

External Quality Assessment Scheme

Faecal calprotectin Round 2, 2023

Specimens

Please find enclosed two lyophilized faecal samples S001 and S002, each 500 µL.

Caution

Quality control samples derived from human stool must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases.

Examinations

Samples are for determination of the faecal calprotectin by quantitative or qualitative method.

Storage and use

After arrival store the samples at +2...8 °C before use. Before analysing add 500 µL distilled or reagent grade water, do not mix at this stage but allow to stand for 10 min at RT. After that, mix (vortex) the samples about 30 seconds. Check that the samples are homogeneous. Analyse after reconstitution same way as a patient sample. Dissolved samples are stable for 12 hours when stored at +2...8°C. Follow the standard operating procedure of your laboratory for disposal of the samples.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). Now the extraction methods have been added to result form. It's mandatory to select your test's extraction method from drop down menu. If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator.

Do not interpret your quantitative results as qualitative. Send only your quantitative results.

S001



S002



2023-05-15

INSTRUCTIONS

Product no. 2751
LQ775123021-022/DE
UN3373

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

The results should be reported no later than **June 2, 2023.**

Inquiries

EQA Coordinator
Anna-Riitta Vanhanen
anna-riitta.vanhanen@labquality.fi

Labquality Oy

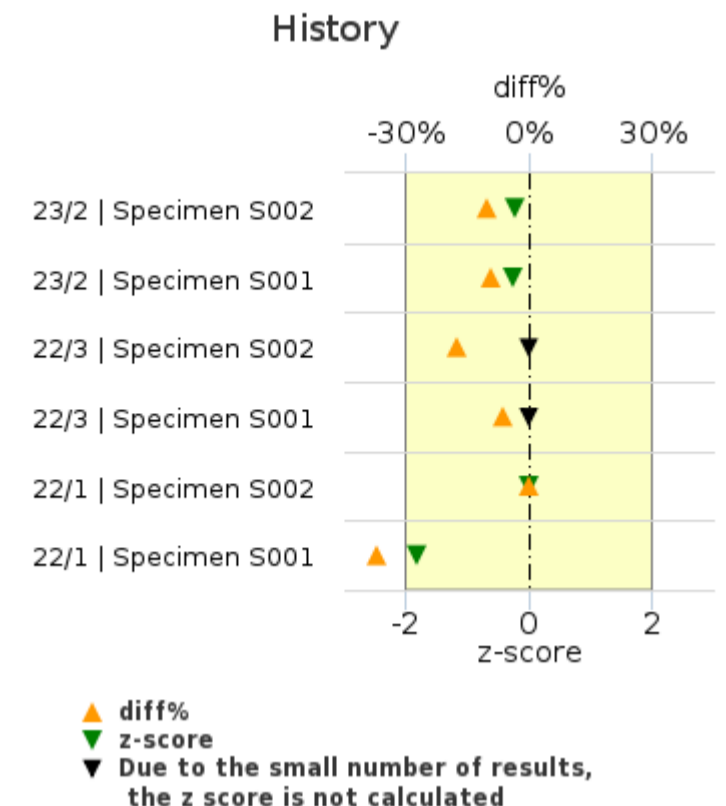
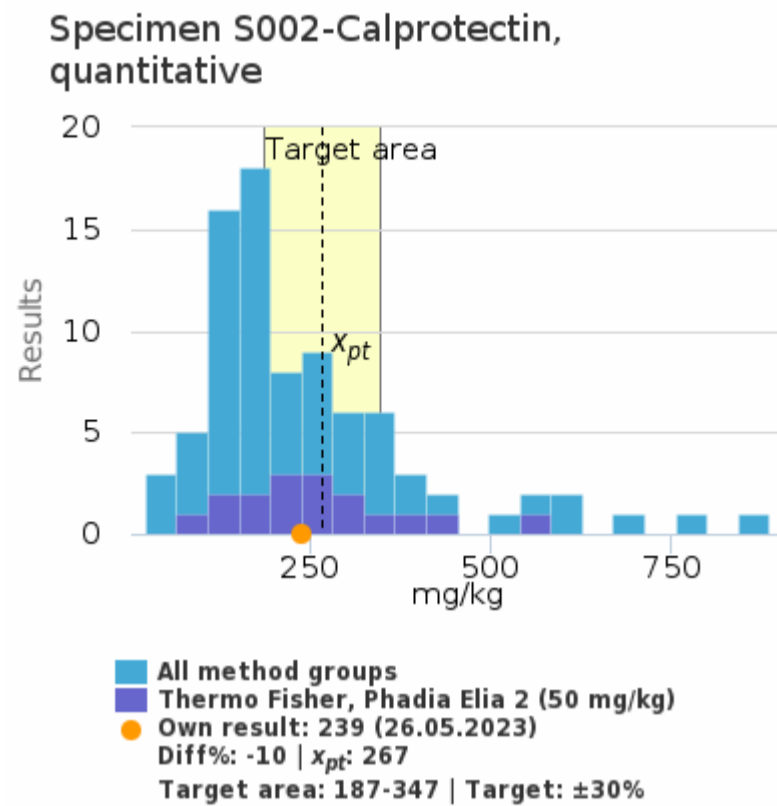
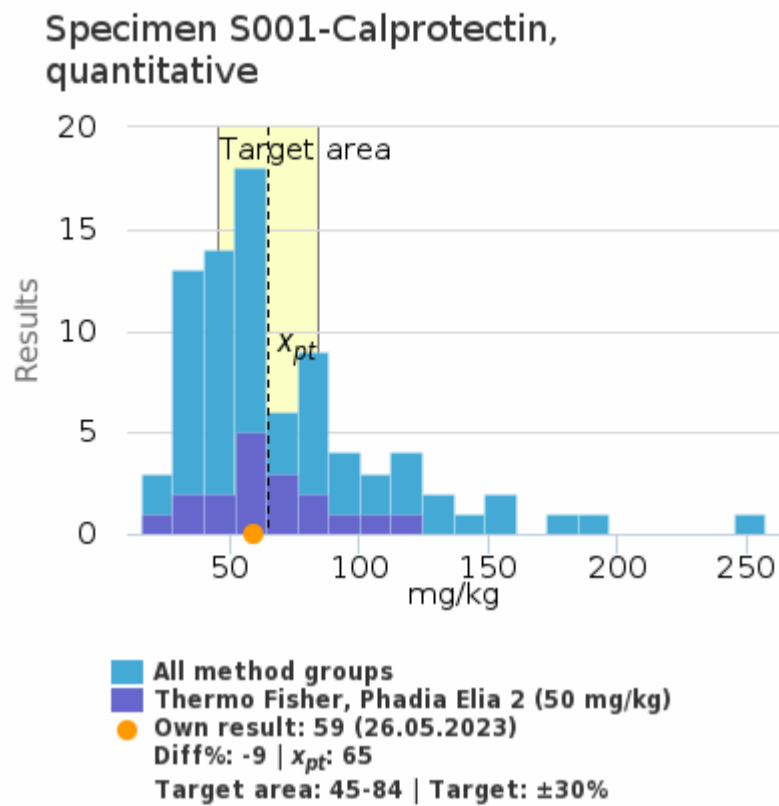
Kumpulantie 15
FI-00520 HELSINKI
Finland

