LABQUALITY

External Quality Assessment Scheme

D-Dimer
Round 1, 2023

Specimens
Please find enclosed 2 buffer diluted human plasma samples S001 and S002, each 0.5 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
D-dimer

Storage and use
Please analyze samples on arrival day. If this is not possible, store samples in a refrigerator (+2…8 °C) and analyze as soon as possible. Let the vials warm to room temperature at least for 15 minutes before the measurement. Analyze as patient samples.

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.

The laboratories are asked to give the results only in FEU units (Fibrinogen Equivalent Unit), 1 FEU = 2 x D-dimer concentration. The following methods give the result straight in FEU units: Roche Tina-quant, Roche Cardiac D-dimer, BioMerieux Vidas D-dimer, STA-Liatest D-dimer, Innovance D-Dimer and HemosIL D-dimer HS 500.

If you are using other method than listed above, please check manual of your reagent/device. If your method gives results as a D-dimer concentration, please multiple result with 2 to get result in FEU unit and report it to LabScala.

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.

S001

LQ708423011

S002

LQ708423012

2023-01-31

INSTRUCTIONS

Product no. 4388
LQ708423011-012/SE

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

The results should be reported no later than **February 20, 2023.**

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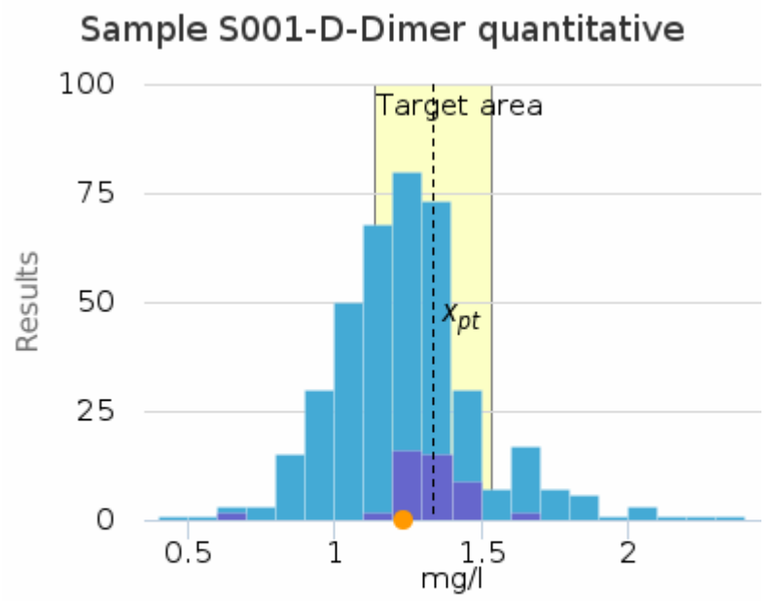
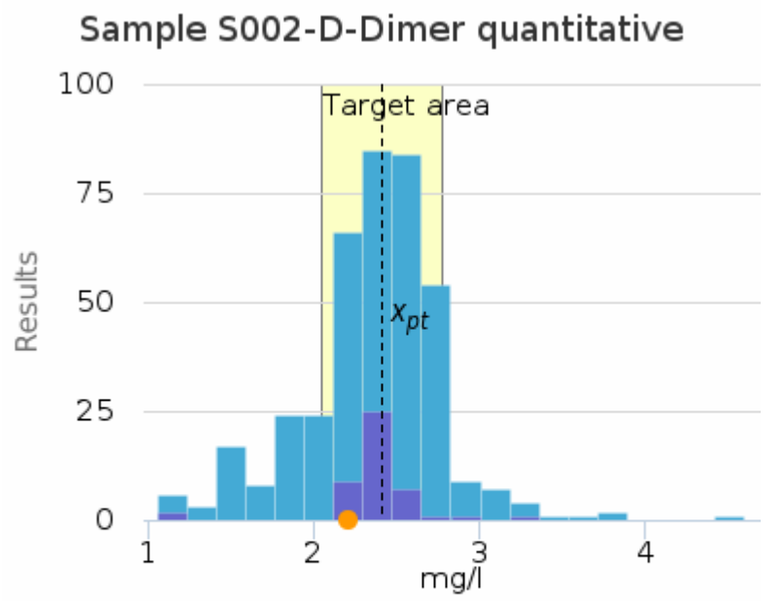
FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015

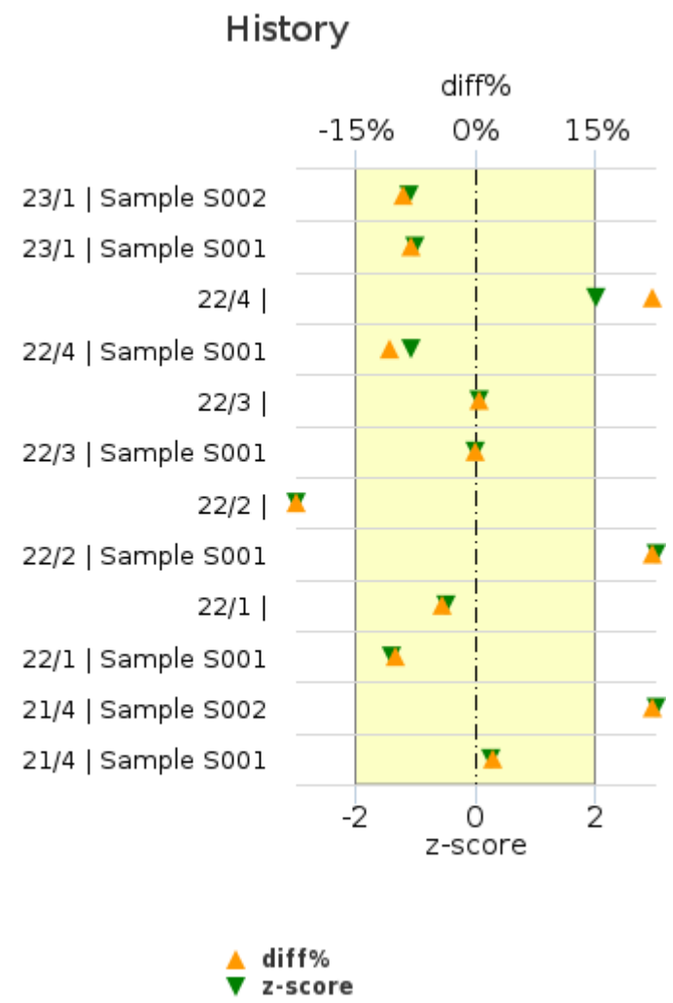
D-Dimer quantitative |sysmex cs



All method groups | Innovance D-dimer
Own result: 1.23 (08.02.2023)
Diff%: -8.02 | x_{pt}: 1.34
Target area: 1.14-1.54 | Target: ±15%



All method groups | Innovance D-dimer
Own result: 2.20 (08.02.2023)
Diff%: -8.91 | x_{pt}: 2.42
Target area: 2.05-2.78 | Target: ±15%



	x_{pt}	sd	SEM	CV%	n
Innovance D-dimer	1.34 mg/l	0.11	0.02	7.9	46
All methods	1.23 mg/l	0.22	0.01	18.0	398

	x_{pt}	sd	SEM	CV%	n
Innovance D-dimer	2.42 mg/l	0.19	0.03	8.0	46
All methods	2.36 mg/l	0.38	0.02	16.2	396

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	2.42	2.20	-8.91%	-1.11
23/1	Sample S001	1.34	1.23	-8.02%	-1.01
22/4		0.50	0.62	24.68%	2.01
22/4	Sample S001	6.48	5.80	-10.55%	-1.07
22/3		0.85	0.85	0.51%	0.06
22/3	Sample S001	3.75	3.75	0.11%	0.01
22/2		4.85	2.28	-52.99%	-4.93
22/2	Sample S001	2.32	4.70	102.16%	12.85
22/1		5.33	5.11	-4.09%	-0.48
22/1	Sample S001	1.30	1.17	-10.02%	-1.40
21/4	Sample S002	5.04	7.68	52.45%	5.39
21/4	Sample S001	0.65	0.66	2.18%	0.26

Report info

Participants

359 participants from 15 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.

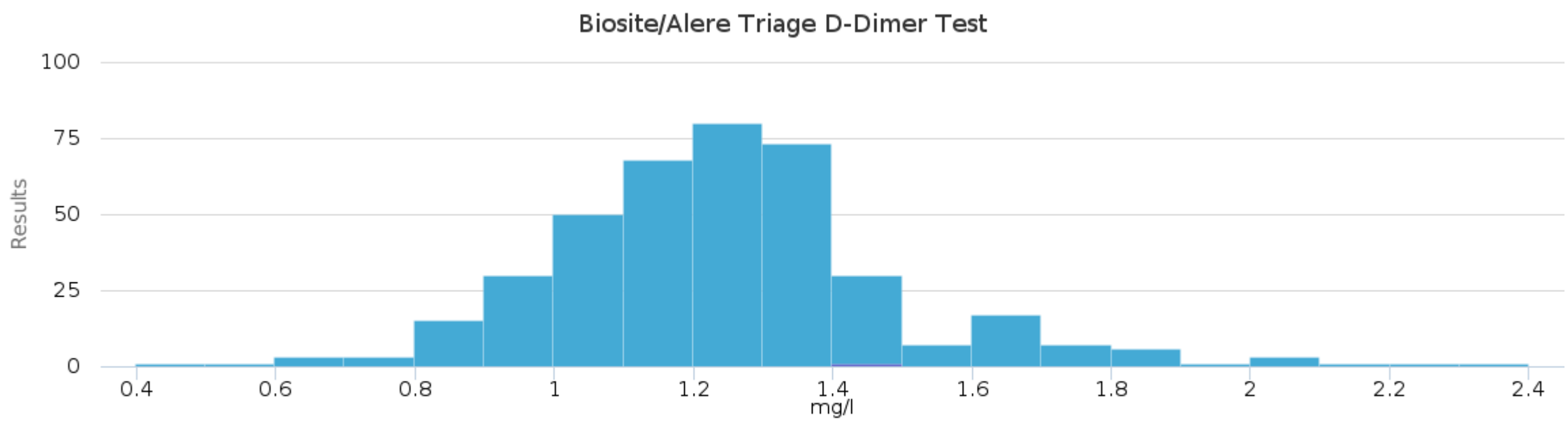
For information on report interpretation and performance evaluation, please see the " EQAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

Sample S001 | D-Dimer qualitative (pos/neg), -

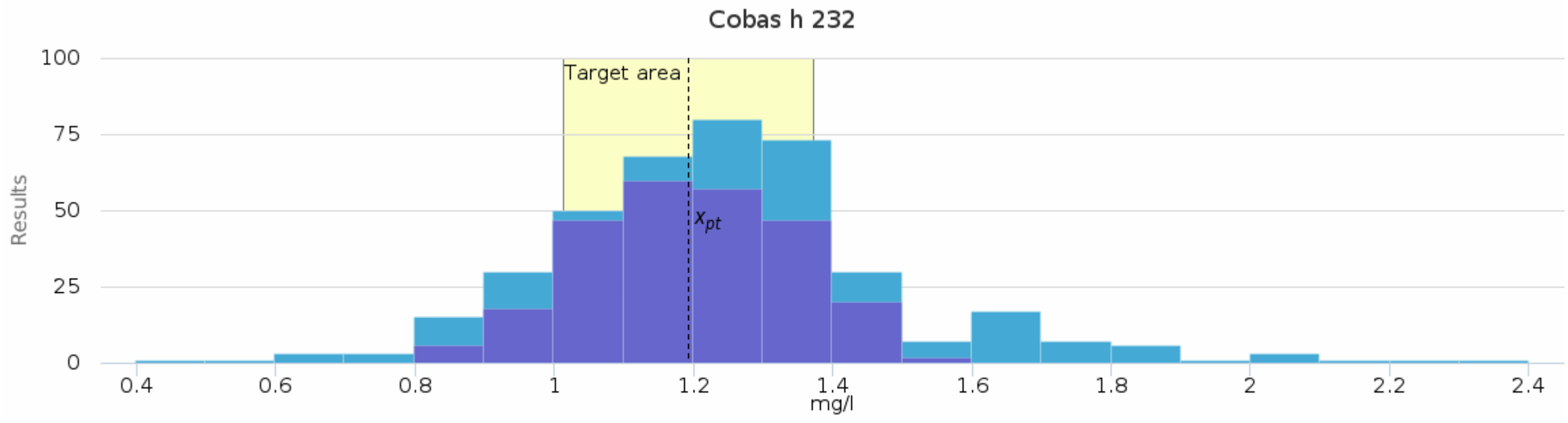
Methodics	Positive	Total
ACRO Biotech D-dimer	5	5
Total	**5**	**5**

