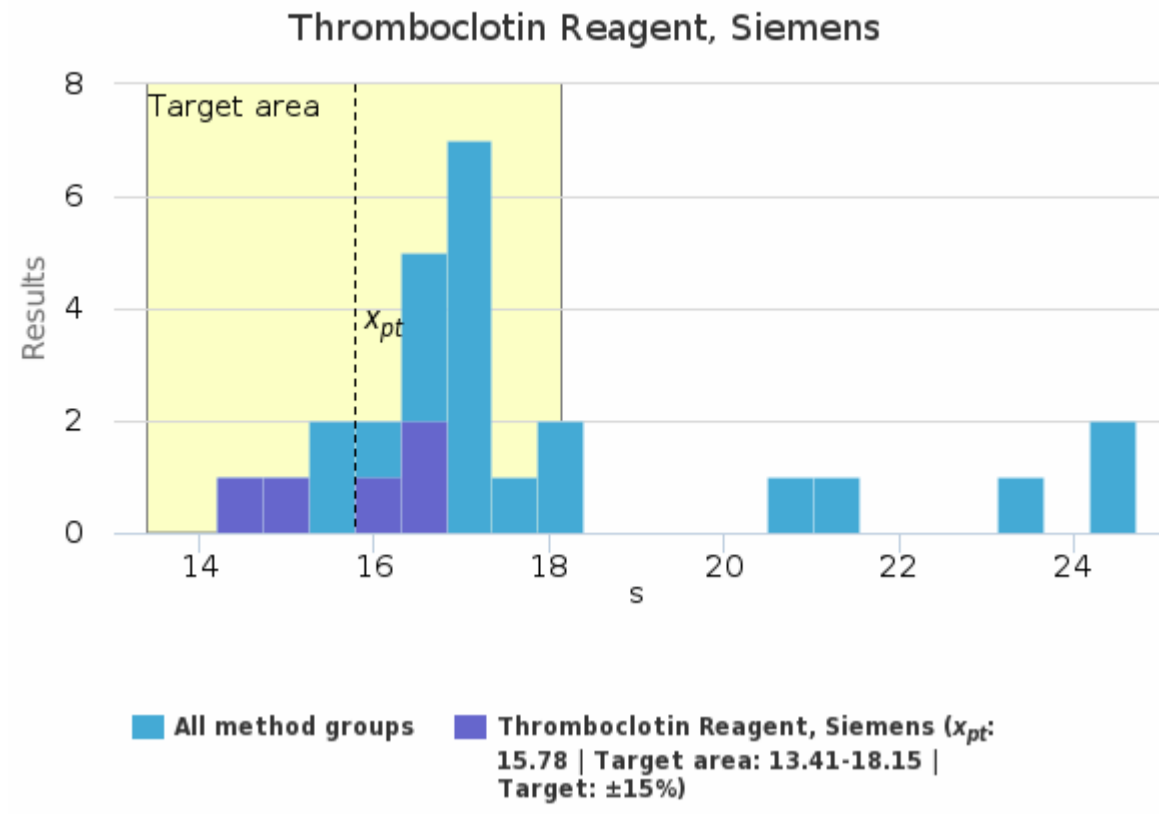
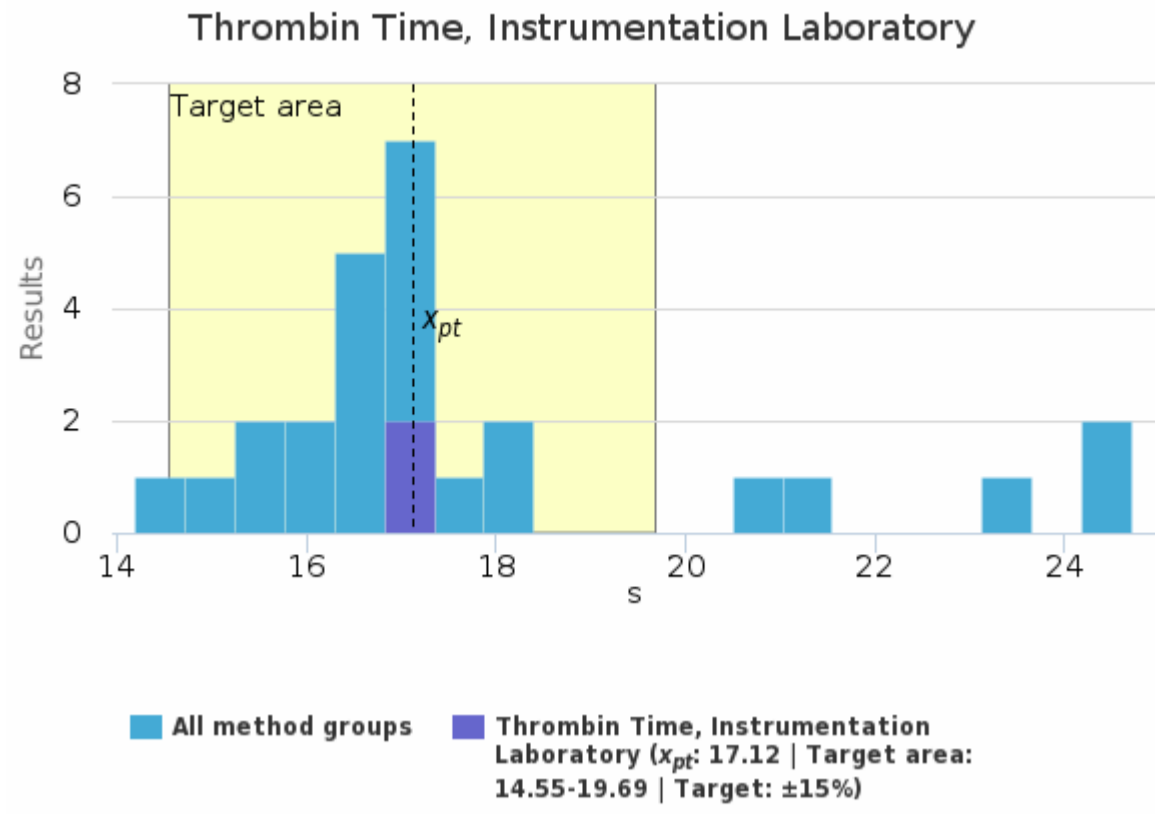


### Sample S001 | Trombin Time, s

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
BC Trombin Reagent, Siemens	-	-	-	-	-	17.20	17.20	-	1
HemosIL Thrombin Time	22.38	23.30	2.84	12.7	1.27	17.90	24.70	-	5
STA thrombin	17.22	16.95	1.97	11.4	0.80	15.60	21.00	-	6
Test Trombin Reagent, Siemens	17.00	16.70	0.78	4.6	0.30	16.10	18.30	-	7
Thrombin Time, Instrumentation Laboratory	17.12	17.12	0.17	1.0	0.12	17.00	17.24	-	2
Thromboclotin Reagent, Siemens	15.78	16.20	1.10	7.0	0.49	14.20	16.80	-	5
<b>All</b>	<b>17.87</b>	<b>17.00</b>	<b>2.78</b>	<b>15.6</b>	<b>0.55</b>	<b>14.20</b>	<b>24.70</b>	-	<b>26</b>