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

info@labquality.fi
www.labquality.com



Calprotectin, quantitative



	x_{pt}	sd	SEM	CV%	n
Thermo Fisher, Phadia Elia 2 (50 mg/kg)	65 mg/kg	24	6	36.9	18
All methods	67 mg/kg	34	4	50.5	82

	x_{pt}	sd	SEM	CV%	n
Thermo Fisher, Phadia Elia 2 (50 mg/kg)	267 mg/kg	121	29	45.3	17
All methods	232 mg/kg	127	14	54.9	84

Round	Sample	x_{pt}	Result	diff%	z-score
23/2	Specimen S002	267	239	-10%	-0.23
23/2	Specimen S001	65	59	-9%	-0.25
22/3	Specimen S002	471	388	-18%	-
22/3	Specimen S001	74	69	-6%	-
22/1	Specimen S002	183	183	0%	-0.01
22/1	Specimen S001	171	108	-37%	-1.82

Extraction methods

Specimen S001

Extraction methods	Number of results
CerTest Turbilatex Sample Collection Tube	1
LIAISON Calprotectin Stool Extraction Device	6
LIAISON Q.S.E.T Device	18
EasyCal	1
EasyCal Turbo	2
Easy Extract	1
Smart-Prep	1
CALEX Cap Device	19
EliA Stool Extraction Kit 2	12
EliA Stool Extraction Kit Plus	7
Roche Faecal sample preparation kit	1
Weighing with scale	3
Other type extraction method	25
CALiaGold pierce Tube	2
Total	99

Specimen S002

Extraction methods	Number of results
CerTest Turbilatex Sample Collection Tube	1
LIAISON Calprotectin Stool Extraction Device	6
LIAISON Q.S.E.T Device	18
EasyCal	1
EasyCal Turbo	2
Easy Extract	1
Smart-Prep	1
CALEX Cap Device	19
EliA Stool Extraction Kit 2	13
EliA Stool Extraction Kit Plus	7
Roche Faecal sample preparation kit	1
Weighing with scale	3
Other type extraction method	25

CALiaGold pierce Tube	2
Total	100

Report info**Participants**

99 participants from 22 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.

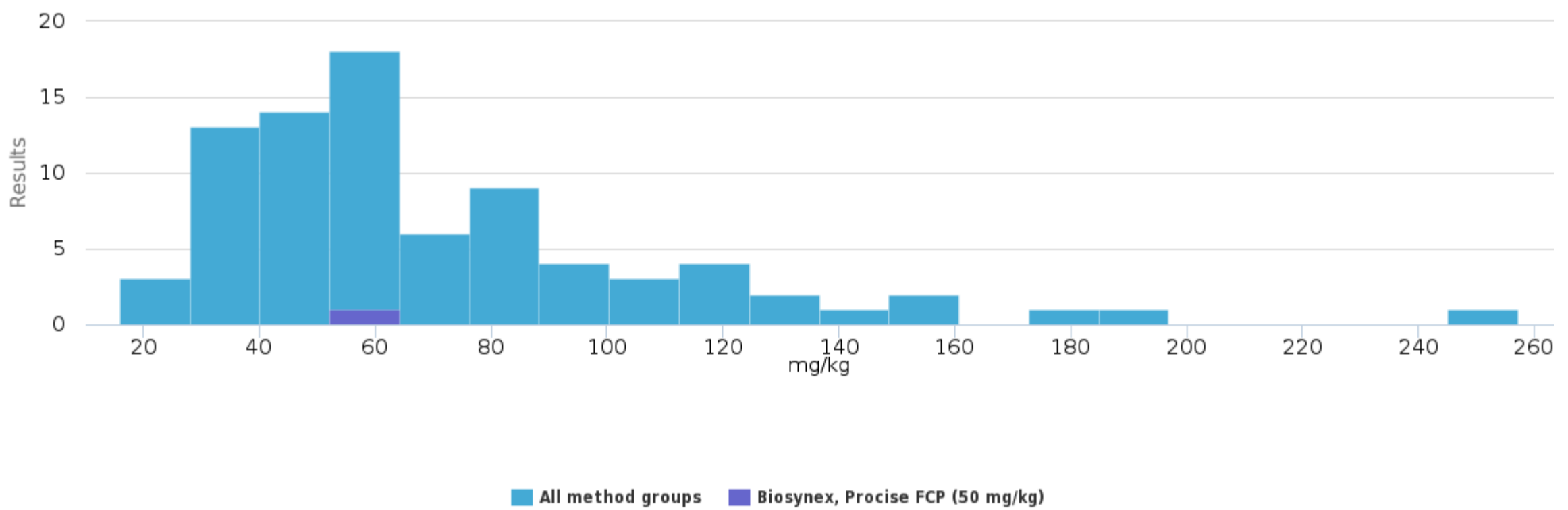
Results reported with $<$ or $>$ -signs cannot be included in the statistics.

