LABQUALITY

External Quality Assessment Scheme

LMW-Heparin/anti-FXa
Round 1, 2023

Specimens
Please find enclosed 2 lyophilized heparin 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
Anti-FXa

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

LQ708623011

S002

LQ708623012

2023-02-06

INSTRUCTIONS

Product no. 4387
LQ708623011-012/AT

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi

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

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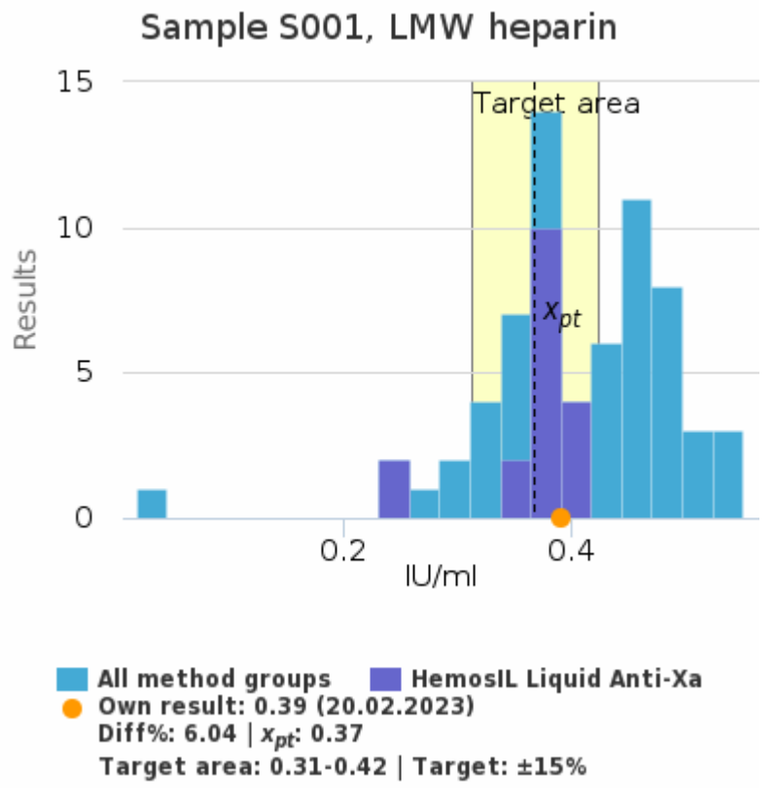
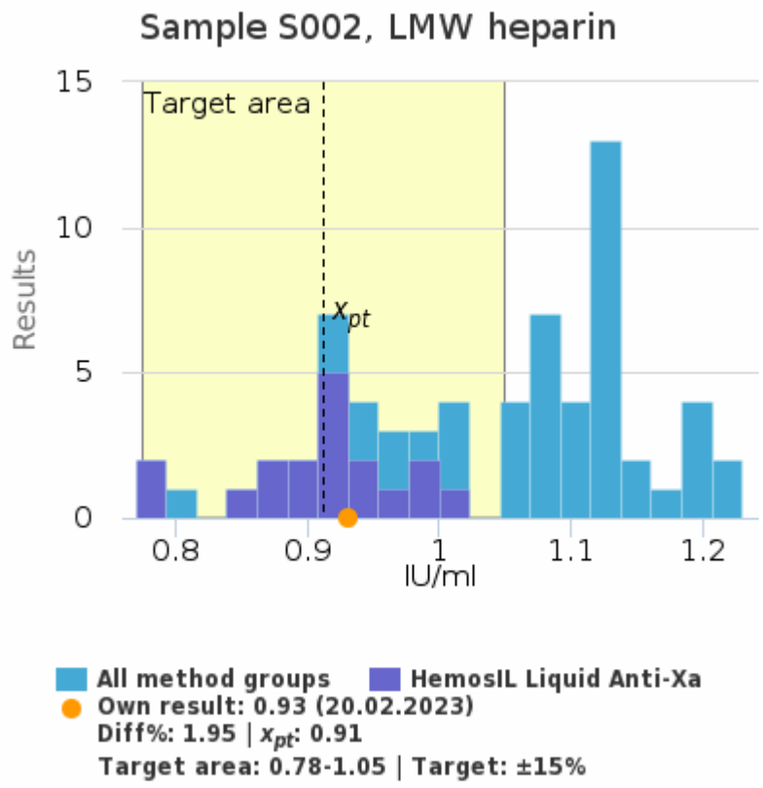
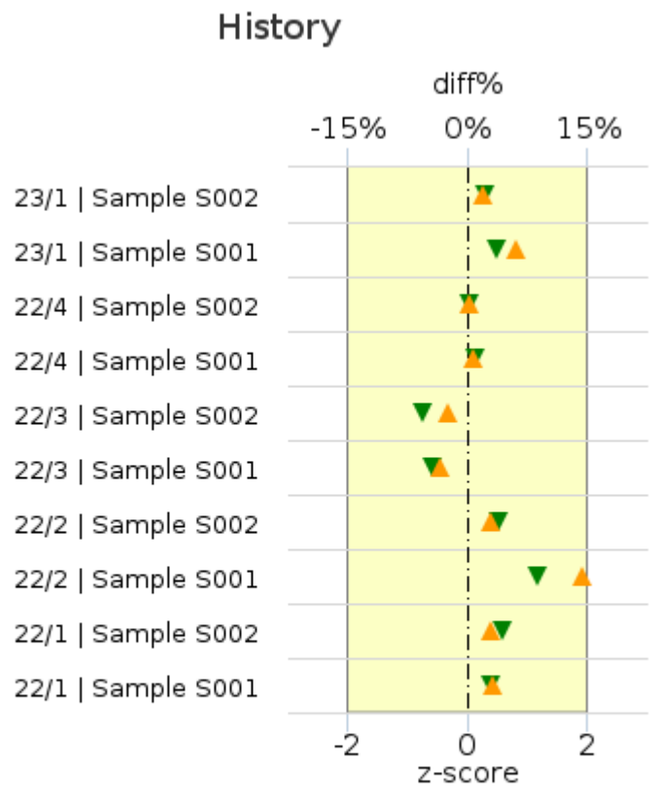
FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015