### Sample S001 | Trombin Time, s | histogram summaries in LabScala

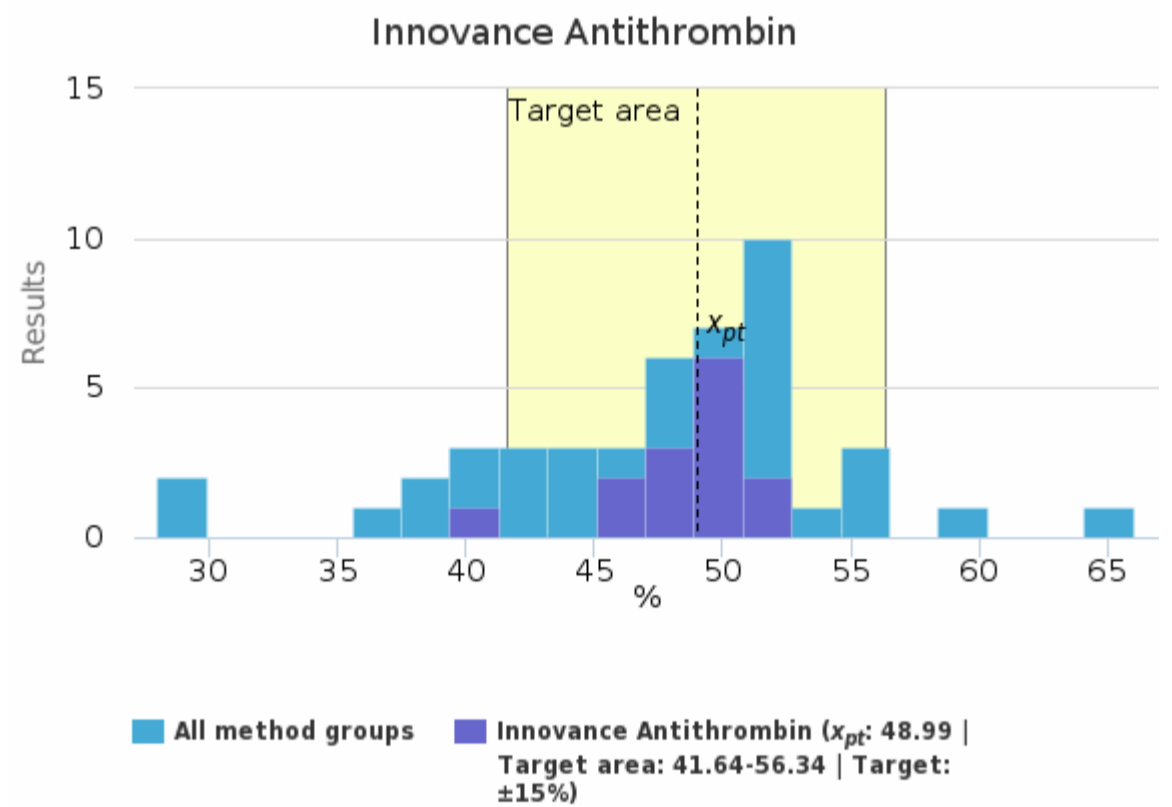
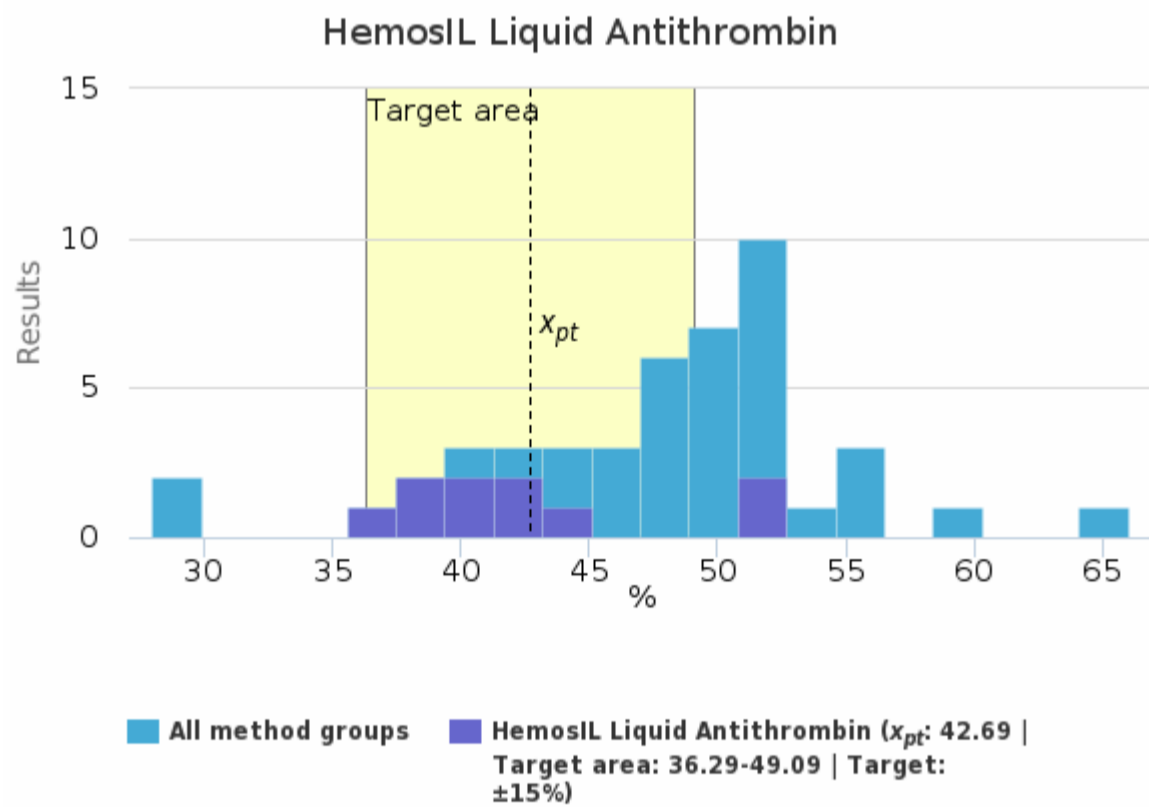
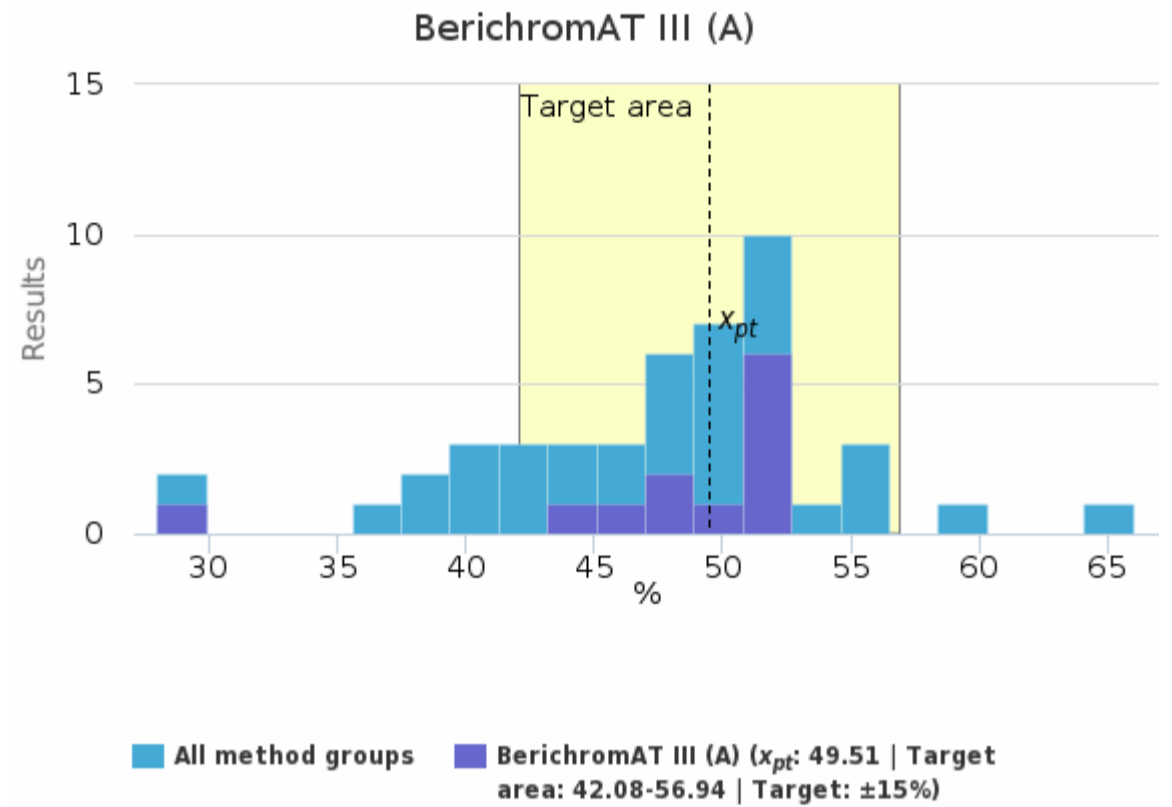
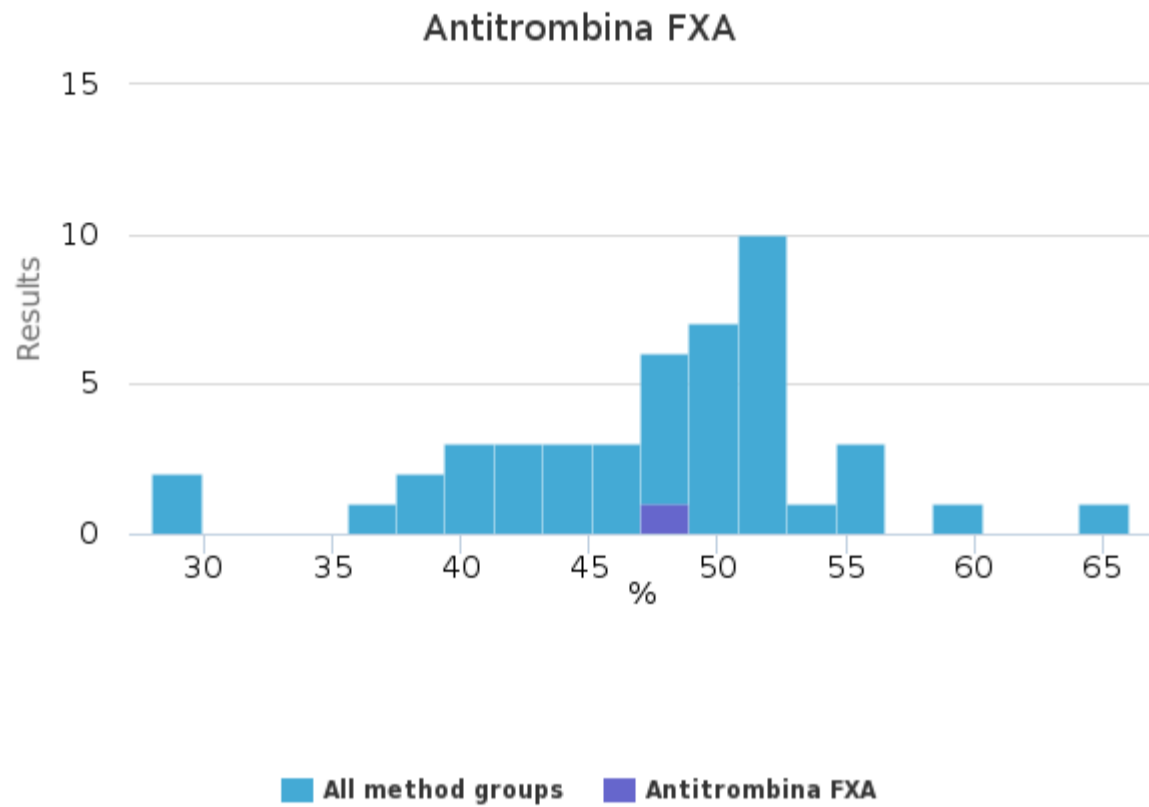


