LABQUALITY

External Quality Assessment Scheme

Prothrombin time
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
Prothrombin time (%)
Prothrombin time INR

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 at least 15 minutes at room temperature before mixing. Mix the samples by inverting the tubes gently 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

LQ708223011

S002

LQ708223012

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

Quality Management
DQS
ISO 9001:2015

Thromboplastin time INR |ACL TOP 500 (A)

SpecimenS001, Thromboplastin time INR

The uncertainty of the assigned value is not negligible, and evaluations could be affected.
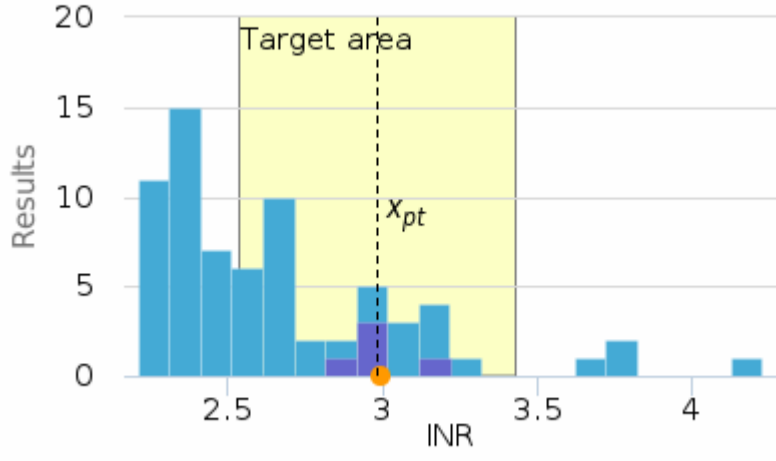
- ■ All method groups   ■ RecombiPlastin 2G
- ● Own result: 2.99 (19.02.2023)
- Diff%: 0.20 | x_{pt}: 2.98
- Target area: 2.54-3.43 | Target: ±15%

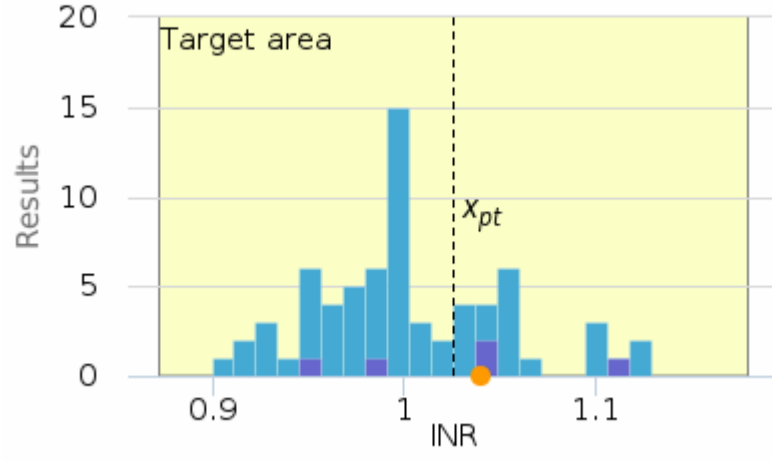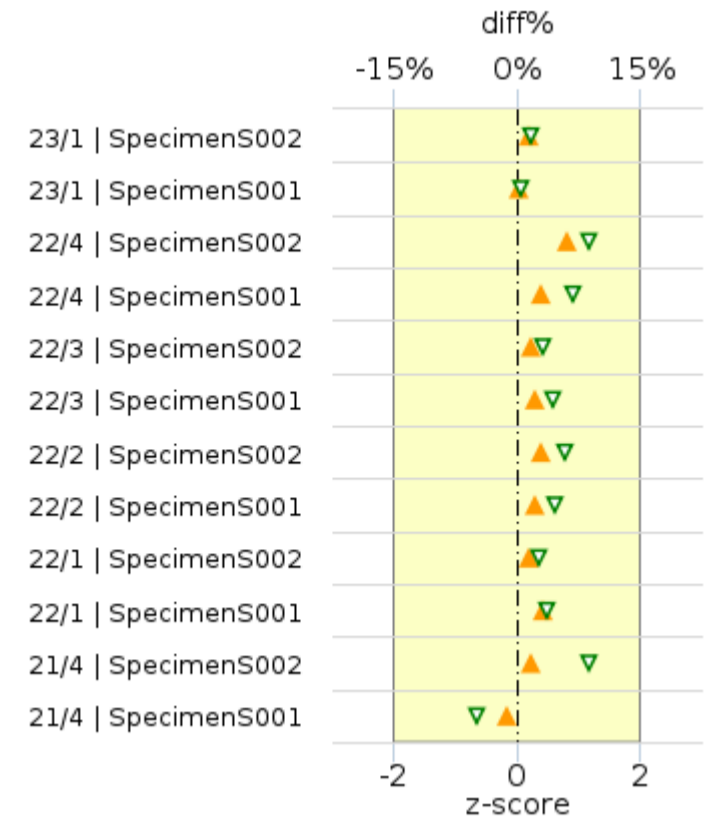### SpecimenS002, Thromboplastin time INR

The uncertainty of the assigned value is not negligible, and evaluations could be affected.
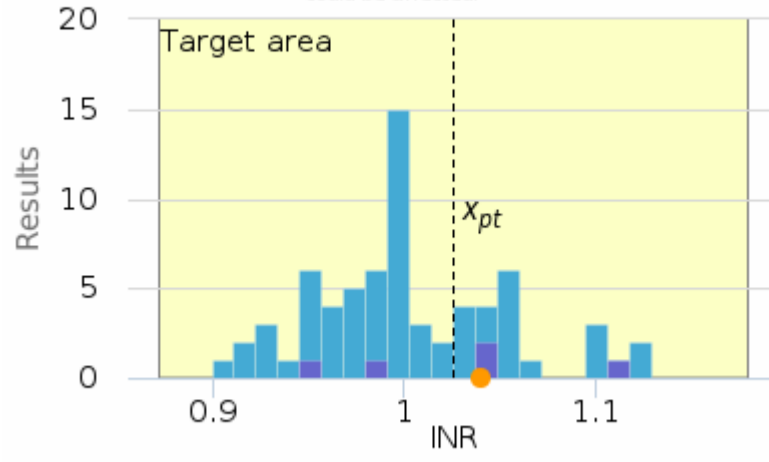
- ■ All method groups   ■ RecombiPlastin 2G
- ● Own result: 1.04 (19.02.2023)
- Diff%: 1.36 | x_{pt}: 1.03
- Target area: 0.87-1.18 | Target: ±15%

History

- ▲ diff%
- ▽ Z-score is uncertain due to the small number of observations

	x_{pt}	sd	SEM	CV%	n
RecombiPlastin 2G	2.98 INR	0.12	0.06	4.1	5
All methods	2.61 INR	0.31	0.04	12.0	70

	x_{pt}	sd	SEM	CV%	n
RecombiPlastin 2G	1.03 INR	0.06	0.03	5.9	5
All methods	1.00 INR	0.05	<0.01	5.0	69

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Specimen S002	1.03	1.04	1.36%	0.23
23/1	Specimen S001	2.98	2.99	0.20%	0.05
22/4	Specimen S002	3.02	3.20	5.96%	1.17
22/4	Specimen S001	2.98	3.06	2.80%	0.91
22/3	Specimen S002	3.71	3.77	1.66%	0.42
22/3	Specimen S001	1.02	1.04	2.30%	0.59
22/2	Specimen S002	3.21	3.30	2.80%	0.77
22/2	Specimen S001	1.02	1.04	2.10%	0.63
22/1	Specimen S002	2.44	2.48	1.51%	0.36
22/1	Specimen S001	3.02	3.12	3.20%	0.48
21/4	Specimen S002	3.00	3.05	1.55%	1.17
21/4	Specimen S001	2.36	2.33	-1.20%	-0.64

Thromboplastin time INR |ACL TOP 500 (B)

### SpecimenS001, Thromboplastin time INR

The uncertainty of the assigned value is not negligible, and evaluations could be affected.

- ■ All method groups ■ RecombiPlastin 2G
- ● Own result: 2.84 (19.02.2023)
- Diff%: -4.83 | x_{pt}: 2.98
- Target area: 2.54-3.43 | Target: ±15%

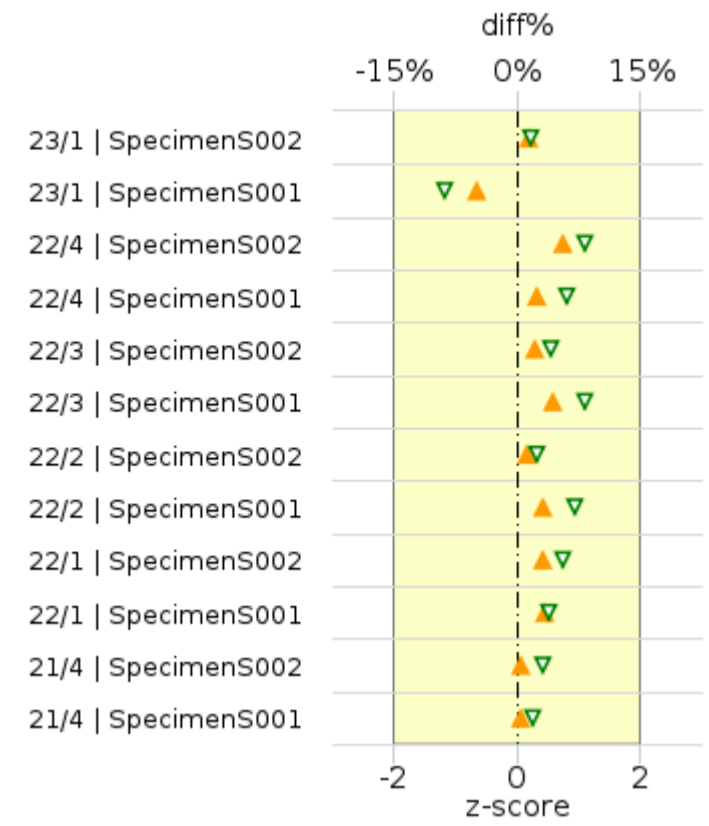|	x_{pt}	sd	SEM	CV%	n
RecombiPlastin 2G	2.98 INR	0.12	0.06	4.1	5
All methods	2.61 INR	0.31	0.04	12.0	70

SpecimenS002, Thromboplastin time INR

The uncertainty of the assigned value is not negligible, and evaluations could be affected.