LMW heparin |koagulologia







	x_{pt}	sd	SEM	CV%	n
HemosIL Liquid Anti-Xa	0.37 IU/ml	0.05	0.01	12.4	18
All methods	0.41 IU/ml	0.07	<0.01	17.3	66

	x_{pt}	sd	SEM	CV%	n
HemosIL Liquid Anti-Xa	0.91 IU/ml	0.06	0.02	7.1	18
All methods	1.04 IU/ml	0.11	0.01	10.8	66

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	0.91	0.93	1.95%	0.28
23/1	Sample S001	0.37	0.39	6.04%	0.49
22/4	Sample S002	0.37	0.37	0.16%	0.02
22/4	Sample S001	0.54	0.54	0.66%	0.13
22/3	Sample S002	0.90	0.88	-2.43%	-0.73
22/3	Sample S001	0.37	0.36	-3.52%	-0.58
22/2	Sample S002	0.89	0.92	2.88%	0.53
22/2	Sample S001	0.37	0.42	14.37%	1.18
22/1	Sample S002	0.65	0.67	2.84%	0.58
22/1	Sample S001	0.37	0.38	3.12%	0.39

Report info

Participants

41 participants from 13 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.”
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For information on report interpretation and performance evaluation, please see the " EQAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

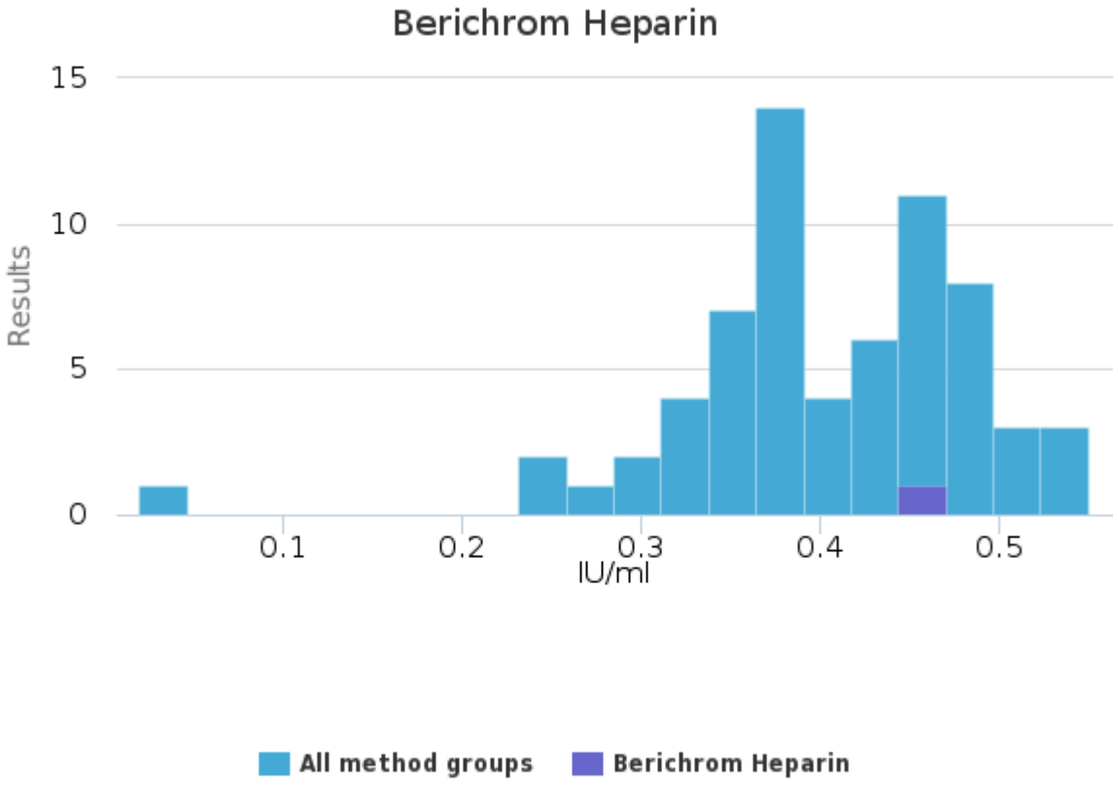
Anticoagulants: LMW-Heparin/antiFXa, February, 1-2023