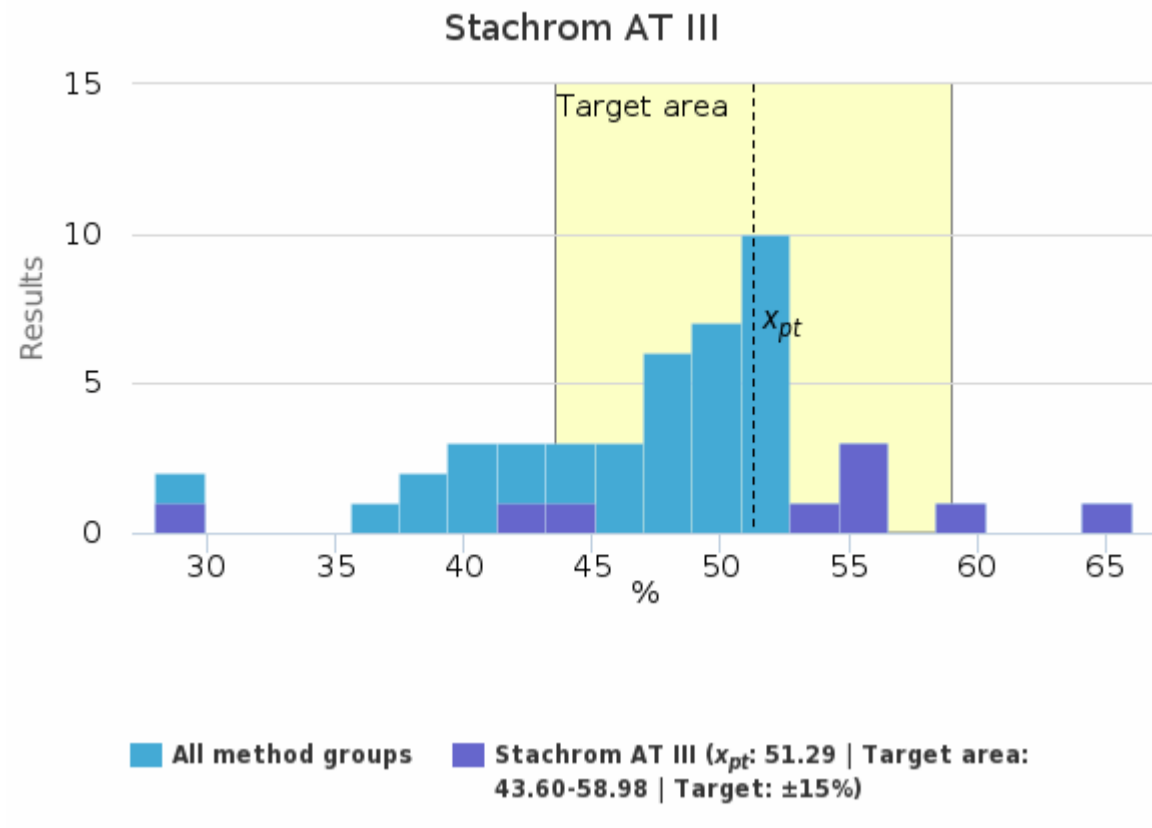


### Sample S002 | Antitrombin III, %

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Antitrombina FXA	-	-	-	-	-	48.70	48.70	-	1
BerichromAT III (A)	49.51	51.00	2.90	5.9	0.87	43.50	52.40	1	12
HemosIL Liquid Antithrombin	42.69	42.05	5.07	11.9	1.60	36.00	51.00	-	10
Innovance Antithrombin	48.99	49.00	1.48	3.0	0.41	45.90	50.90	1	14
Stachrom AT III	51.29	56.00	11.29	22.0	3.76	28.00	66.00	-	9
<b>All</b>	<b>47.53</b>	<b>48.80</b>	<b>7.03</b>	<b>14.8</b>	<b>1.04</b>	<b>28.00</b>	<b>66.00</b>	-	<b>46</b>