- ■ All method groups ■ RecombiPlastin 2G
- ● Own result: 1.04 (19.02.2023)
- Diff%: 1.36 | x_{pt}: 1.03
- Target area: 0.87-1.18 | Target: ±15%

	x_{pt}	sd	SEM	CV%	n
RecombiPlastin 2G	1.03 INR	0.06	0.03	5.9	5
All methods	1.00 INR	0.05	<0.01	5.0	69

History

- ▲ diff%
- ▽ Z-score is uncertain due to the small number of observations

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Specimen S002	1.03	1.04	1.36%	0.23
23/1	Specimen S001	2.98	2.84	-4.83%	-1.16
22/4	Specimen S002	3.02	3.19	5.63%	1.10
22/4	Specimen S001	2.98	3.05	2.46%	0.80
22/3	Specimen S002	3.71	3.79	2.20%	0.56
22/3	Specimen S001	1.02	1.06	4.26%	1.10
22/2	Specimen S002	3.21	3.25	1.25%	0.34
22/2	Specimen S001	1.02	1.05	3.09%	0.93
22/1	Specimen S002	2.44	2.52	3.14%	0.75
22/1	Specimen S001	3.02	3.13	3.53%	0.53
21/4	Specimen S002	3.00	3.02	0.55%	0.42
21/4	Specimen S001	2.36	2.37	0.49%	0.26

Report info

Participants

61 participants from 8 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.
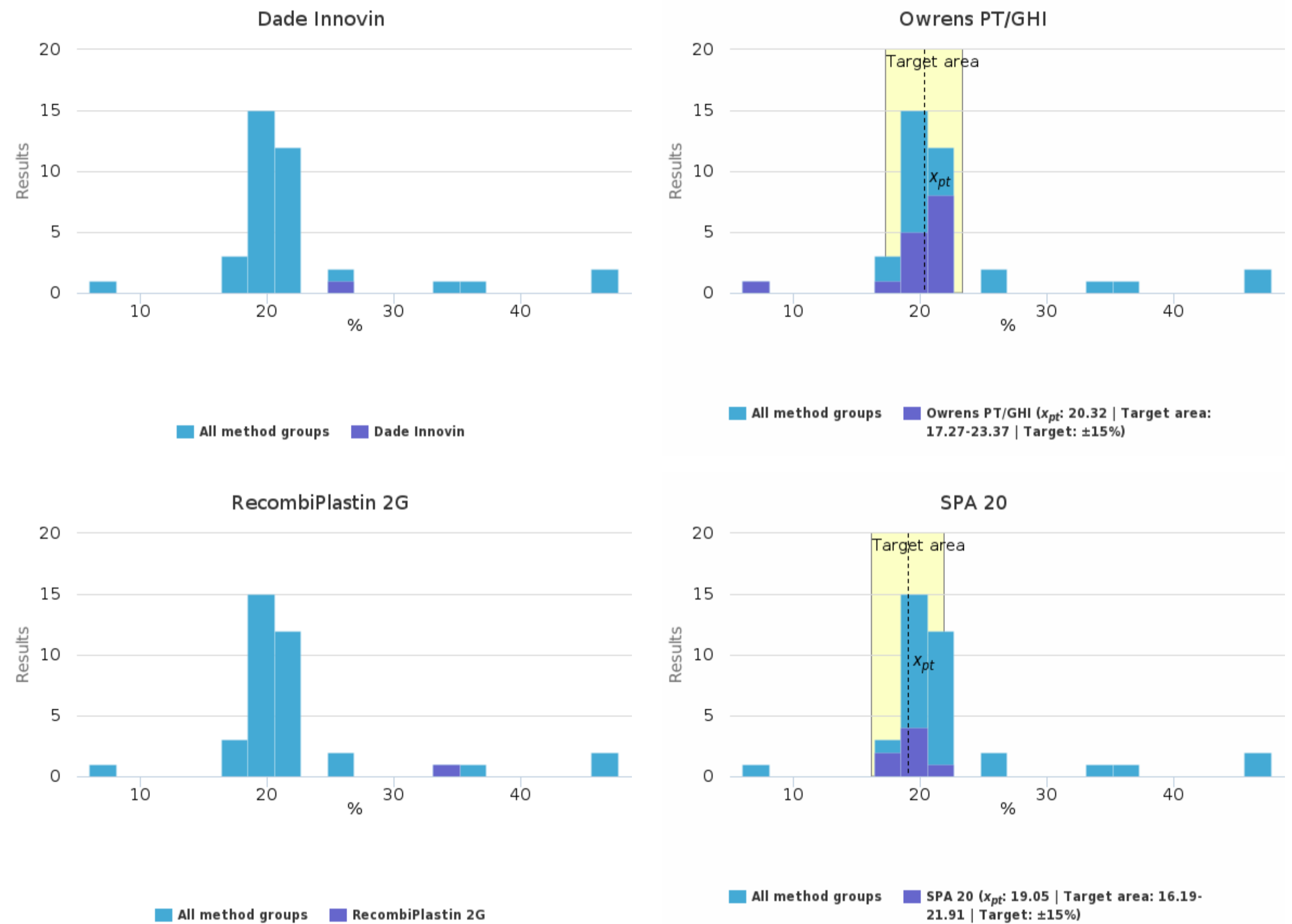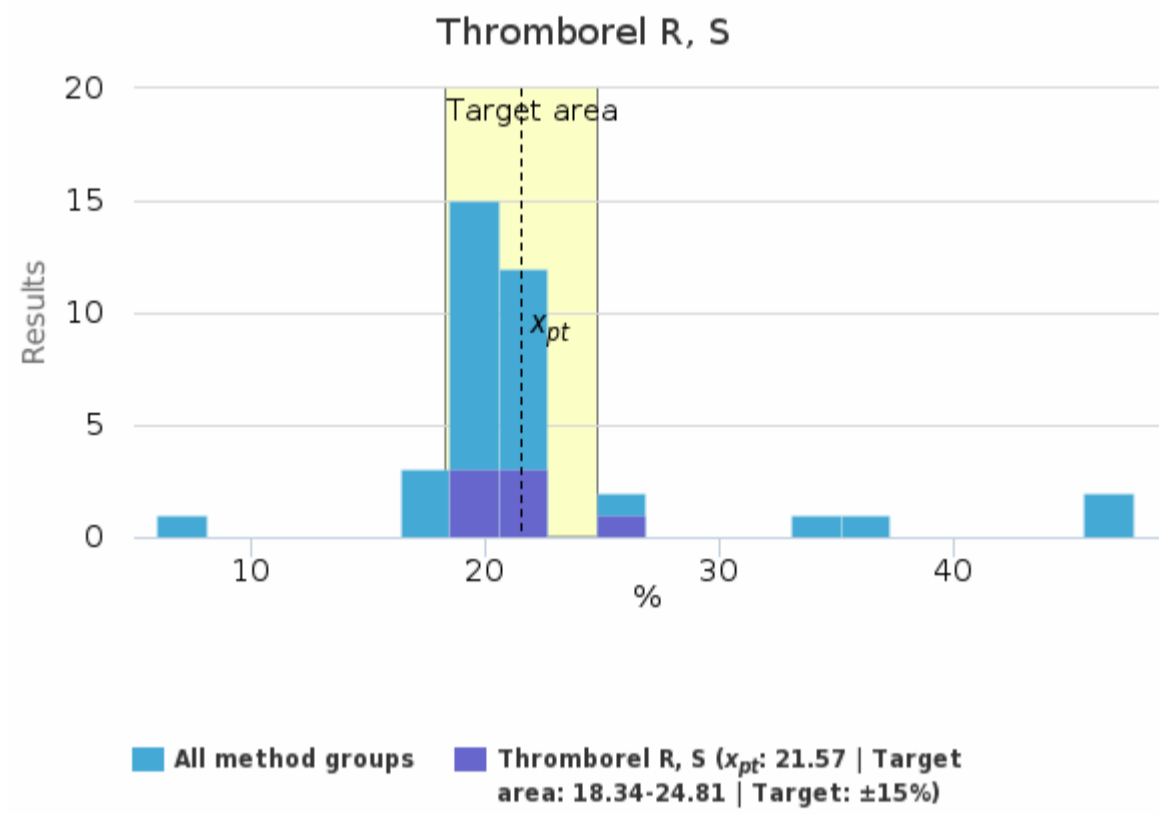Results reported with < or > -signs cannot be included in the statistics.
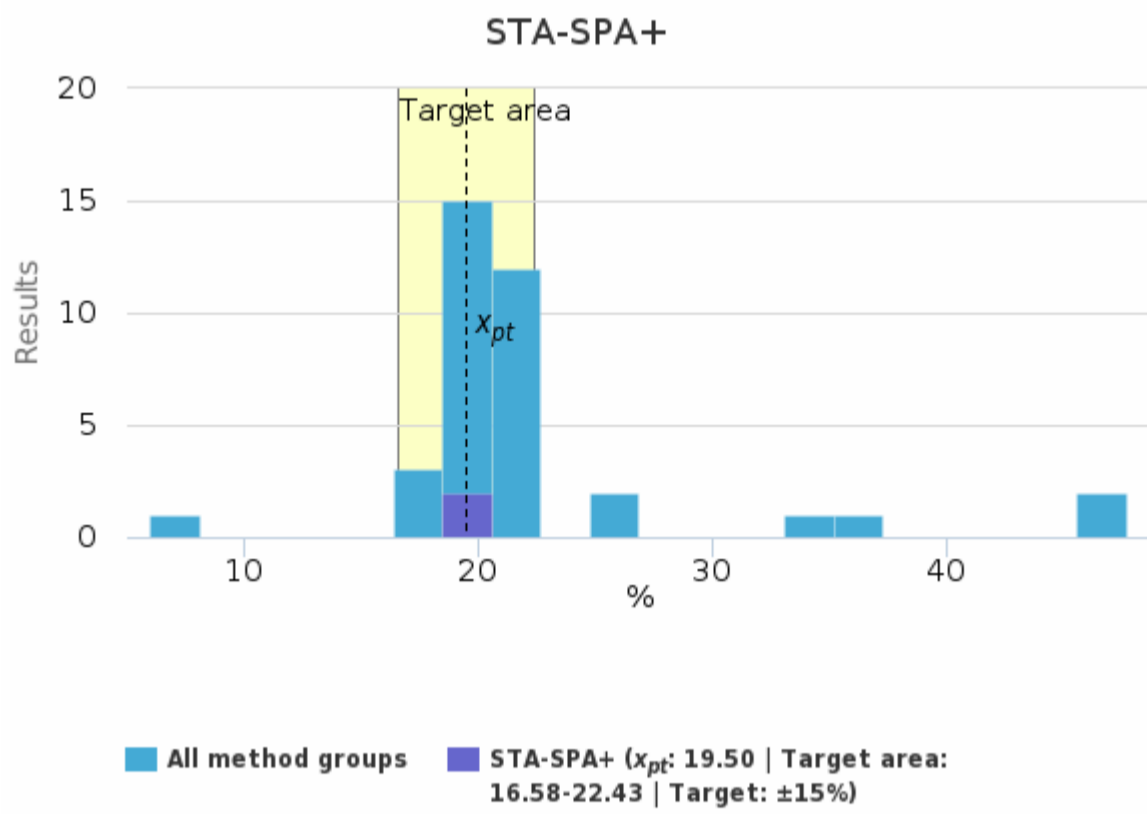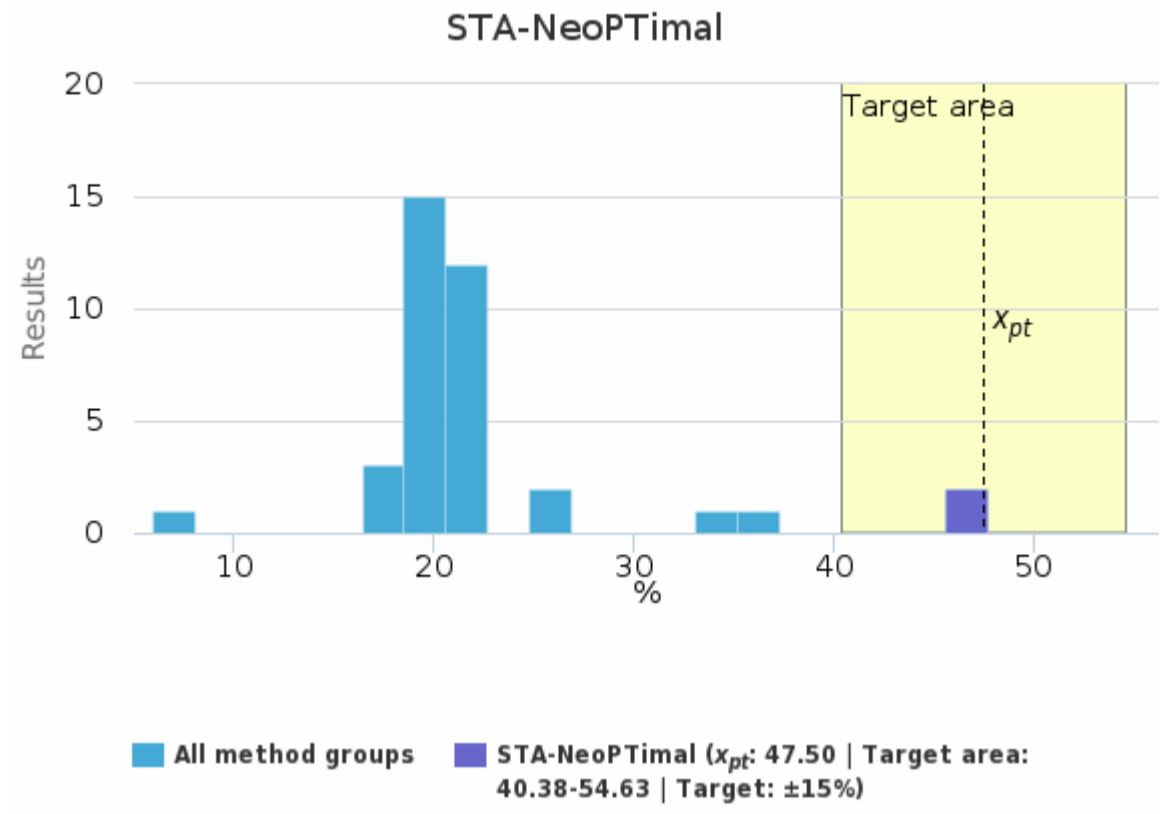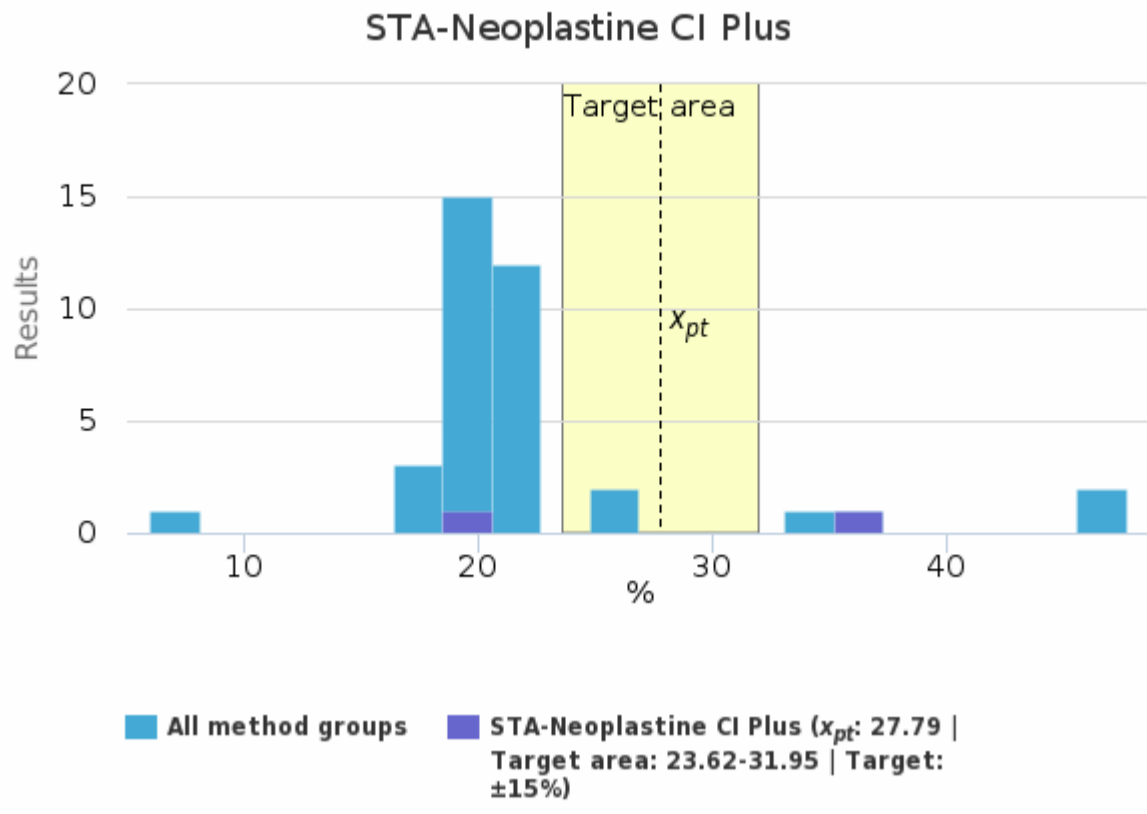
For information on report interpretation and performance evaluation, please see the " EQAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