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

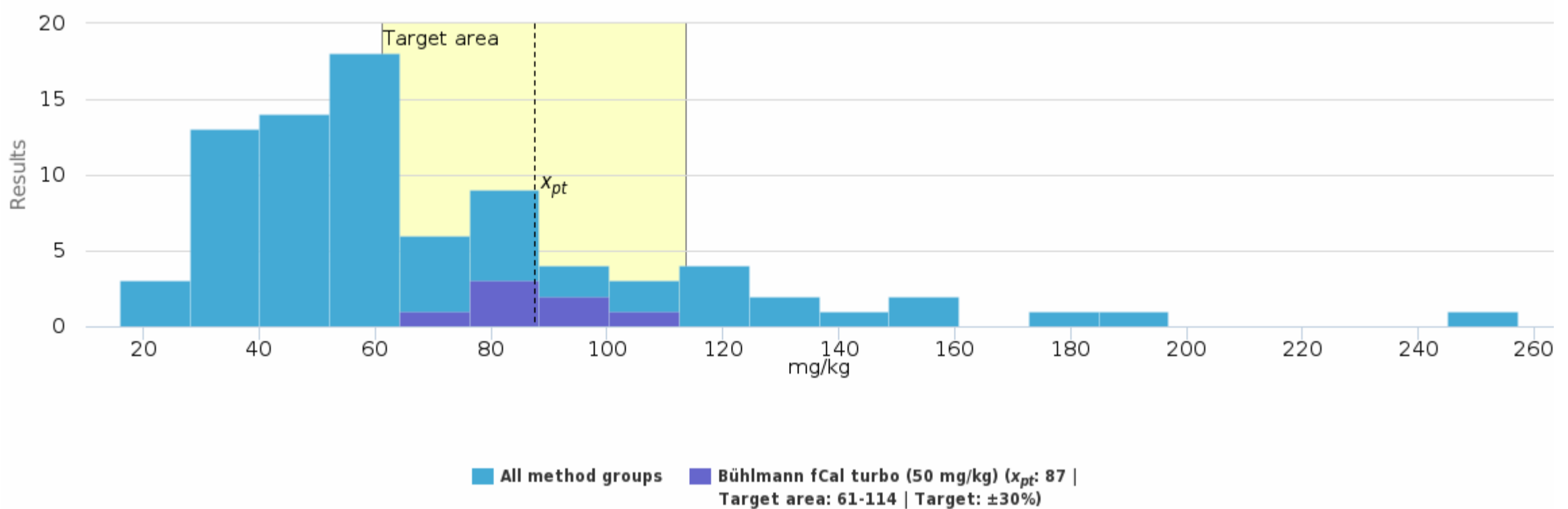
Specimen S001 | Calprotectin, quantitative, mg/kg

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Biosynex, Procise FCP (50 mg/kg)	-	-	-	-	-	55	55	-	1
Bühlmann fCal turbo (50 mg/kg)	87	88	11	12.7	4	68	102	-	7
Bühlmann Quantum Blue fCal (50 mg/kg)	77	78	11	14.6	4	61	91	-	8
Calpro, CalproLab Elisa (ALP) (50 mg/kg)	52	52	7	13.9	5	47	57	-	2
CerTest Biotec Turbilatex (50 mg/kg)	-	-	-	-	-	75	75	-	1
DiaSorin, Liaison Clia (50 mg/kg)	46	46	9	18.7	2	31	60	-	24
Euroimmun, ELISA (50 mg/kg)	43	43	12	26.9	7	31	54	-	3
Eurospital, CalFast, ELISA (70 mg/kg)	-	-	-	-	-	122	122	-	1
Eurospital, Calprest, ELISA (50 mg/kg)	-	-	-	-	-	30	30	-	1
Eurospital, Calprest, TURBO (50 mg/kg)	-	-	-	-	-	16	16	-	1
Inova Diagnostics, QUANTA Flash (50 mg/kg)	30	31	8	26.2	4	20	38	-	4
Orgentec, ELISA (50 mg/kg)	146	147	30	20.7	12	111	196	-	6
R-Biopharm, Ridascreen (50 mg/kg)	-	-	-	-	-	127	127	-	1
Sentinel Diagnostics, CALiaGold (50 mg/kg)	169	135	77	45.7	45	115	257	-	3
Thermo Fisher, Phadia Elia 2 (50 mg/kg)	65	61	24	36.9	6	24	114	-	18
Thermo Fisher, Phadia Elia (50 mg/kg)	-	-	-	-	-	182	182	-	1
All	67	57	34	50.5	4	16	182	2	82

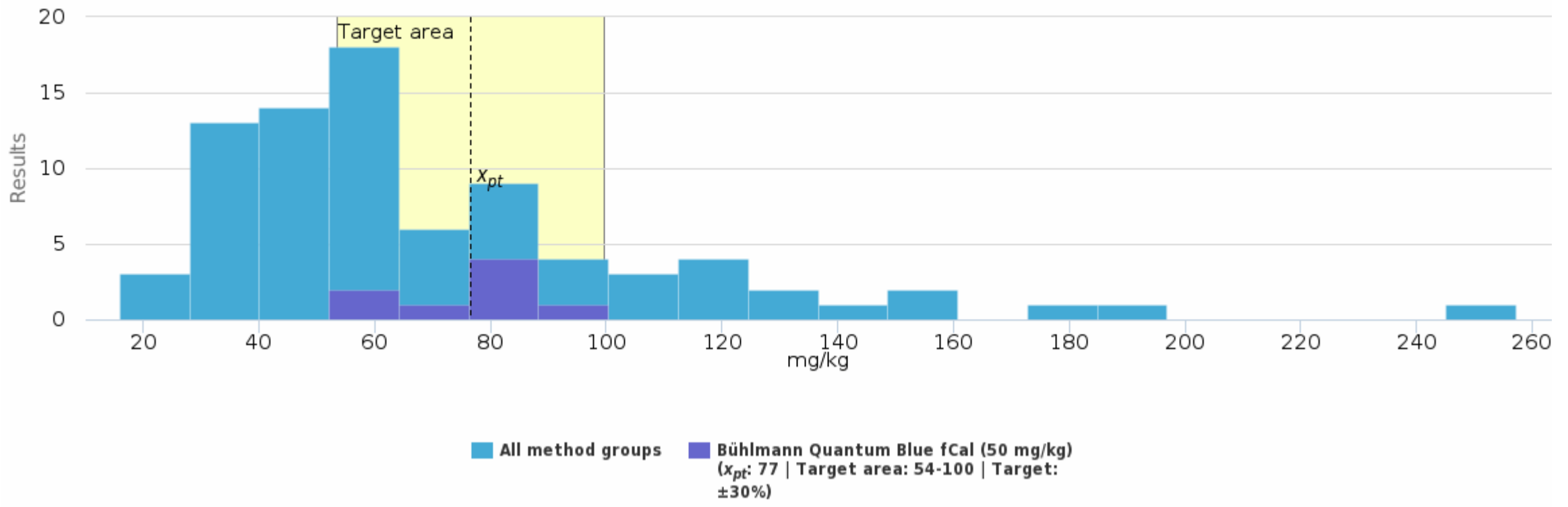
Biosynex, Procise FCP (50 mg/kg)