### Sample S002 | Antitrombin III, % | histogram summaries in LabScala

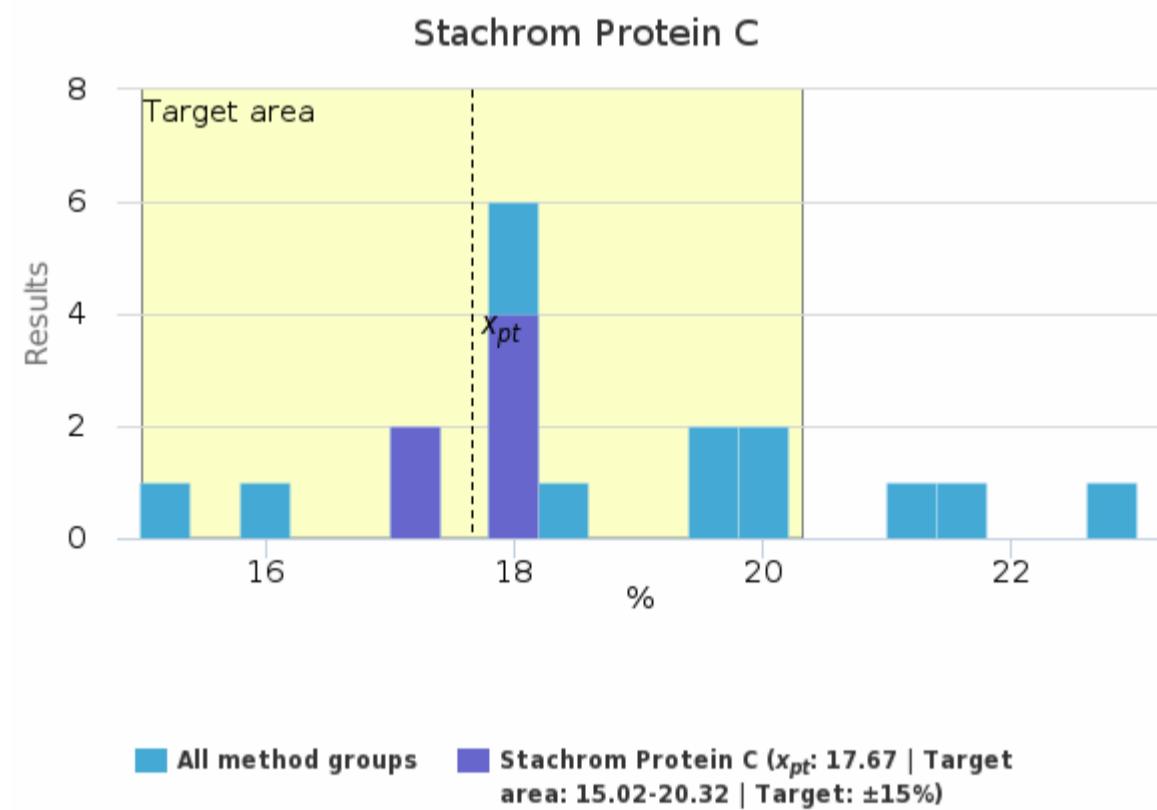
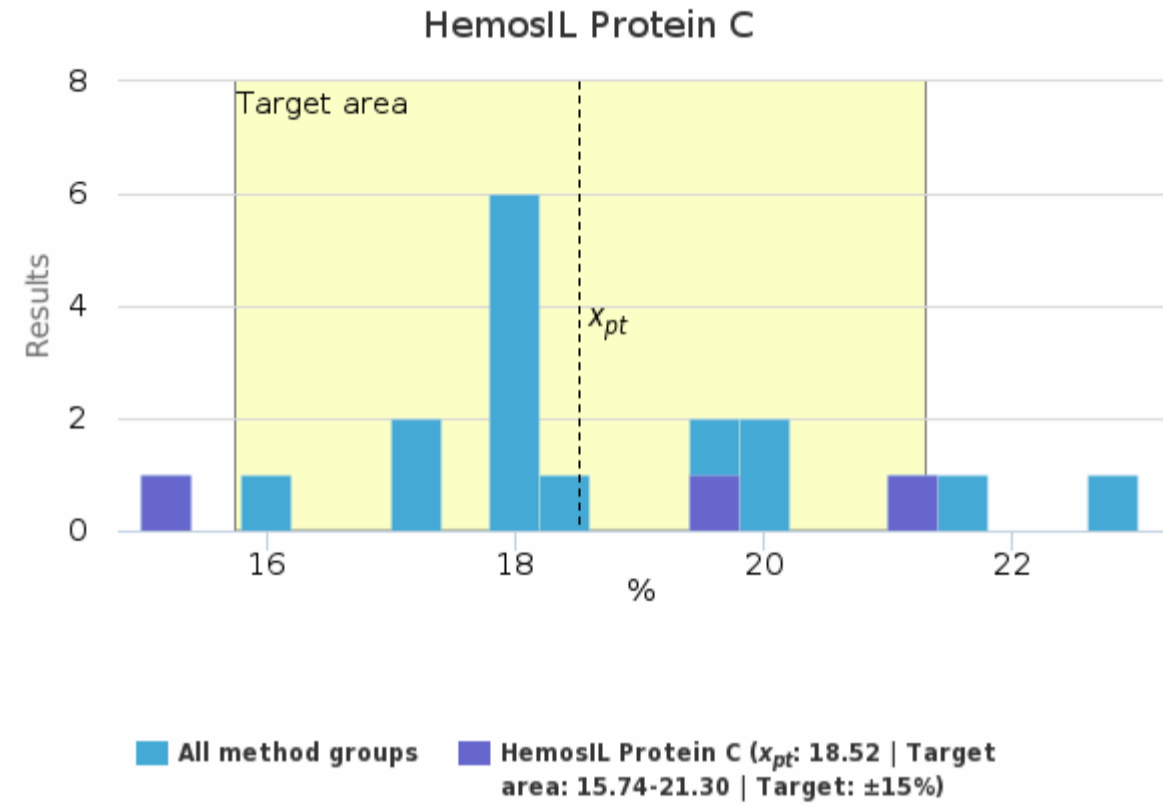
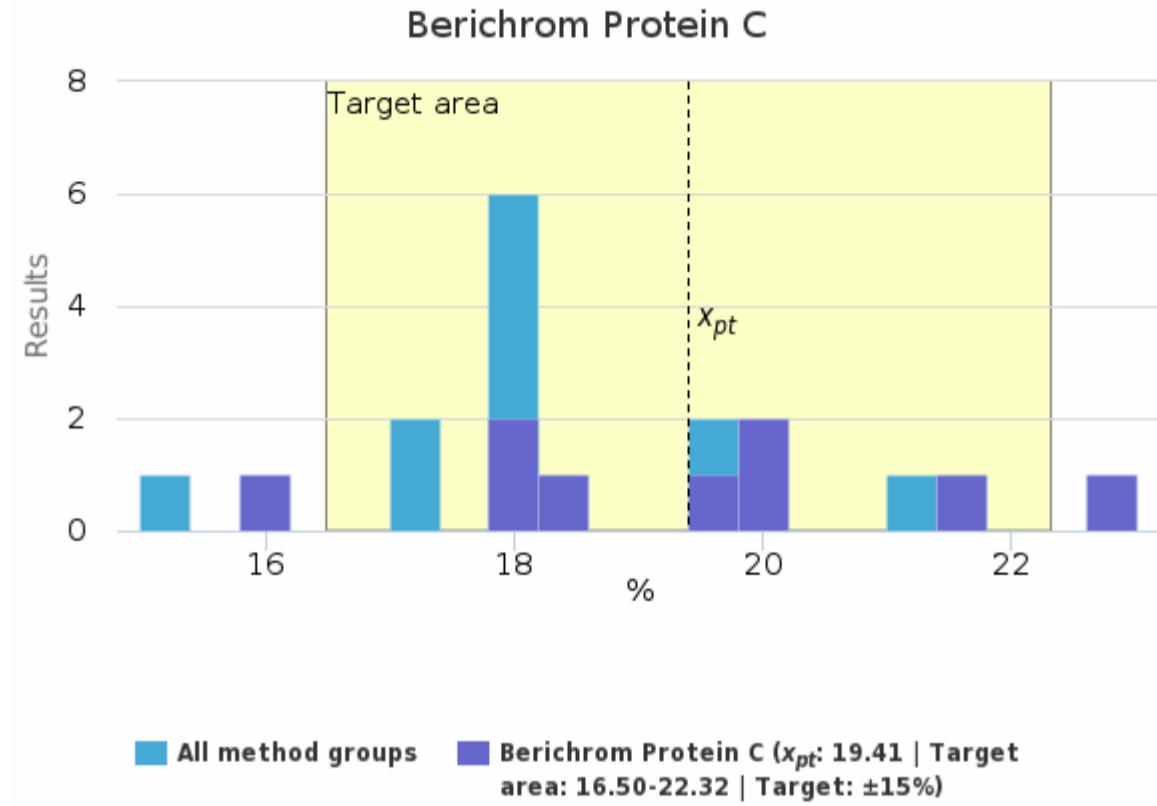




### Sample S002 | Protein C, %

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Berichrom Protein C	19.41	19.50	2.10	10.8	0.70	16.00	23.00	-	9
HemosIL Protein C	18.52	19.57	3.13	16.9	1.81	15.00	21.00	-	3
Stachrom Protein C	17.67	18.00	0.52	2.9	0.21	17.00	18.00	-	6
<b>All</b>	<b>18.68</b>	<b>18.09</b>	<b>1.99</b>	<b>10.6</b>	<b>0.47</b>	<b>15.00</b>	<b>23.00</b>	-	<b>18</b>