Sample S001 | D-Dimer quantitative, mg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Biosite/Alere Triage D-Dimer Test	-	-	-	-	-	1.43	1.43	-	1
Cobas h 232	1.19	1.19	0.14	12.0	<0.01	0.81	1.58	-	257
D-Dimer OSR60135	0.95	0.95	<0.01	<0.1	<0.01	0.95	0.95	-	2
GeTein D-Dimer	-	-	-	-	-	1.38	1.38	-	1
Helena D-Dimer	-	-	-	-	-	1.78	1.78	-	1
HemosIL D-dimer HS	-	-	-	-	-	0.65	0.65	-	1
HemosIL D-dimer HS 500	1.68	1.69	0.08	5.0	0.02	1.56	1.89	1	32
iChroma D-Dimer	-	-	-	-	-	0.40	0.40	-	1
Immulite D-dimer	-	-	-	-	-	0.91	0.91	-	1
Innovance D-dimer	1.34	1.32	0.11	7.9	0.02	1.17	1.65	2	46
LumiraDx D-Dimer	-	-	-	-	-	2.26	2.26	-	1
Quantia D-Dimer	1.26	1.26	0.06	5.1	0.05	1.21	1.30	-	2
Radiometer D-Dimer	-	-	-	-	-	0.56	0.56	-	1
STA- Liatest	0.93	0.93	0.06	6.2	0.01	0.85	1.03	1	18
Thermo Fisher D-dimer	-	-	-	-	-	0.77	0.77	-	1
Tina-quant	1.39	1.30	0.32	23.4	0.06	1.01	2.19	-	27
VIDAS D-Dimer Exclusion II	0.80	0.82	0.06	7.1	0.03	0.73	0.86	-	5
All	**1.23**	**1.23**	**0.22**	**18.0**	**0.01**	**0.56**	**1.98**	**7**	**398**

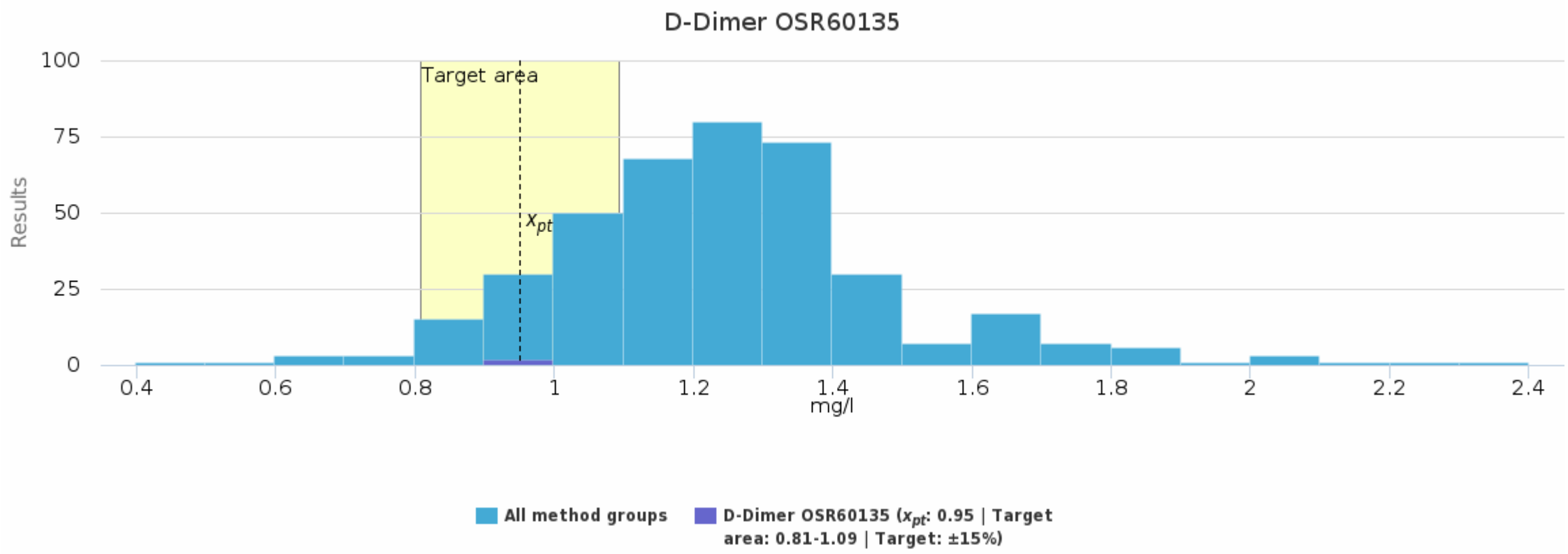


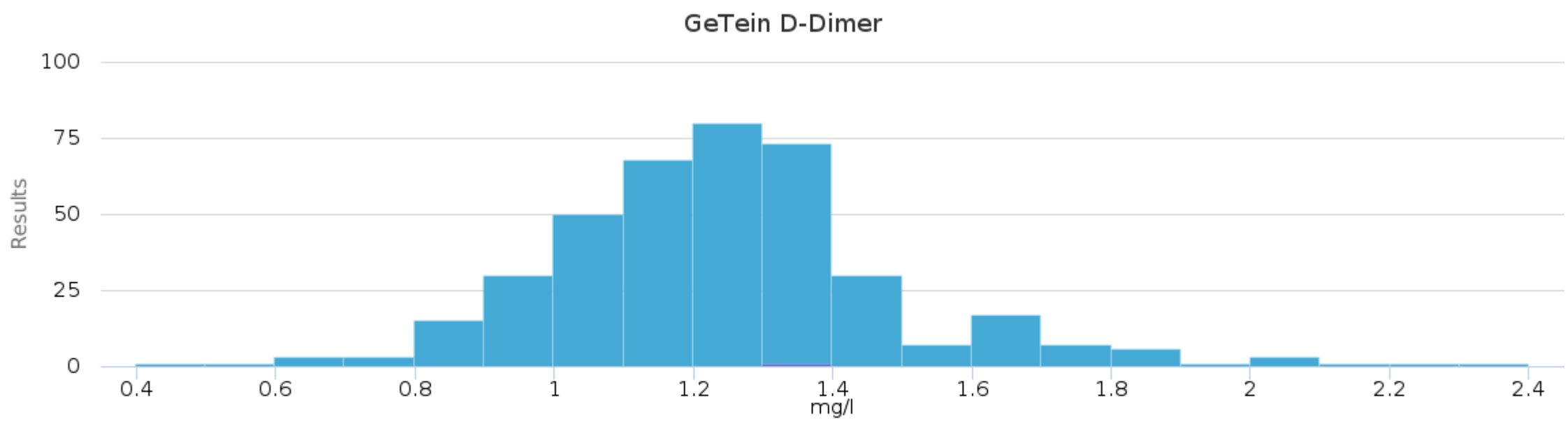
All method groups Biosite/Alere Triage D-Dimer Test

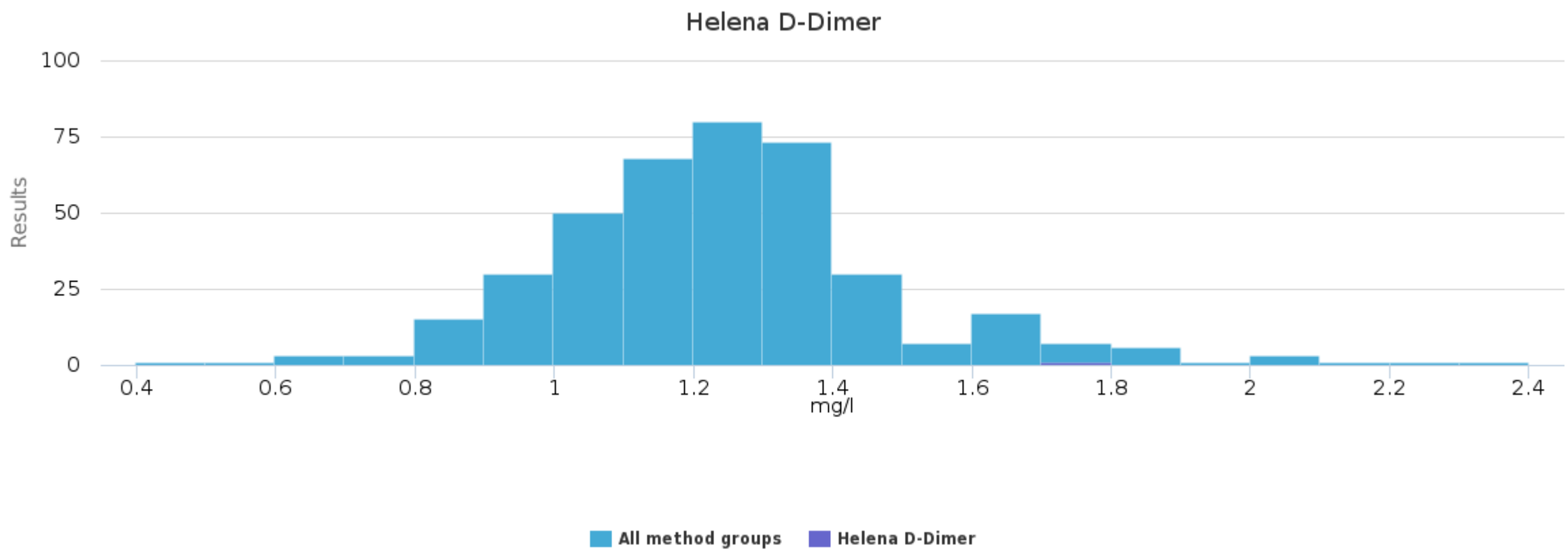


All method groups Cobas h 232 (x_{pt}: 1.19 | Target area: 1.01-1.37 | Target: ±15%)