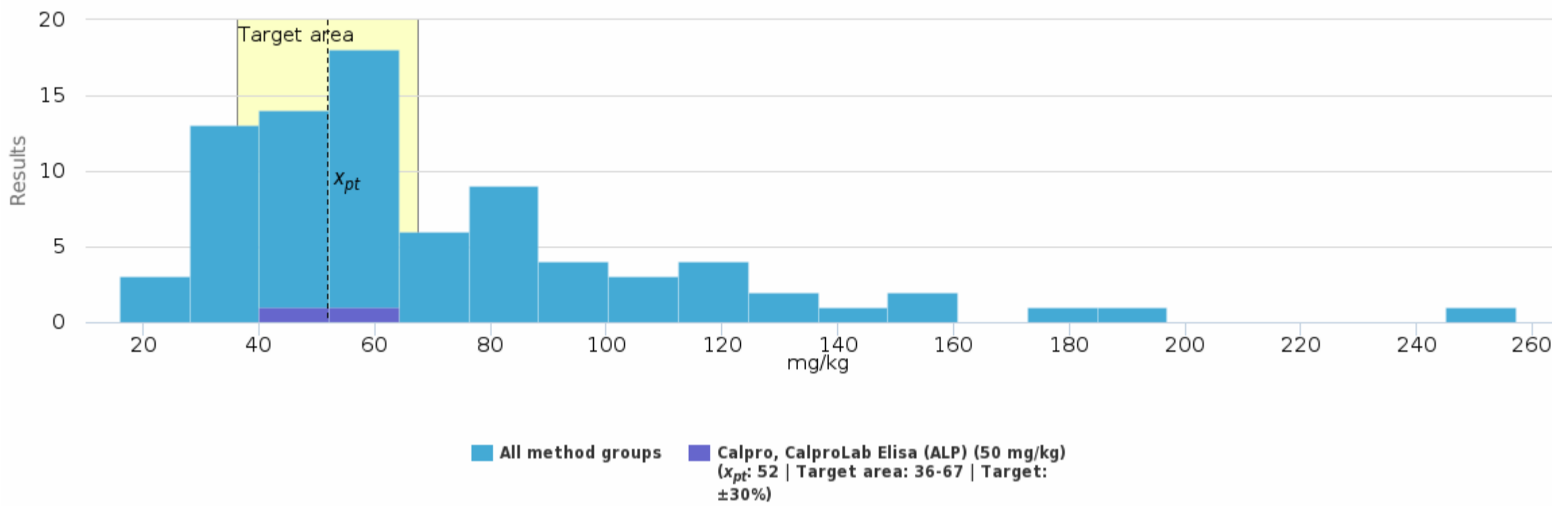
Bühlmann fCal turbo (50 mg/kg)



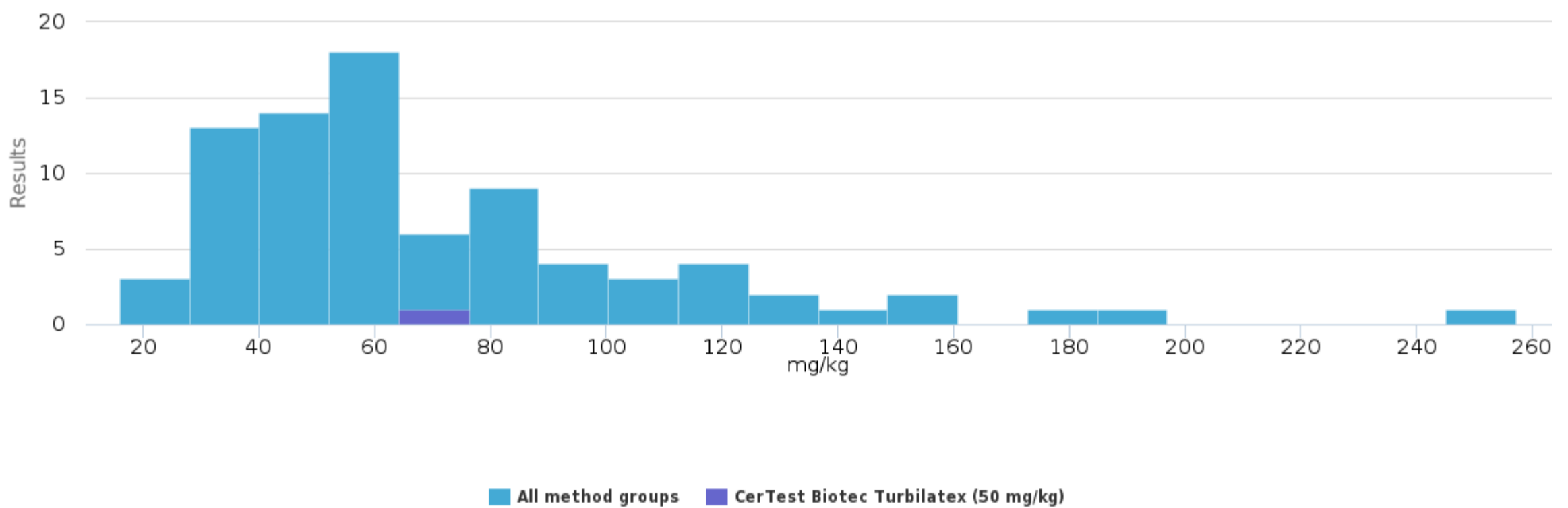
Bühlmann Quantum Blue fCal (50 mg/kg)