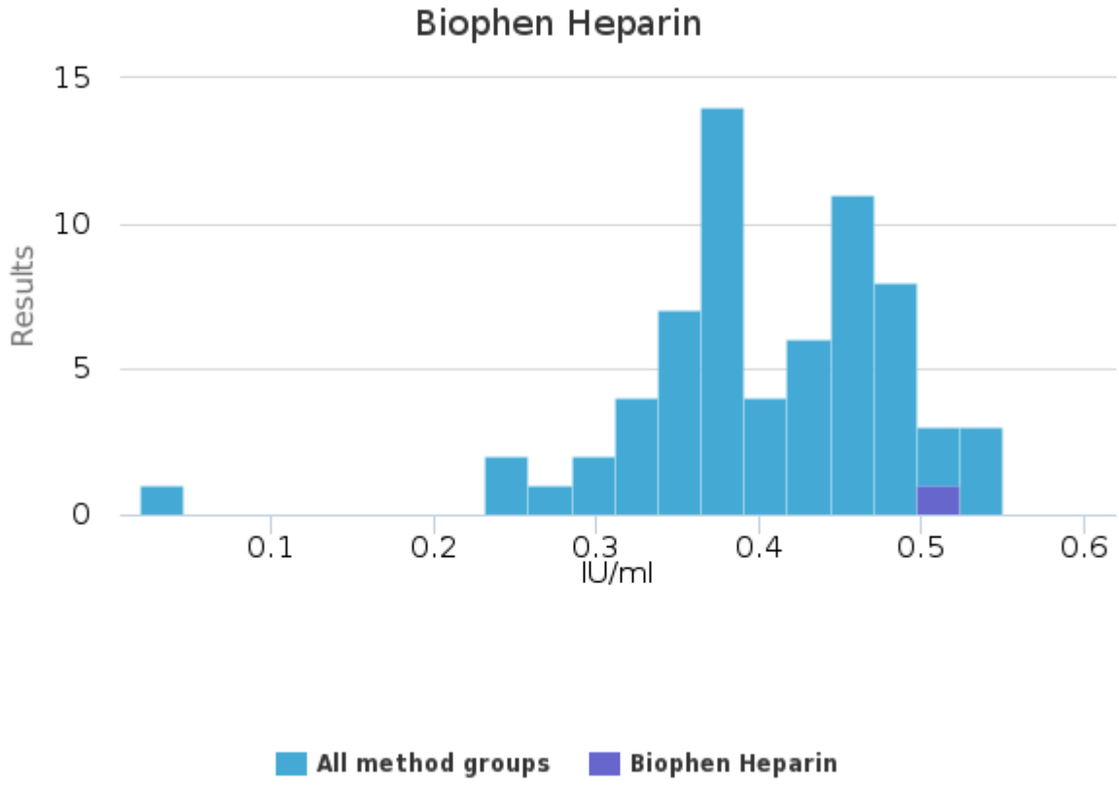
Quantitative report

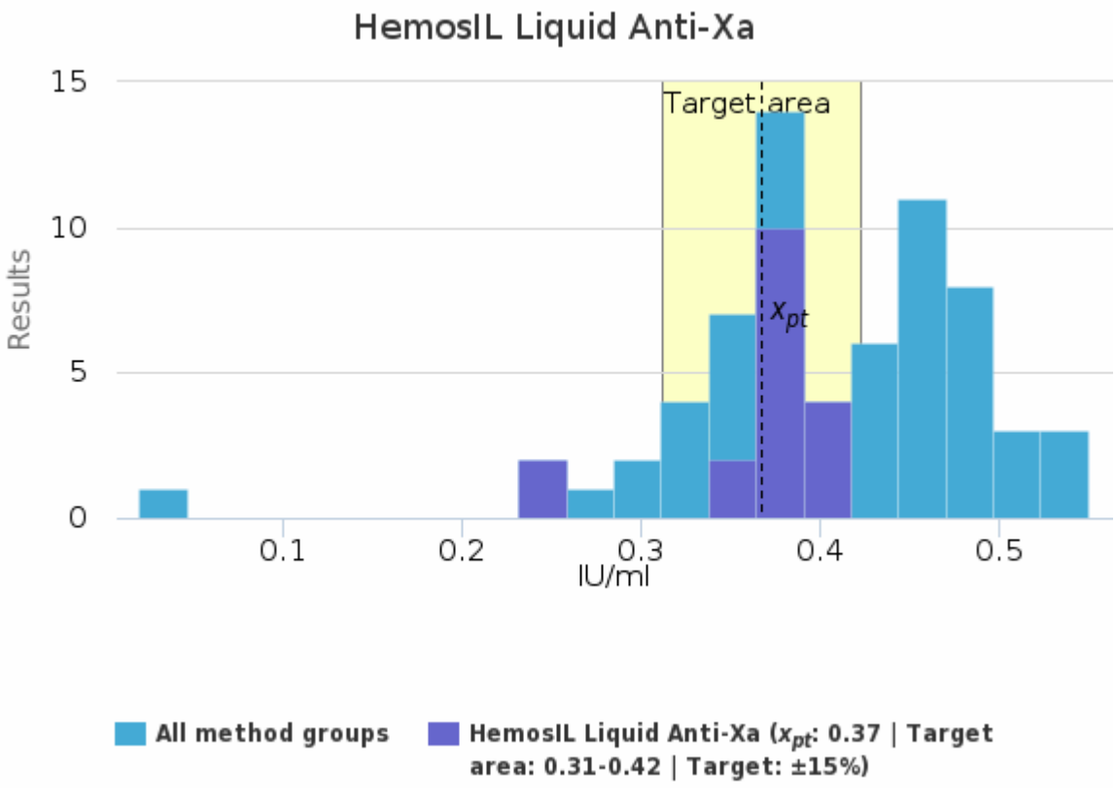
Sample S001 | LMW heparin, IU/ml

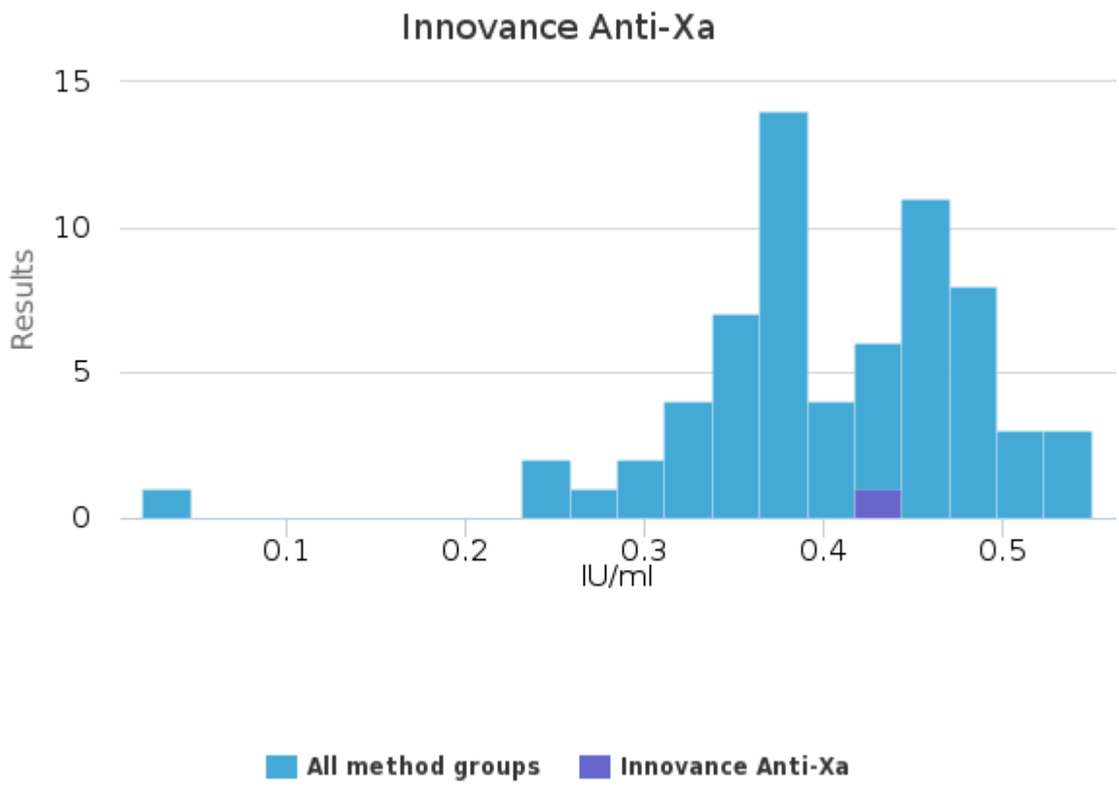
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Berichrom Heparin	-	-	-	-	-	0.47	0.47	-	1
Biophen Heparin	-	-	-	-	-	0.52	0.52	-	1
HemosIL Liquid Anti-Xa	0.37	0.38	0.05	12.4	0.01	0.25	0.41	-	18
Innovance Anti-Xa	-	-	-	-	-	0.44	0.44	-	1
Innovance Heparin	0.46	0.47	0.05	10.0	<0.01	0.34	0.55	-	32
Stago Liquid anti-Xa	0.33	0.33	0.03	9.0	<0.01	0.27	0.38	1	13
All	**0.41**	**0.40**	**0.07**	**17.3**	**<0.01**	**0.25**	**0.55**	**1**	**66**