Specimen S001 | Thromboplastin time (%), %

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Dade Innovin	-	-	-	-	-	25.30	25.30	-	1
Owrens PT/GHI	20.32	21.00	1.41	6.9	0.38	17.50	22.10	1	15
RecombiPlastin 2G	-	-	-	-	-	33.70	33.70	-	1
SPA 20	19.05	19.35	1.53	8.0	0.58	17.00	21.00	-	7
STA-Neoplastine CI Plus	27.79	27.79	11.01	39.6	7.79	20.00	35.57	-	2
STA-NeoPTimal	47.50	47.50	0.28	0.6	0.20	47.30	47.70	-	2
STA-SPA+	19.50	19.50	0.71	3.6	0.50	19.00	20.00	-	2
Thromborel R, S	21.57	22.10	2.42	11.2	0.91	18.70	26.00	-	7
All	**20.81**	**20.20**	**4.64**	**22.3**	**0.78**	**6.00**	**35.57**	**2**	**37**

Specimen S001 | Thromboplastin time (%), %| histogram summaries in LabScala

LABQUALITY

STA-Neoplastine CI Plus

Target area

x_{pt}

■ All method groups   ■ STA-Neoplastine CI Plus (x_{pt}: 27.79 | Target area: 23.62-31.95 | Target: ±15%)

STA-NeoPTimal

Target area

x_{pt}

■ All method groups   ■ STA-NeoPTimal (x_{pt}: 47.50 | Target area: 40.38-54.63 | Target: ±15%)

STA-SPA+

Target area

x_{pt}

■ All method groups   ■ STA-SPA+ (x_{pt}: 19.50 | Target area: 16.58-22.43 | Target: ±15%)