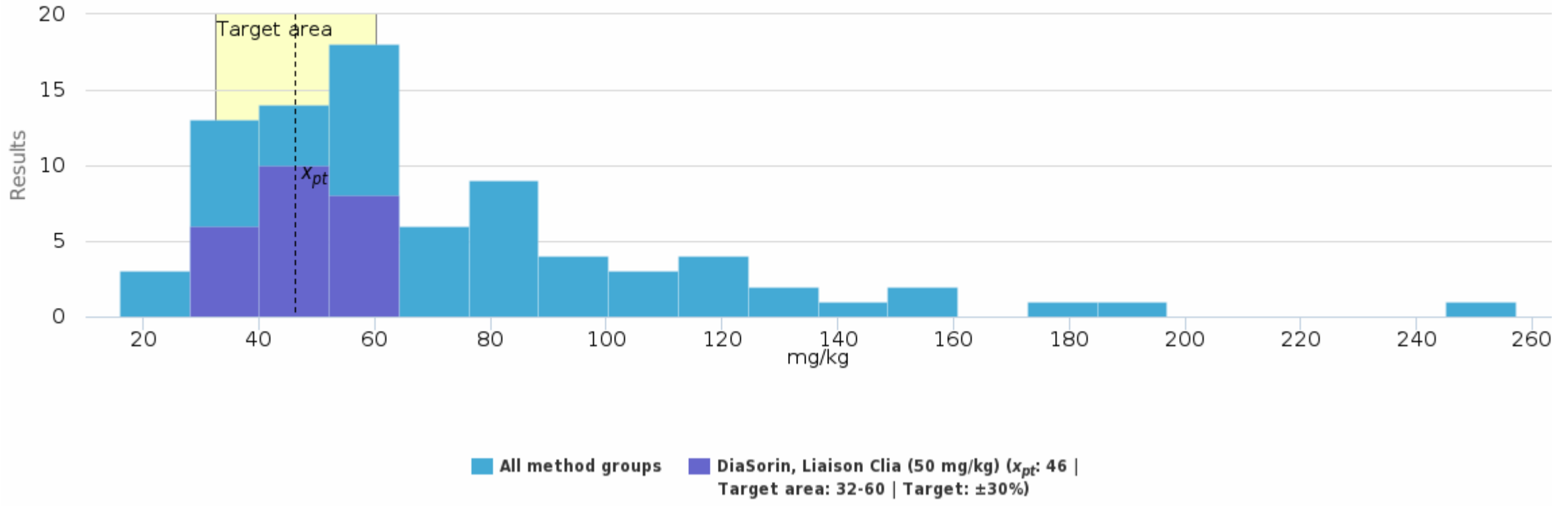
Calpro, CalproLab Elisa (ALP) (50 mg/kg)



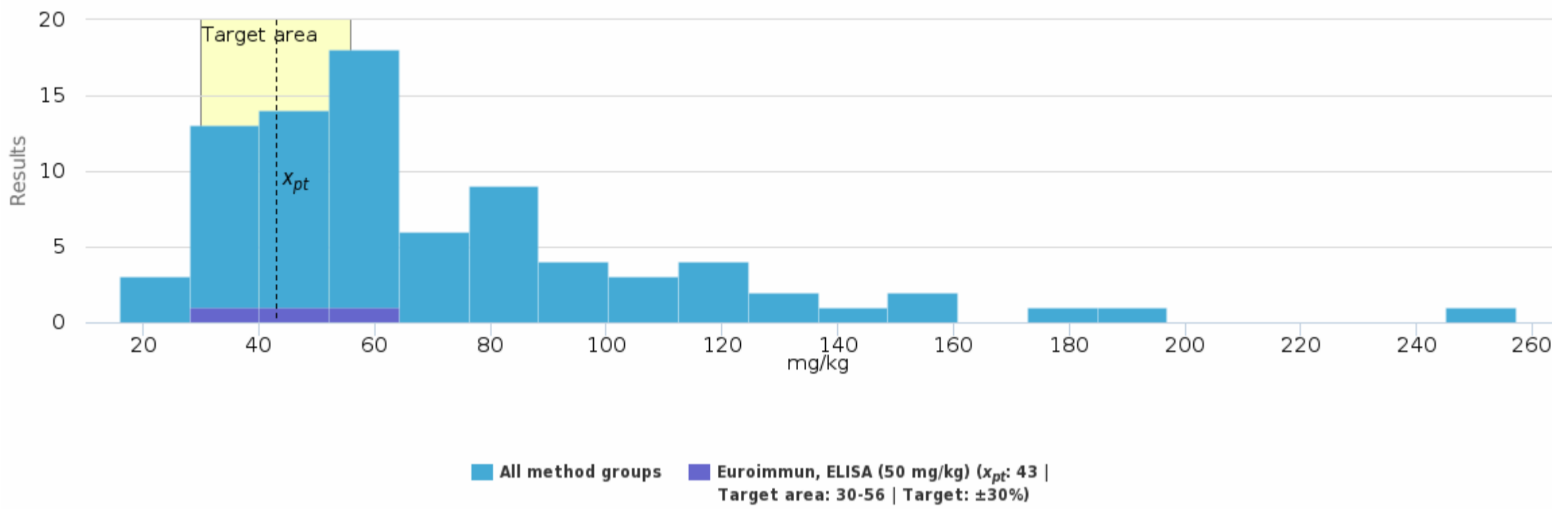
CerTest Biotec Turbilatex (50 mg/kg)



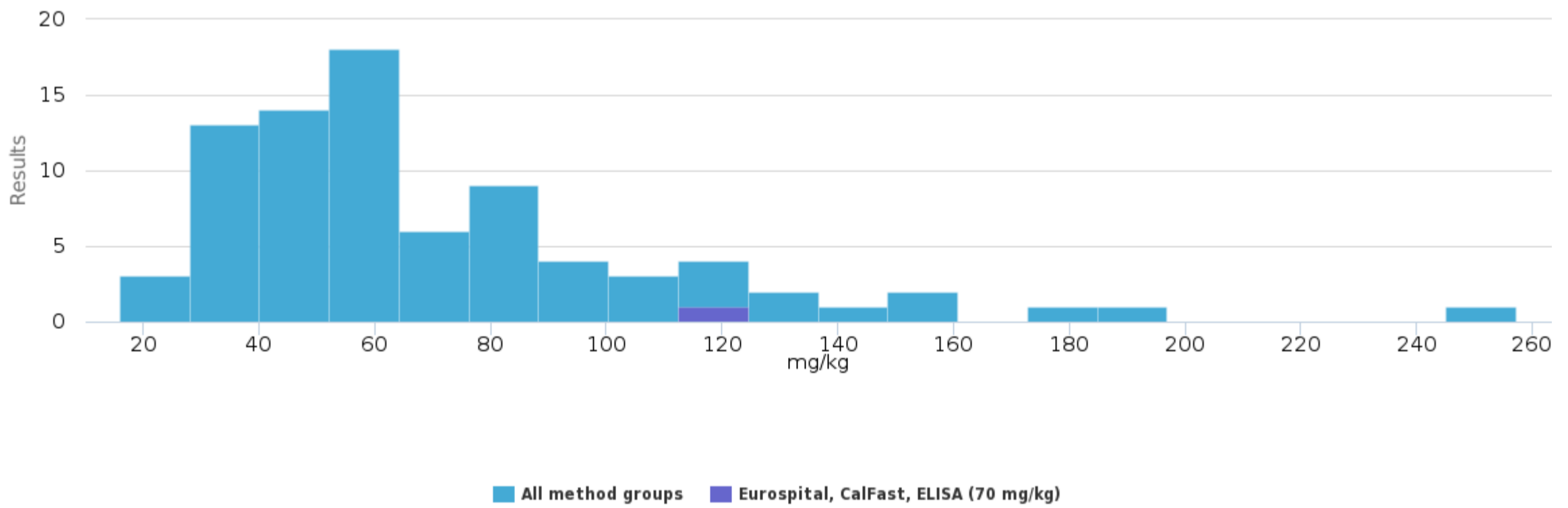
DiaSorin, Liaison Clia (50 mg/kg)