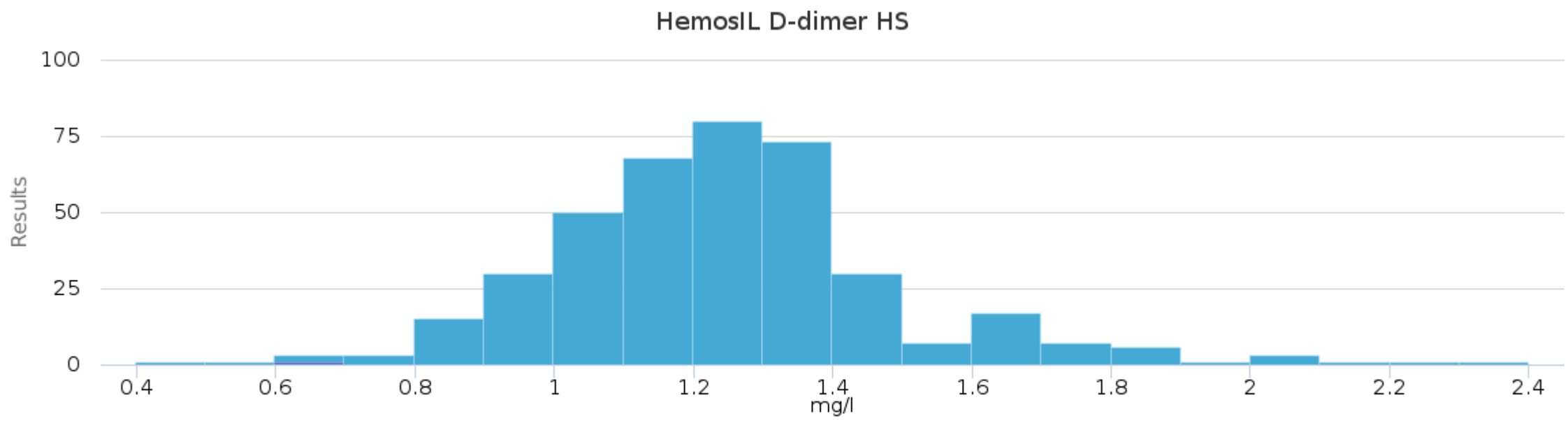
D-dimer, February, 1-2023



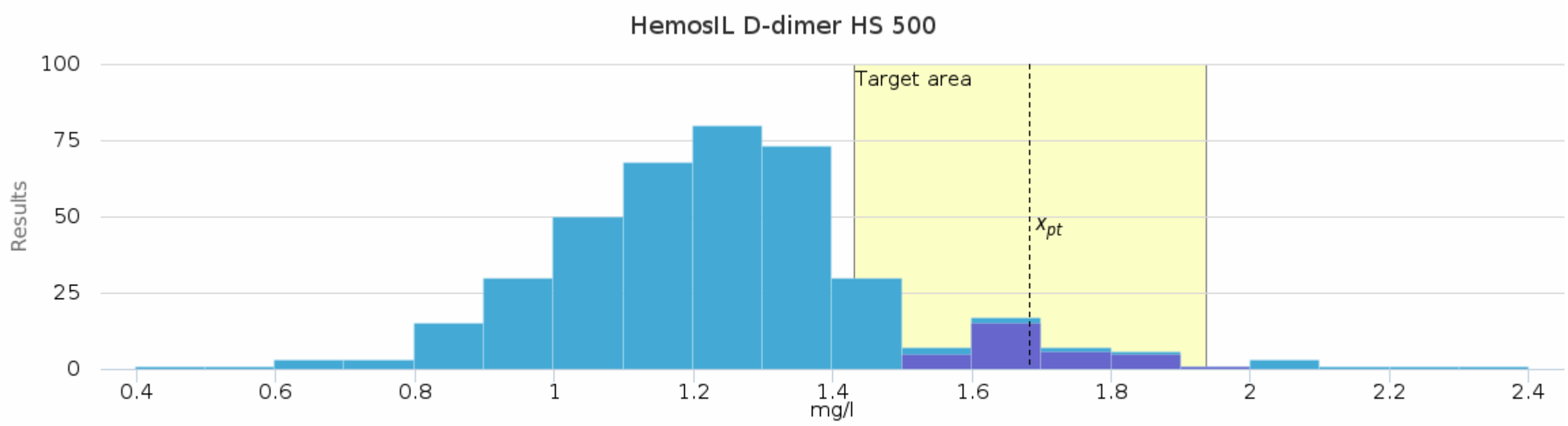




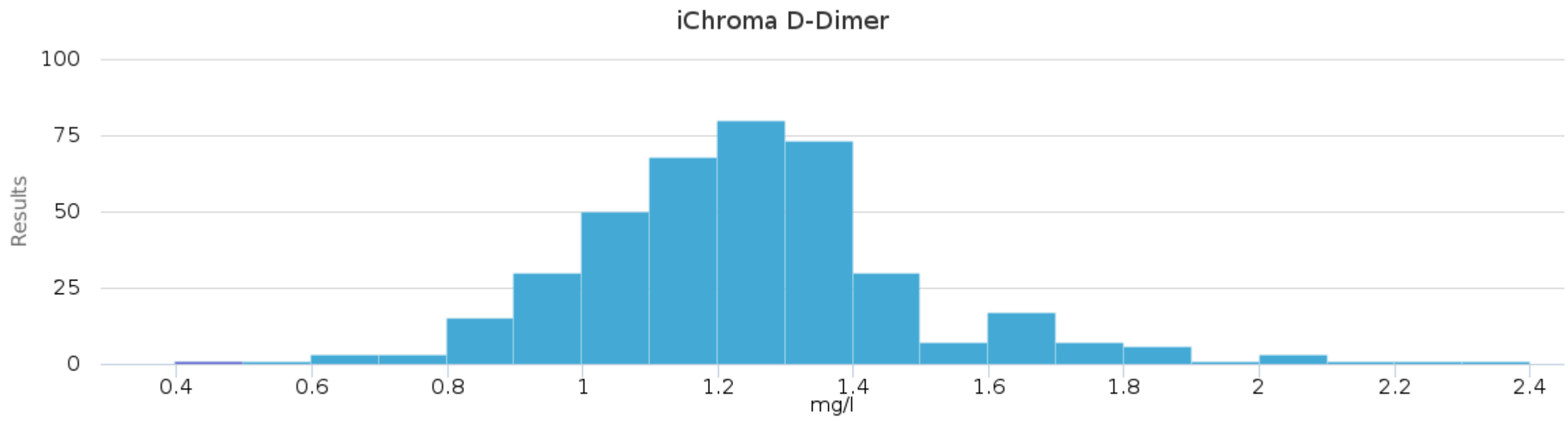
D-dimer, February, 1-2023



All method groups HemosIL D-dimer HS

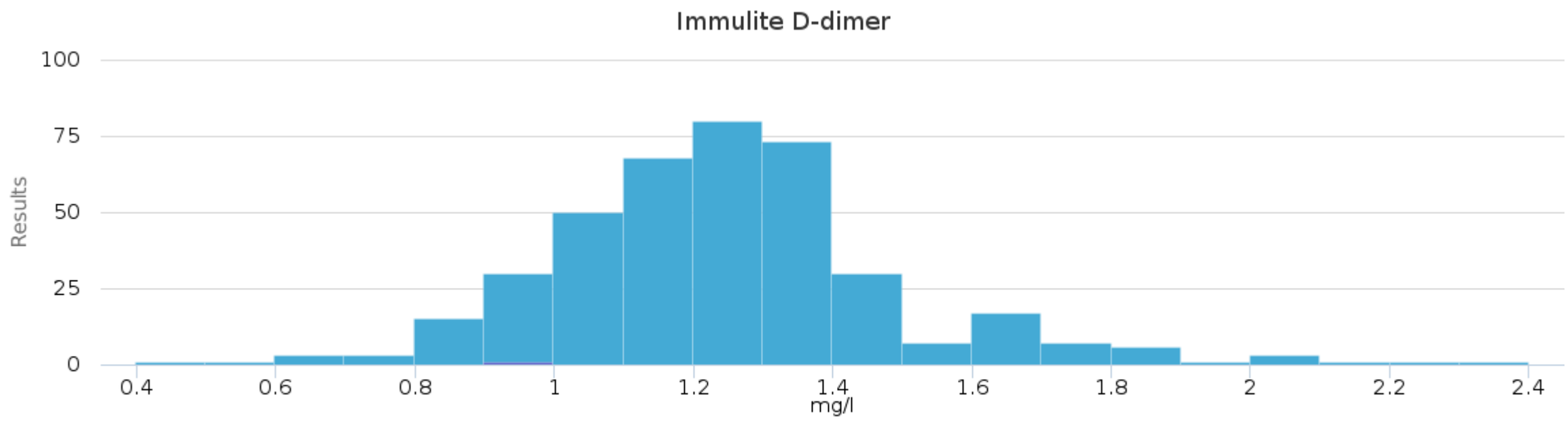


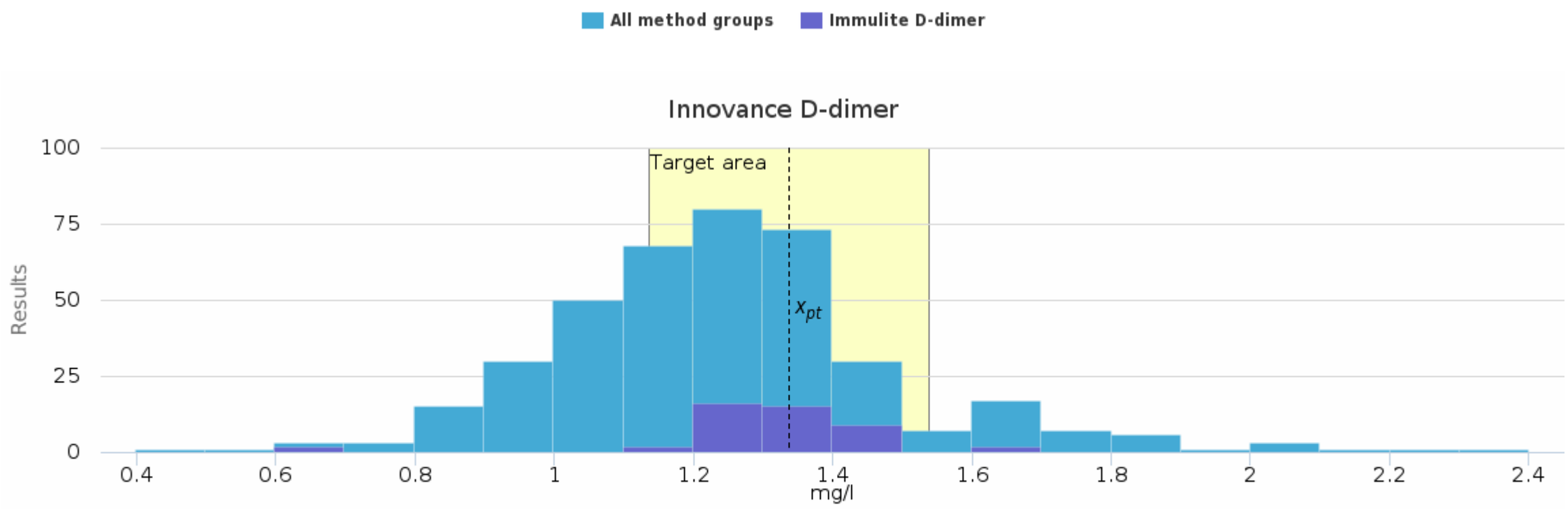
All method groups HemosIL D-dimer HS 500 (x_{pt}: 1.68 | Target area: 1.43-1.94 | Target: ±15%)