Thromborel R, S

Target area

x_{pt}

■ All method groups   ■ Thromborel R, S (x_{pt}: 21.57 | Target area: 18.34-24.81 | Target: ±15%)
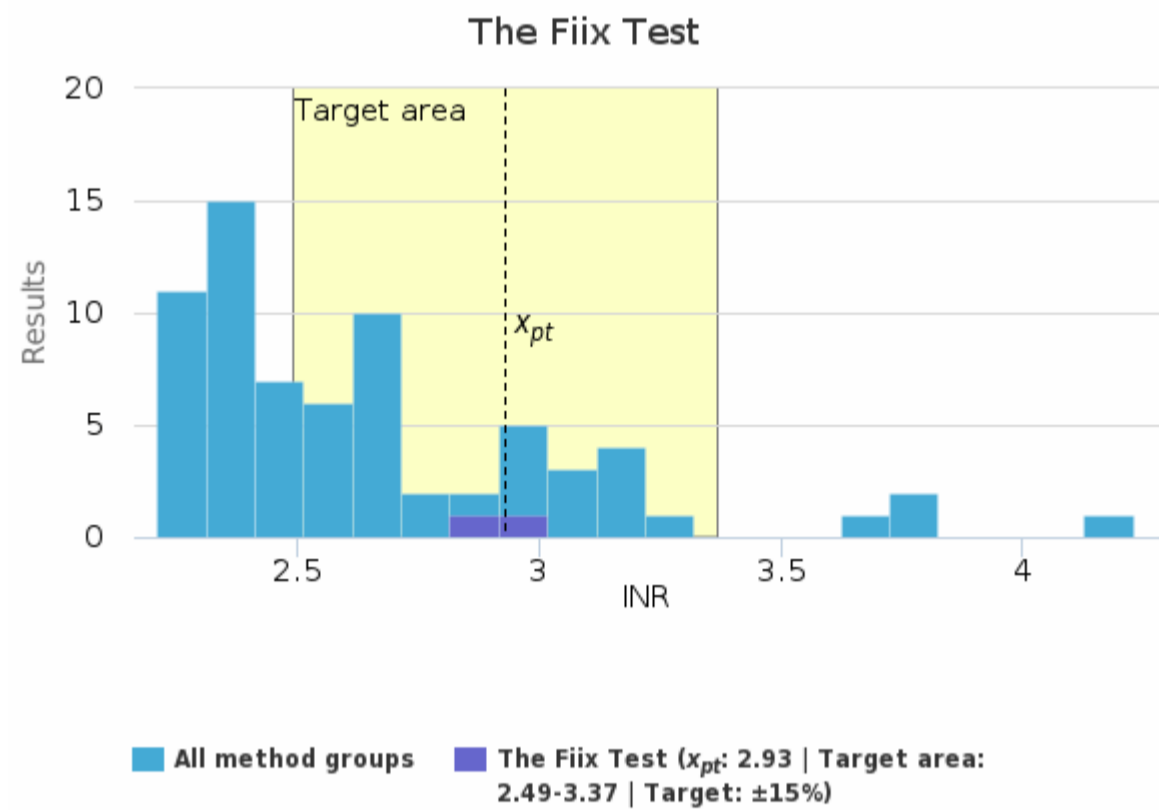
Specimen S001 | Thromboplastin time INR, INR

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Dade Innovin	2.64	2.63	0.03	1.2	0.01	2.62	2.69	-	5
Owrens PT/GHI	2.40	2.39	0.11	4.6	0.02	2.21	2.66	1	33
RecombiPlastin 2G	2.98	2.97	0.12	4.1	0.06	2.84	3.18	-	5
SPA 20	2.58	2.61	0.20	7.7	0.06	2.35	2.92	-	11
STA-Neoplastine CI Plus	3.44	3.44	0.50	14.6	0.36	3.08	3.79	-	2
STA-NeoPTimal	3.91	3.80	0.28	7.2	0.16	3.70	4.23	-	3
STA-SPA+	2.38	2.38	0.11	4.5	0.08	2.30	2.45	-	2
The Fiix Test	2.93	2.93	0.10	3.4	0.07	2.86	3.00	-	2
Thromborel R, S	3.06	3.15	0.21	6.9	0.08	2.62	3.24	-	7
All	**2.61**	**2.52**	**0.31**	**12.0**	**0.04**	**2.21**	**3.70**	**3**	**70**