Sample S001 | LMW heparin, IU/ml| histogram summaries in LabScala



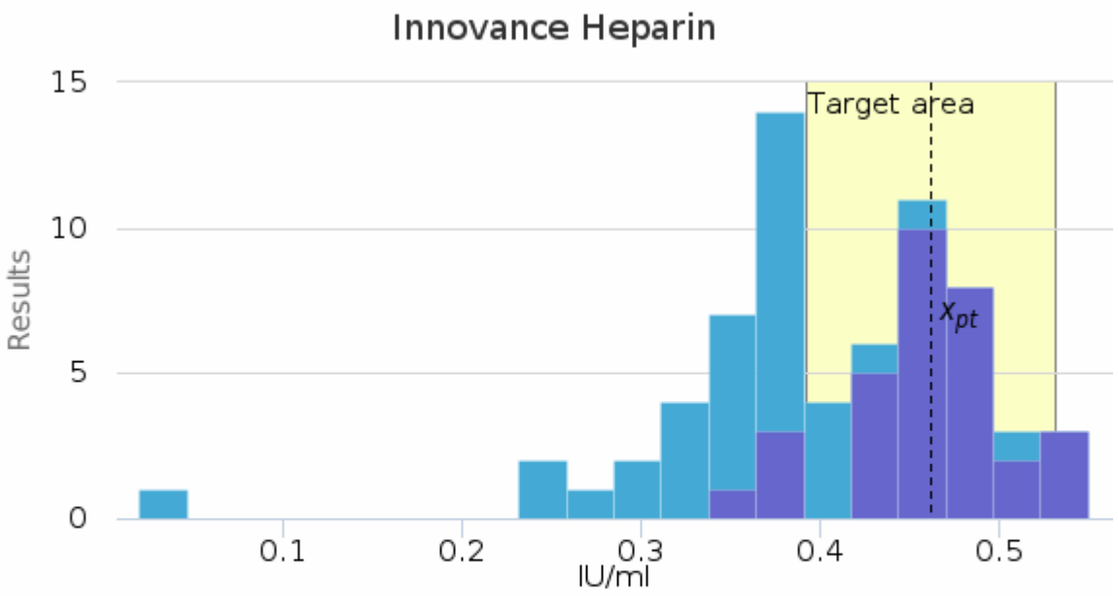


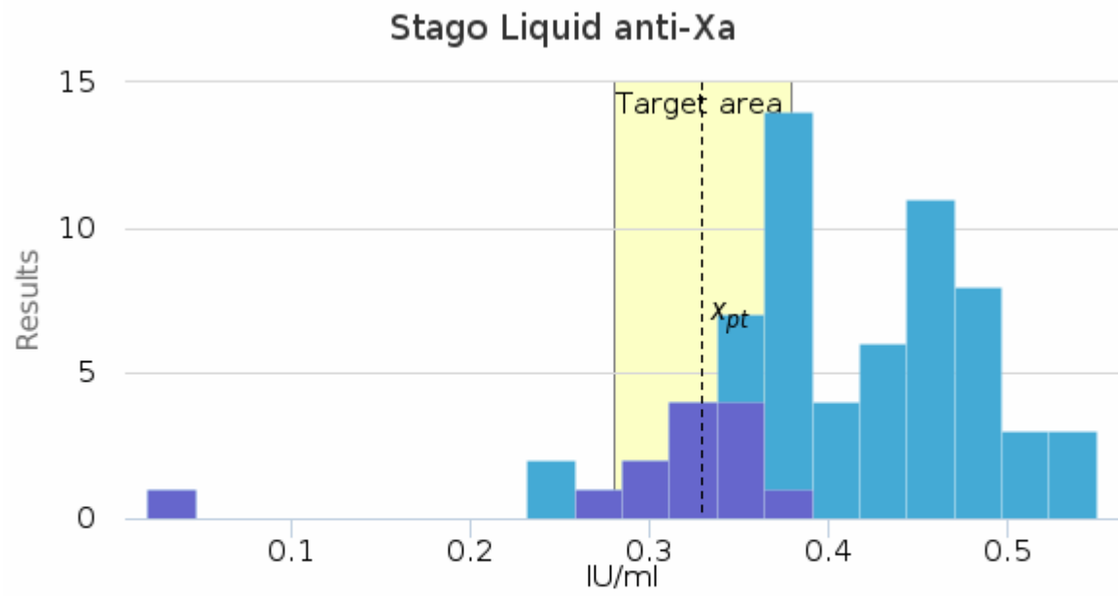




Anticoagulants: LMW-Heparin/antiFXa, February, 1-2023

Quantitative report





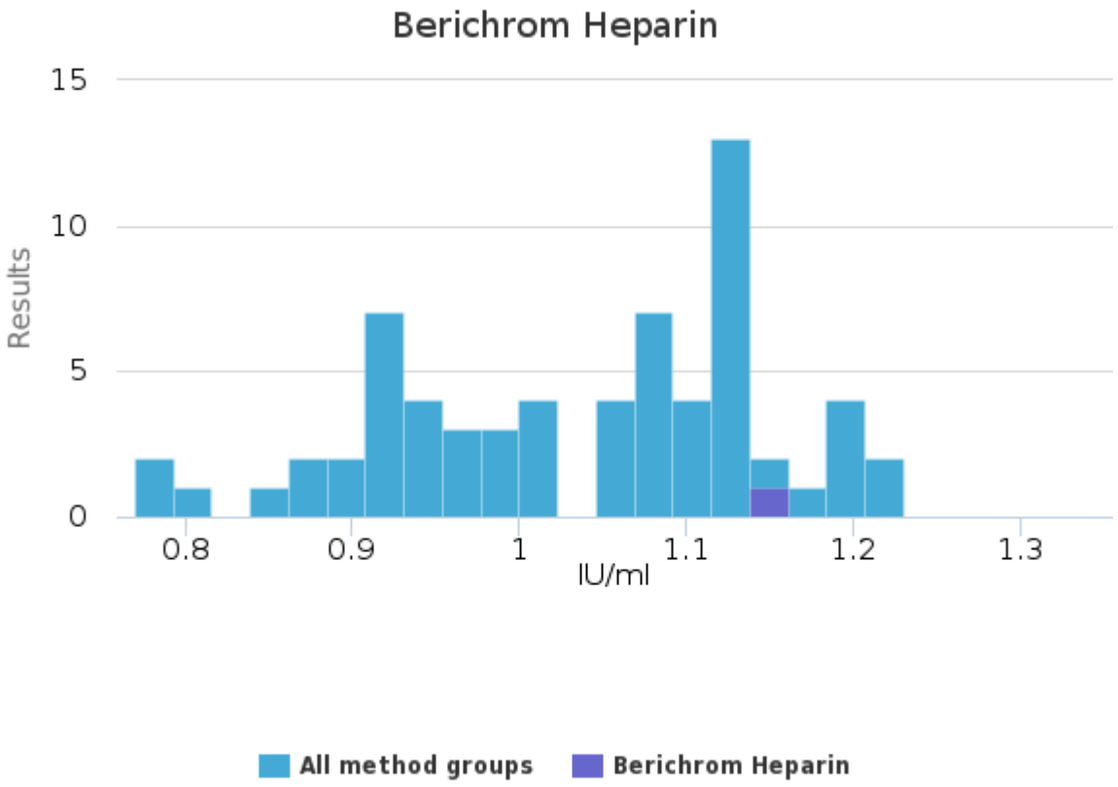
Anticoagulants: LMW-Heparin/antiFXa, February, 1-2023