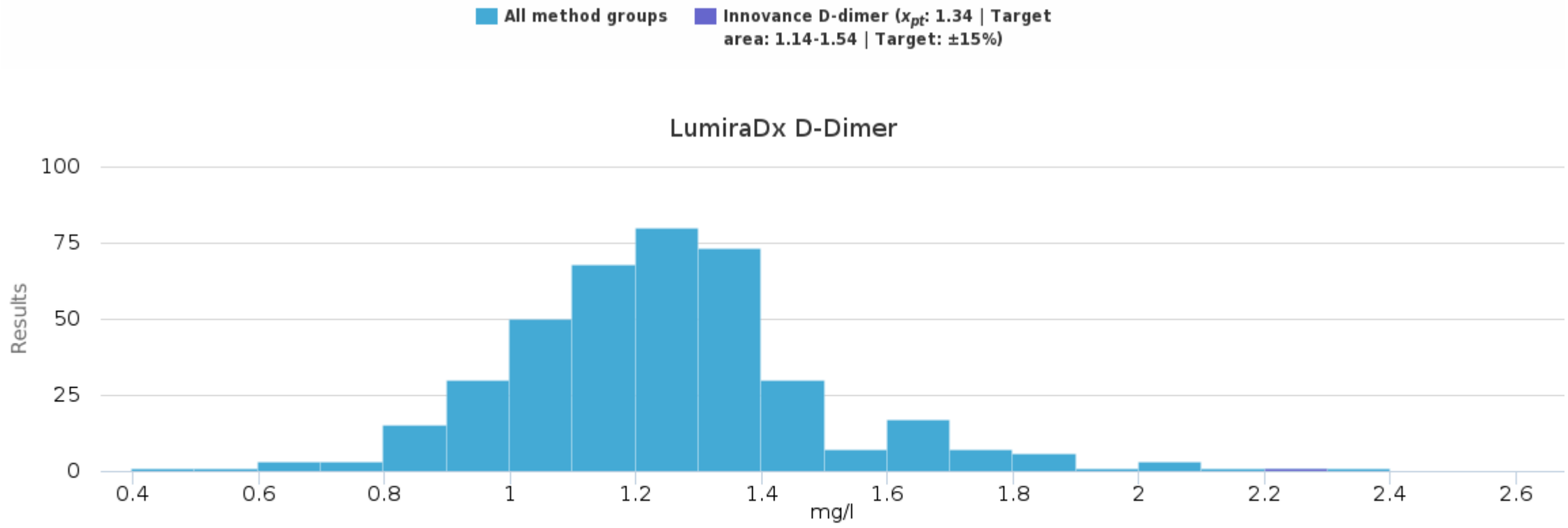


All method groups iChroma D-Dimer

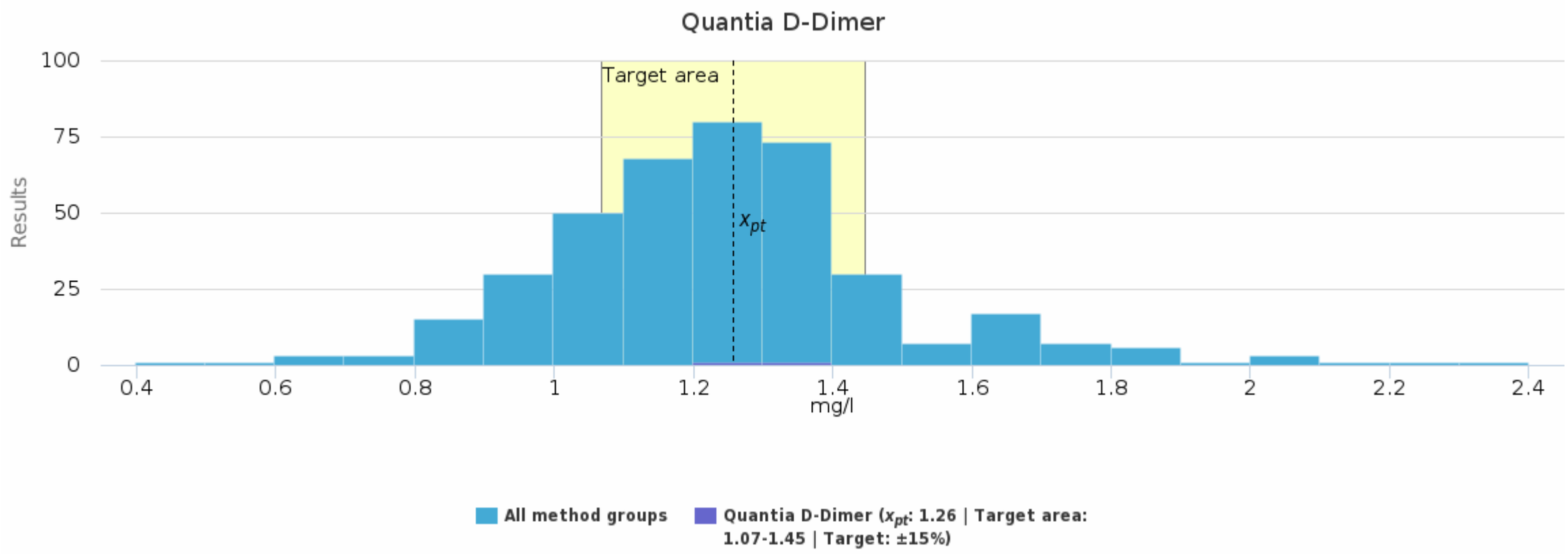
D-dimer, February, 1-2023

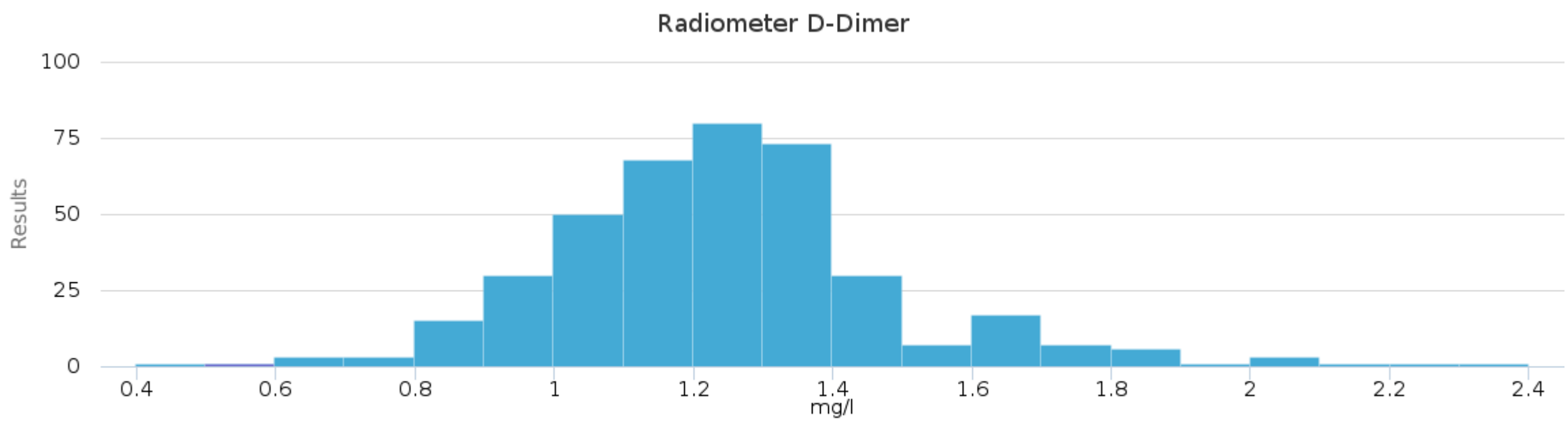


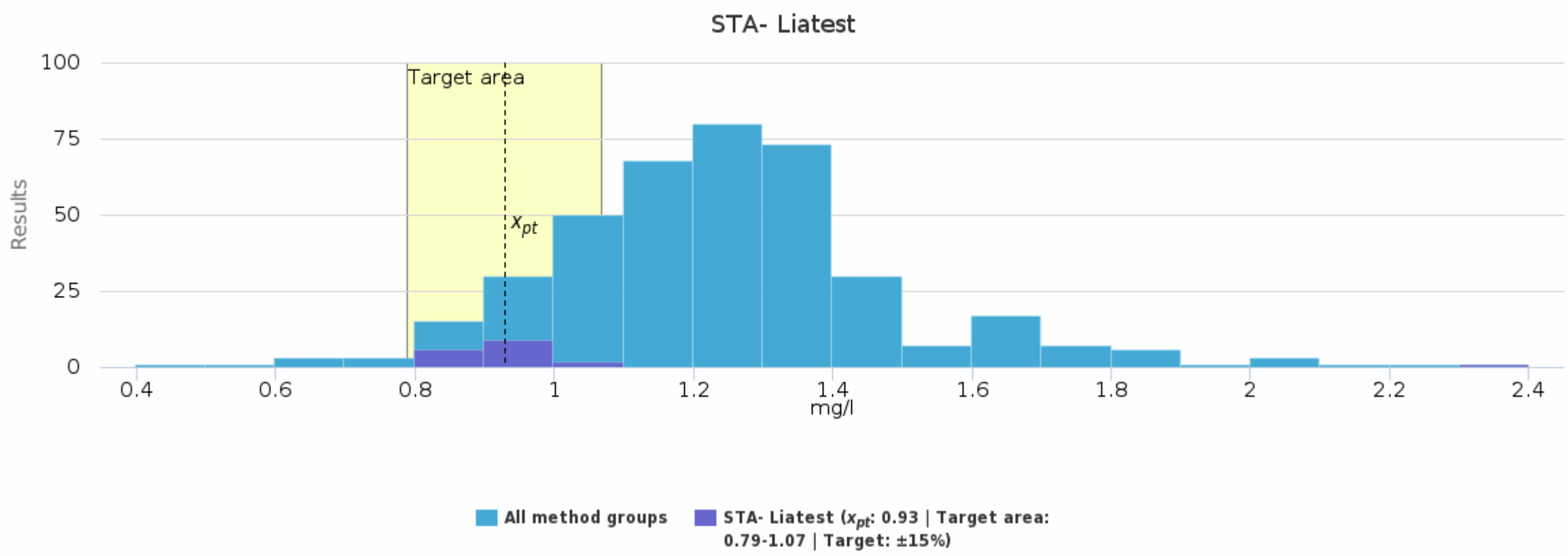




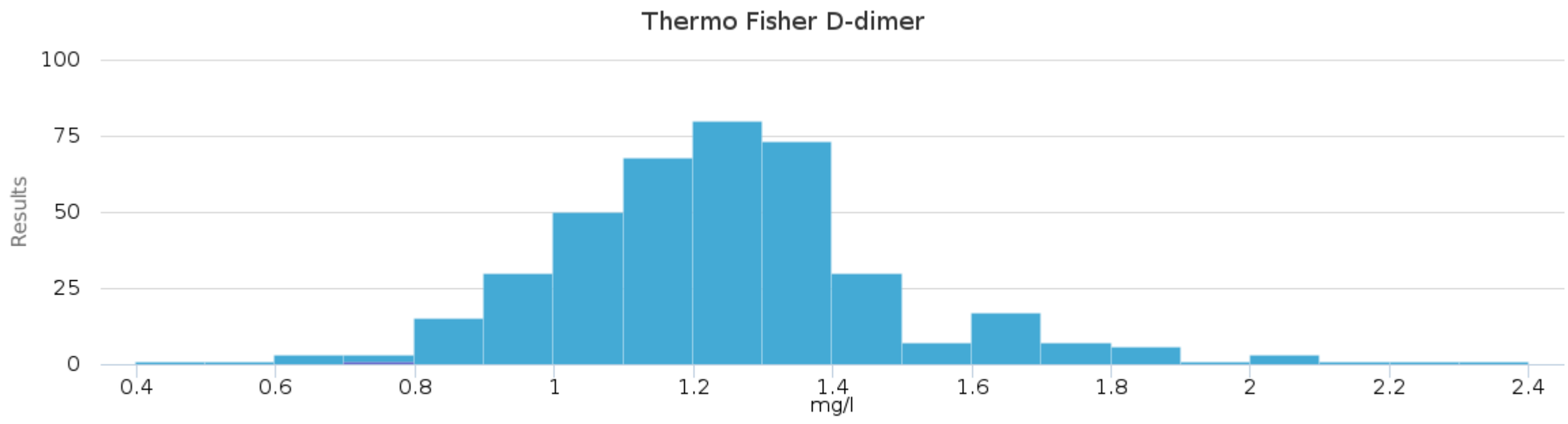
All method groups LumiraDx D-Dimer



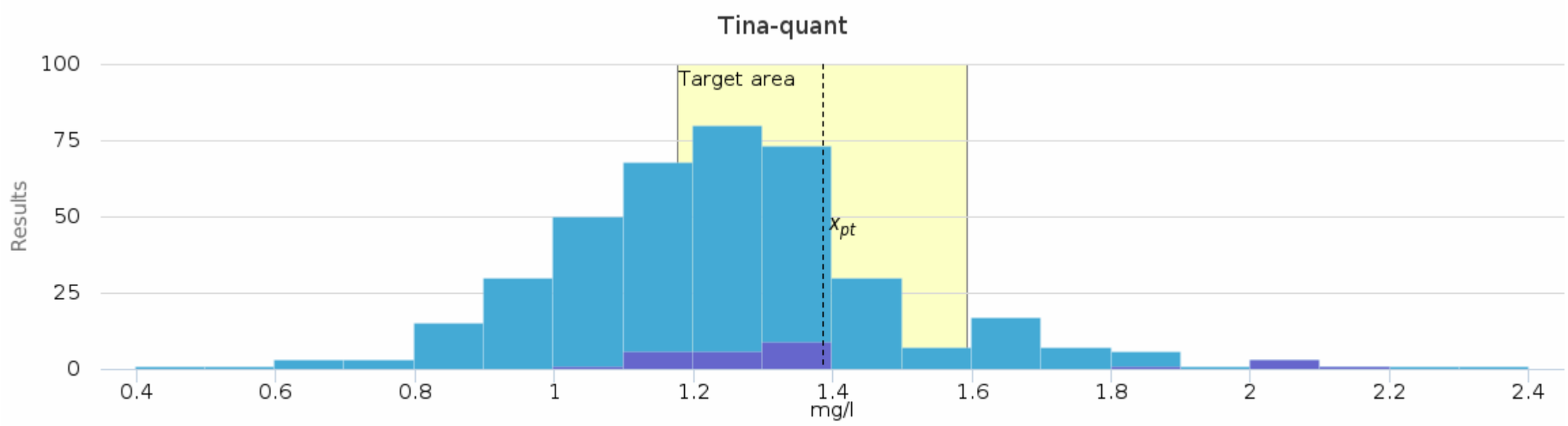




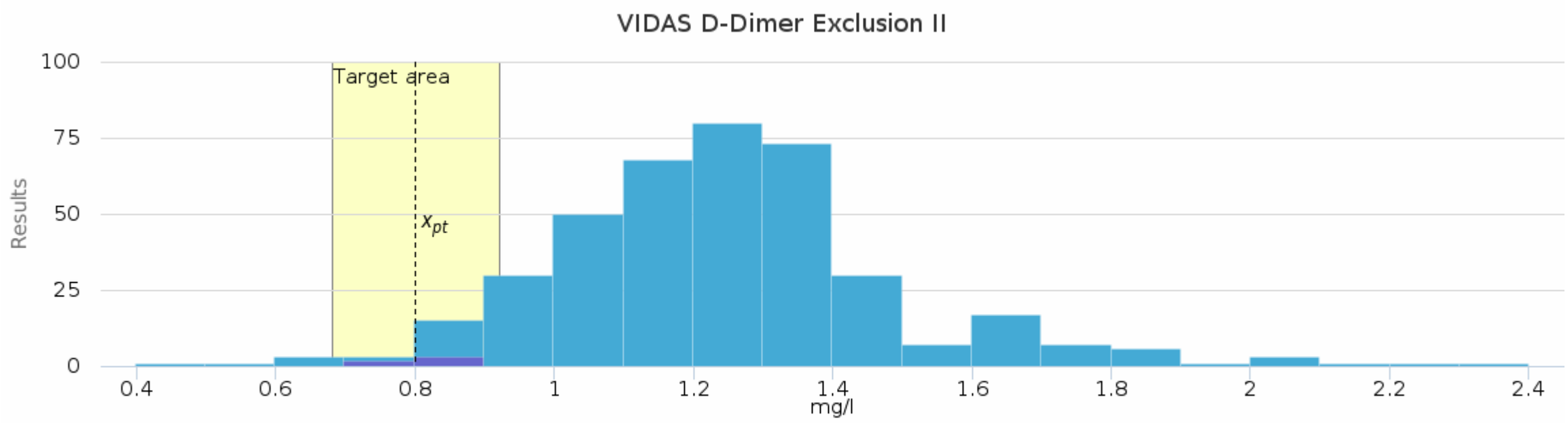
D-dimer, February, 1-2023



All method groups Thermo Fisher D-dimer