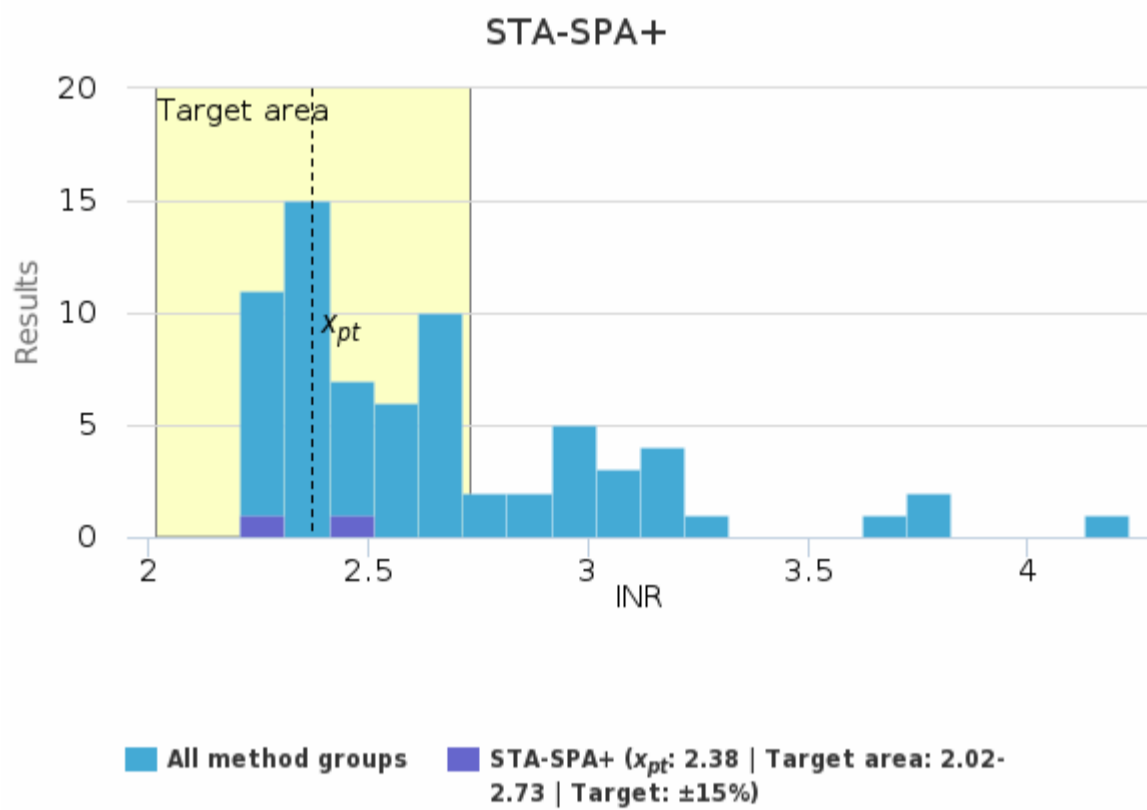## Specimen S001 | Thromboplastin time INR, INR| histogram summaries in LabScala
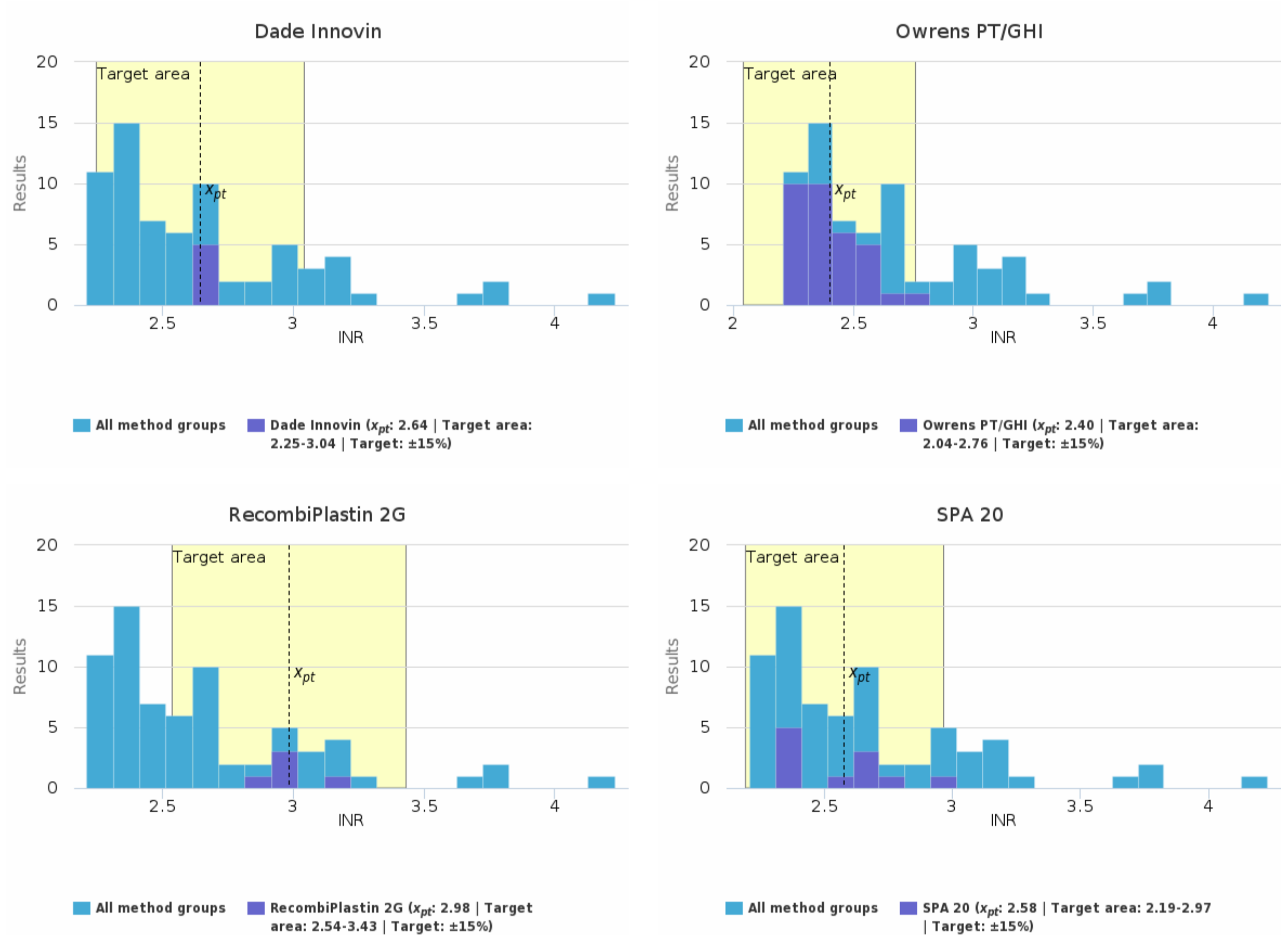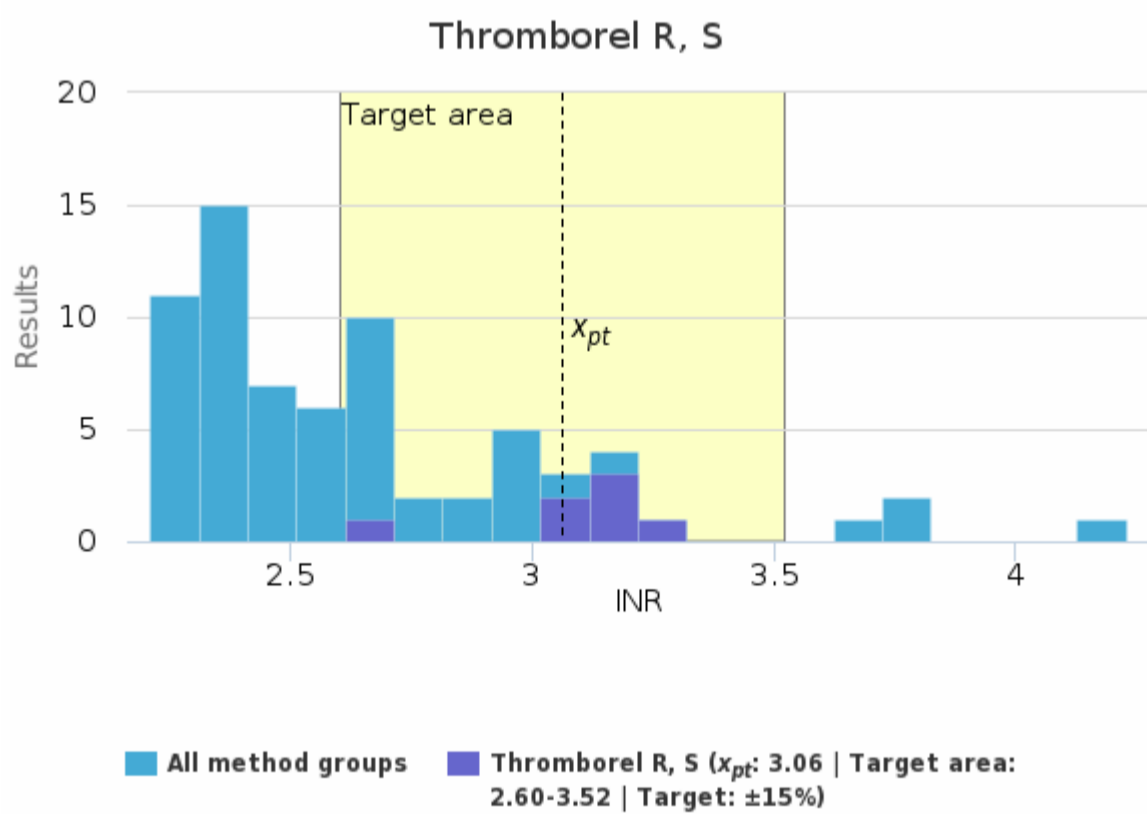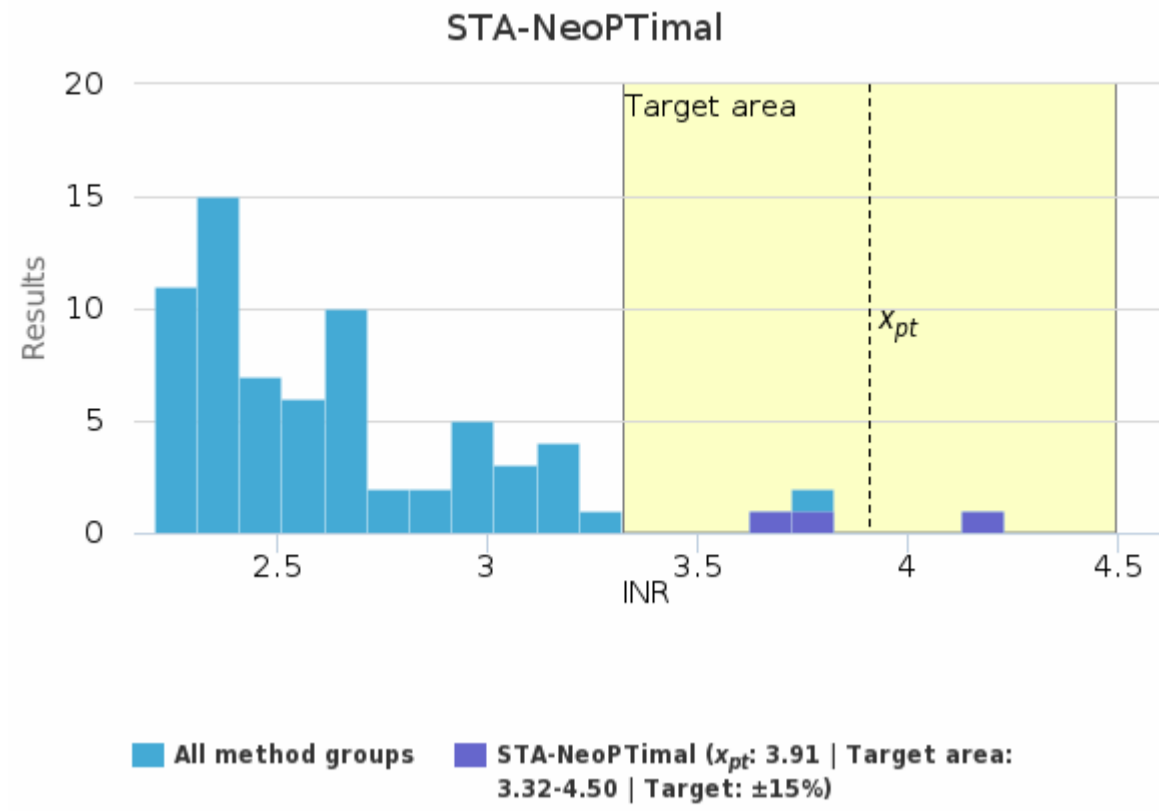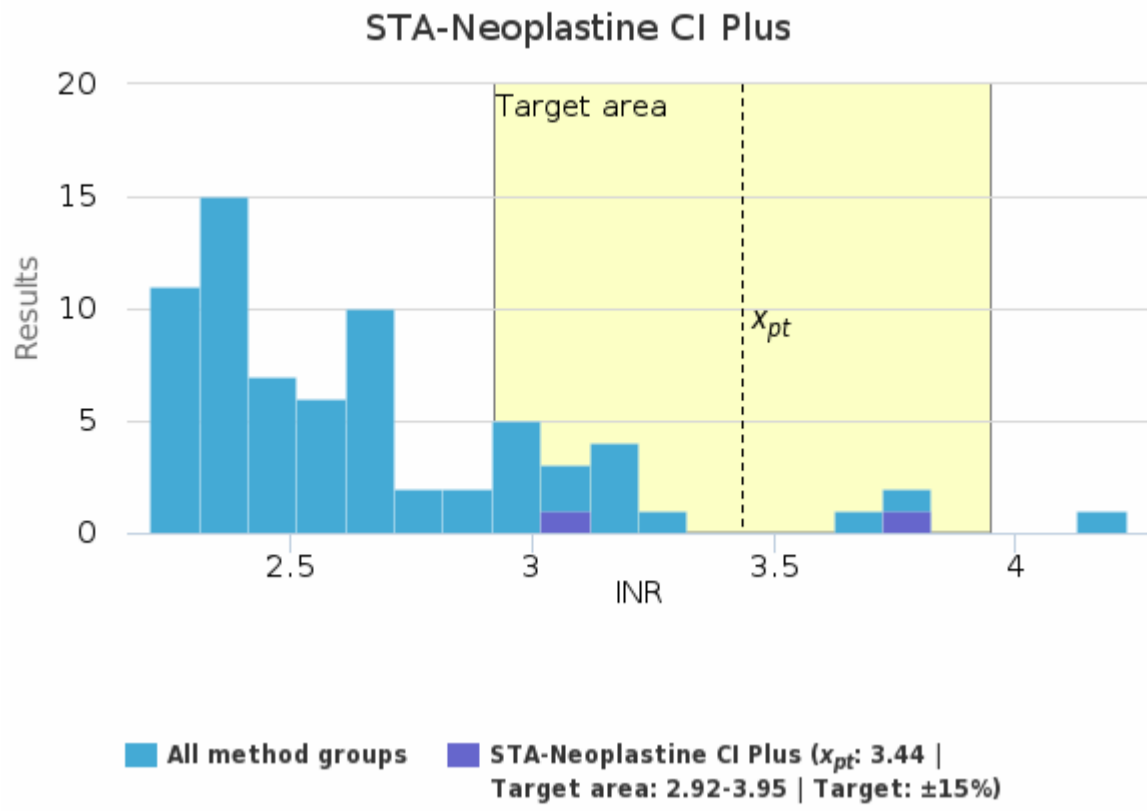
Prothrombin time, February, 1-2023
Quantitative report

STA-Neoplastine CI Plus

- ■ All method groups
- ■ STA-Neoplastine CI Plus (x_{pt}: 3.44 | Target area: 2.92-3.95 | Target: ±15%)

STA-NeoPTimal

- ■ All method groups
- ■ STA-NeoPTimal (x_{pt}: 3.91 | Target area: 3.32-4.50 | Target: ±15%)

STA-SPA+

- ■ All method groups
- ■ STA-SPA+ (x_{pt}: 2.38 | Target area: 2.02-2.73 | Target: ±15%)