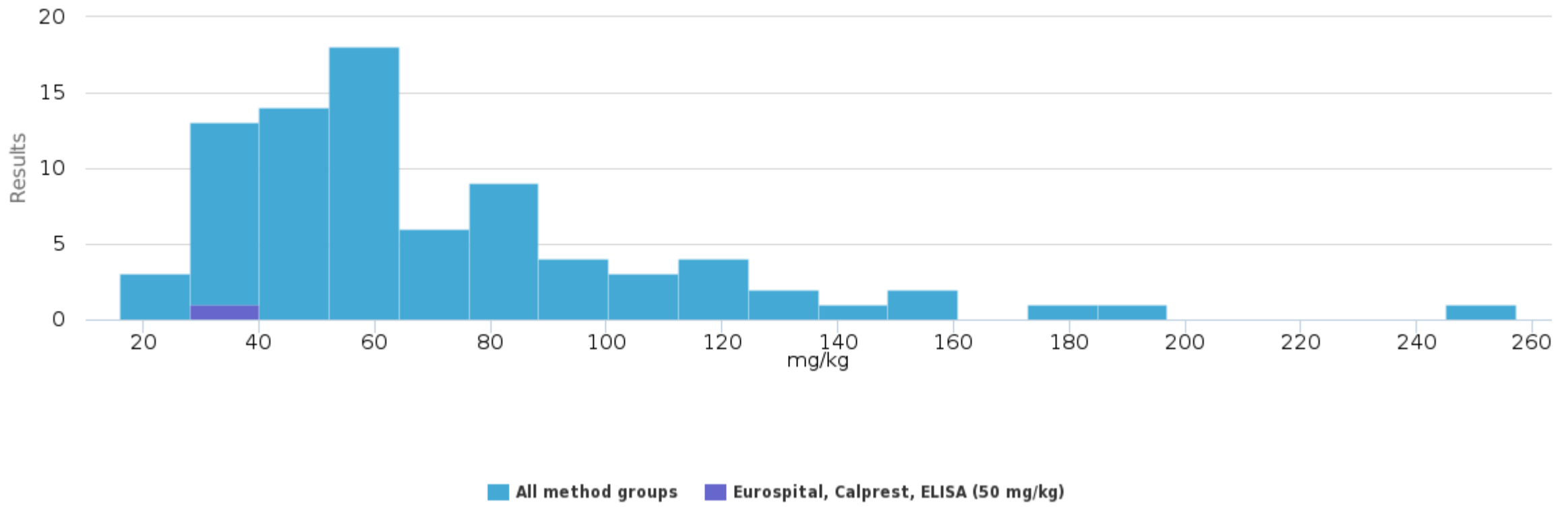
Euroimmun, ELISA (50 mg/kg)



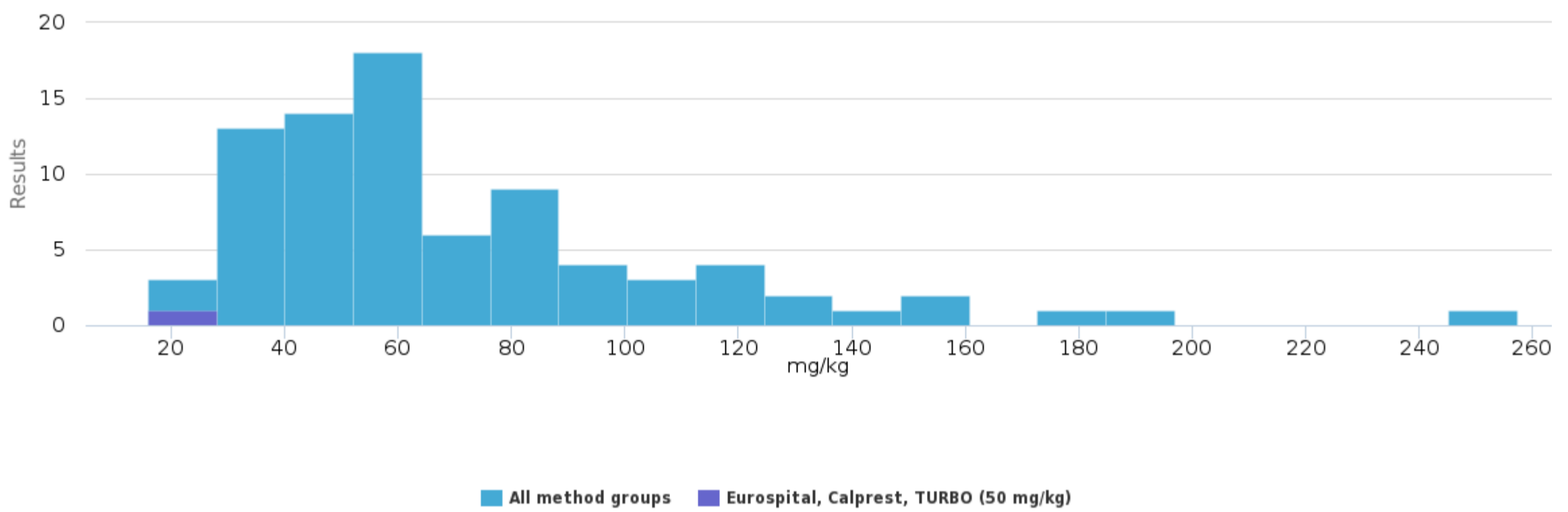
Eurospital, CalFast, ELISA (70 mg/kg)



