

External Quality Assessment Scheme

C-reactive protein (CRP), POCT Round 1, 2023

Specimens

Please find enclosed 2 liquid human plasma samples S001 and S002, each 1mL.

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

CRP

Storage and use

The samples are ready to use and shall be analysed as soon as possible after arrival. The samples should be stored at + 2 ... 8 °C. Let them reach room temperature before analysis. Mix the sample by turning the vial upside down about 10 times before use. They should be analysed as patient plasma samples, exception: see the note for Orion/Aidian QuikRead device users below.

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. If the result is above > some concentration, the sample should be diluted. If dilution is not possible, please inform the result as it is. If you get a result < or >, please mark it also in the comment box. Labquality will handle those results separately if needed.

Note! Orion Diagnostica/Aidian QuikRead device users:

(The newer model OuikRead GO recognizes the sample type automatically, so you do not need to select it yourself. The instructions below therefore apply only to the older model, QuikRead.)

With the older model, QuikRead, please select and analyse the sample as whole blood sample (sample volume 20 µL) and in LabScala, please report the result as it is (in device).

Please mark also the lot number and the exp.date of the reagent, if needed. Labquality can use this information when examining the result deviation between method groups. Note! If the reagents come in a box, mark the lot number from the whole package, not from a single item in the box.

S001



S002



2023-01-31

INSTRUCTIONS

Product no. 2132
LQ735123011-012/FI

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 28, 2023.

Inquiries

EQA Coordinator
Liisa Ylitepsa
liisa.ylitepsa@labquality.fi

Labquality Oy

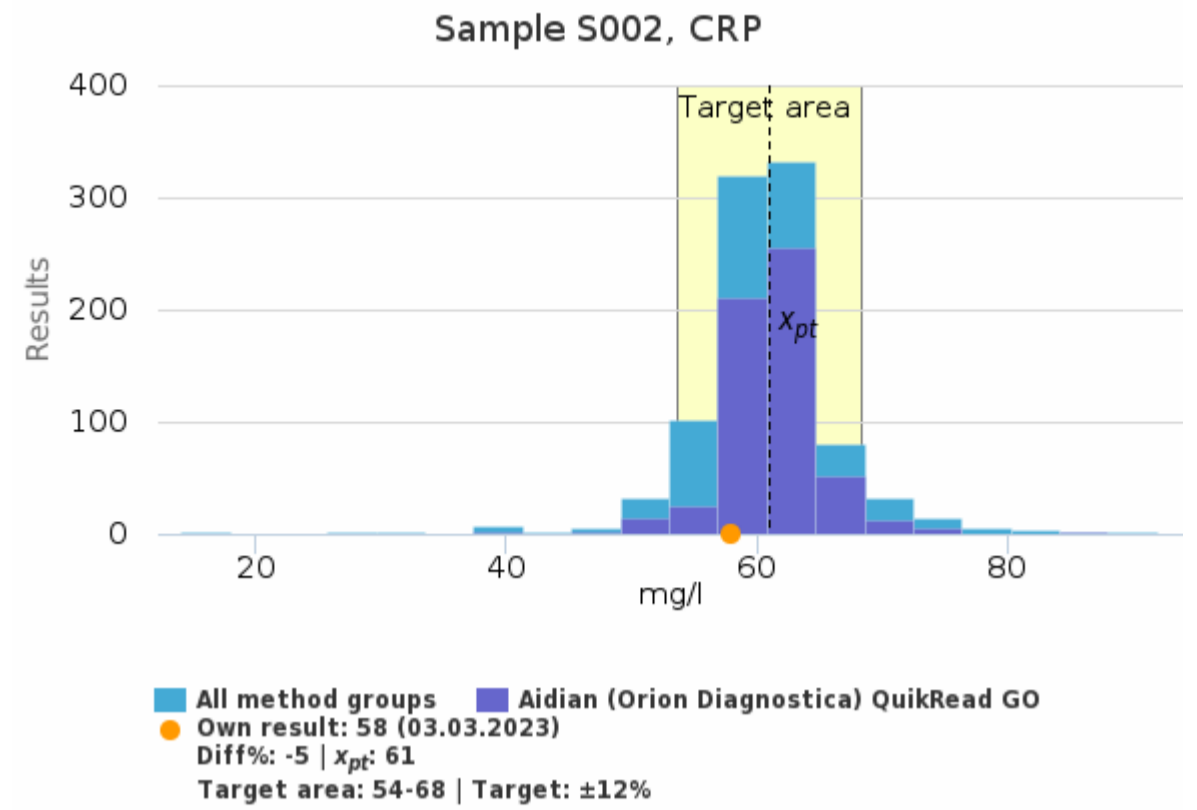
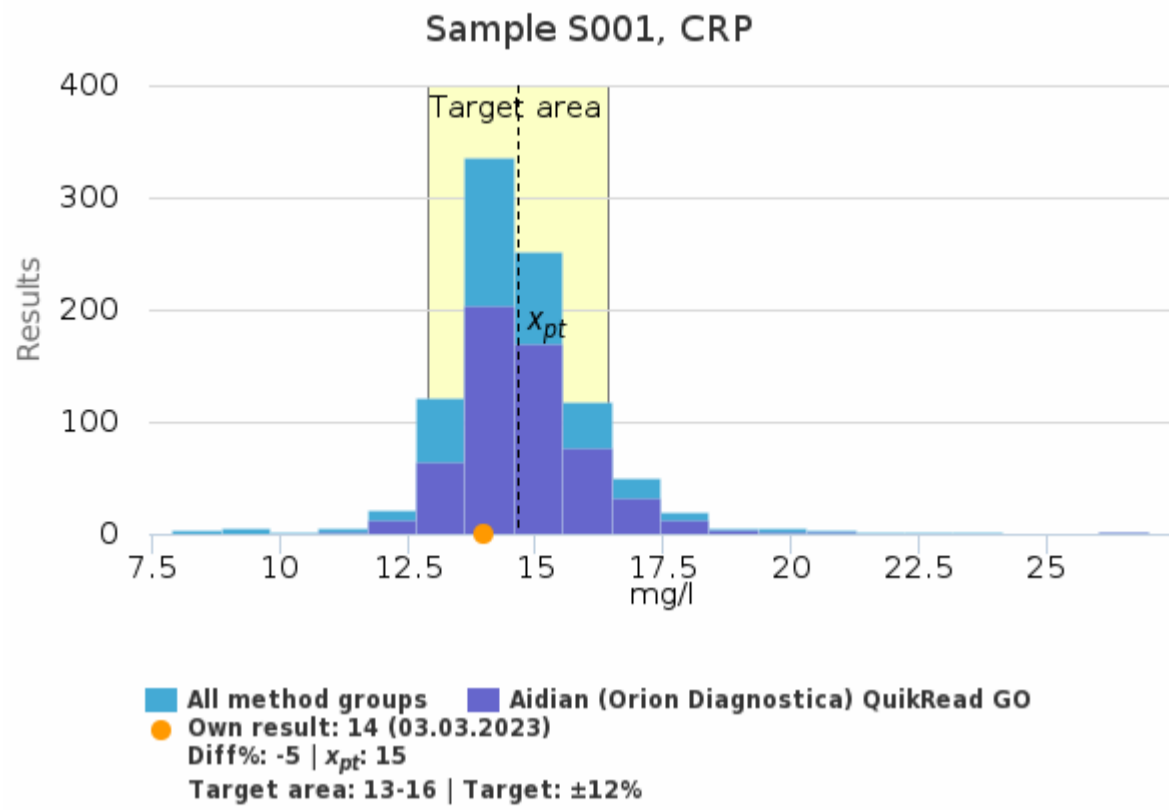
Kumpulantie 15
FI-00520 HELSINKI
Finland

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Fax + 358 9 8566 8280

info@labquality.fi
www.labquality.com



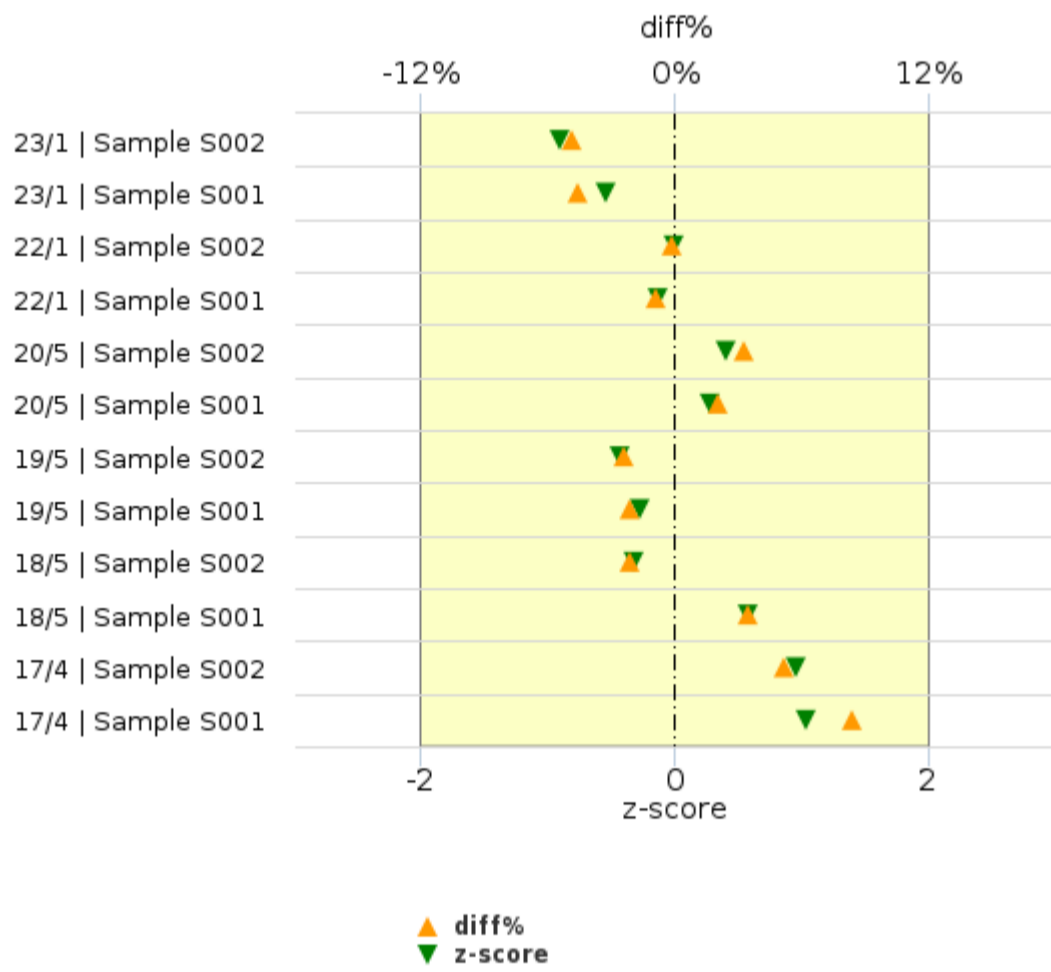
CRP | Orion QuikRead Go



	x_{pt}	sd	SEM	CV%	n
Aidian (Orion Diagnostica) QuikRead GO	15 mg/l	1	<1	8.5	578
All methods	15 mg/l	1	<1	8.8	949

	x_{pt}	sd	SEM	CV%	n
Aidian (Orion Diagnostica) QuikRead GO	61 mg/l	3	<1	5.4	578
All methods	61 mg/l	4	<1	7.4	946

History



Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	61	58	-5%	-0.91
23/1	Sample S001	15	14	-5%	-0.54
22/1	Sample S002	62	62	0%	-0.01
22/1	Sample S001	39	39	-1%	-0.13
20/5	Sample S002	42	43	3%	0.40
20/5	Sample S001	26	27	2%	0.27
19/5	Sample S002	62	61	-2%	-0.43
19/5	Sample S001	40	39	-2%	-0.28
18/5	Sample S002	29	28	-2%	-0.33
18/5	Sample S001	38	39	3%	0.57
17/4	Sample S002	78	82	5%	0.95
17/4	Sample S001	17	18	8%	1.04

Report info**Participants**

807 participants from 10 countries.