### Sample S002 | Protein C, % | histogram summaries in LabScala

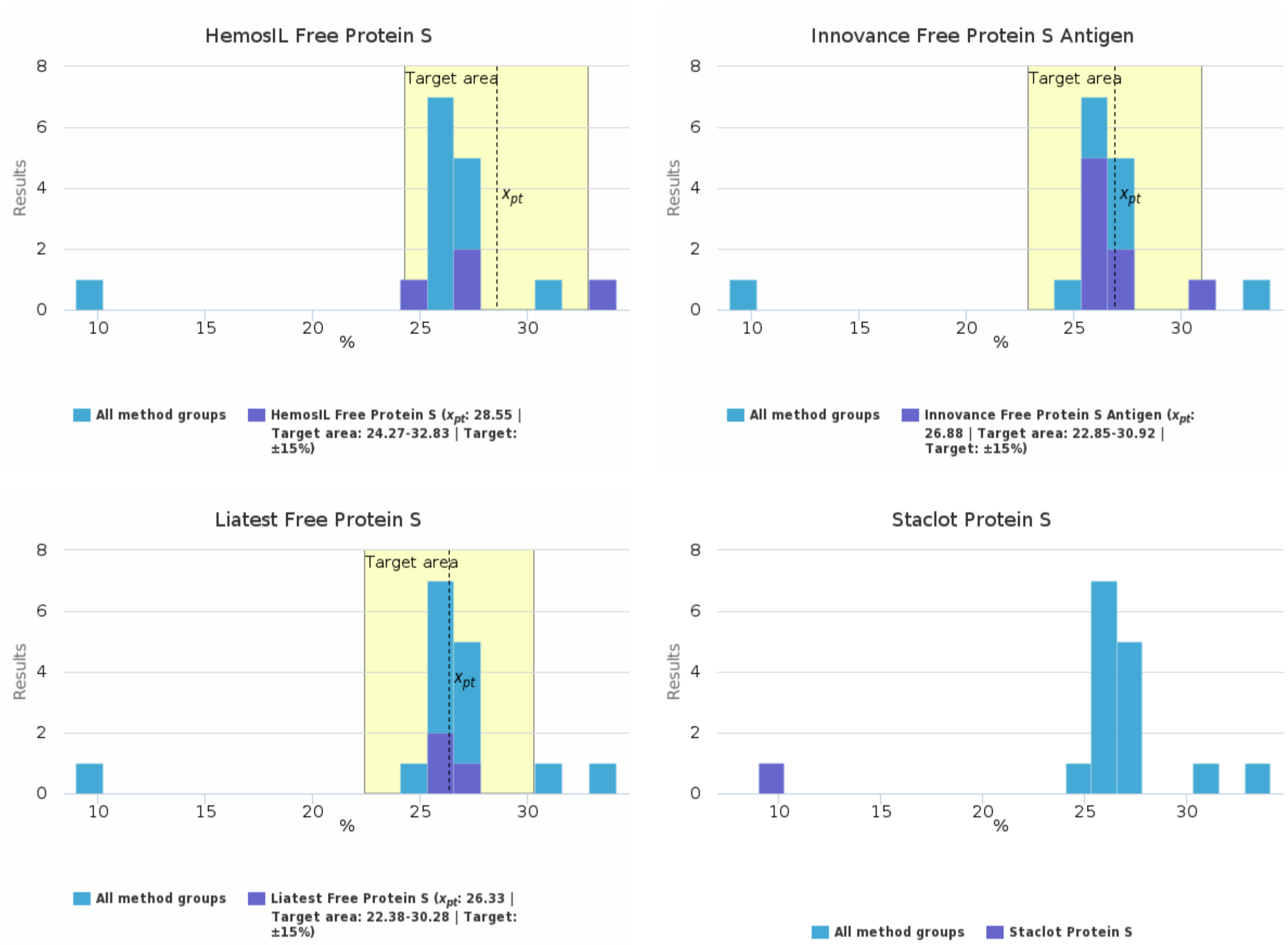




### Sample S002 | Protein S, %

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
HemosIL Free Protein S	28.55	27.55	3.90	13.6	1.95	25.00	34.10	-	4
Innovance Free Protein S Antigen	26.88	26.15	1.76	6.5	0.62	25.70	31.07	-	8
Liatest Free Protein S	26.33	26.00	0.58	2.2	0.33	26.00	27.00	-	3
Staclot Protein S	-	-	-	-	-	9.00	9.00	-	1
<b>All</b>	<b>27.22</b>	<b>26.30</b>	<b>2.36</b>	<b>8.7</b>	<b>0.61</b>	<b>25.00</b>	<b>34.10</b>	<b>1</b>	<b>16</b>