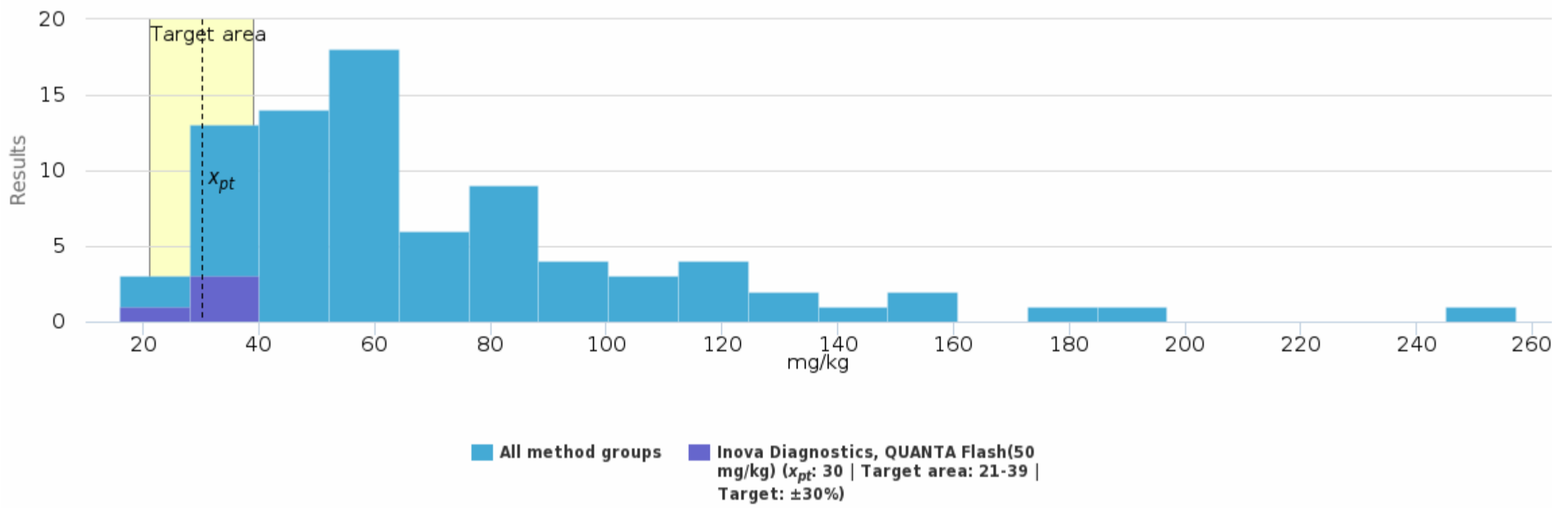
Eurospital, Calprest, ELISA (50 mg/kg)

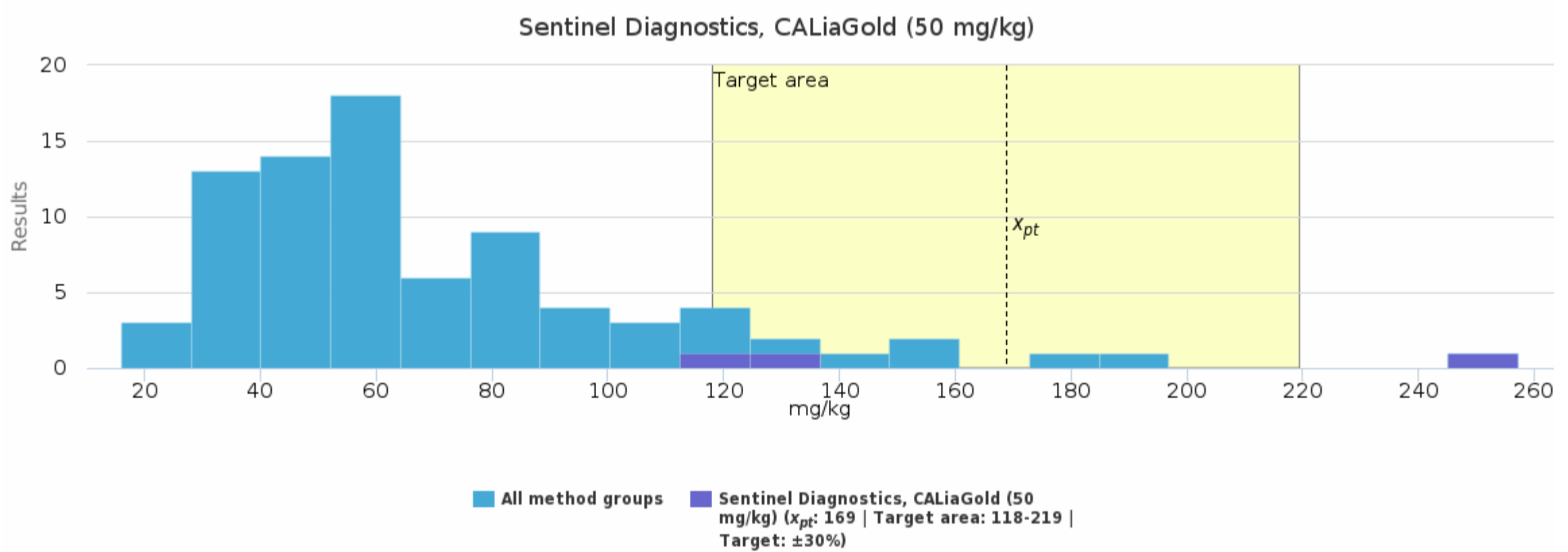
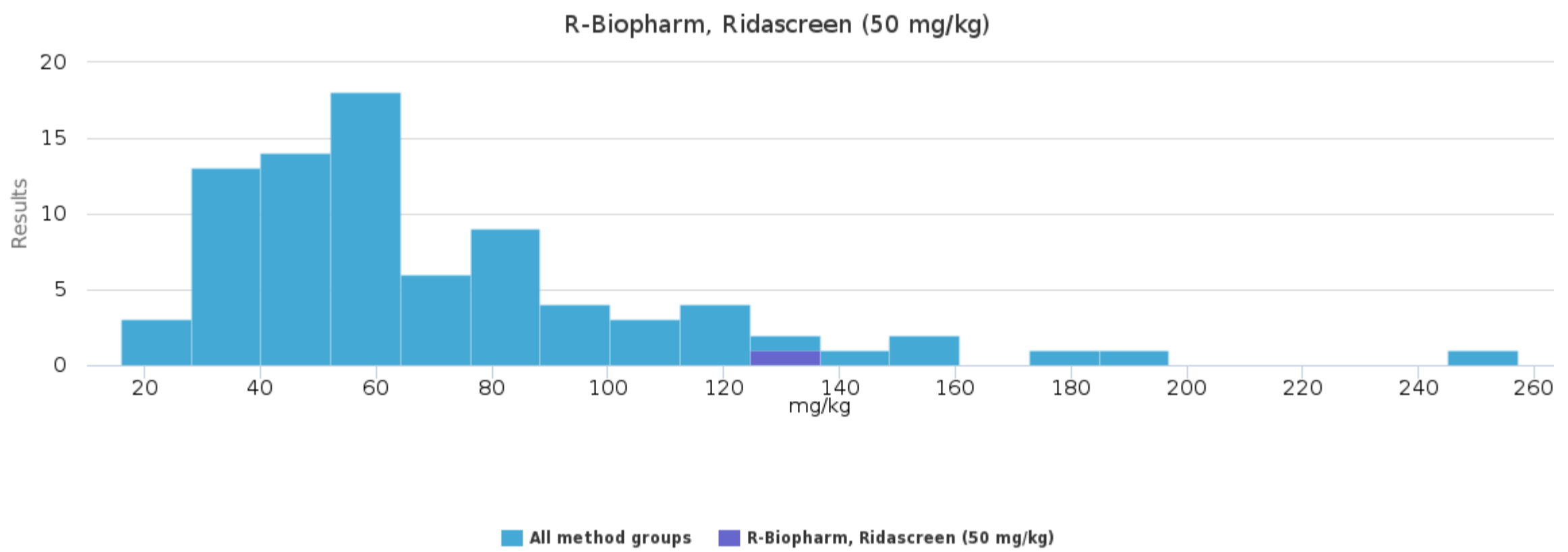
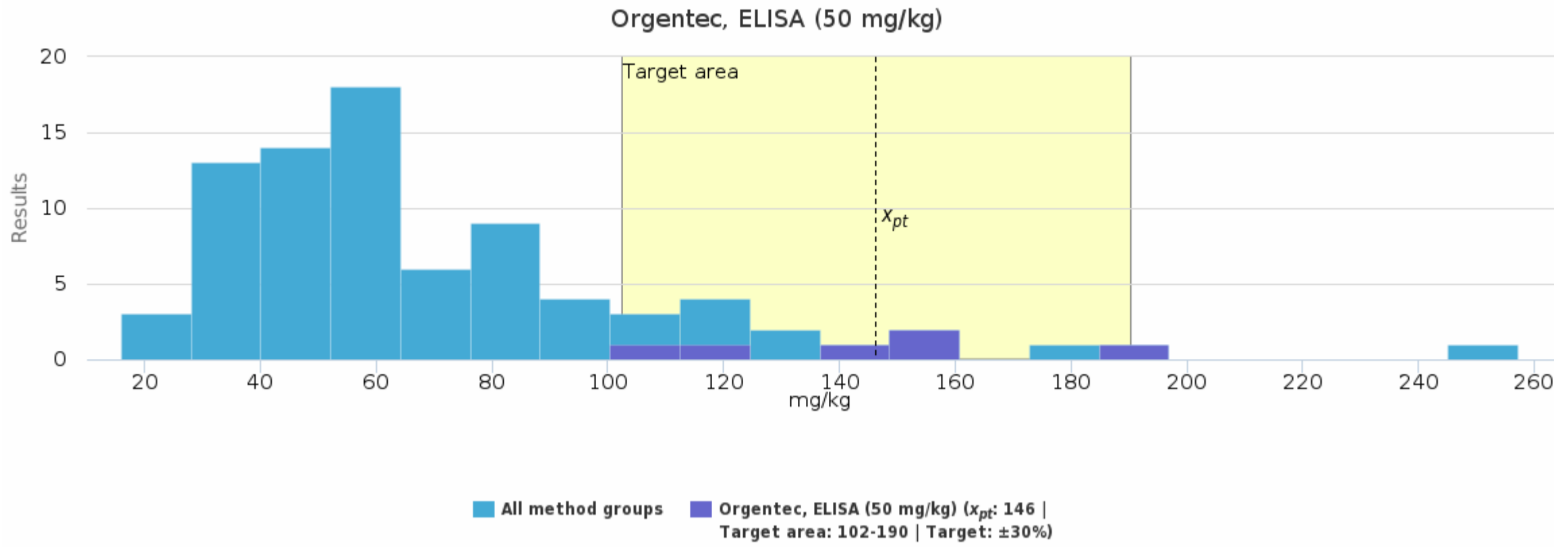