The Fiix Test

- ■ All method groups
- ■ The Fiix Test (x_{pt}: 2.93 | Target area: 2.49-3.37 | Target: ±15%)

Thromborel R, S

- ■ All method groups
- ■ Thromborel R, S (x_{pt}: 3.06 | Target area: 2.60-3.52 | Target: ±15%)

![Labquality]

Specimen S002 | Thromboplastin time (%), %

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Dade Innovin	-	-	-	-	-	101.80	101.80	-	1
Owrens PT/GHI	105.08	106.00	7.80	7.4	2.16	87.60	117.90	-	13
RecombiPlastin 2G	-	-	-	-	-	100.90	100.90	-	1
SPA 20	98.79	101.00	10.97	11.1	4.15	79.00	109.00	-	7
STA-Neoplastine CI Plus	51.98	51.98	55.18	106.2	39.02	12.96	91.00	-	2
STA-NeoPTimal	13.85	13.85	0.49	3.6	0.35	13.50	14.20	-	2
STA-SPA+	109.50	109.50	6.36	5.8	4.50	105.00	114.00	-	2
Thromborel R, S	90.23	90.40	6.03	6.7	2.28	81.70	99.50	-	7
All	**100.06**	**101.10**	**9.82**	**9.8**	**1.74**	**79.00**	**117.90**	**3**	**35**

Specimen S002 | Thromboplastin time (%), %| histogram summaries in LabScala

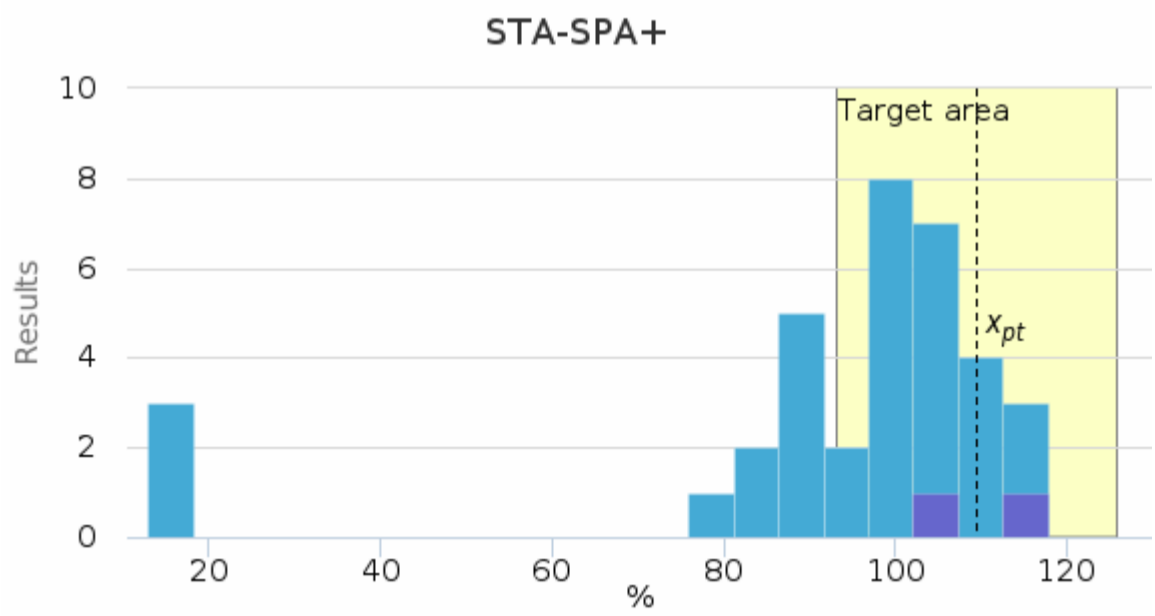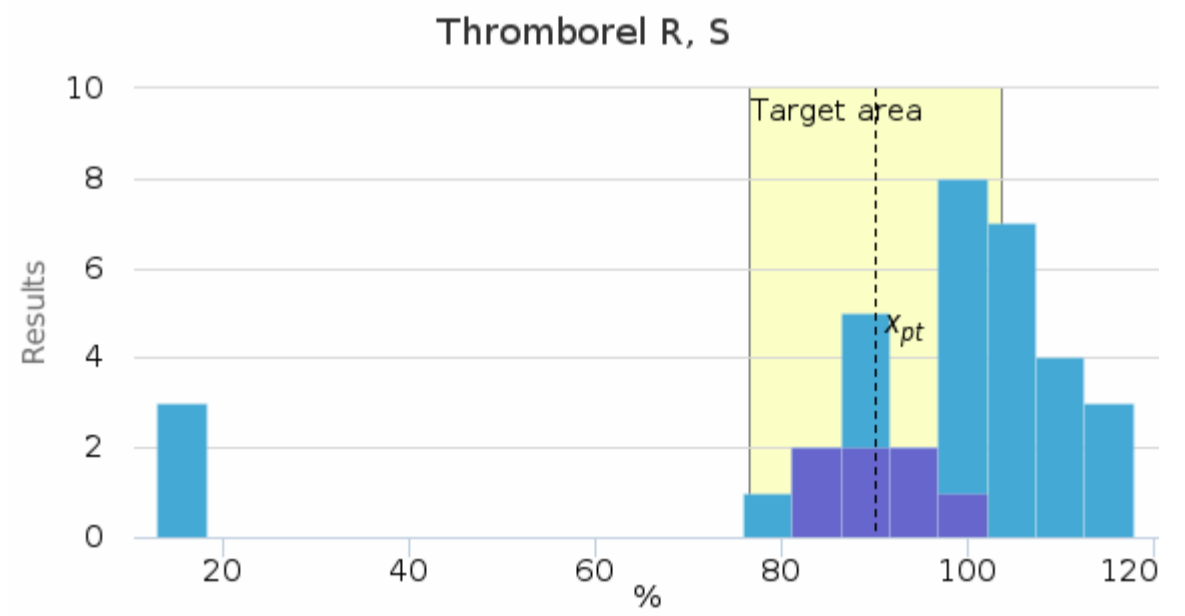# Prothrombin time, February, 1-2023

Quantitative report

STA-Neoplastine CI Plus
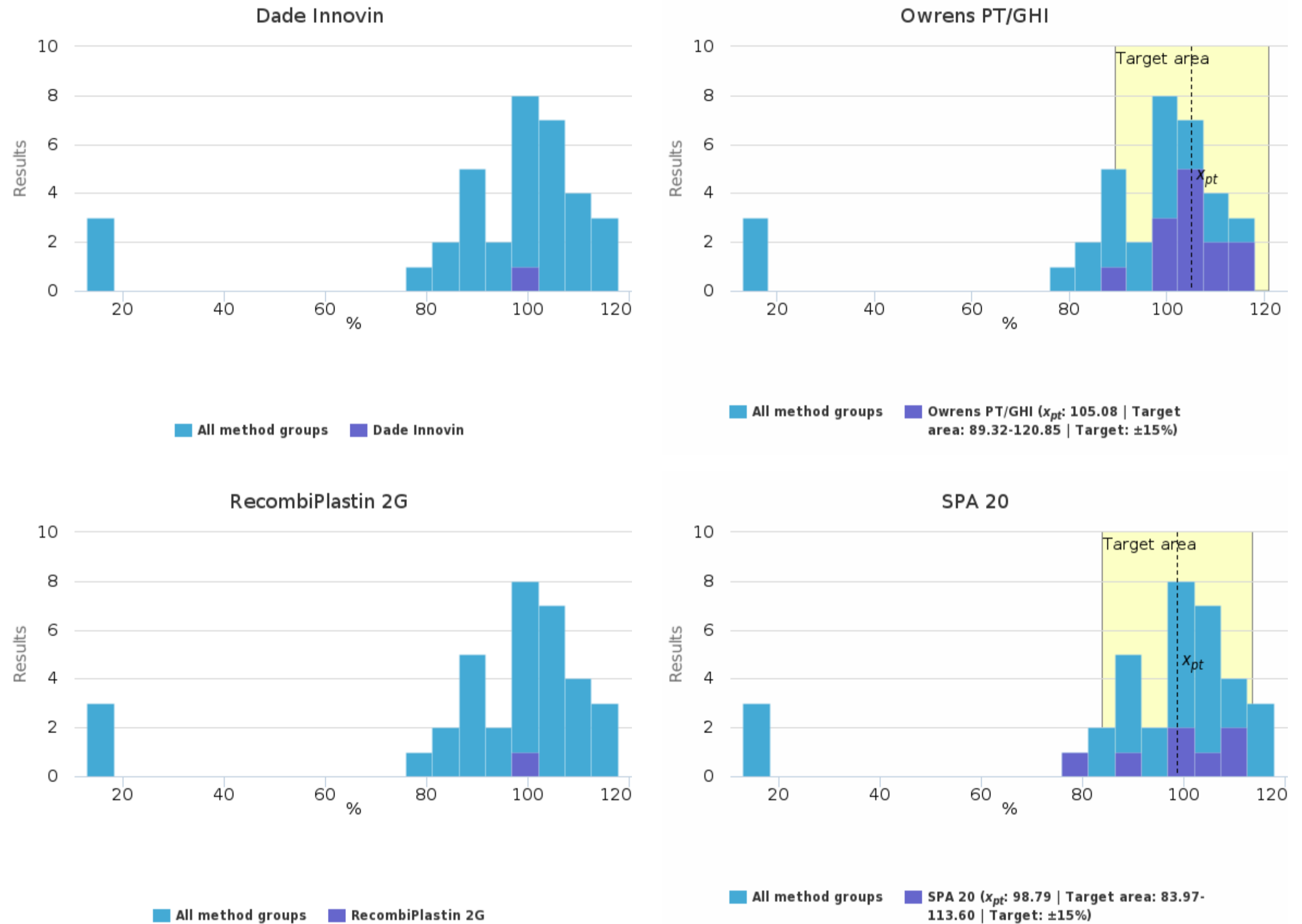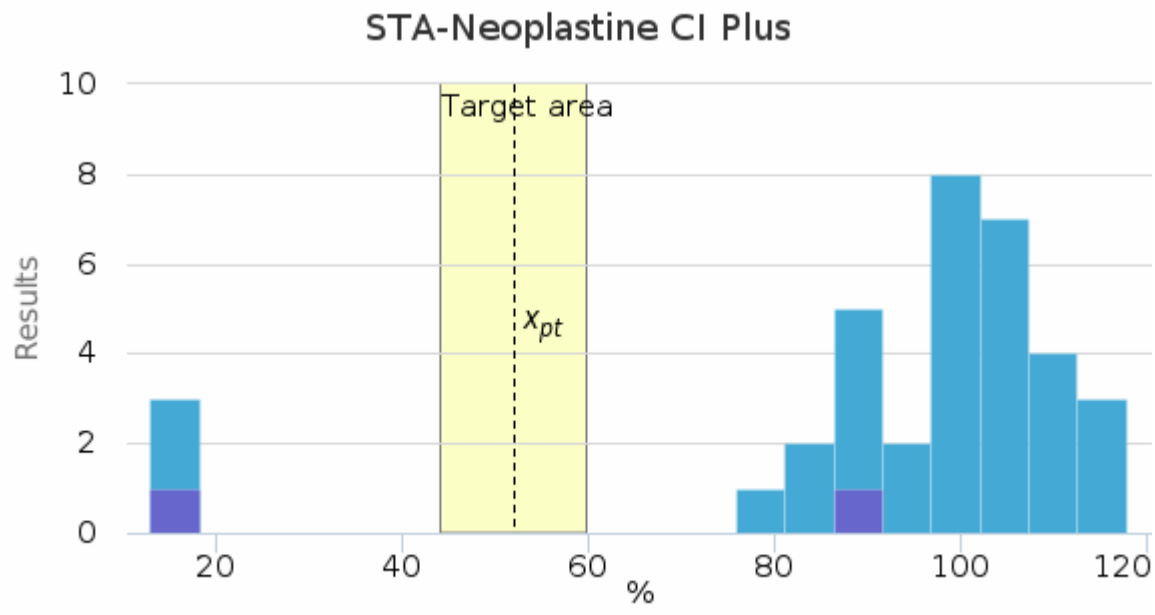
Legend: ■ All method groups ■ STA-Neoplastine CI Plus (x_{pt}: 51.98 | Target area: 44.18-59.78 | Target: ±15%)