Report info

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

Assigned values (\bar{x}_p , 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."

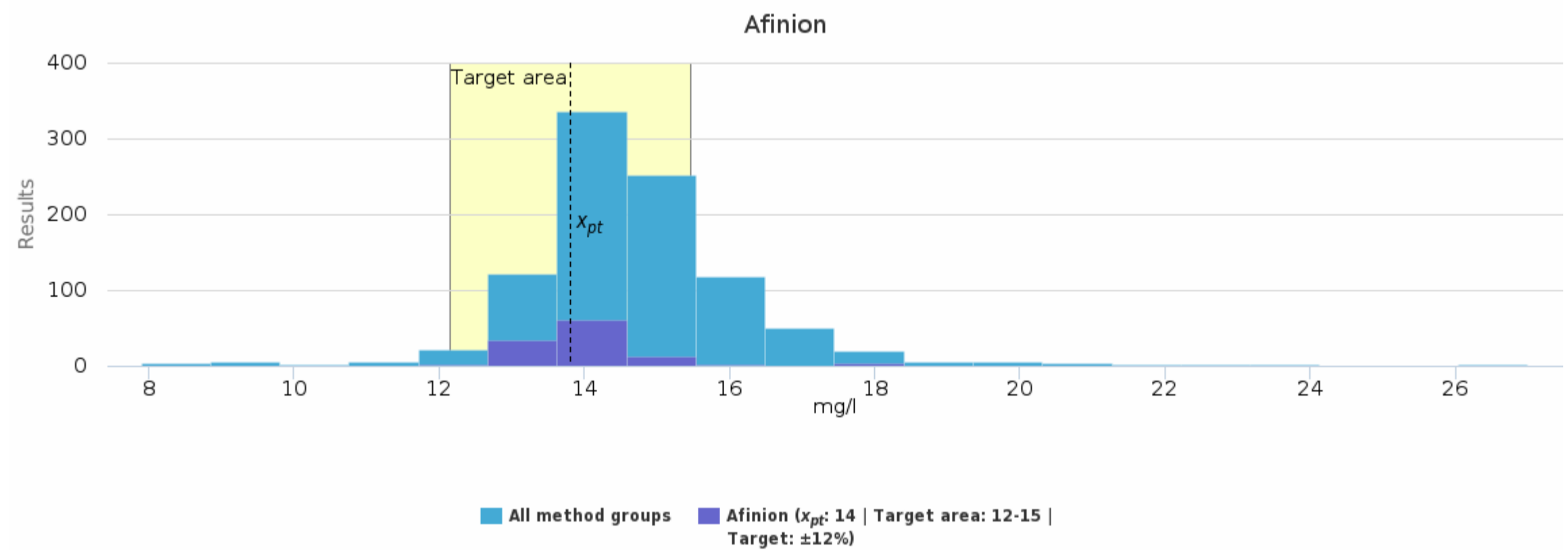
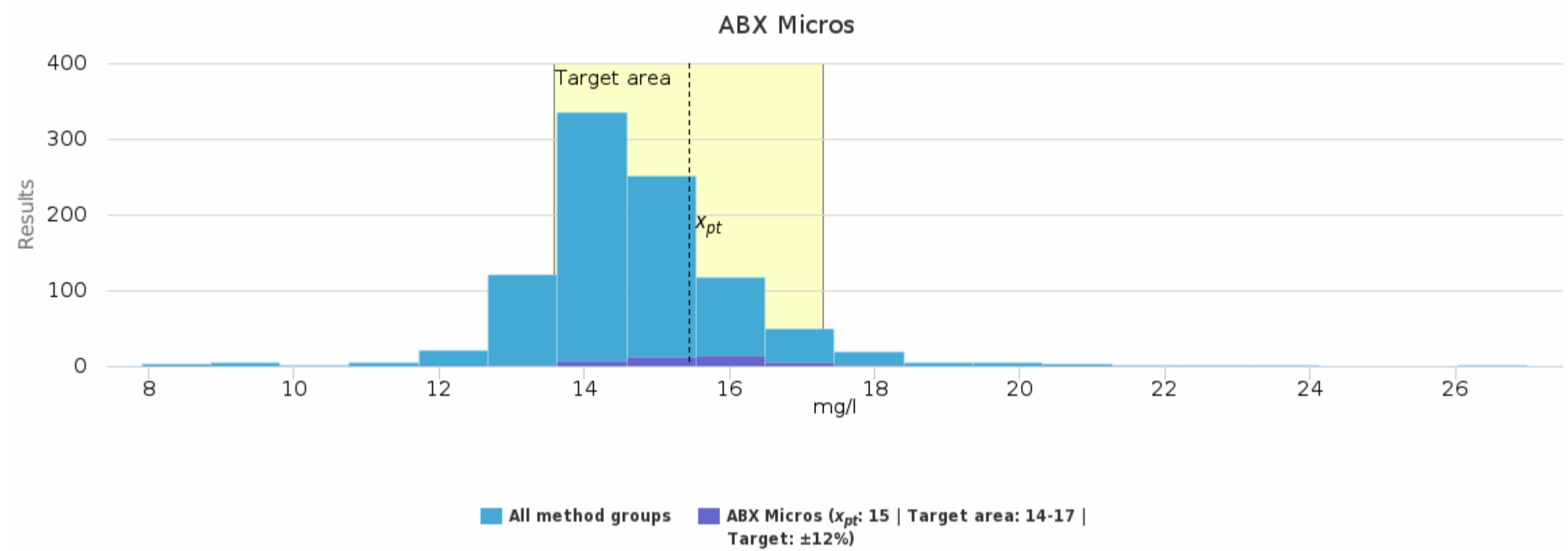
In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are only a few results in the client's own method group, the result can be compared to all method mean or to a group that is similar to the own method.

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

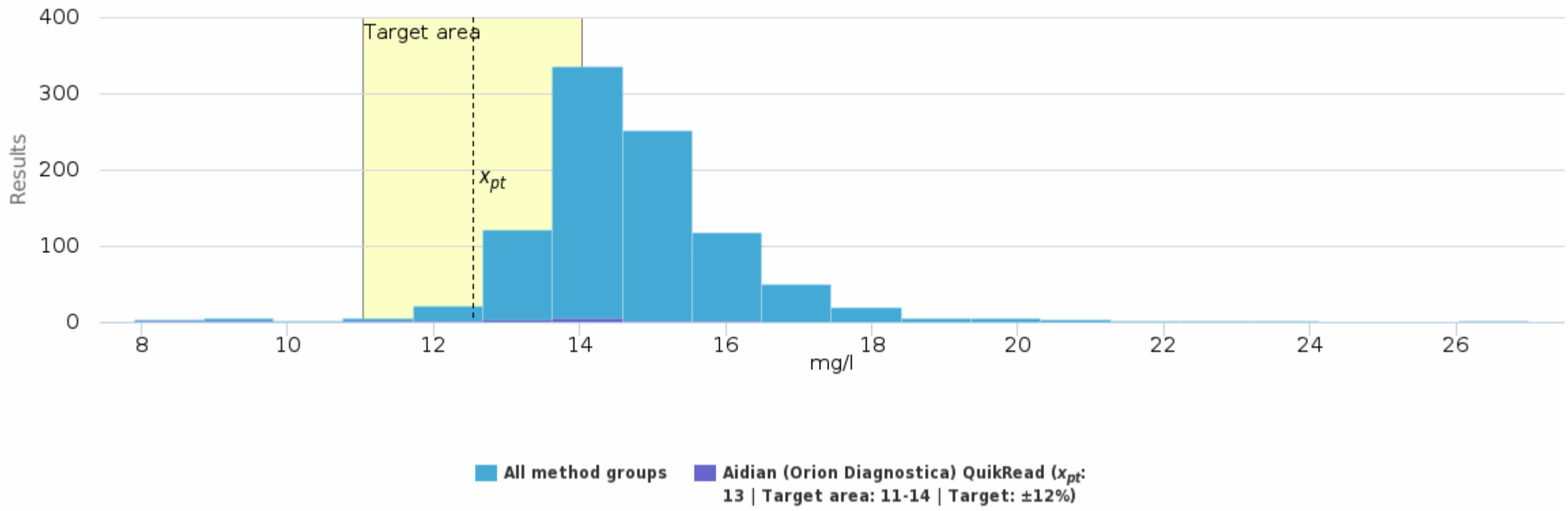
For information on report interpretation and performance evaluation, please see the "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

Sample S001 | CRP, mg/l

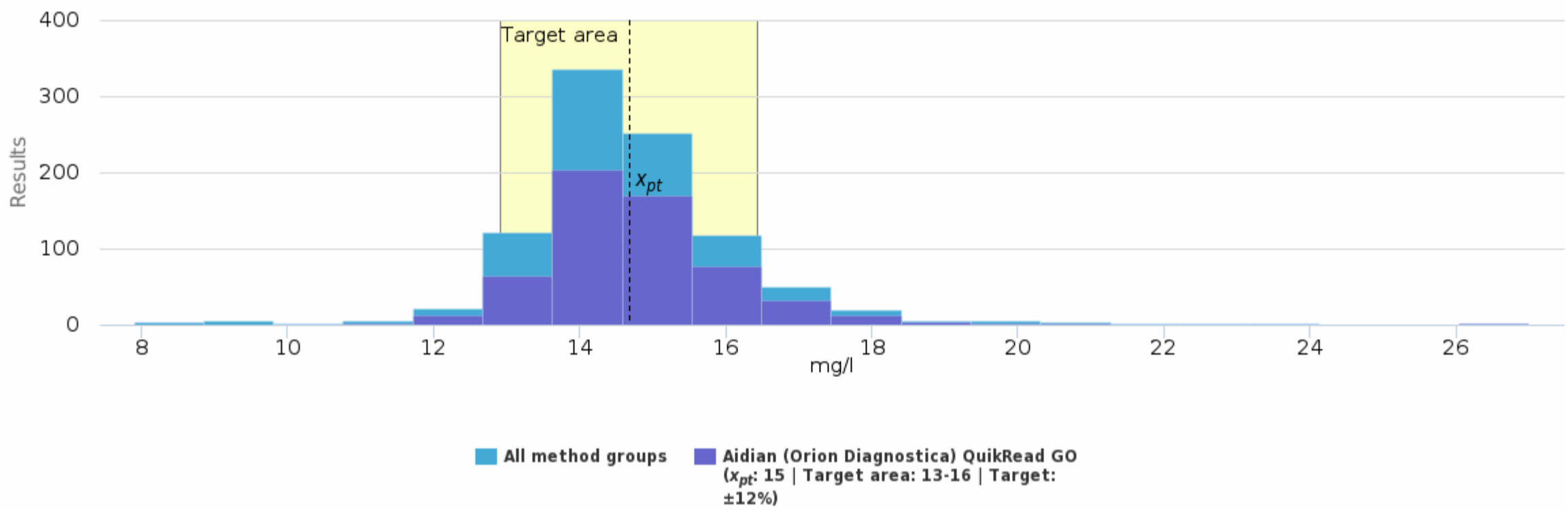
Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
ABX Micros	15	16	1	7.1	<1	13	18	-	43
Afinion	14	14	<1	5.0	<1	12	16	3	113
Aidian (Orion Diagnostica) QuikRead	13	13	2	18.7	<1	8	16	-	19
Aidian (Orion Diagnostica) QuikRead GO	15	15	1	8.5	<1	11	19	4	578
Aidian (Orion Diagnostica) QuikRead go easy CRP	15	15	2	10.8	<1	10	20	1	128
Aidian (Orion Diagnostica) QuikRead wrCRP	15	15	2	10.3	<1	13	19	-	16
Boditech ichroma Reader	16	16	2	10.8	<1	13	18	-	12
Eurolyser	21	21	<1	3.5	<1	21	22	-	3
Exdia TRF Plus	17	15	5	31.5	3	13	23	-	3
LumiraDx CRP	-	-	-	-	-	8	8	-	1
Nal von Minden Colibri	10	10	<1	3.4	<1	9	10	-	4
NycoCard Reader	-	-	-	-	-	14	14	-	1
SD Biosensor CRP	15	15	1	8.8	<1	12	17	-	27
Vedalab CRP	-	-	-	-	-	14	14	-	1
All	15	14	1	8.8	<1	9	18	22	949