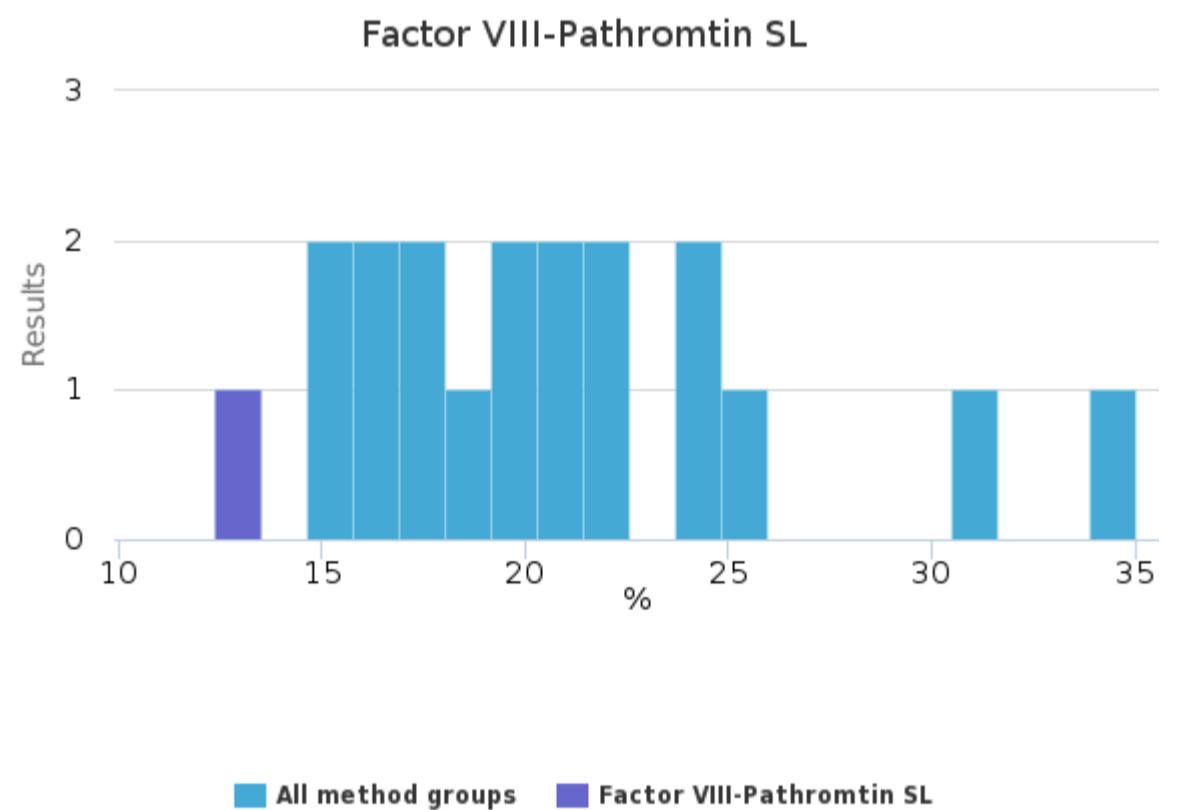
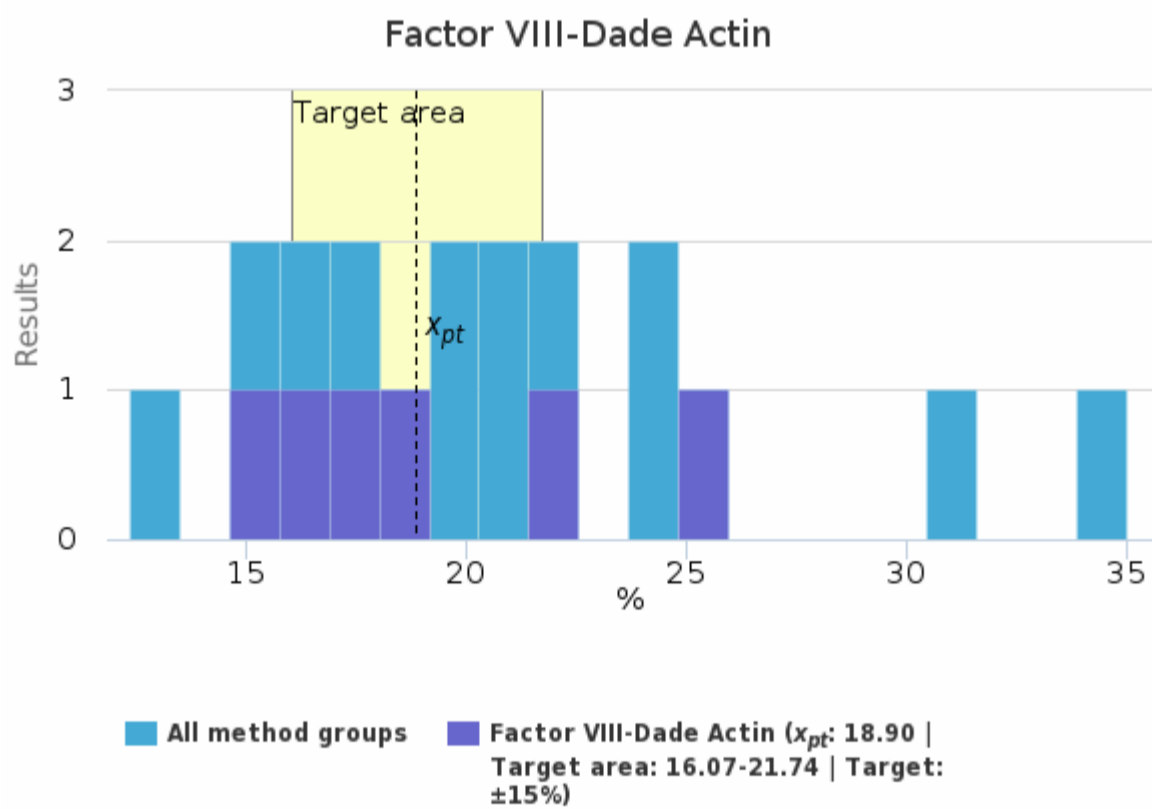
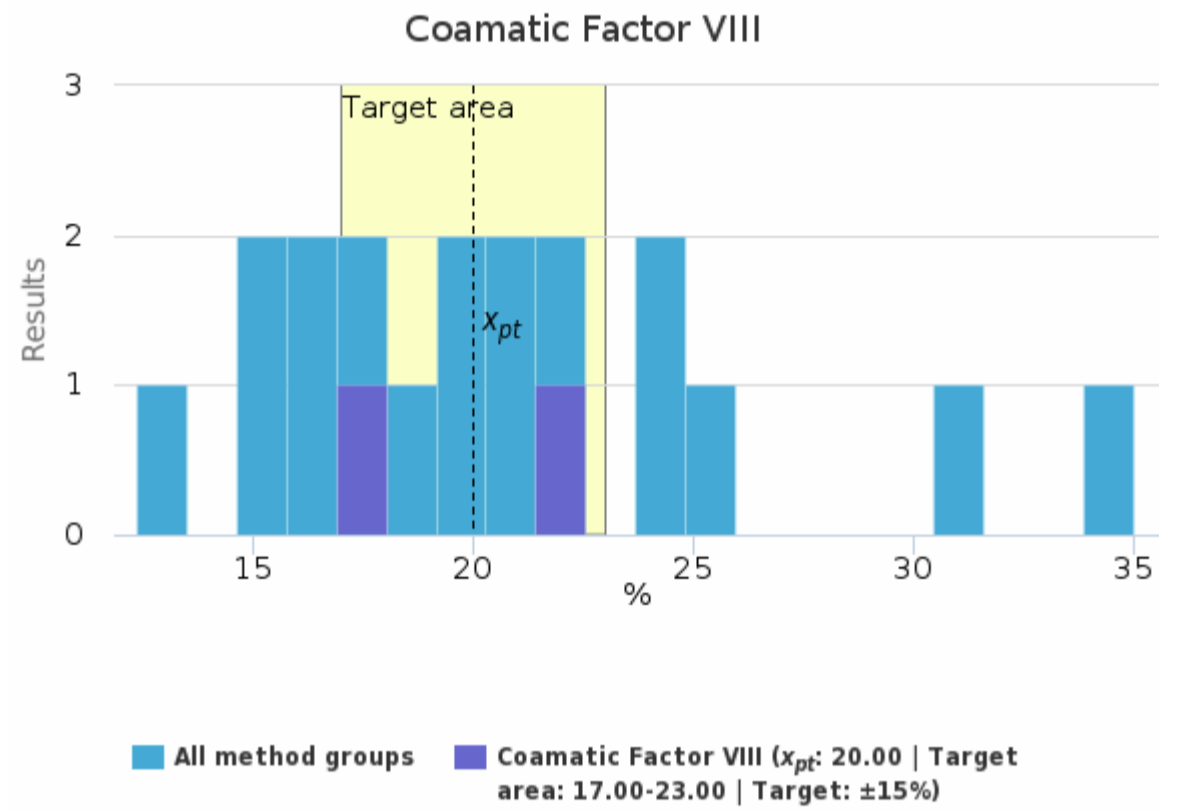
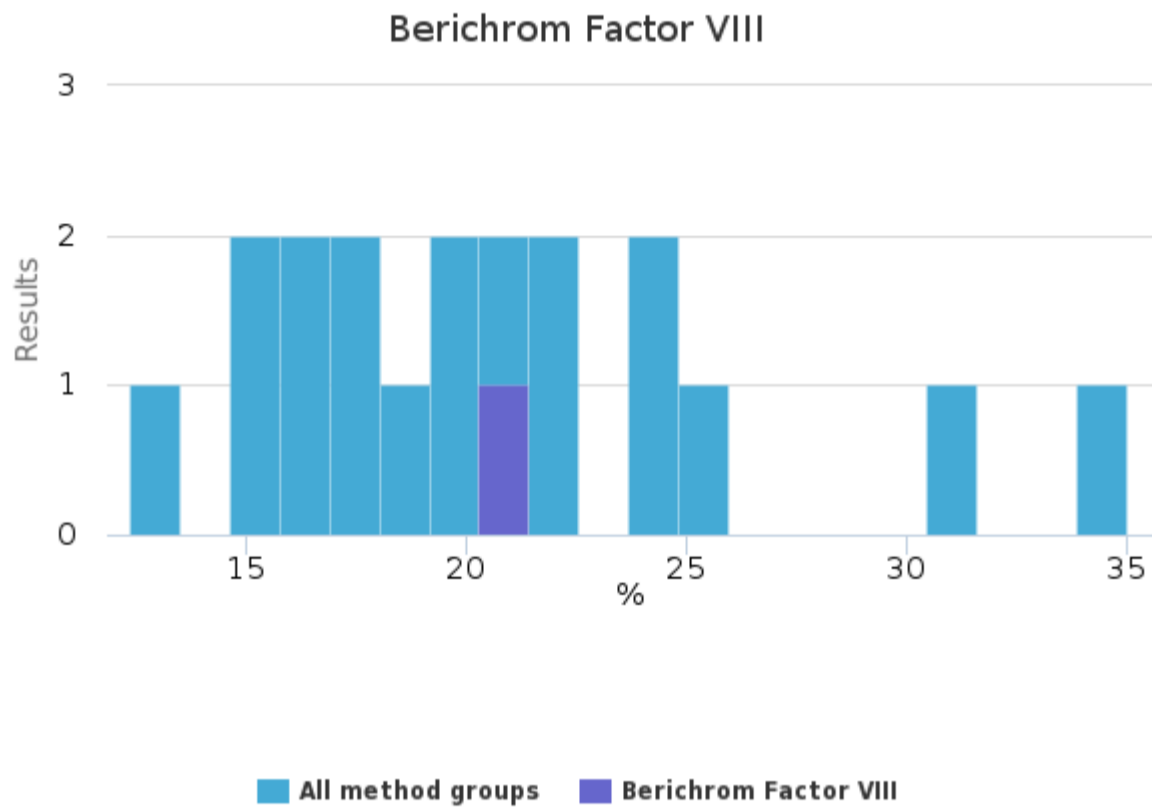
### Sample S002 | Protein S, % | histogram summaries in LabScala