All method groups Tina-quant (x_{pt}: 1.39 | Target area: 1.18-1.59 | Target: ±15%)



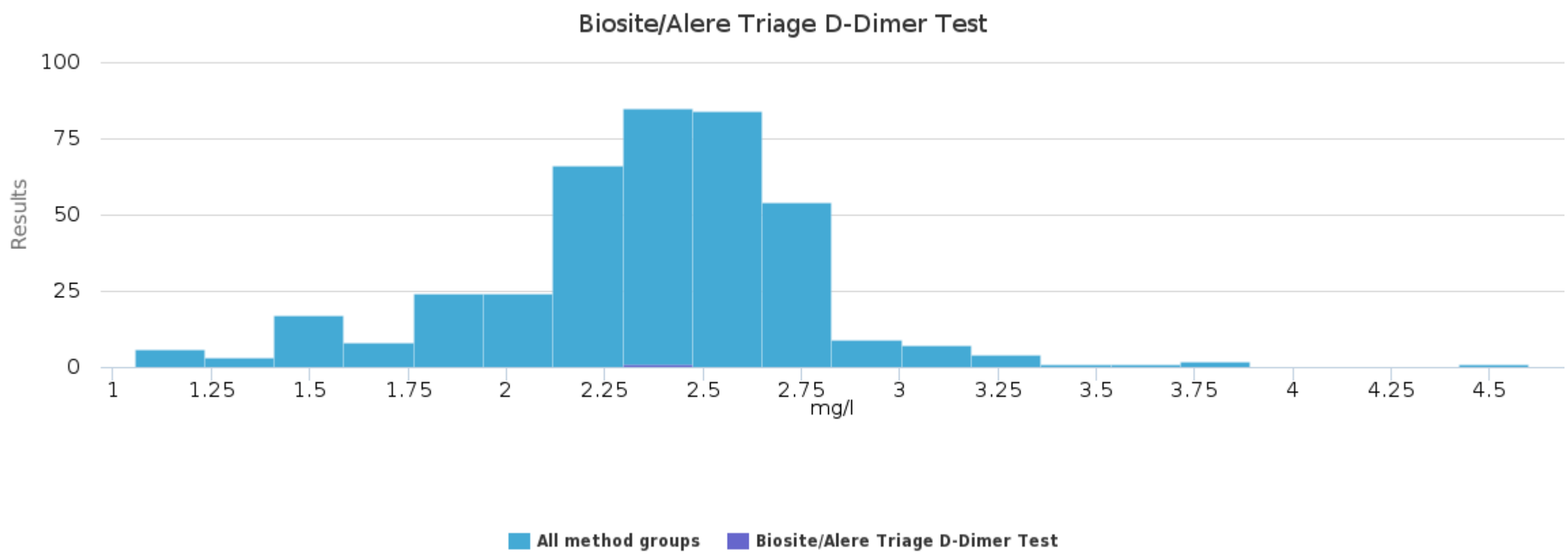
All method groups VIDAS D-Dimer Exclusion II (x_{pt}: 0.80 | Target area: 0.68-0.92 | Target: ±15%)

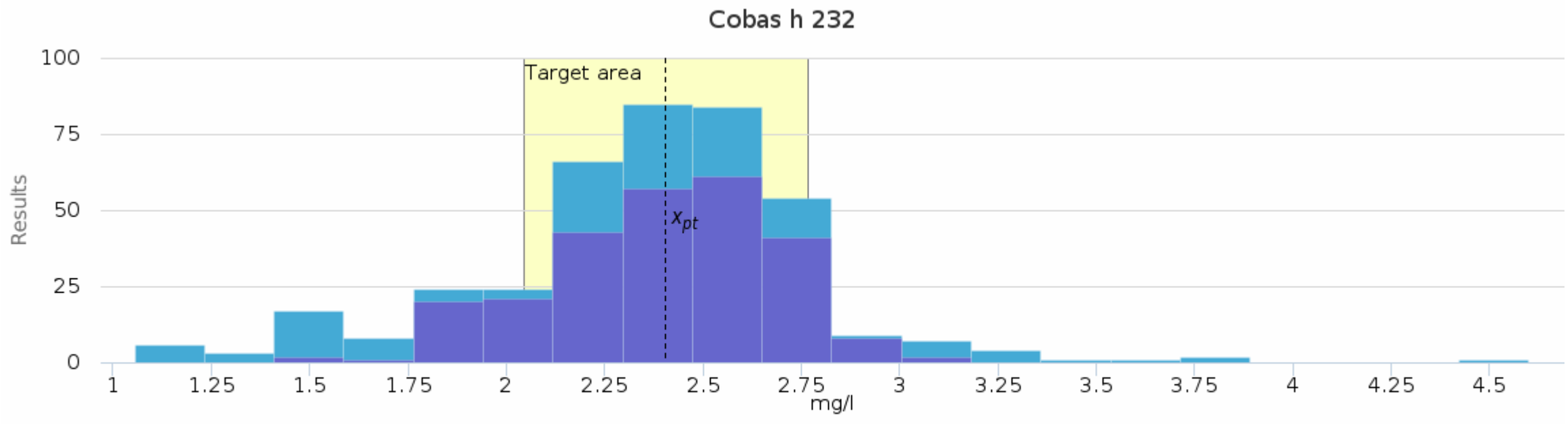
Sample S002 | D-Dimer qualitative (pos/neg), -

Methodics	Positive	Total
ACRO Biotech D-dimer	4	4
Total	**4**	**4**

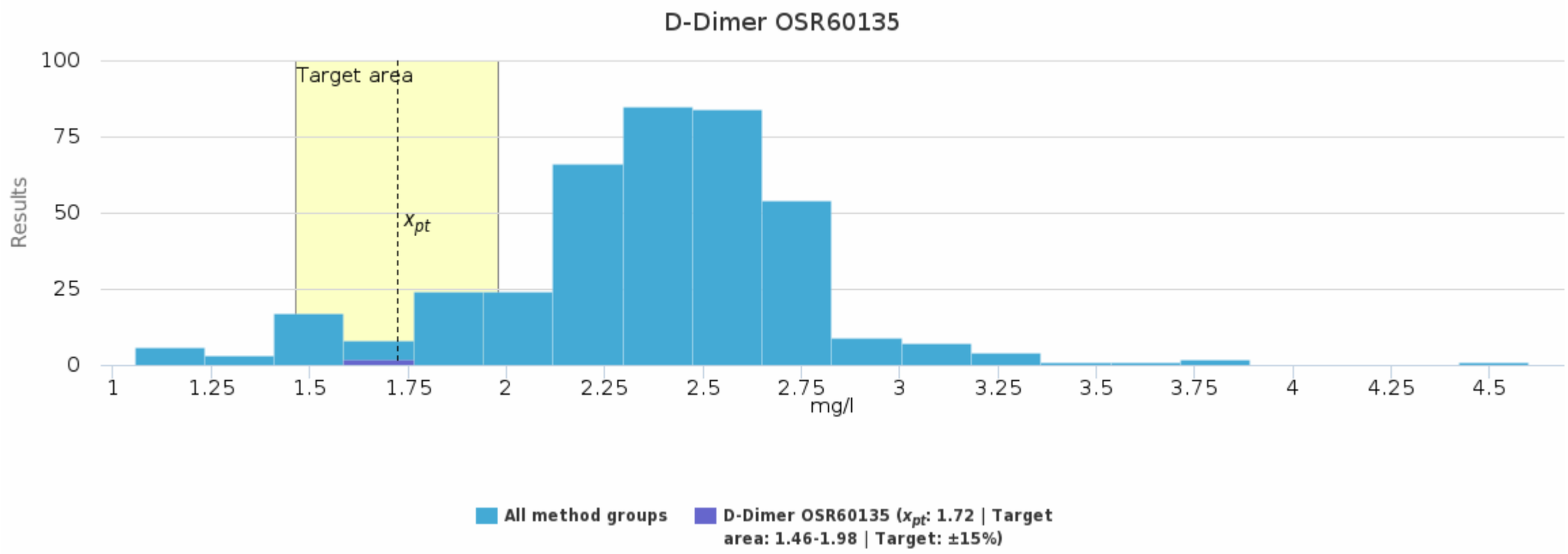
Sample S002 | D-Dimer quantitative, mg/l