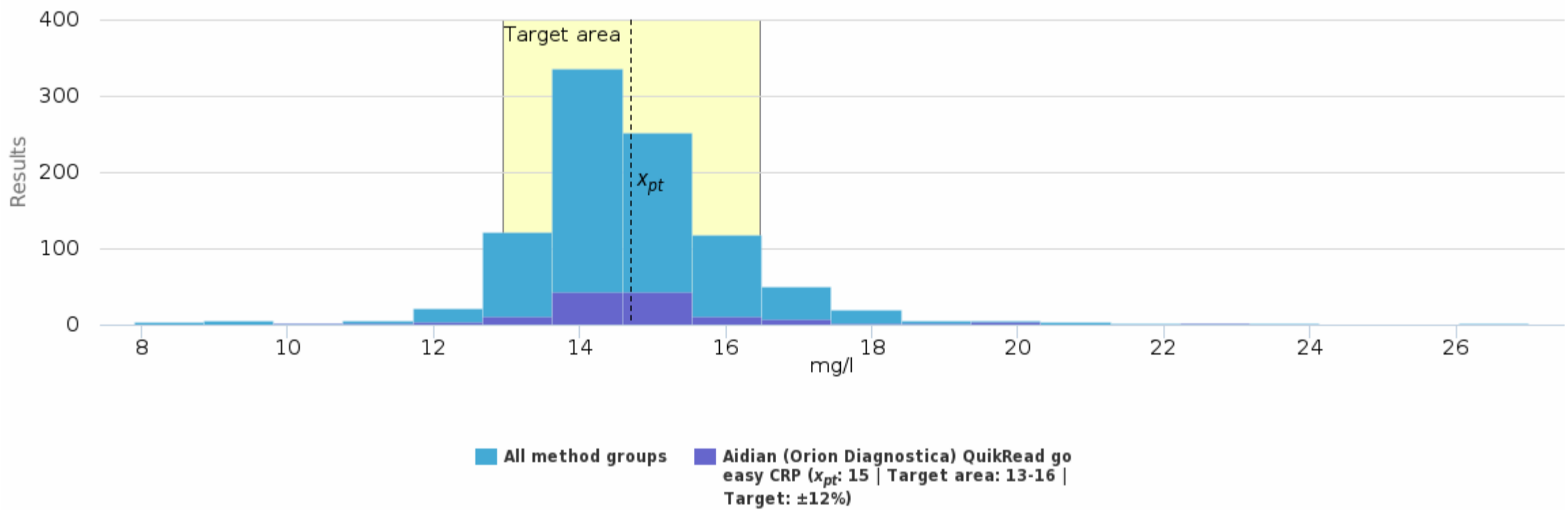
Aidian (Orion Diagnostica) QuikRead



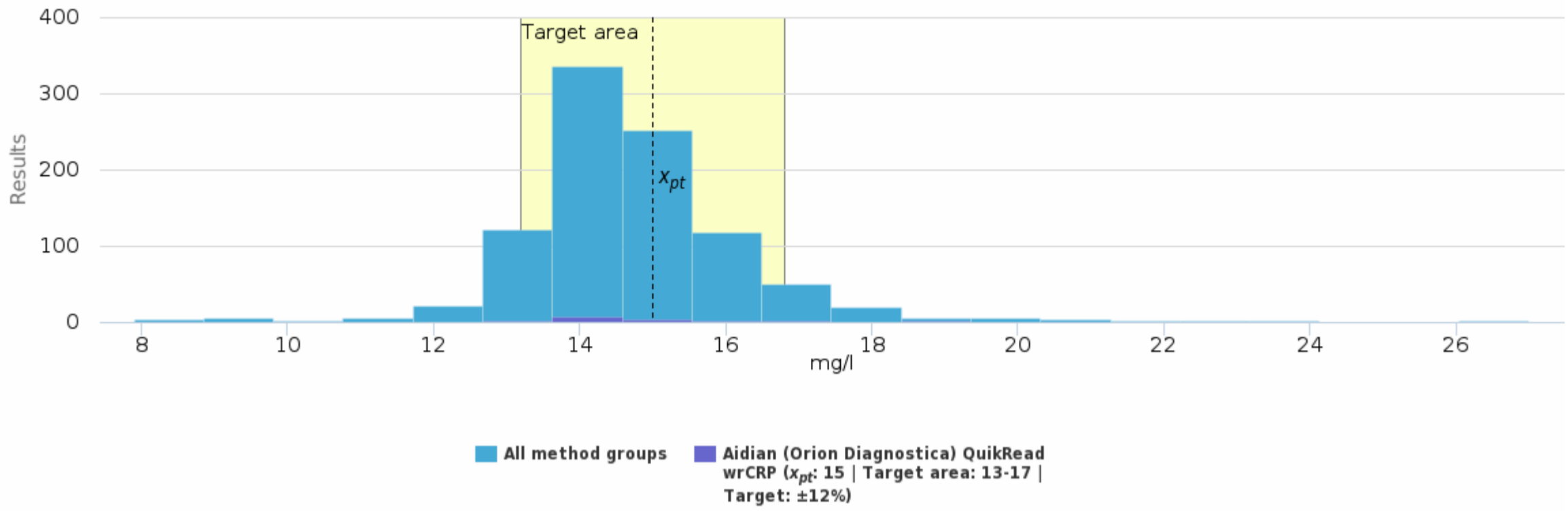
Aidian (Orion Diagnostica) QuikRead GO



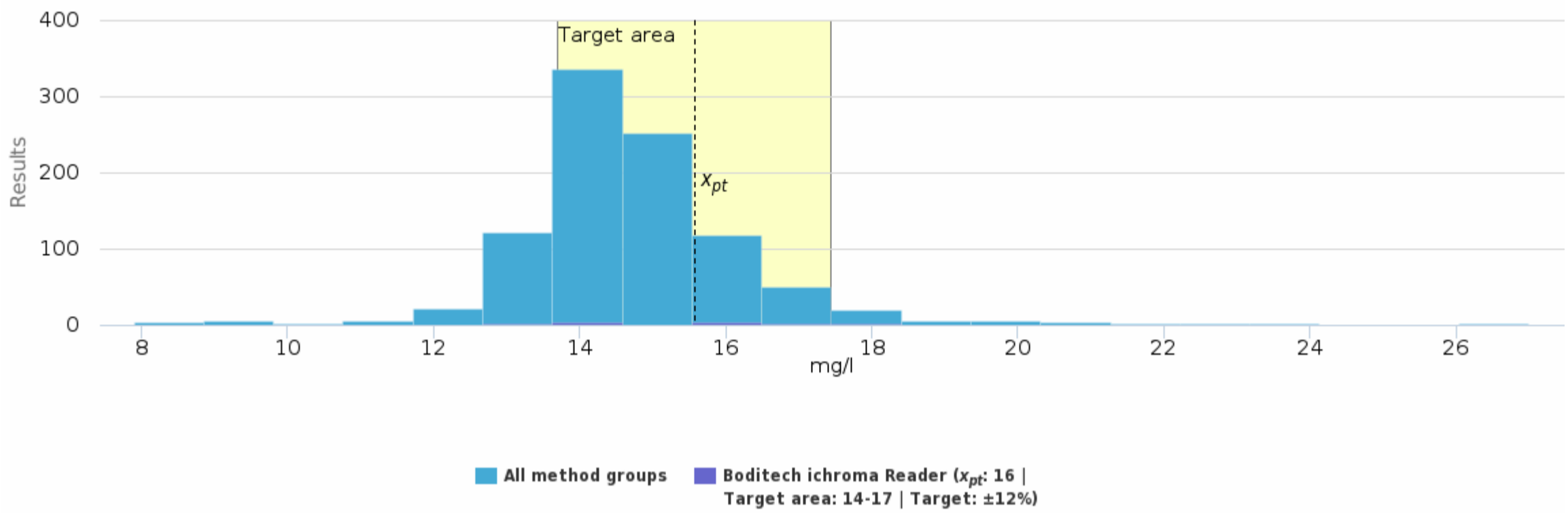
Aidian (Orion Diagnostica) QuikRead go easy CRP



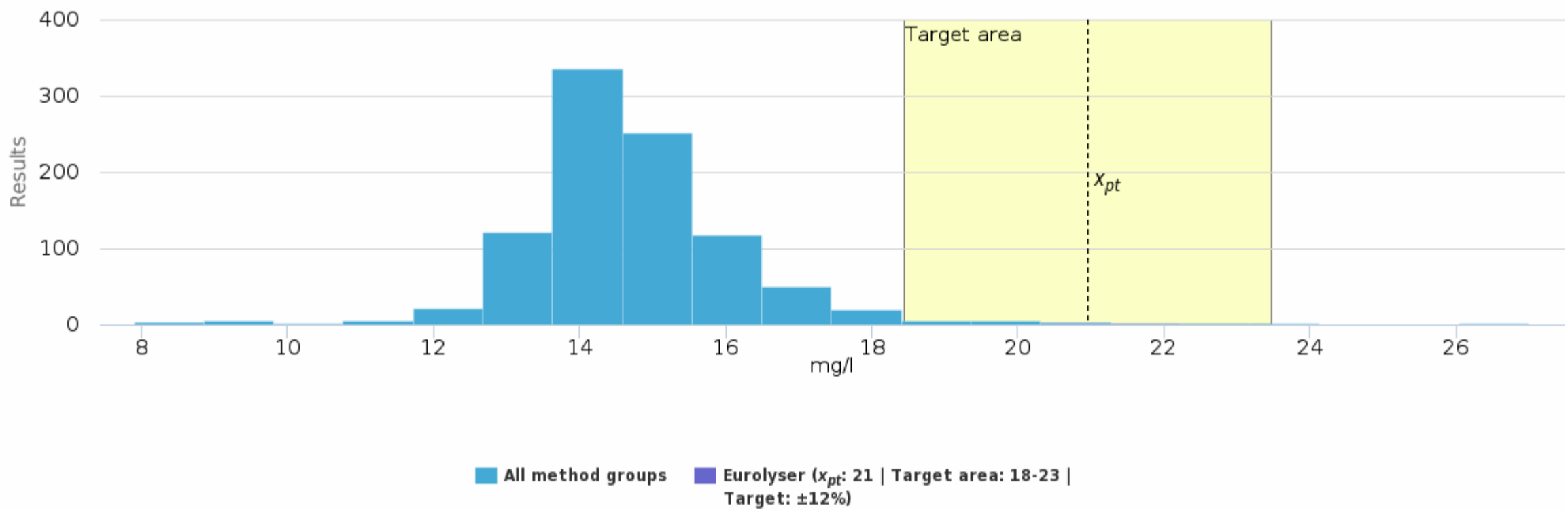
Aidian (Orion Diagnostica) QuikRead wrCRP