STA-NeoPTimal
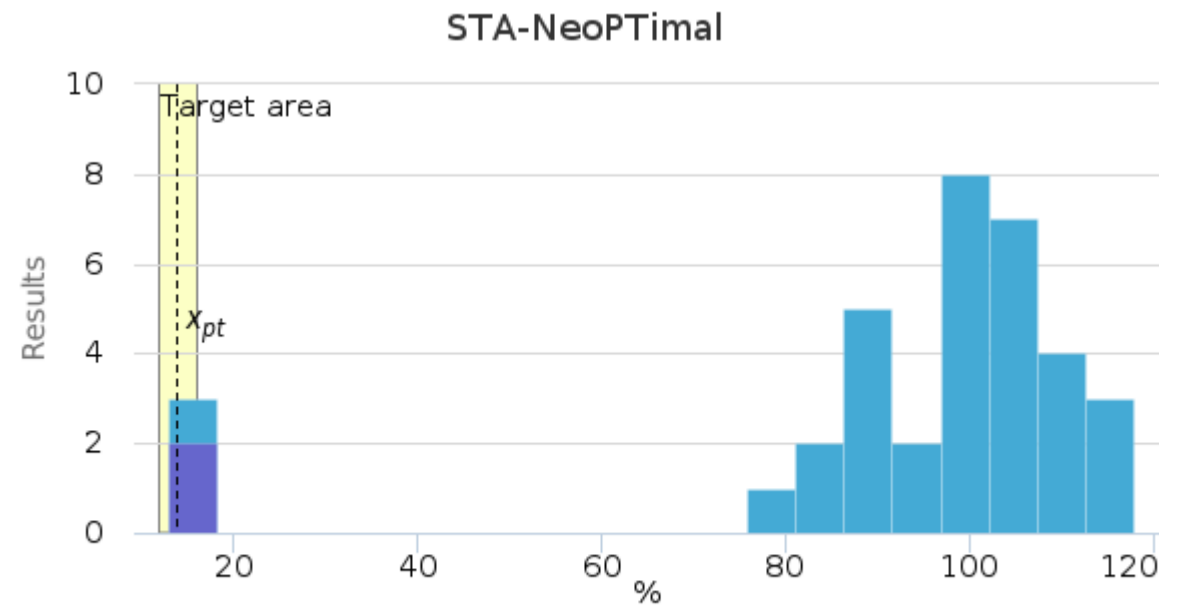
Legend: ■ All method groups ■ STA-NeoPTimal (x_{pt}: 13.85 | Target area: 11.77-15.93 | Target: ±15%)