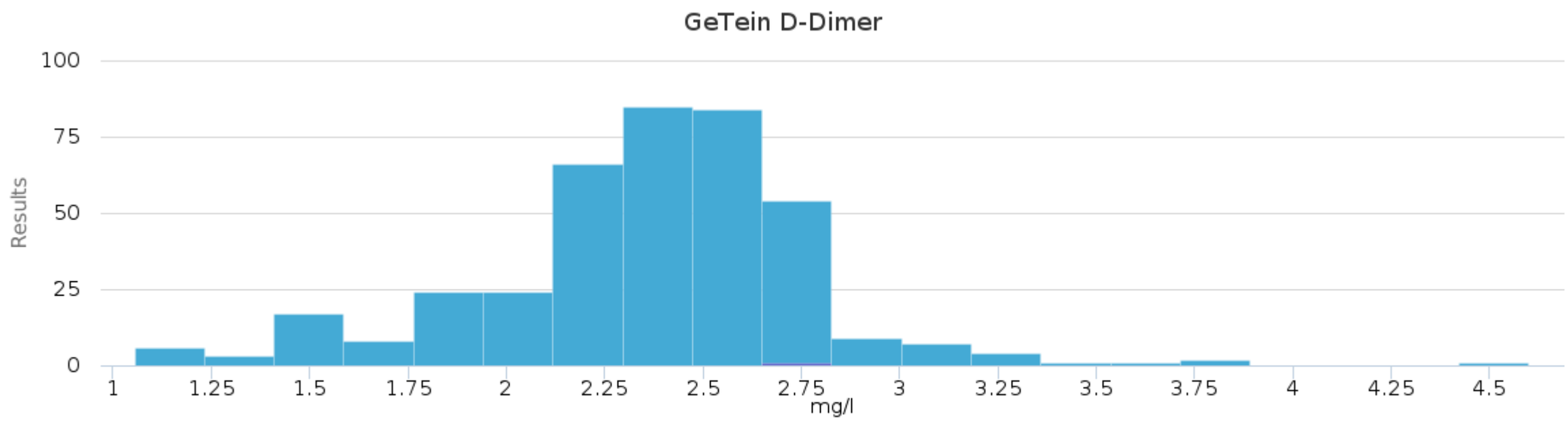
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Biosite/Alere Triage D-Dimer Test	-	-	-	-	-	2.34	2.34	-	1
Cobas h 232	2.41	2.43	0.29	11.9	0.02	1.72	3.15	2	256
D-Dimer OSR60135	1.72	1.72	0.03	1.9	0.02	1.70	1.75	-	2
GeTein D-Dimer	-	-	-	-	-	2.78	2.78	-	1
Helena D-Dimer	-	-	-	-	-	3.83	3.83	-	1
HemosIL D-dimer HS	-	-	-	-	-	1.09	1.09	-	1
HemosIL D-dimer HS 500	2.75	2.65	0.30	10.8	0.05	2.49	3.61	1	32
iChroma D-Dimer	-	-	-	-	-	1.15	1.15	-	1
Immulite D-dimer	-	-	-	-	-	1.56	1.56	-	1
Innovance D-dimer	2.42	2.38	0.19	8.0	0.03	2.13	3.25	2	46
LumiraDx D-Dimer	-	-	-	-	-	3.04	3.04	-	1
Quantia D-Dimer	1.88	1.88	0.01	0.8	0.01	1.87	1.89	-	2
Radiometer D-Dimer	-	-	-	-	-	1.06	1.06	-	1
STA- Liatest	1.55	1.55	0.07	4.5	0.02	1.41	1.69	1	17
Thermo Fisher D-dimer	-	-	-	-	-	1.34	1.34	-	1
Tina-quant	2.29	2.20	0.35	15.4	0.07	1.74	3.08	-	27
VIDAS D-Dimer Exclusion II	1.38	1.41	0.12	8.7	0.05	1.19	1.48	-	5
All	**2.36**	**2.41**	**0.38**	**16.2**	**0.02**	**1.15**	**3.61**	**6**	**396**