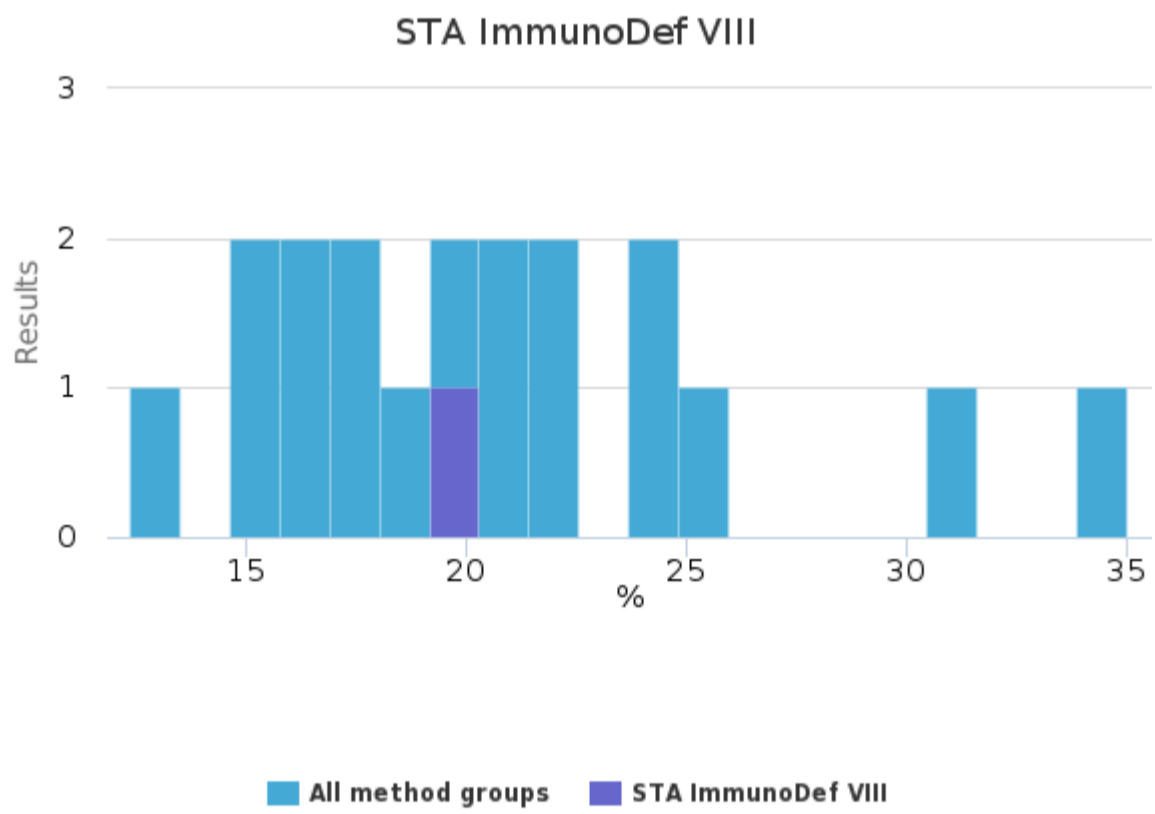
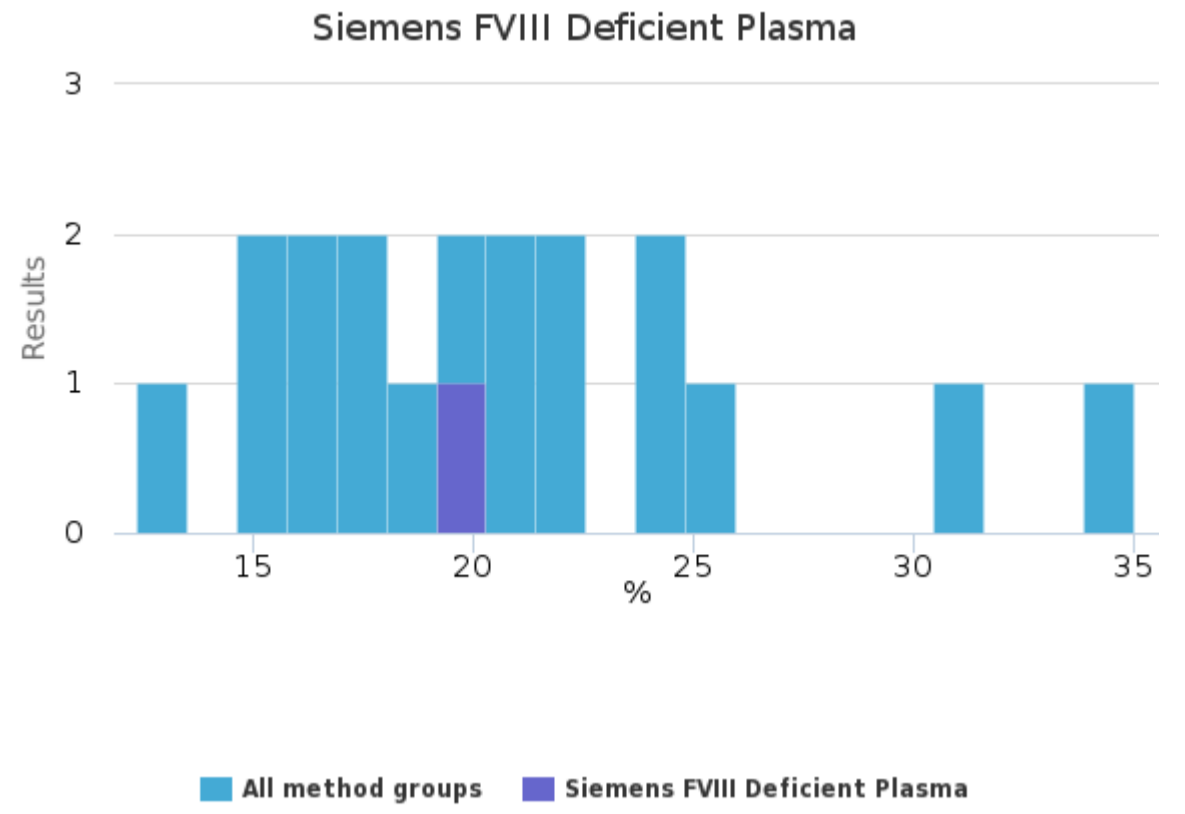
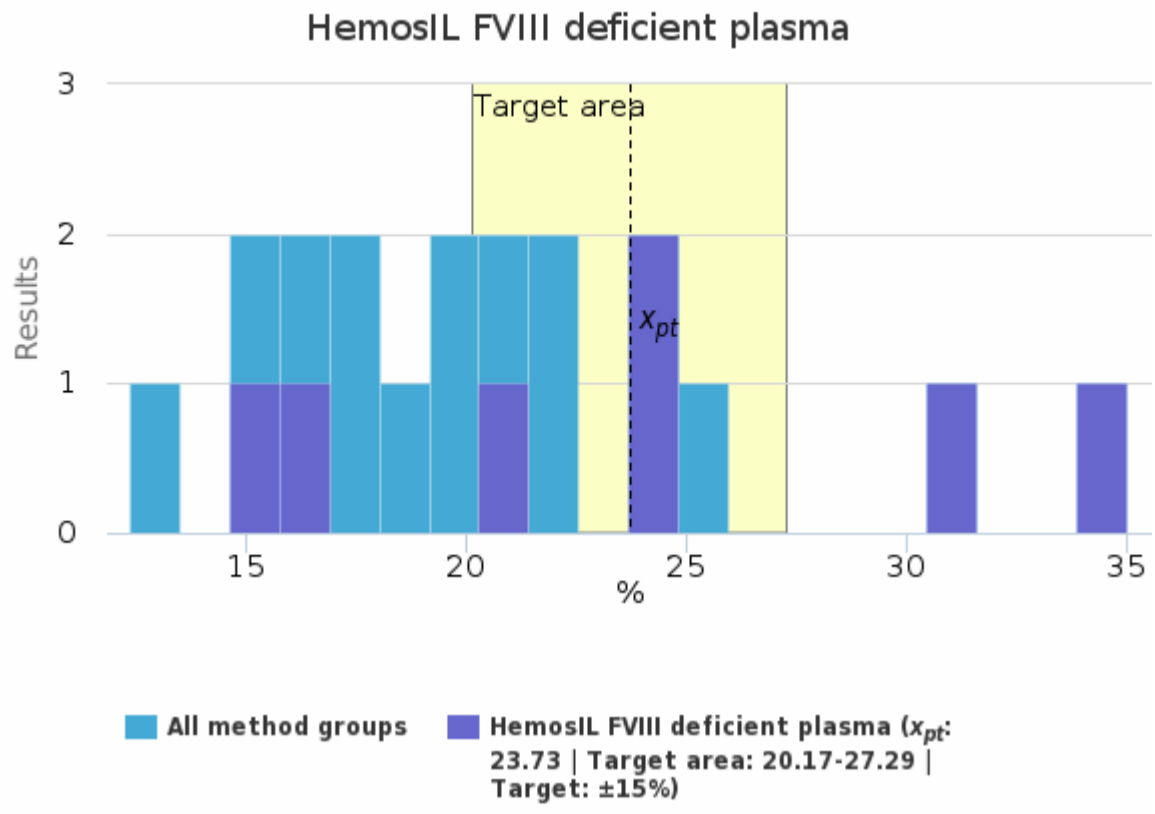