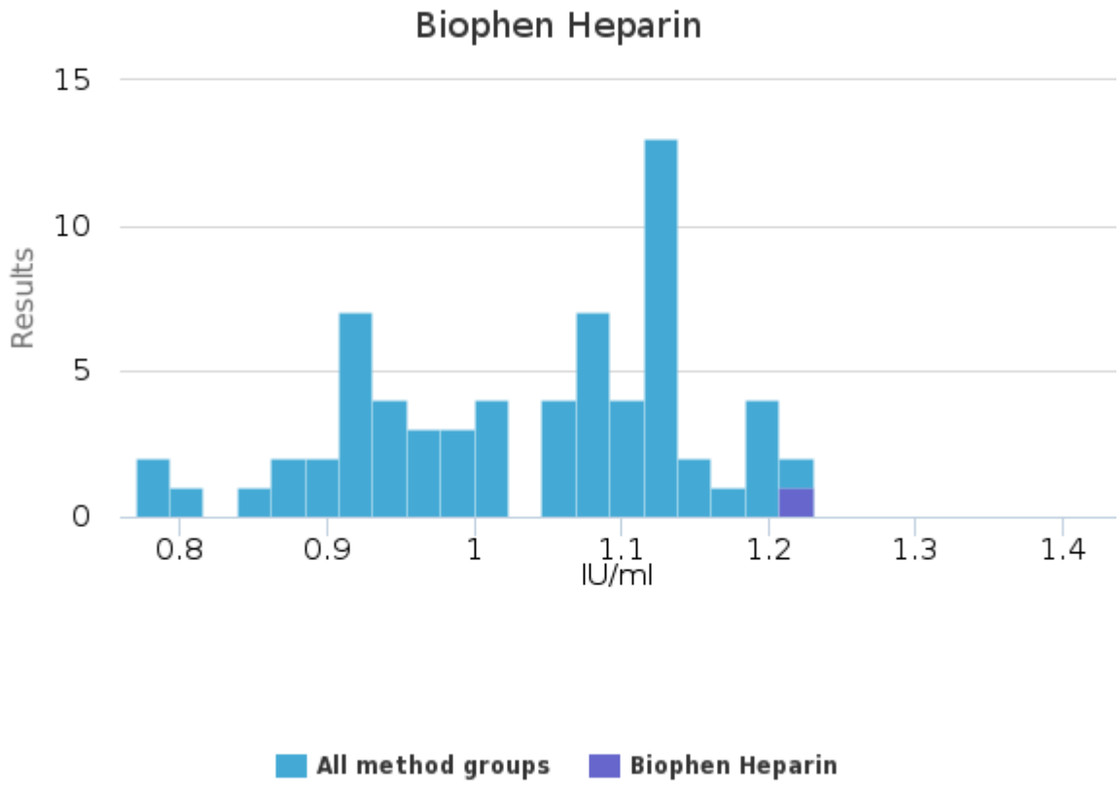
Quantitative report

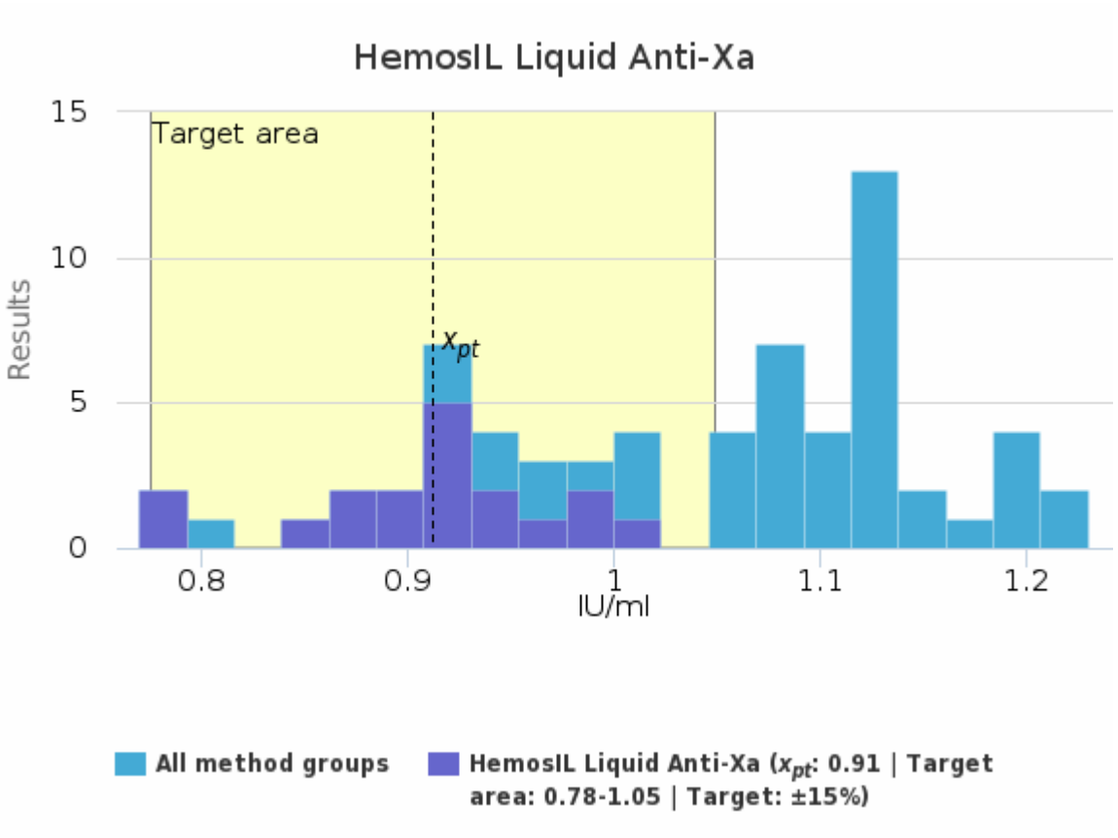
Sample S002 | LMW heparin, IU/ml

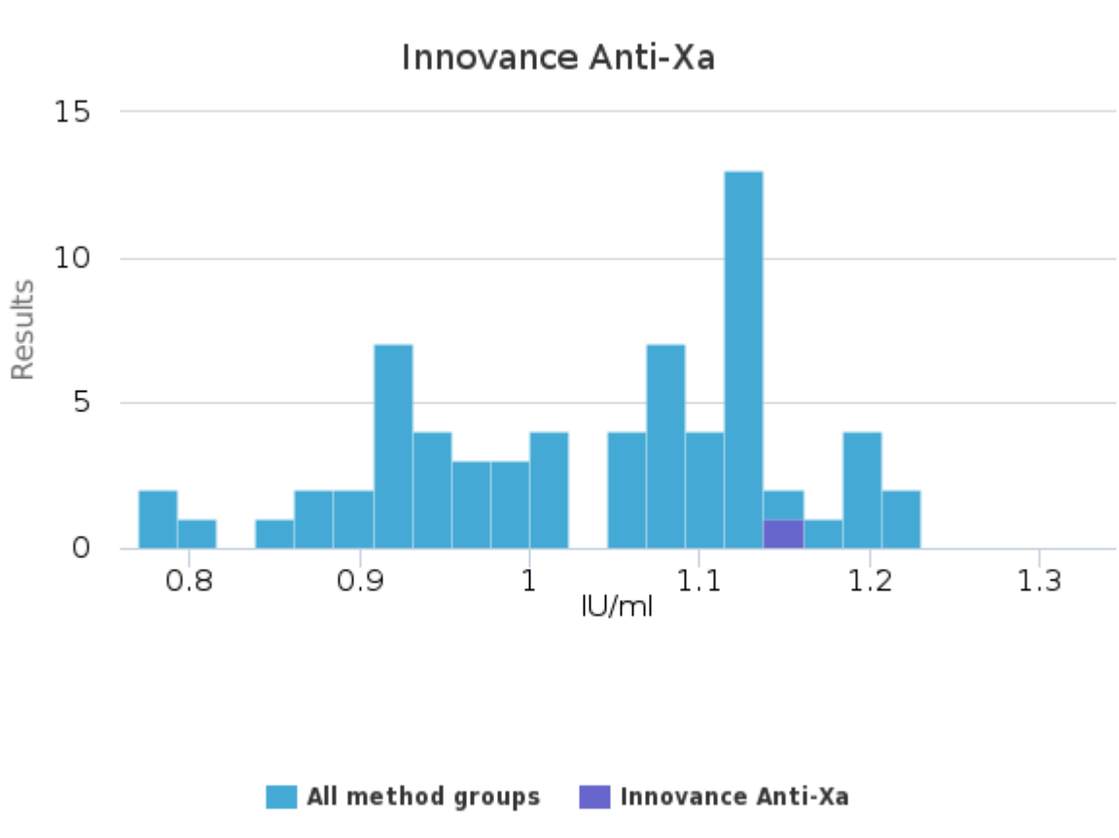
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Berichrom Heparin	-	-	-	-	-	1.16	1.16	-	1
Biophen Heparin	-	-	-	-	-	1.23	1.23	-	1
HemosIL Liquid Anti-Xa	0.91	0.93	0.06	7.1	0.02	0.77	1.02	-	18
Innovance Anti-Xa	-	-	-	-	-	1.15	1.15	-	1
Innovance Heparin	1.12	1.12	0.04	3.9	<0.01	1.05	1.22	1	32
Stago Liquid anti-Xa	0.98	0.98	0.07	7.6	0.02	0.80	1.08	-	13
All	**1.04**	**1.07**	**0.11**	**10.8**	**0.01**	**0.77**	**1.23**	**-**	**66**