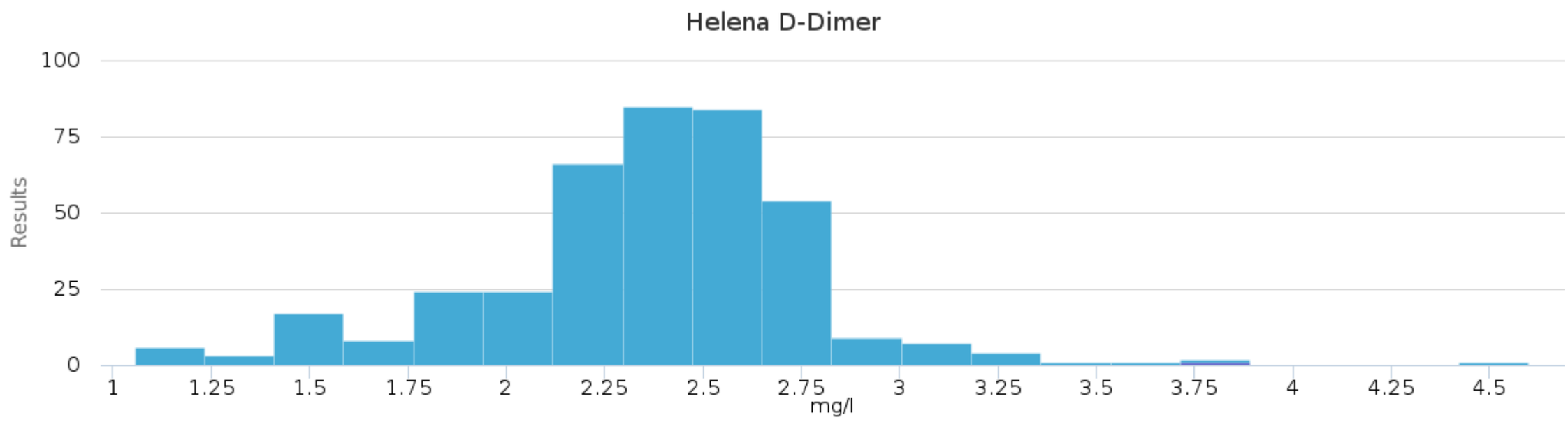




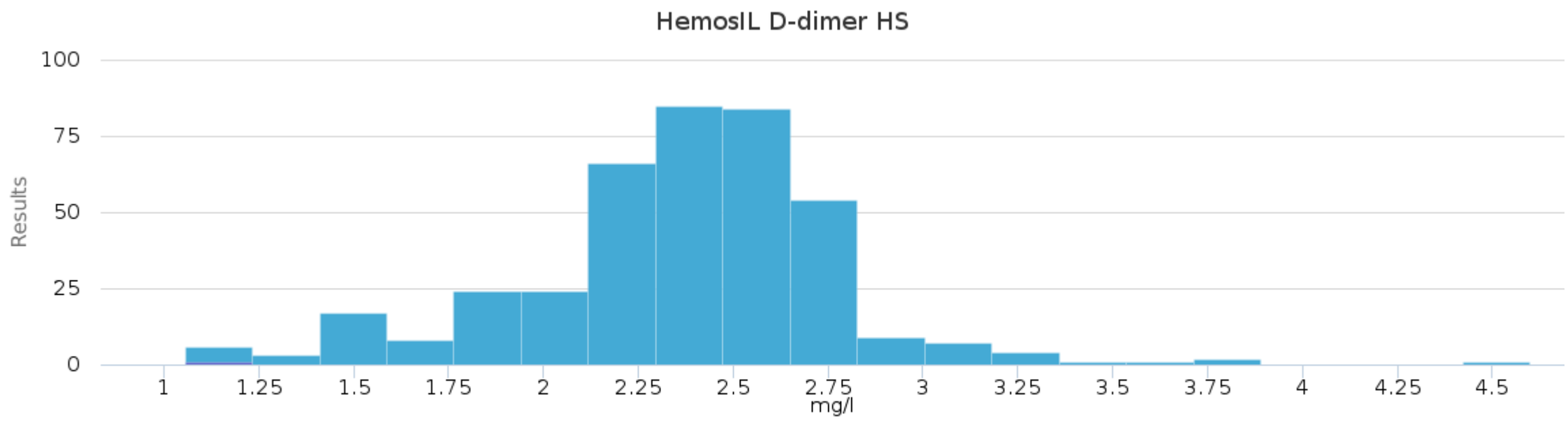
D-dimer, February, 1-2023



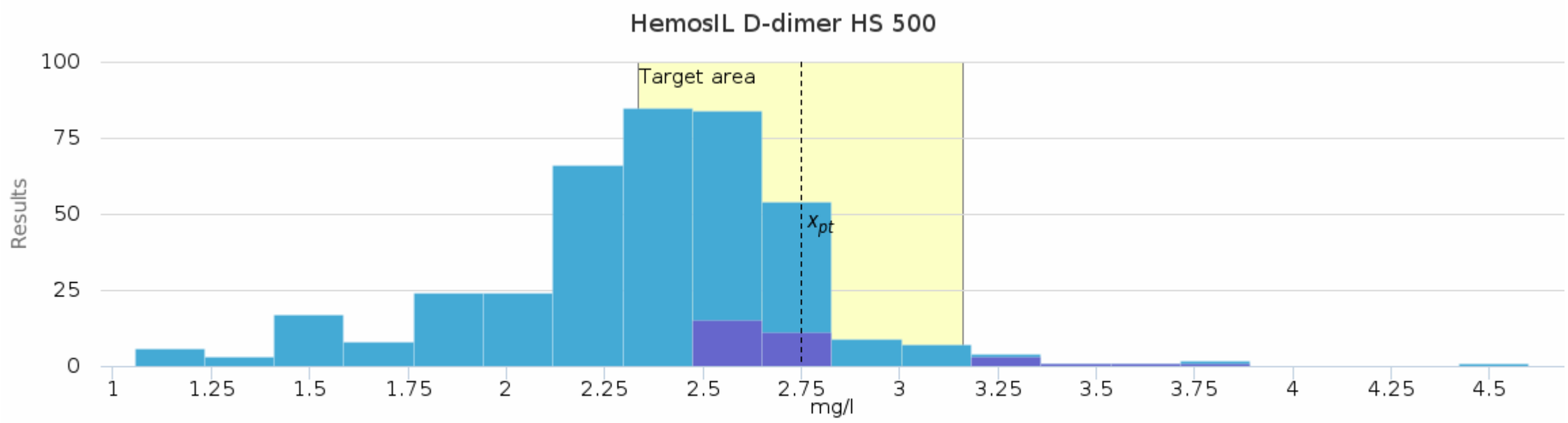




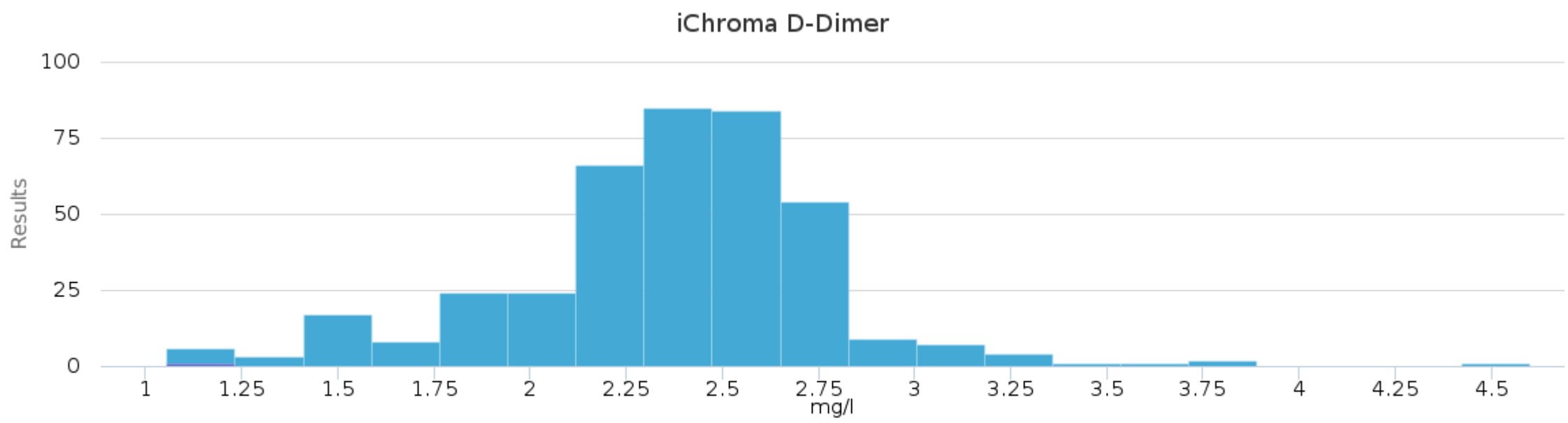
D-dimer, February, 1-2023



All method groups HemosIL D-dimer HS

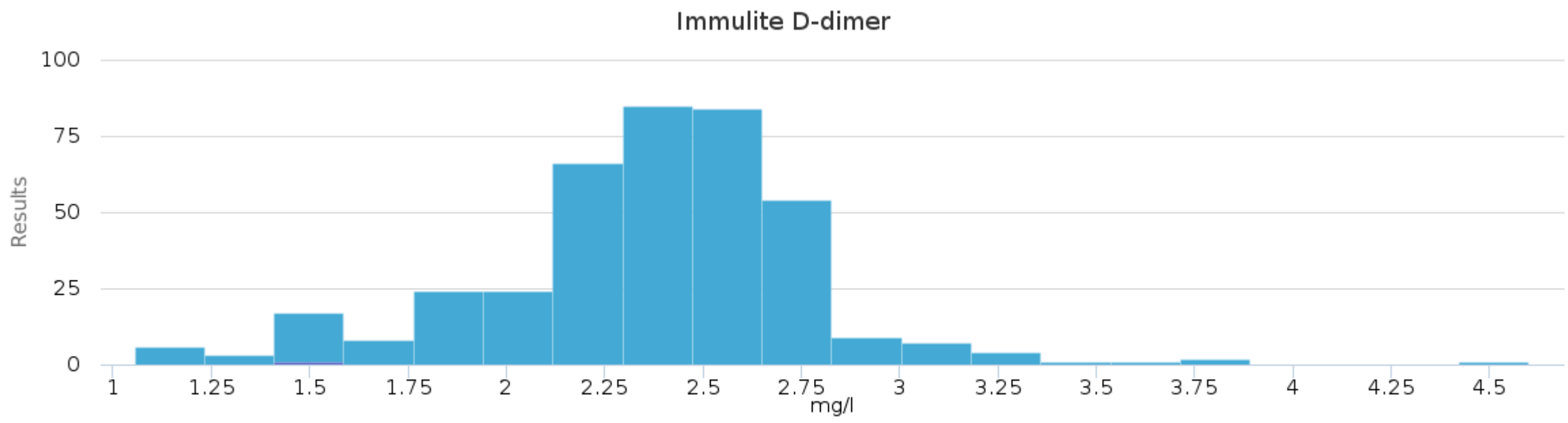


All method groups HemosIL D-dimer HS 500 (x_{pt}: 2.75 | Target area: 2.34-3.16 | Target: ±15%)