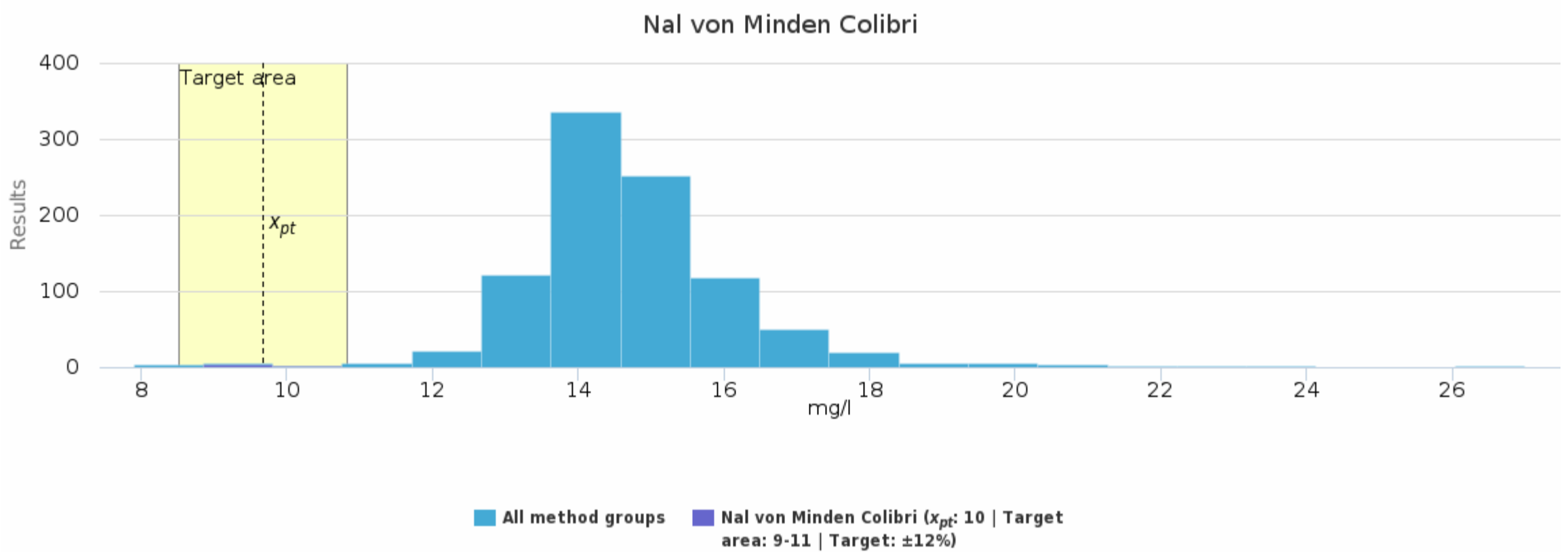
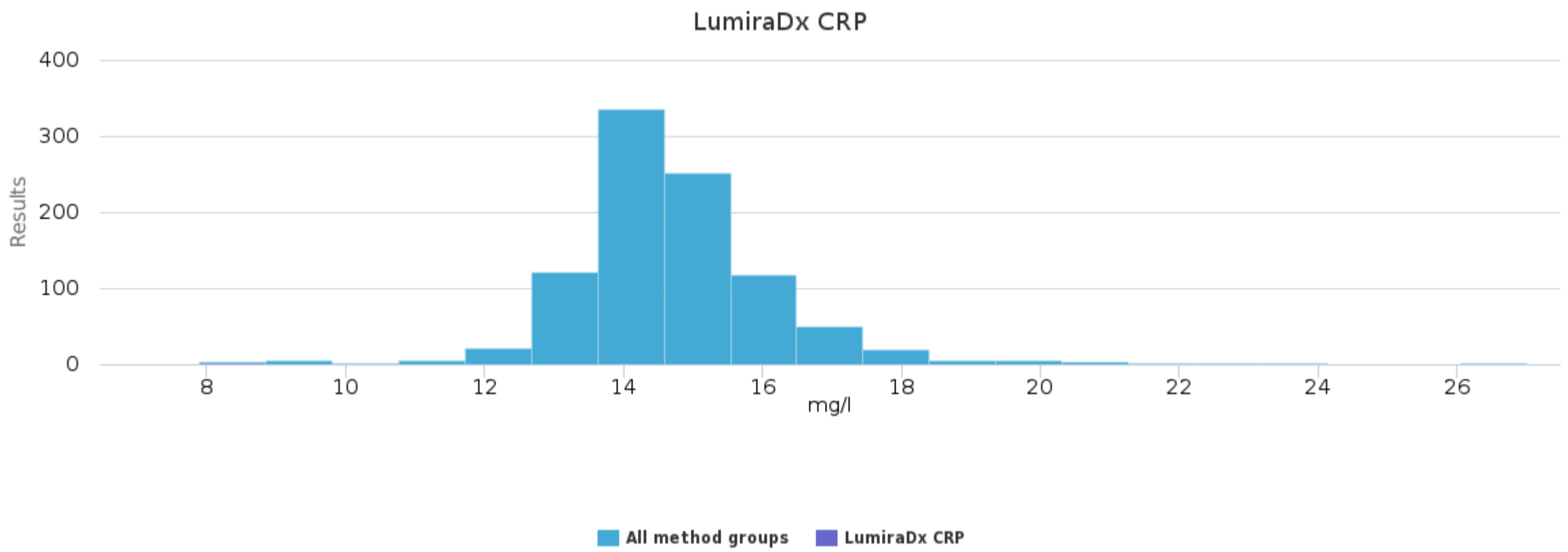
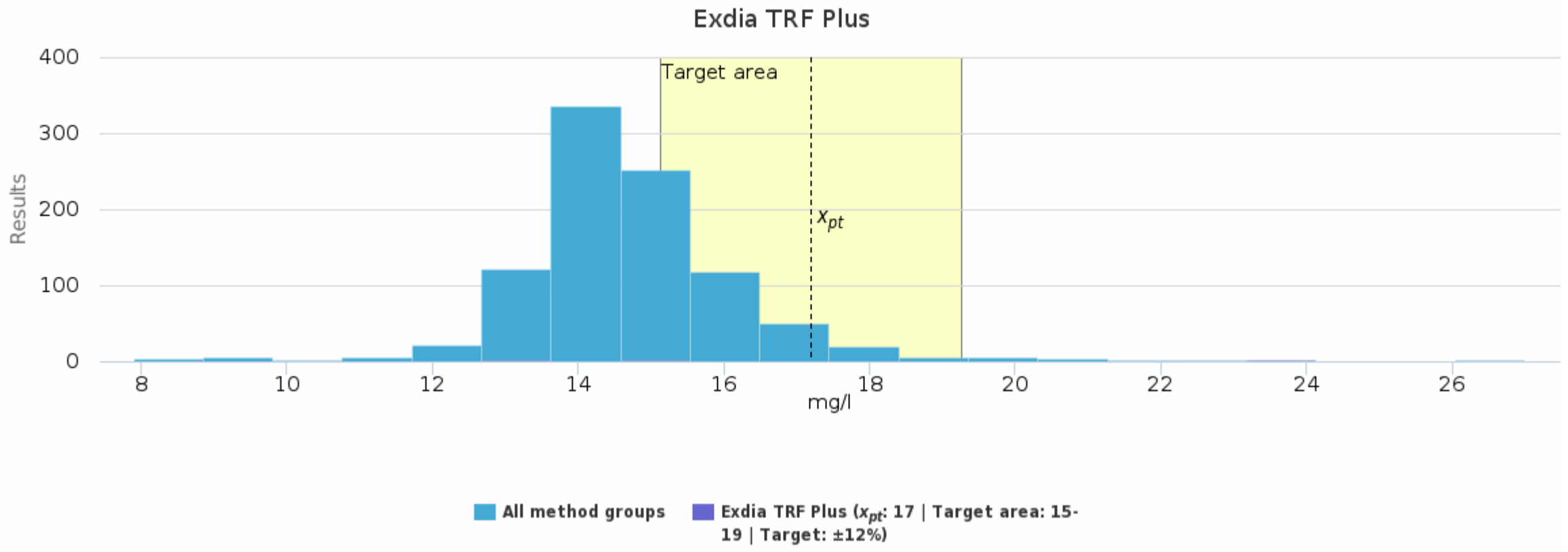


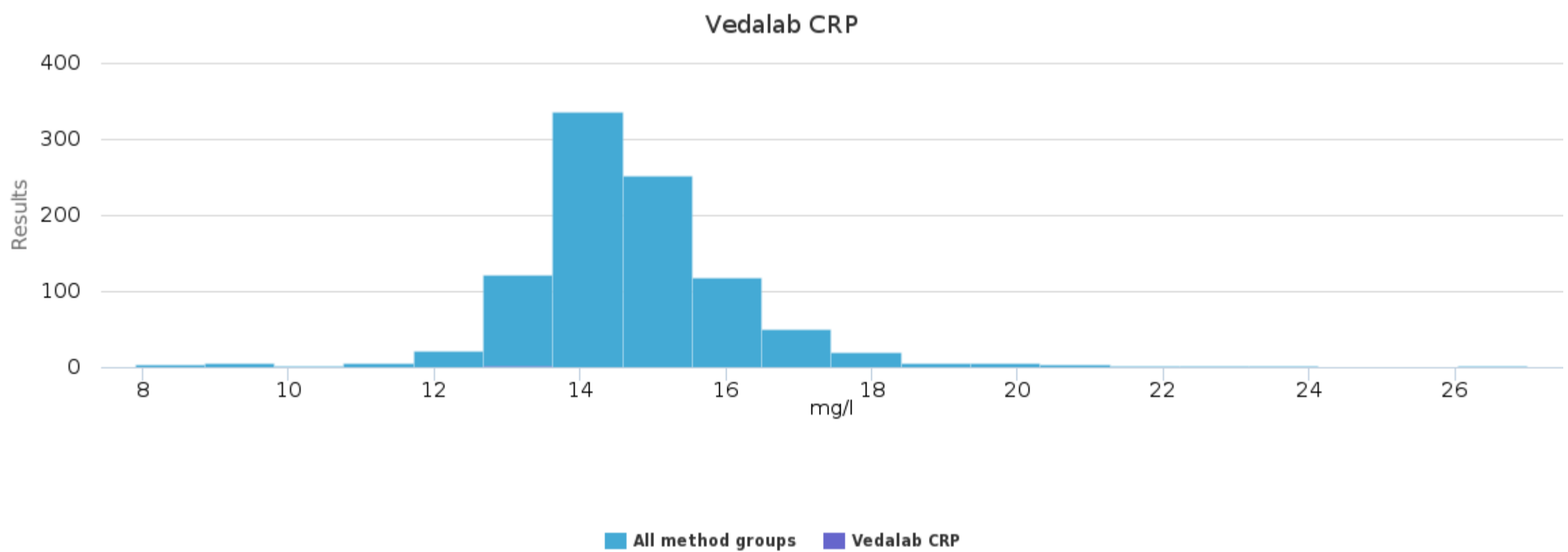
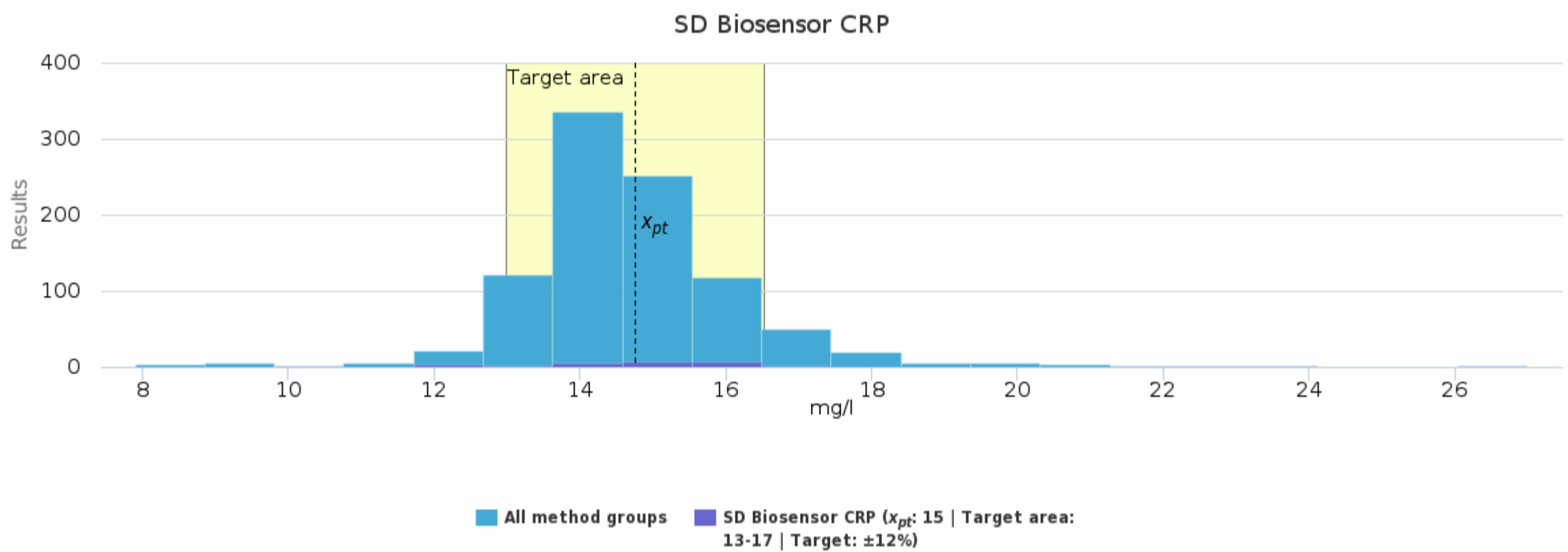
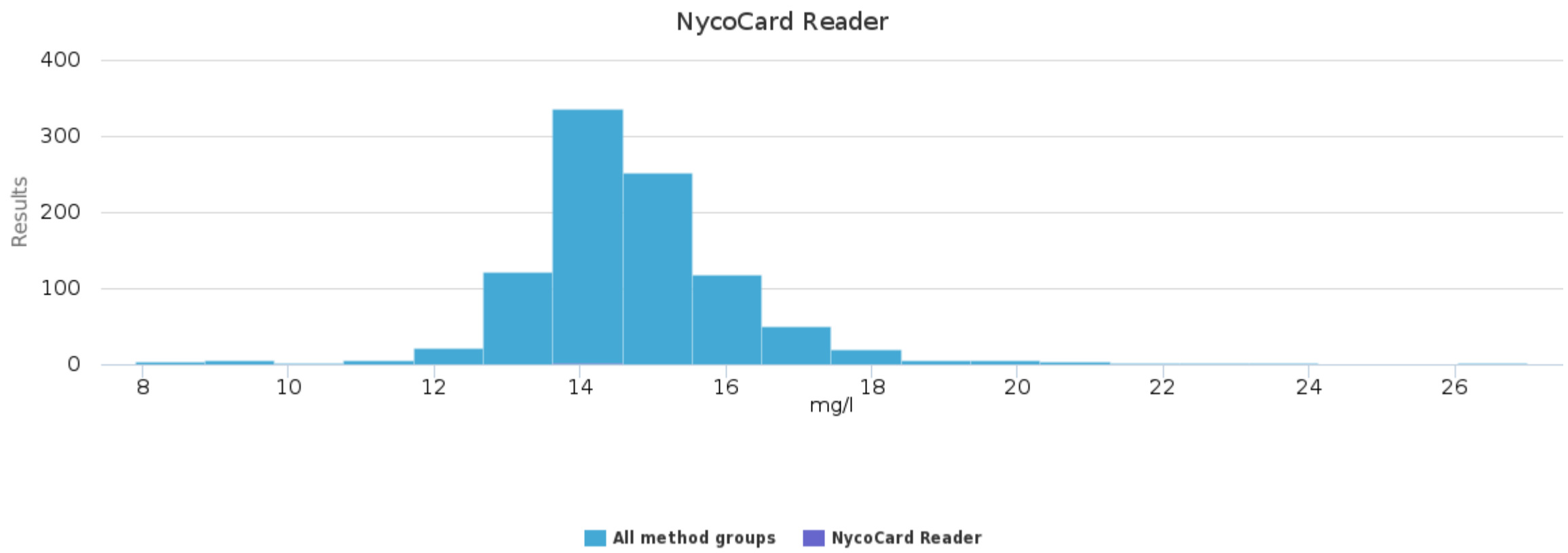
Boditech ichroma Reader