Sample S002 | LMW heparin, IU/ml| histogram summaries in LabScala



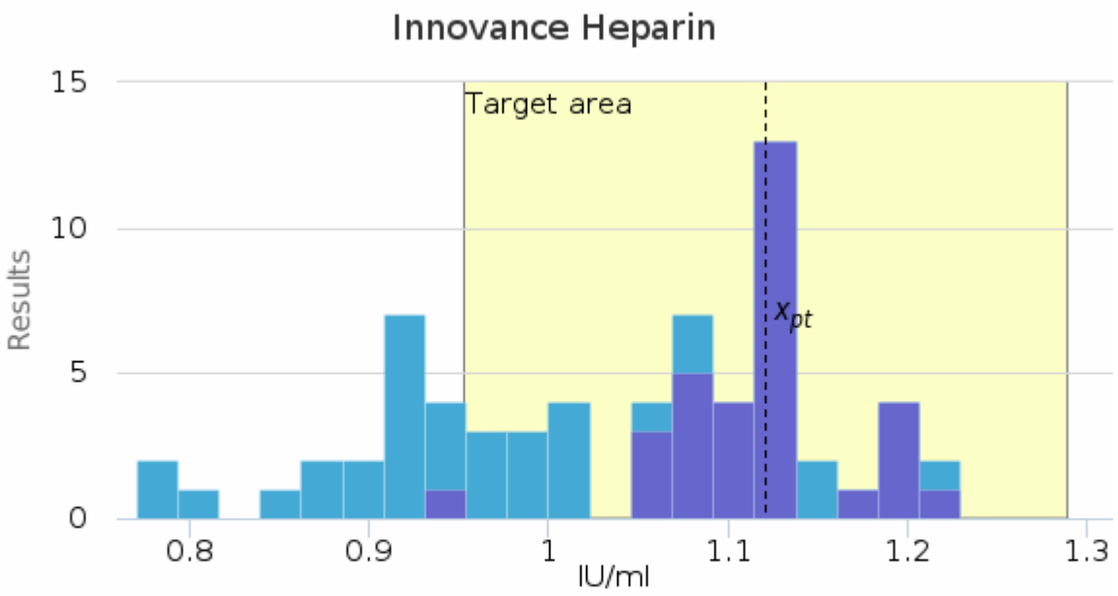


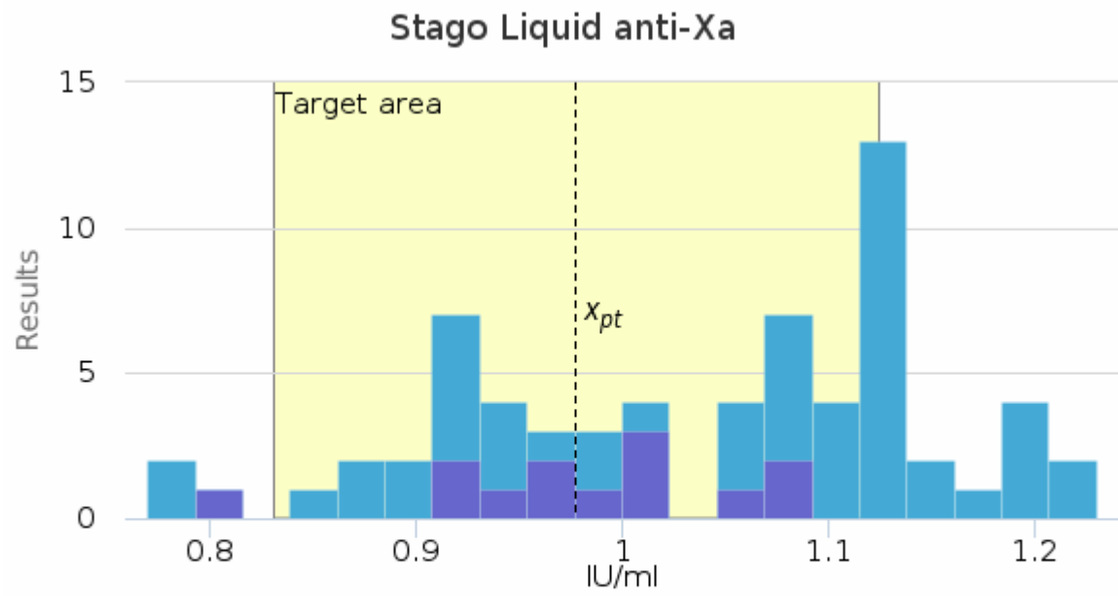




Anticoagulants: LMW-Heparin/antiFXa, February, 1-2023

Quantitative report





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Quantitative report

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LABQUALITY

External Quality Assessment Scheme

LMWH-Heparin/anti-FXa
Round 1, 2023

Specimens
Sample S001 (LQ7086223011) and sample S002 (LQ708623012) 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
Sample S001 was low-level sample, the average of all results was 0.41 IU/mL. Results ranged from 0.25 to 0.44 IU/mL. Sample S002 was a high-level sample. The mean of all results for sample S002 was 1.04 IU/mL. The results ranged from 0.77 to 1.23 IU/mL. The results were uniform within the method groups, with the exception of a few deviating results.

End of report

2023-02-23

FINAL REPORT

Product no. 4387

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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