### Sample S002 | Factor VIII, %

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
Berichrom Factor VIII	-	-	-	-	-	21.00	21.00	-	1
Coamatic Factor VIII	20.00	20.00	2.83	14.1	2.00	18.00	22.00	-	2
Factor VIII-Dade Actin	18.90	17.70	3.85	20.4	1.57	15.00	25.00	-	6
Factor VIII-Pathromtin SL	-	-	-	-	-	12.40	12.40	-	1
HemosIL FVIII deficient plasma	23.73	23.90	7.30	30.7	2.76	15.01	35.00	-	7
Siemens FVIII Deficient Plasma	-	-	-	-	-	19.41	19.41	-	1
STA ImmunoDef VIII	-	-	-	-	-	20.00	20.00	-	1
<b>All</b>	<b>20.65</b>	<b>20.00</b>	<b>5.57</b>	<b>27.0</b>	<b>1.28</b>	<b>12.40</b>	<b>35.00</b>	-	<b>19</b>

### Sample S002 | Factor VIII, % | histogram summaries in LabScala

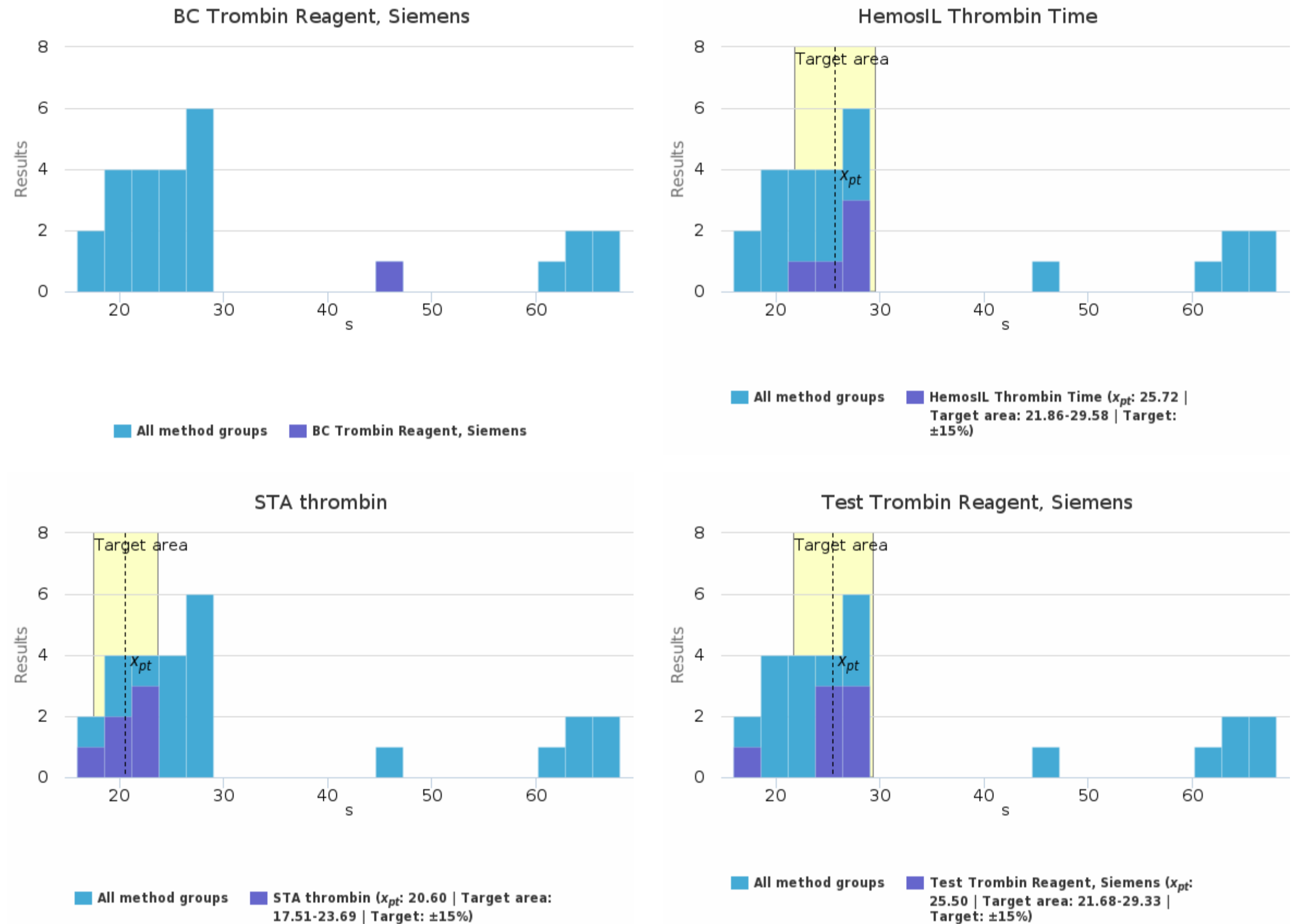


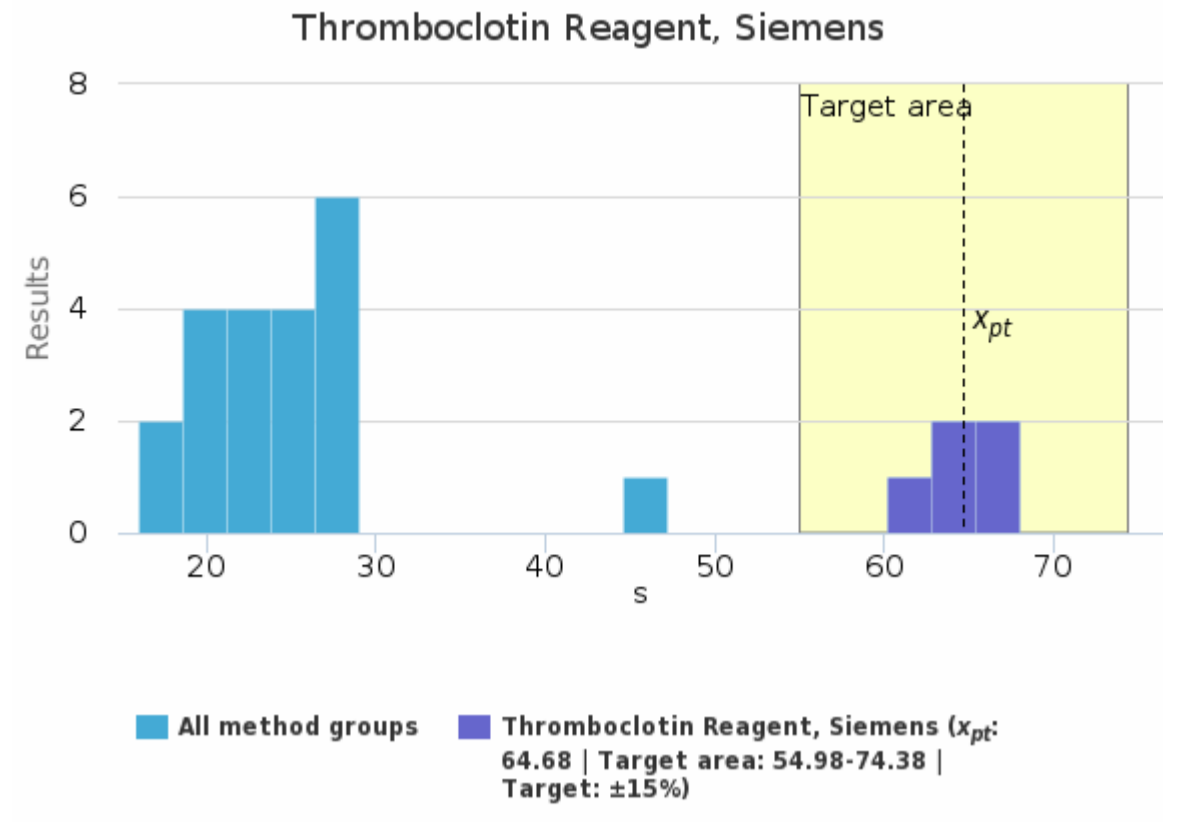
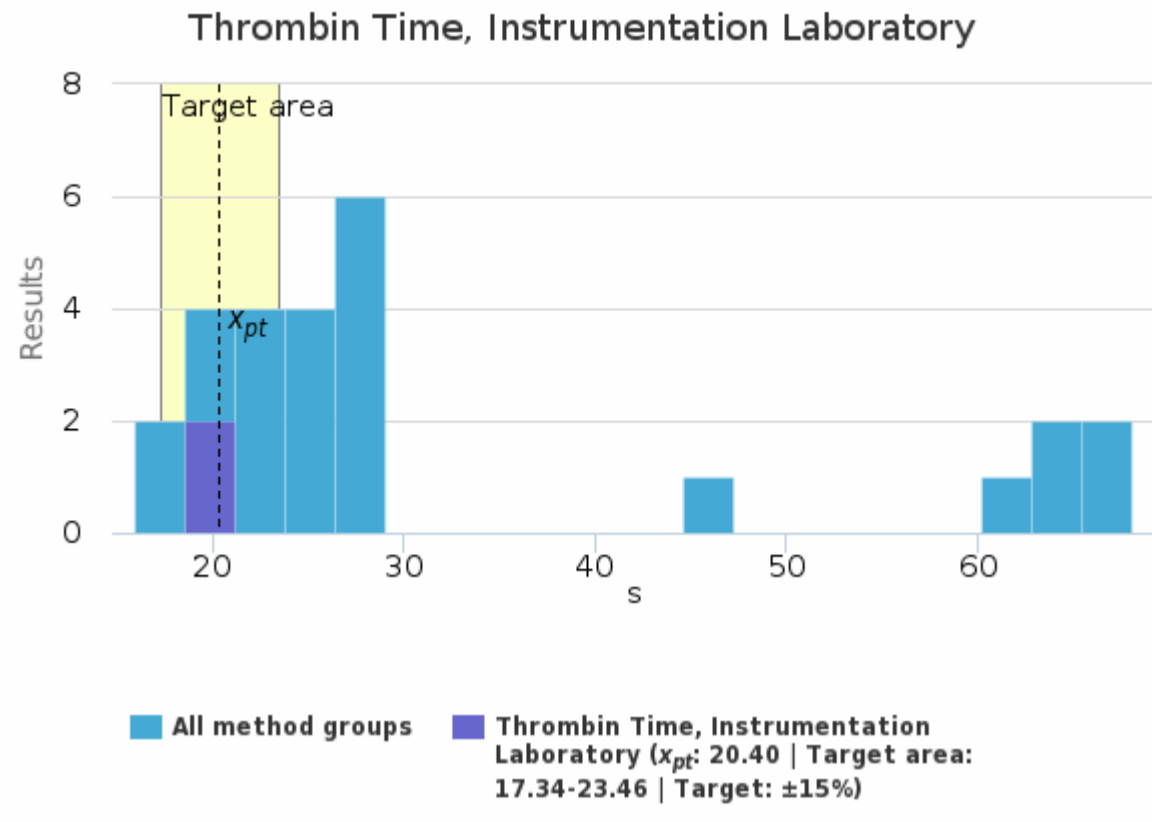


### Sample S002 | Trombin Time, s

Methodics	$x_{pt}$	Median	sd	CV%	SEM	min	max	Outliers	n
BC Trombin Reagent, Siemens	-	-	-	-	-	45.70	45.70	-	1
HemosIL Thrombin Time	25.72	26.60	2.62	10.2	1.17	21.80	28.00	-	5
STA thrombin	20.60	21.25	2.34	11.4	0.96	16.00	22.40	-	6
Test Trombin Reagent, Siemens	25.50	26.20	3.49	13.7	1.32	18.10	28.60	-	7
Thrombin Time, Instrumentation Laboratory	20.40	20.40	0.14	0.7	0.10	20.30	20.50	-	2
Thromboclotin Reagent, Siemens	64.68	63.50	2.72	4.2	1.22	61.50	68.00	-	5
<b>All</b>	<b>32.33</b>	<b>25.90</b>	<b>17.00</b>	<b>52.6</b>	<b>3.33</b>	<b>16.00</b>	<b>68.00</b>	-	<b>26</b>

### Sample S002 | Trombin Time, s | histogram summaries in LabScala





**Report info****Participants**

42 participants from 12 countries.

**Report info**

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

Assigned values ( $x_p$ , target values) are means of the results where results deviating more than  $\pm 3$  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 "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

External Quality Assessment Scheme

## Special coagulation Round 1, 2023

### Specimens

Sample S001 (LQ708523011) and sample S002 (LQ708523012) were lyophilized plasma 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 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

One customer had clearly mixed up the samples, these results have been removed from the calculation.

### Antithrombin III

The results of sample S001 were consistent within the method groups, except for a few outliers. For those using the Stachrom AT III reagent, the dispersion in the results of sample S002 was large (CV% 22%).

### Protein C

Round went well and almost all results were within the target range.

### Protein S

Almost all results were within the target range. With Staclot Protein S reagent, the results of sample S002 were lower than with other reagents.

### Factor VIII

With the HemosIL FVIII deficient plasma reagent, the dispersion of the results of both samples was high (CV% sample S001: 25.3% and sample S002: 30.7%). Also in the Factor VIII-Dade Actin method group, there was a lot of dispersion in the results of sample S002.

### Thrombin time

The results were uniform within the method groups, but between the method groups there was variation in the result level.

### End of report

2023-02-23

### FINAL REPORT

Product no. 4386

Samples sent	2023-02-06
Round closed	2023-02-21
Final report	2023-02-23

### 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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