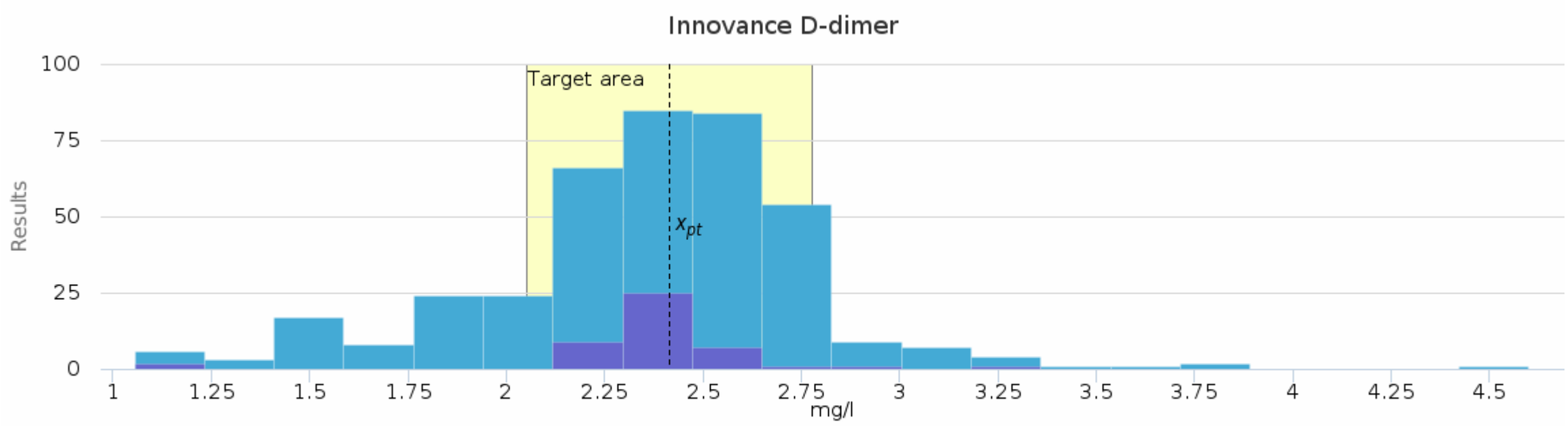


All method groups iChroma D-Dimer

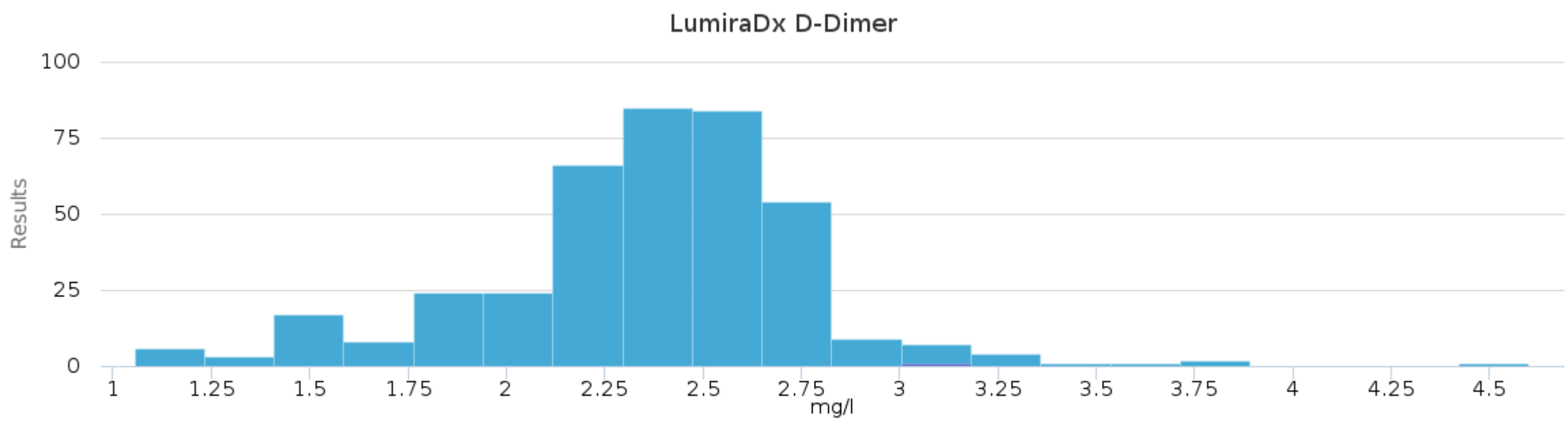
D-dimer, February, 1-2023



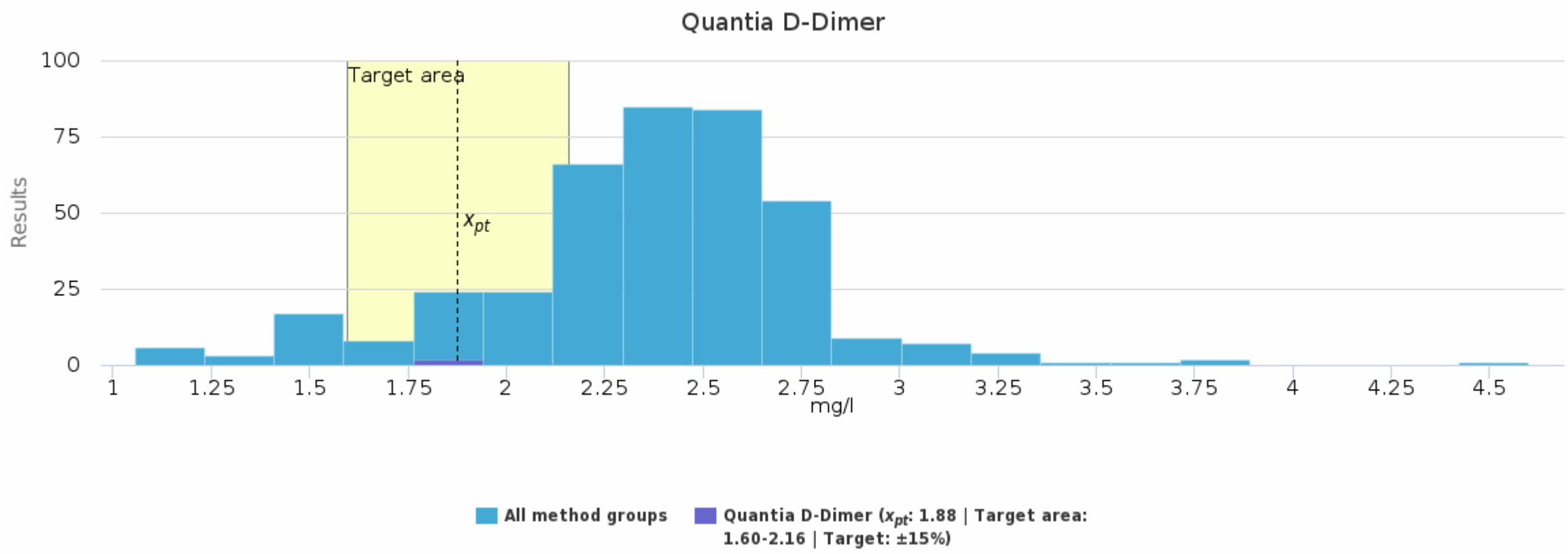
All method groups Immulite D-dimer

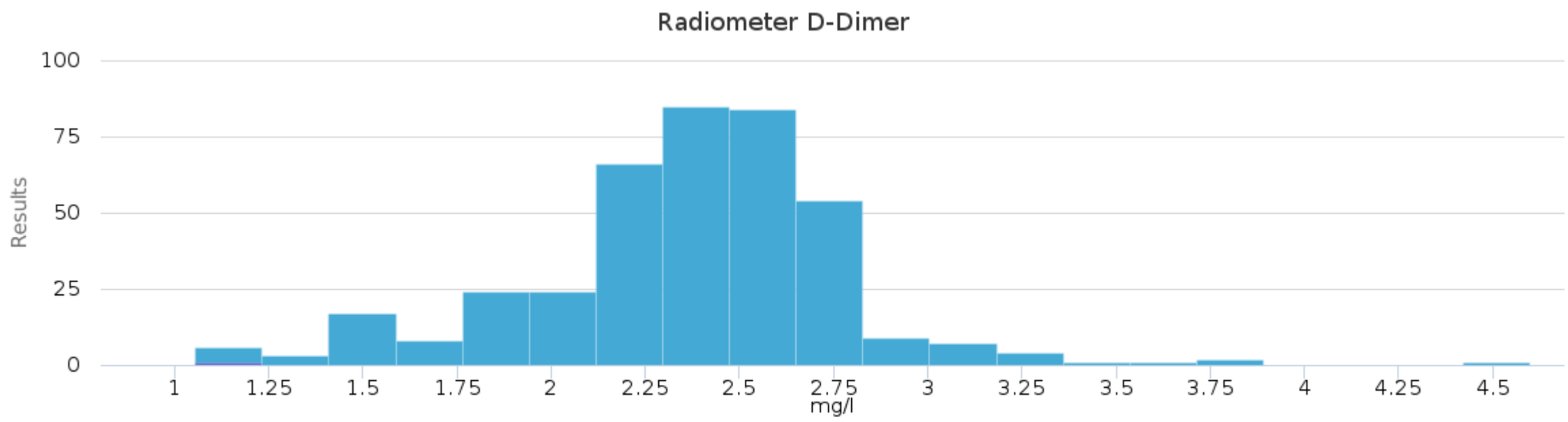


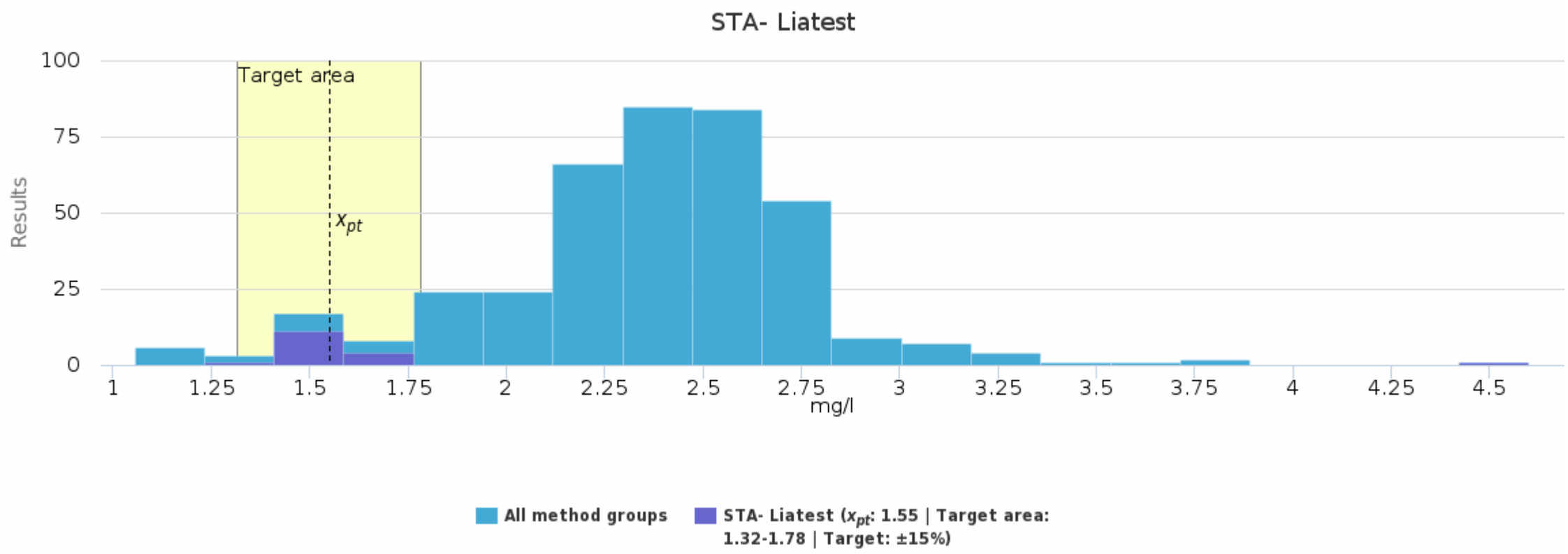
All method groups Innovance D-dimer (x_{pt}: 2.42 | Target area: 2.05-2.78 | Target: ±15%)



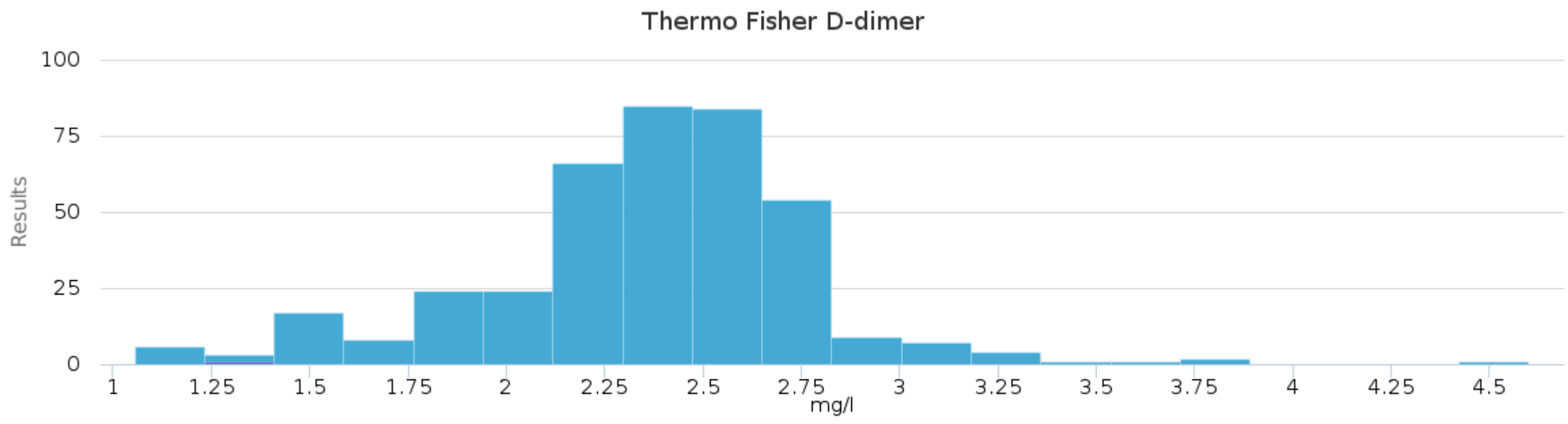
All method groups LumiraDx D-Dimer



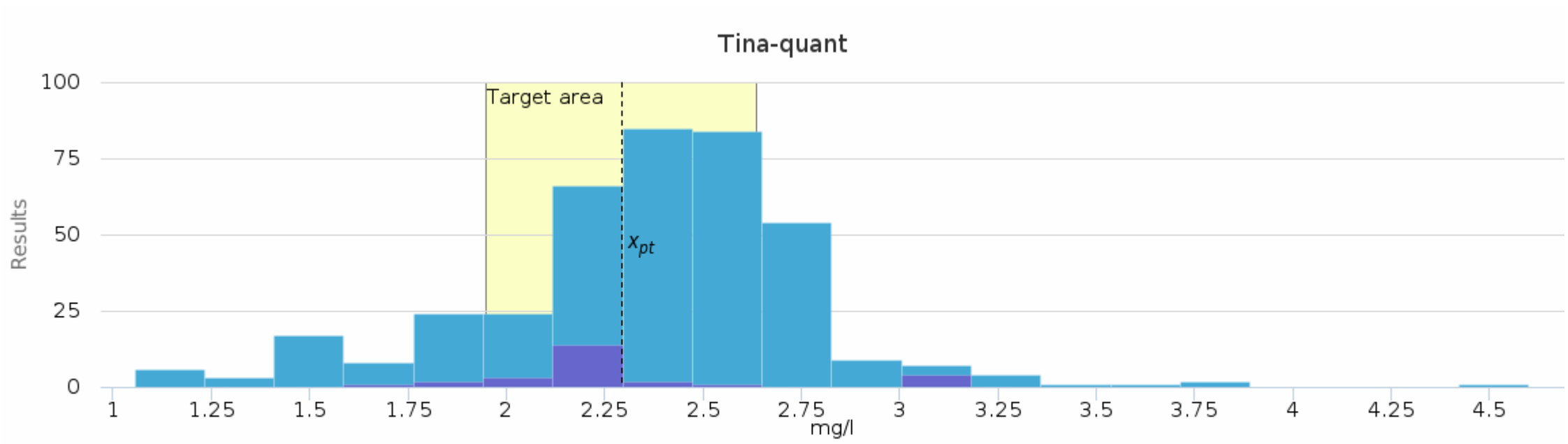




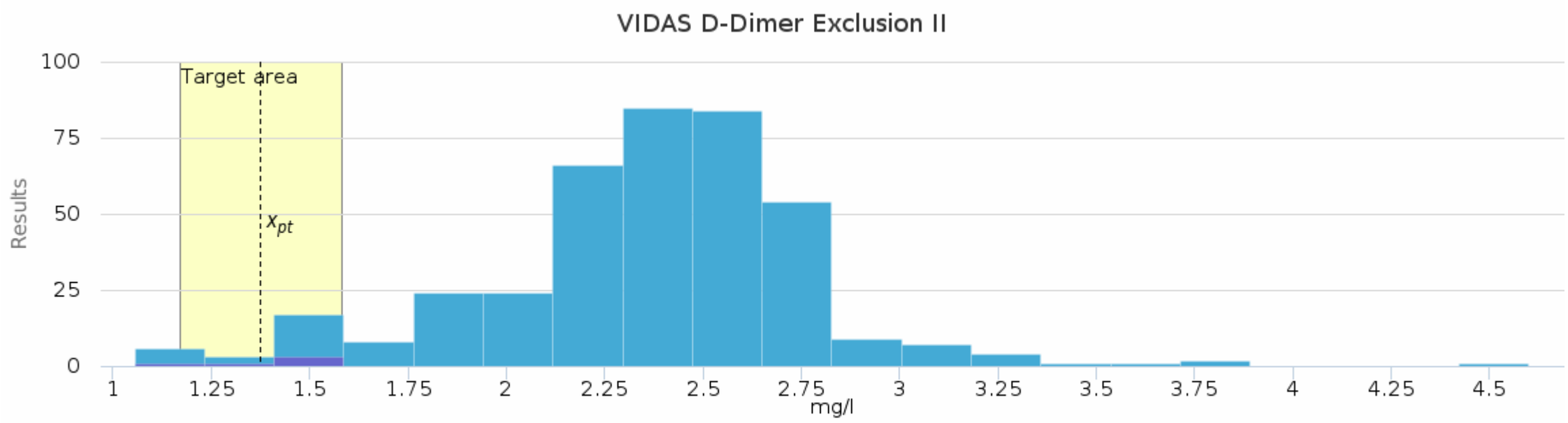
D-dimer, February, 1-2023



All method groups Thermo Fisher D-dimer



All method groups Tina-quant (x_{pt}: 2.29 | Target area: 1.95-2.64 | Target: ±15%)



All method groups VIDAS D-Dimer Exclusion II (x_{pt}: 1.38 | Target area: 1.17-1.58 | Target: ±15%)

Report info

Participants

359 participants from 15 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

D-Dimer
Round 1, 2023

Specimens
Sample S001 (LQ708423011) and sample S002 (LQ708423012) were liquid human 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
In this round, the D-dimer level was elevated in both samples S001 (average of all methods was 1.23 mg/L) and S002 (average of all methods was 2.36 mg/L). One iChroma D-Dimer user reported a result below the reference limit of 0.5 mg/L from sample S001, otherwise all participants reported results over the reference limit for both samples. As expected, different methods gave different levels of results, which is explained by the varying sensitivities of the different methods. Participants should always look at the results within their own method group.

End of report

2023-02-24

FINAL REPORT

Product no. 4388

Samples sent	2023-01-31
Round closed	2023-02-20
Final report	2023-02-24

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.

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Quality Management
ISO 9001:2015