STA-SPA+

Legend: ■ All method groups ■ STA-SPA+ (x_{pt}: 109.50 | Target area: 93.08-125.93 | Target: ±15%)
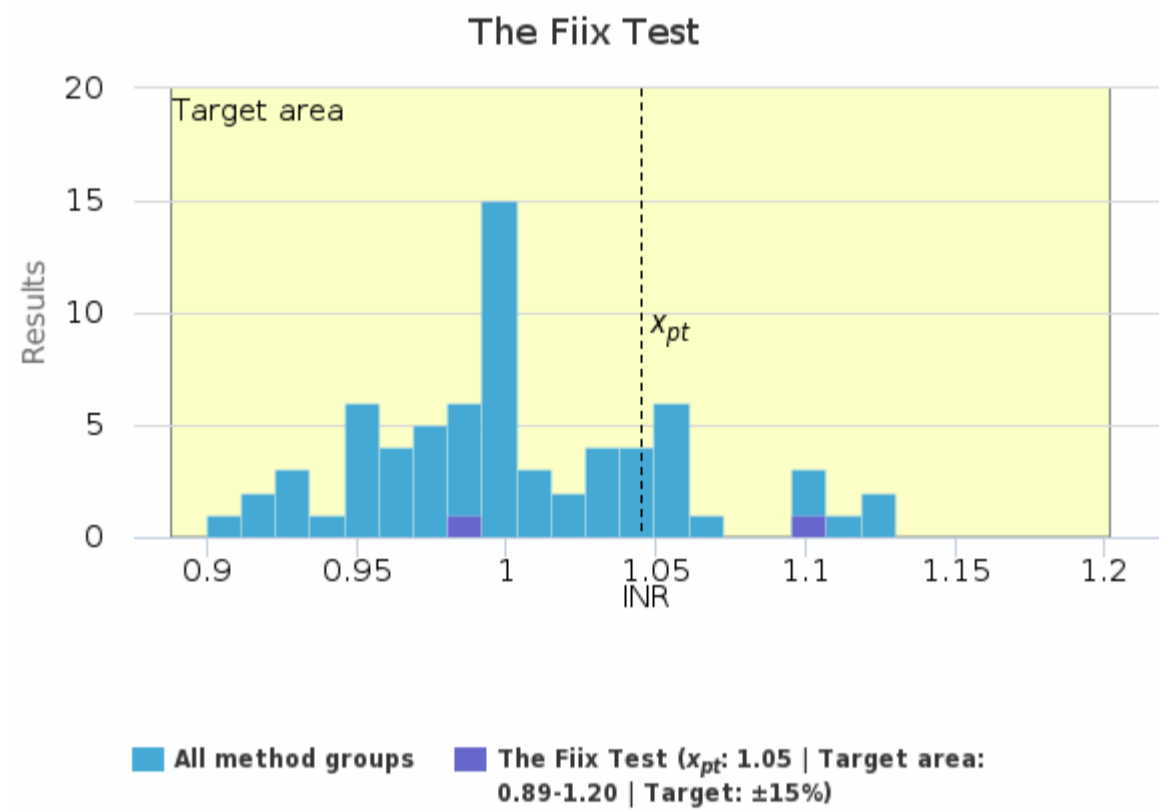
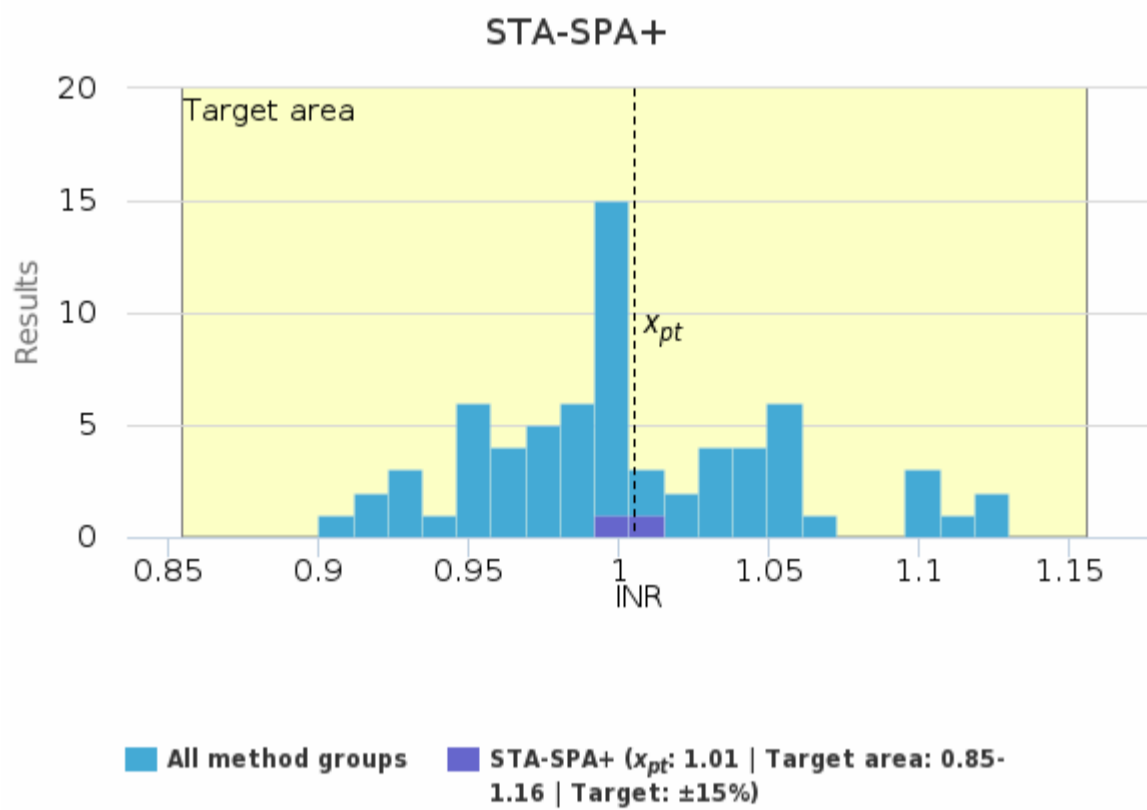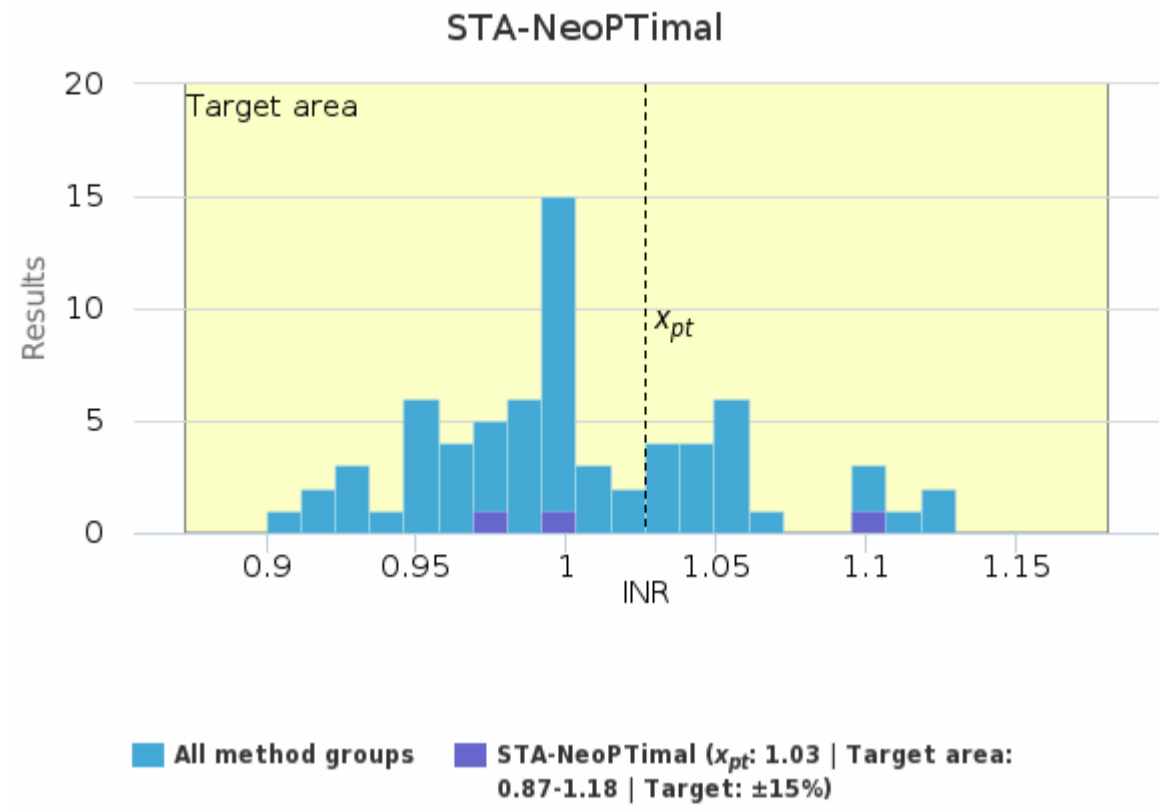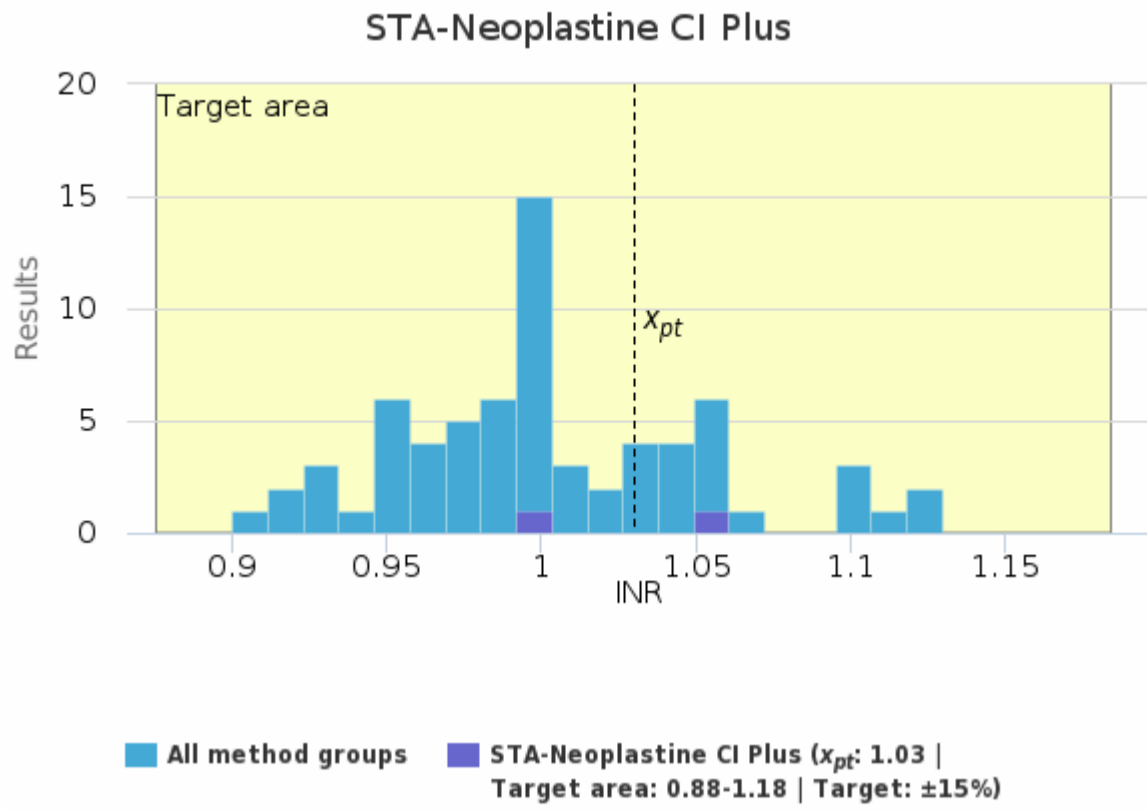## Thromborel R, S

Legend: ■ All method groups ■ Thromborel R, S (x_{pt}: 90.23 | Target area: 76.69-103.76 | Target: ±15%)

![LABQUALITY]

Specimen S002 | Thromboplastin time INR, INR

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Dade Innovin	1.03	1.03	0.02	2.0	<0.01	1.01	1.06	-	5
Owrens PT/GHI	0.97	0.97	0.03	3.6	<0.01	0.90	1.04	-	33
RecombiPlastin 2G	1.03	1.04	0.06	5.9	0.03	0.95	1.11	-	5
SPA 20	1.02	1.00	0.05	4.6	0.01	0.97	1.13	-	10
STA-Neoplastine CI Plus	1.03	1.03	0.04	4.1	0.03	1.00	1.06	-	2
STA-NeoPTimal	1.03	1.00	0.06	6.3	0.04	0.98	1.10	-	3
STA-SPA+	1.01	1.01	<0.01	0.7	<0.01	1.00	1.01	-	2
The Fiix Test	1.05	1.05	0.08	7.4	0.06	0.99	1.10	-	2
Thromborel R, S	1.06	1.05	0.04	4.0	0.02	1.00	1.12	-	7
All	**1.00**	**1.00**	**0.05**	**5.0**	**<0.01**	**0.90**	**1.13**	**-**	**69**

Specimen S002 | Thromboplastin time INR, INR| histogram summaries in LabScala

Dade Innovin — All method groups; Dade Innovin (x_{pt}: 1.03 | Target area: 0.88-1.19 | Target: ±15%)

Owrens PT/GHI — All method groups; Owrens PT/GHI (x_{pt}: 0.97 | Target area: 0.83-1.12 | Target: ±15%)

RecombiPlastin 2G — All method groups; RecombiPlastin 2G (x_{pt}: 1.03 | Target area: 0.87-1.18 | Target: ±15%)

SPA 20 — All method groups; SPA 20 (x_{pt}: 1.02 | Target area: 0.87-1.18 | Target: ±15%)

Prothrombin time, February, 1-2023
Quantitative report

STA-Neoplastine CI Plus

■ All method groups ■ STA-Neoplastine CI Plus (x_{pt}: 1.03 | Target area: 0.88-1.18 | Target: ±15%)

STA-NeoPTimal

■ All method groups ■ STA-NeoPTimal (x_{pt}: 1.03 | Target area: 0.87-1.18 | Target: ±15%)

STA-SPA+

■ All method groups ■ STA-SPA+ (x_{pt}: 1.01 | Target area: 0.85-1.16 | Target: ±15%)

The Fiix Test

■ All method groups ■ The Fiix Test (x_{pt}: 1.05 | Target area: 0.89-1.20 | Target: ±15%)

Thromborel R, S

■ All method groups ■ Thromborel R, S (x_{pt}: 1.06 | Target area: 0.90-1.22 | Target: ±15%)

LABQUALITY

Report info

Participants

61 participants from 8 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

Prothrombin time
Round 1, 2023

Specimens
Sample S001 (LQ708223011) and sample S002 (LQ708223012) 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
As in previous rounds, STA-NeoPTimal and STA-Neoplastine Plus reagents had clearly different PT% results level. Participants are asked to note that the results should be given in percentages, not seconds. The INR results were consistent for both samples within the method groups, with the exception of a few outliers.

End of Report

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