Eurolyser







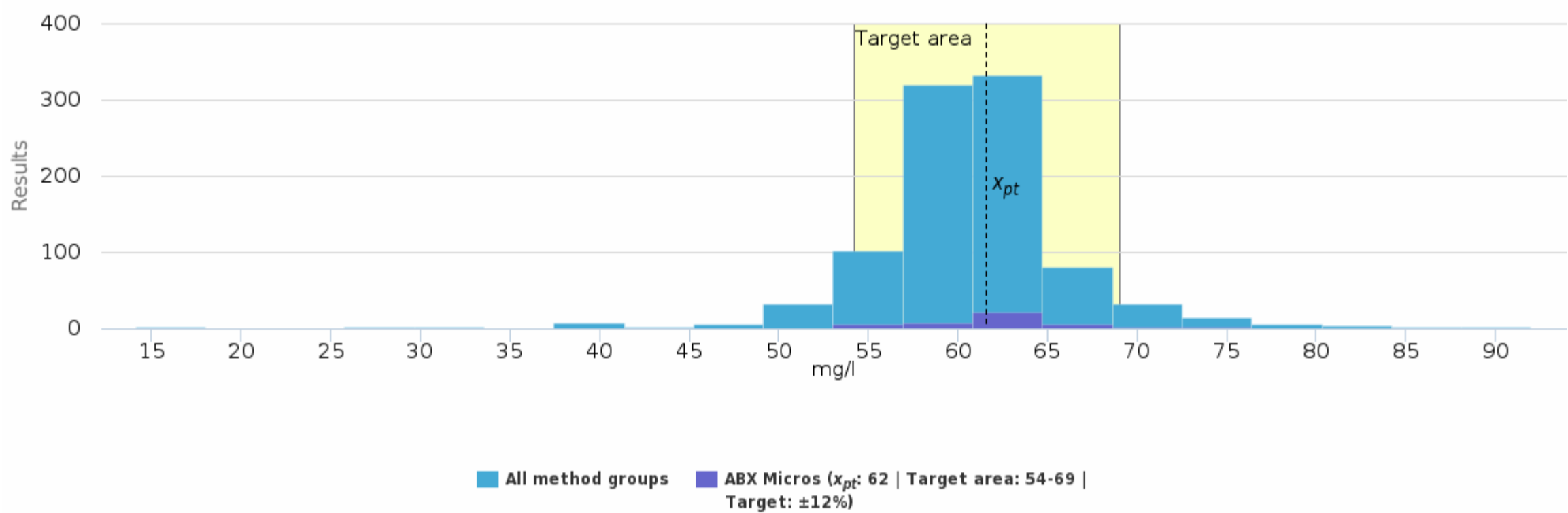
Methodics	Instrument	x_{pt}	sd	CV%	n
ABX Micros		15	1	7.1	43
	ABX Micros CRP 200	16	2	12.5	3
	Micros CRP	-	-	-	1
	Microsemi CRP	15	1	6.8	39
Afinion		14	<1	5.0	113
	Afinion AS100	14	1	8.0	68
	Afinion 2	14	<1	4.8	45
Aidian (Orion Diagnostica) QuikRead		13	2	18.7	19
	QuikRead	13	2	13.5	2

	QuikRead 101	13	2	19.5	17
Aidian (Orion Diagnostica) QuikRead GO		15	1	8.5	578
	QuikRead Go	15	1	9.5	578
Aidian (Orion Diagnostica) QuikRead go easy CRP		15	2	10.8	128
	QuikRead Go	15	2	11.8	128
Aidian (Orion Diagnostica) QuikRead wrCRP		15	2	10.3	16
	QuikRead Go	15	2	10.3	16
Boditech ichroma Reader		16	2	10.8	12
	i-Chroma II Reader	17	<1	5.3	3
	iChroma II Reader	14	<1	5.4	3
	iChroma Reader	16	1	8.1	6
Eurolyser		21	<1	3.5	3
	Eurolyser CUBE	21	<1	3.5	3
Exdia TRF Plus		17	5	31.5	3
	Exdia TRF Plus	17	5	31.5	3
LumiraDx CRP		-	-	-	1
	LumiraDx	-	-	-	1
Nal von Minden Colibri		10	<1	3.4	4
	Colibri	10	<1	3.4	4
NycoCard Reader		-	-	-	1
	Nycocard Reader II	-	-	-	1
SD Biosensor CRP		15	1	8.8	27
	Standard F100	15	<1	3.6	3
	Standard F200	15	1	9.2	24
Vedlab CRP		-	-	-	1
	Easy Reader +	-	-	-	1

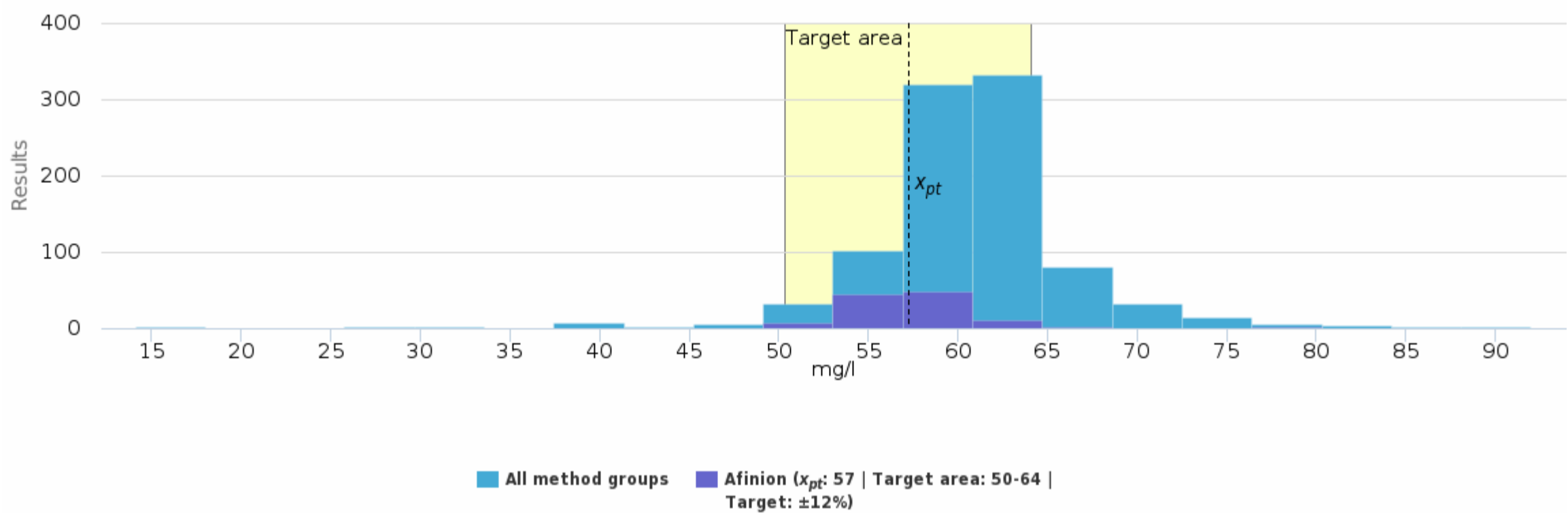
Sample S002 | CRP, mg/l

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
ABX Micros	62	62	4	6.1	<1	54	70	1	42
Afinion	57	57	3	4.8	<1	51	67	1	112
Aidian (Orion Diagnostica) QuikRead	58	63	12	20.0	3	33	70	-	19
Aidian (Orion Diagnostica) QuikRead GO	61	61	3	5.4	<1	50	72	10	578
Aidian (Orion Diagnostica) QuikRead go easy CRP	59	59	6	10.1	<1	45	79	2	127
Aidian (Orion Diagnostica) QuikRead wrCRP	60	60	4	6.2	<1	54	69	-	16
Boditech ichroma Reader	65	63	4	6.3	1	61	73	-	10
Eurolyser	78	74	9	11.6	5	72	89	-	3
Exdia TRF Plus	85	84	2	2.0	<1	84	87	-	3
LumiraDx CRP	20	20	8	42.0	6	14	26	-	2
Nal von Minden Colibri	41	41	<1	1.8	<1	40	42	-	4
NycoCard Reader	-	-	-	-	-	58	58	-	1
SD Biosensor CRP	69	69	6	8.9	1	57	83	-	28
Vedalab CRP	-	-	-	-	-	49	49	-	1
All	61	61	4	7.4	<1	45	77	22	946

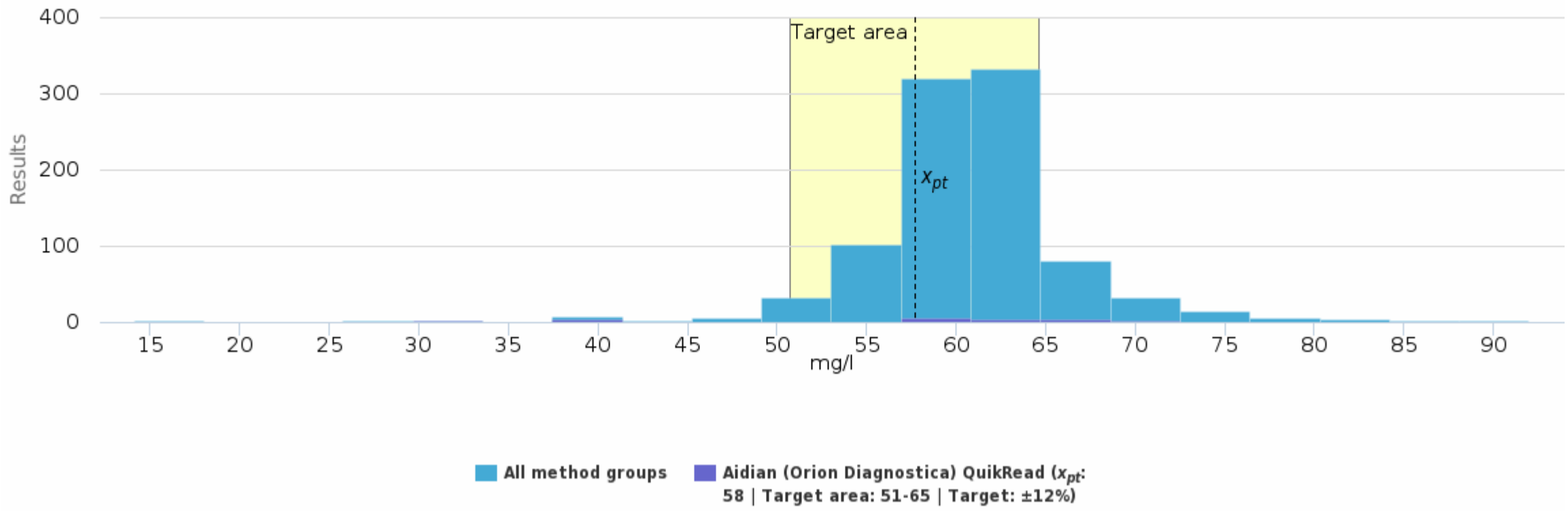
ABX Micros



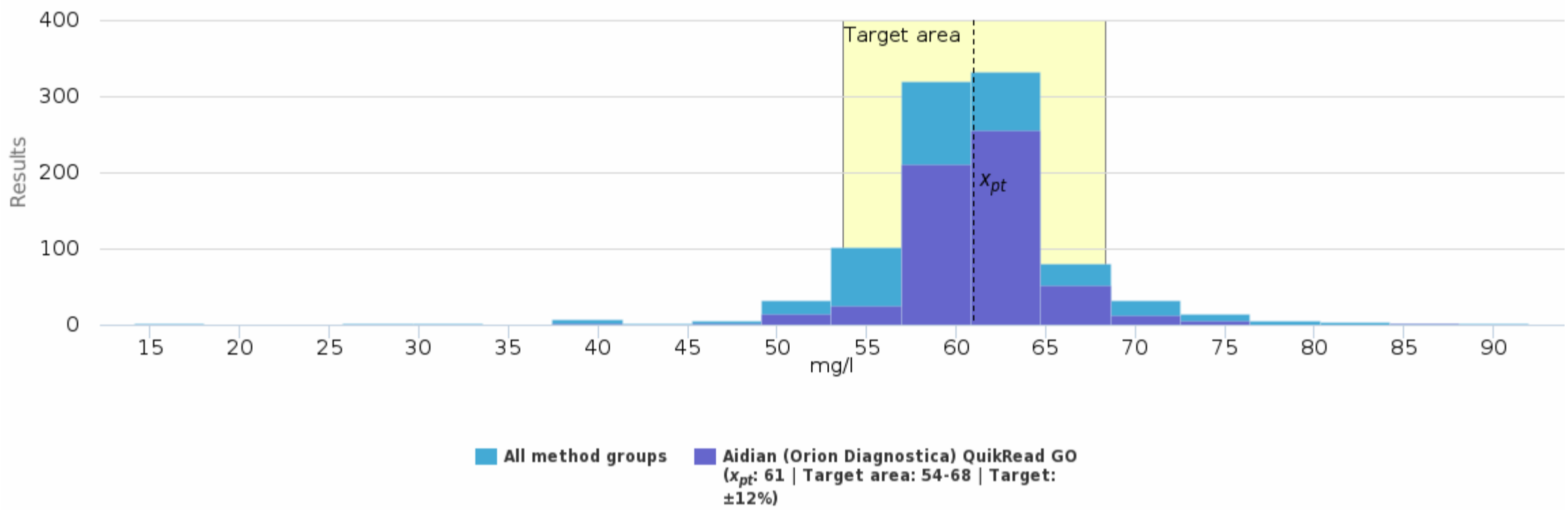
Afinion



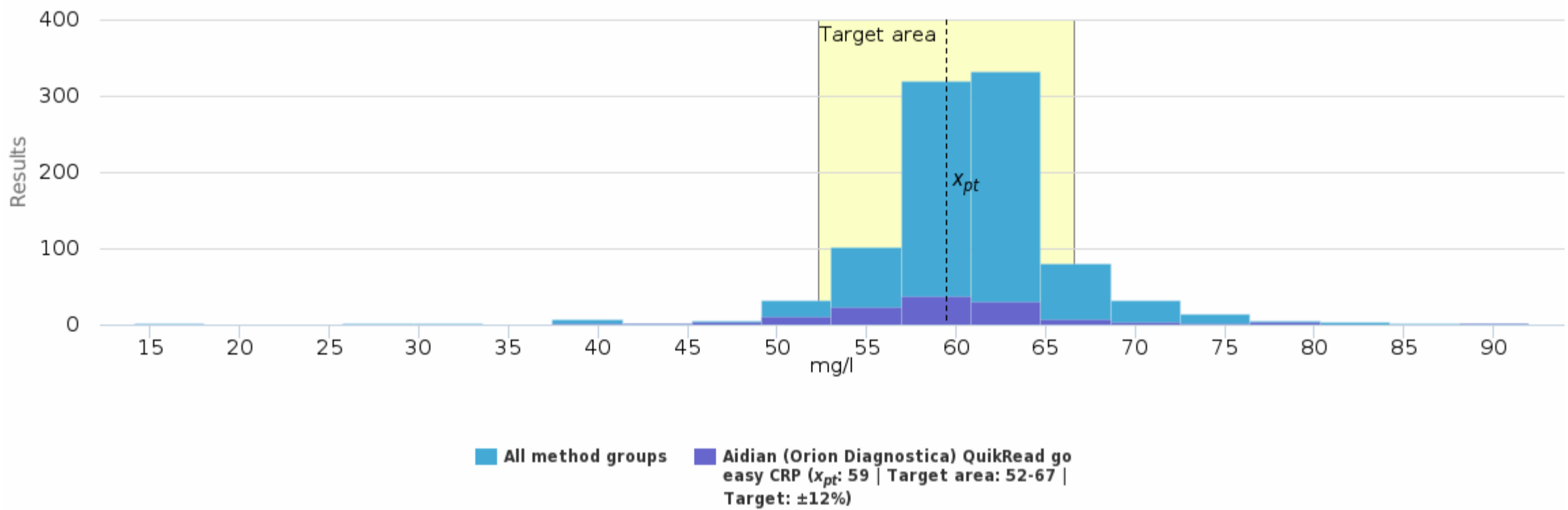
Aidian (Orion Diagnostica) QuikRead



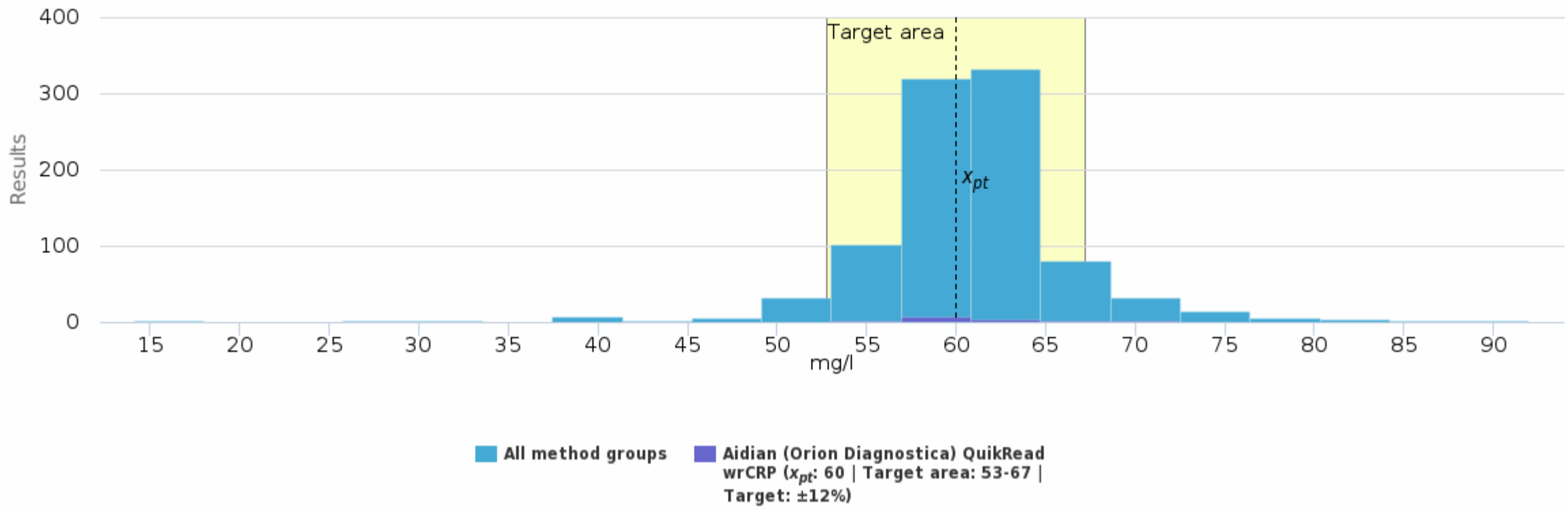
Aidian (Orion Diagnostica) QuikRead GO



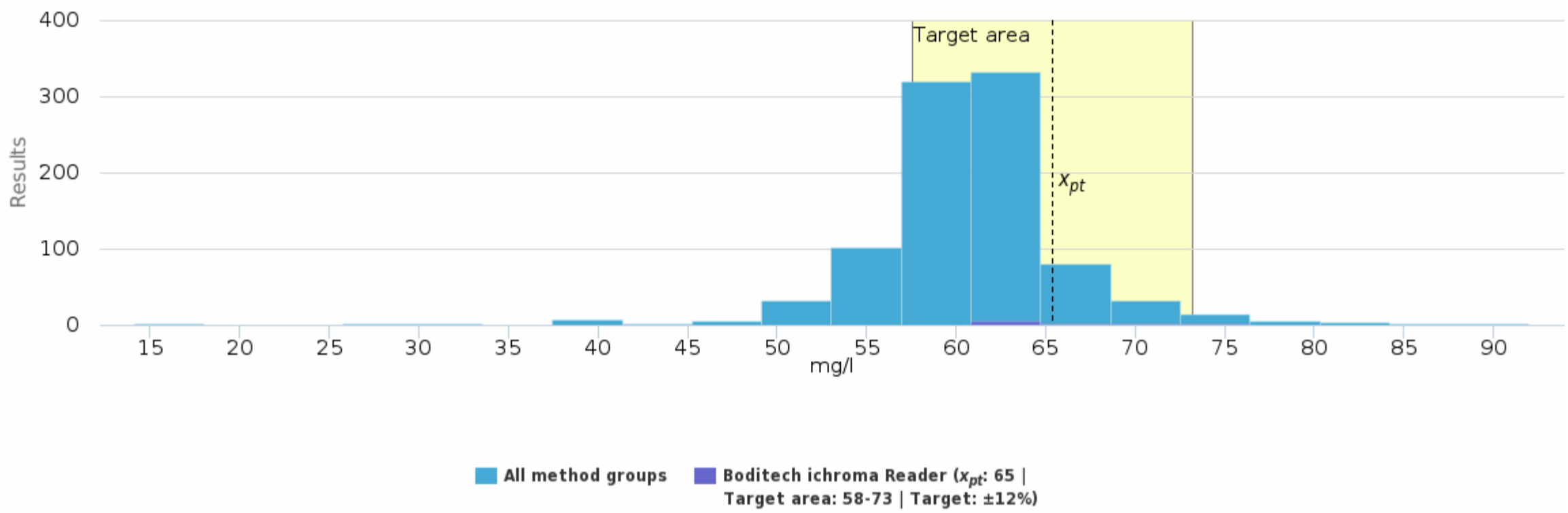
Aidian (Orion Diagnostica) QuikRead go easy CRP



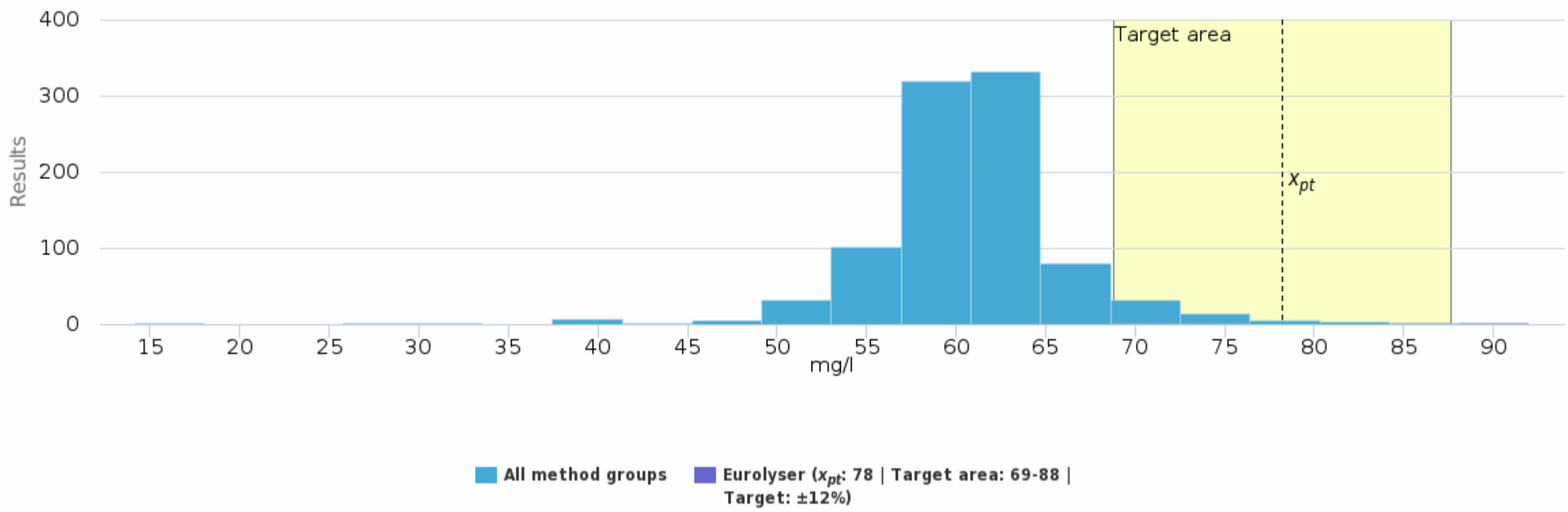
Aidian (Orion Diagnostica) QuikRead wrCRP

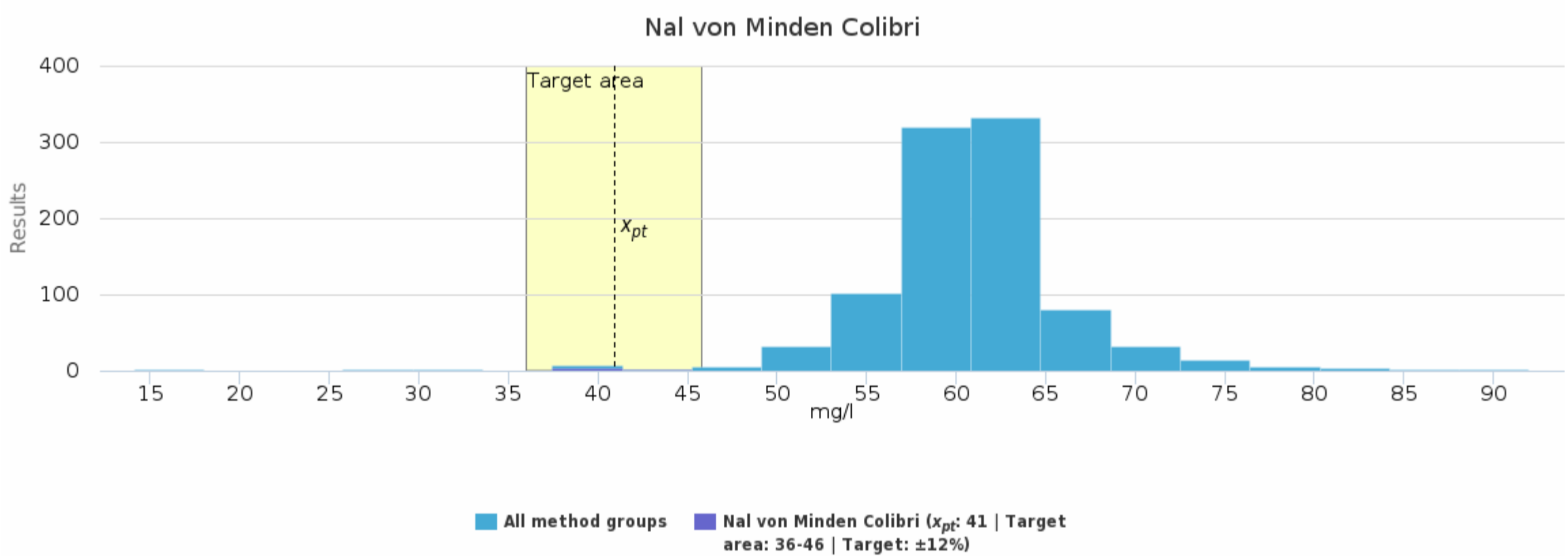
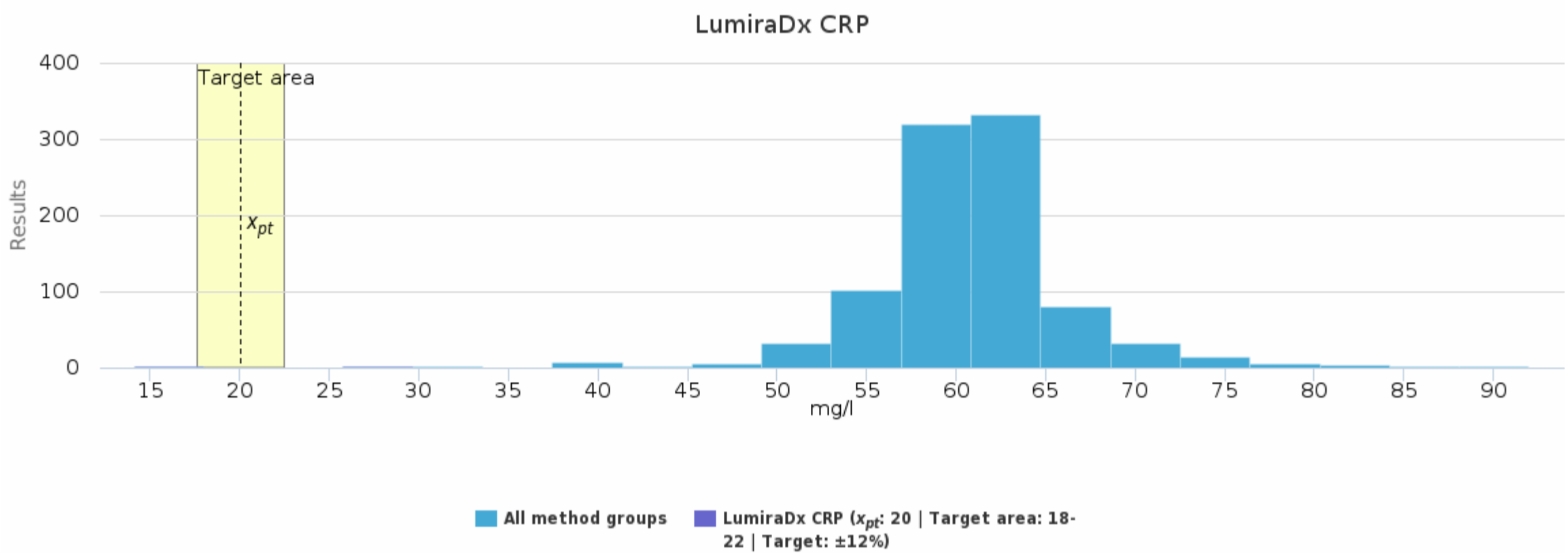
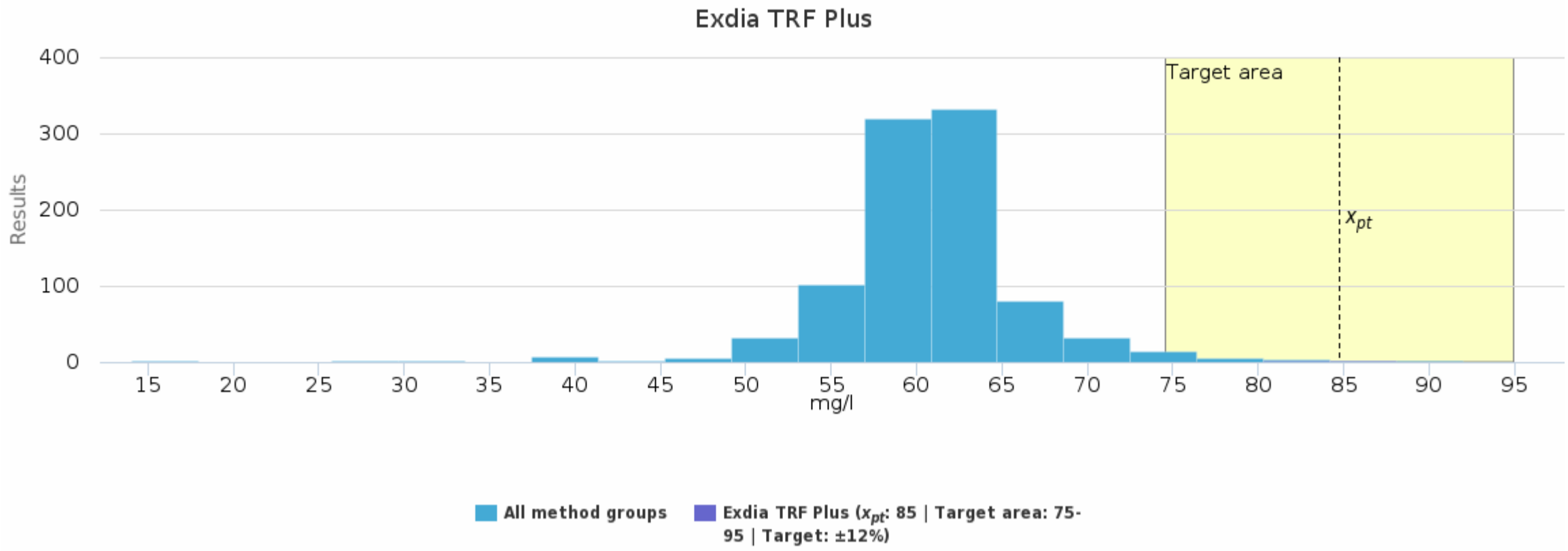


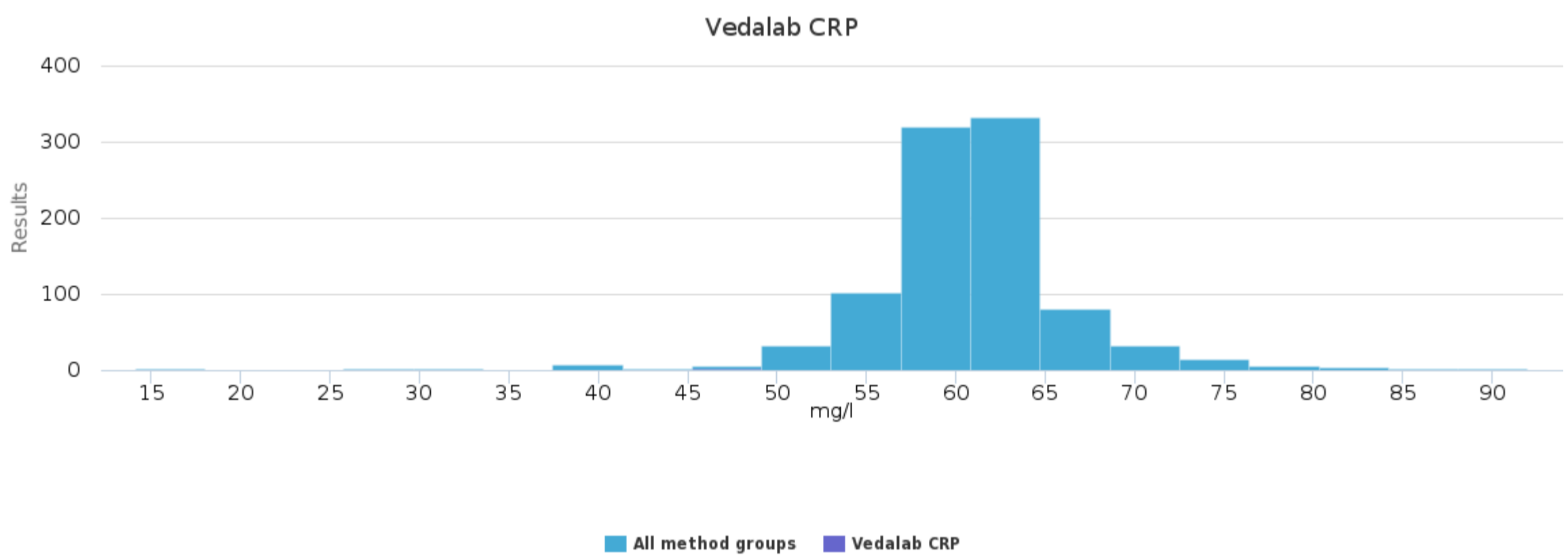
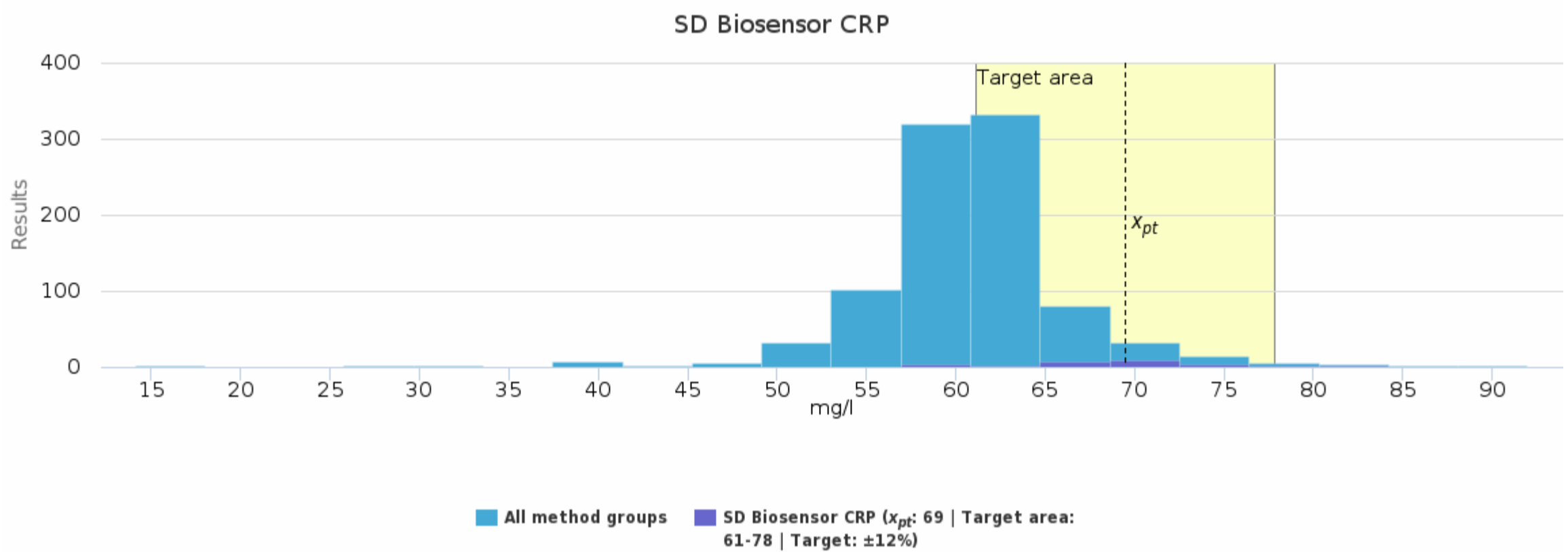
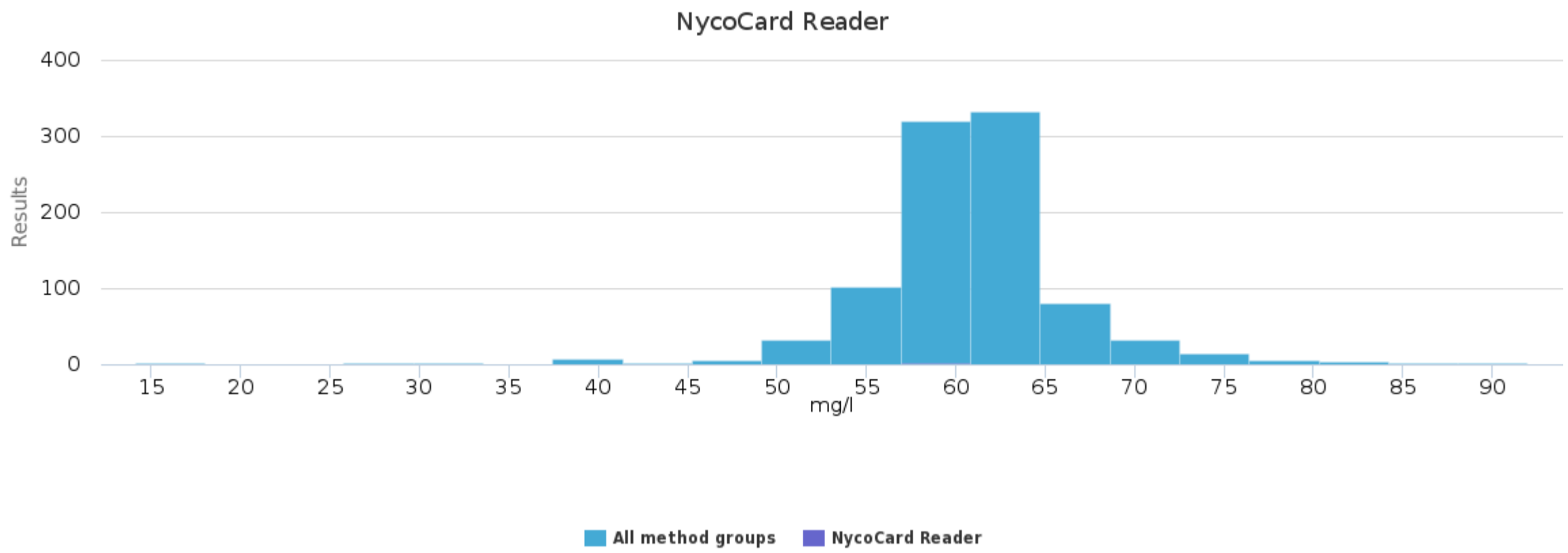
Boditech ichroma Reader



Eurolyser







Methodics	Instrument	x_{pt}	sd	CV%	n
ABX Micros		62	4	6.1	42
	ABX Micros CRP 200	62	4	6.6	3
	Micros CRP	-	-	-	1
	Microsemi CRP	62	4	7.2	38
Afinion		57	3	4.8	112
	Afinion AS100	58	4	7.0	66
	Afinion 2	57	2	4.2	46
Aidian (Orion Diagnostica) QuikRead		58	12	20.0	19
	QuikRead	64	1	2.0	2

	QuikRead 101	57	12	21.1	17
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	QuikRead Go	61	4	6.3	578
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	QuikRead Go	60	7	11.6	127
Aidian (Orion Diagnostica) QuikRead wrCRP		60	4	6.2	16
	QuikRead Go	60	4	6.2	16
Boditech ichroma Reader		65	4	6.3	10
	i-Chroma II Reader	-	-	-	1
	iChroma II Reader	62	<1	1.3	3
	iChroma Reader	67	5	7.0	6
Eurolyser		78	9	11.6	3
	Eurolyser CUBE	78	9	11.6	3
Exdia TRF Plus		85	2	2.0	3
	Exdia TRF Plus	85	2	2.0	3
LumiraDx CRP		20	8	42.0	2
	LumiraDx	20	8	42.0	2
Nal von Minden Colibri		41	<1	1.8	4
	Colibri	41	<1	1.8	4
NycoCard Reader		-	-	-	1
	Nycocard Reader II	-	-	-	1
SD Biosensor CRP		69	6	8.9	28
	Standard F100	66	4	6.8	3
	Standard F200	70	6	9.0	25
Vedalab CRP		-	-	-	1
	Easy Reader +	-	-	-	1

Report info**Participants**

807 participants from 10 countries.

Report info

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

Assigned values (\bar{x}_p , 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 "EOAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

LABQUALITY

External Quality Assessment Scheme

C-reactive protein (CRP), POCT, Round 1, 2023

Specimens

Samples S001 (LQ735123011) and S002 (LQ735123012) were human plasma products containing < 0.1% Na-azide.

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

Values of the manufacturer for the samples were:

Sample S001: about 15 mg/L.

Sample S002: about 60 mg/L.

The target values of the samples are traced to ERM® - DA474/IFCC.

The values of the samples given by the sample manufacturer are only indicative. Laboratories should compare their results primarily to the calculated assigned value of their method group i.e to the corrected method mean (marked as Xpt in the reports).

Comments – Expert

The results of this round are little better than in the previous rounds. The distributions of the results are congruent. The results from sample S001 vary between 8 and 23 mg/L and from sample S002 the results vary between 14 and 89 mg/L. The result level of a few methods (Exdia TFR Plus, LumiraDx CRP, Nal von Minden Colibri) clearly deviates from the target level stated by the manufacturer. Also in many other groups there are reported results that deviate clearly from the mean results. Fifteen results have also been rejected from the processing of the results, because they deviate too much from other results. CRP is a method based on the results of which significant decisions are made in terms of patient care. The result level of the method should correspond to the result level traced to the international calibrator. If your result deviates from the distribution, check your method and equipment according to the instruction described in the appendix.

Annex 1.

Instructions how to proceed if your result is out of the acceptable limits.

End of report

2023-03-08

FINAL REPORT

Product no. 2132

Samples sent	2023-01-31
Round closed	2023-02-28
Final report	2023-03-08

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 Ylitespa

liisa.ylitespa@labquality.fi

Expert

PhD, Docent, Kari Åkerman
Central Hospital of Seinäjoki
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Fax + 358 9 8566 8280

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Annex 1.

Result outside acceptable limits:

- Please read the meter and strip manual.
- Check that the strips / reagents included in the device are correct and the device is in working order. Check your measurement technique.
- Check and replace strips / reagents that are outdated, wetted, or stored, for example, at the wrong temperature.
- The device's own or unit's internal controls should be used regularly as instructed by the meter manufacturer / laboratory.
- Contact the person in charge at the support laboratory or the device manufacturer.