Eurospital, Calprest, TURBO (50 mg/kg)

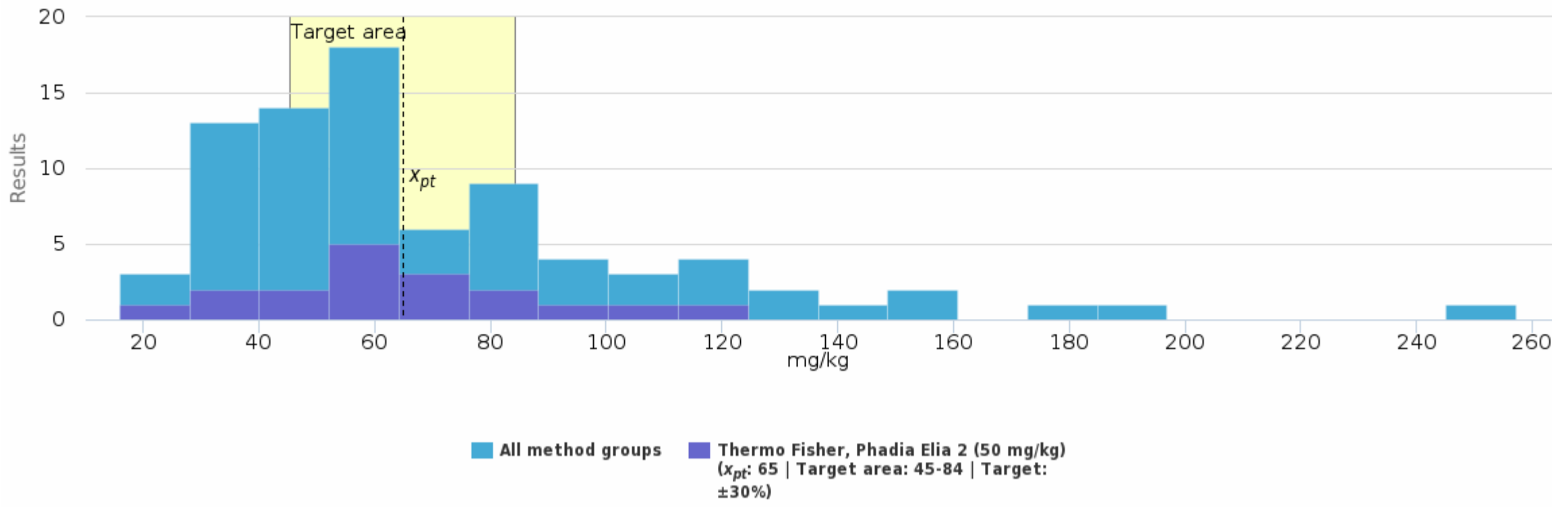


Inova Diagnostics, QUANTA Flash(50 mg/kg)

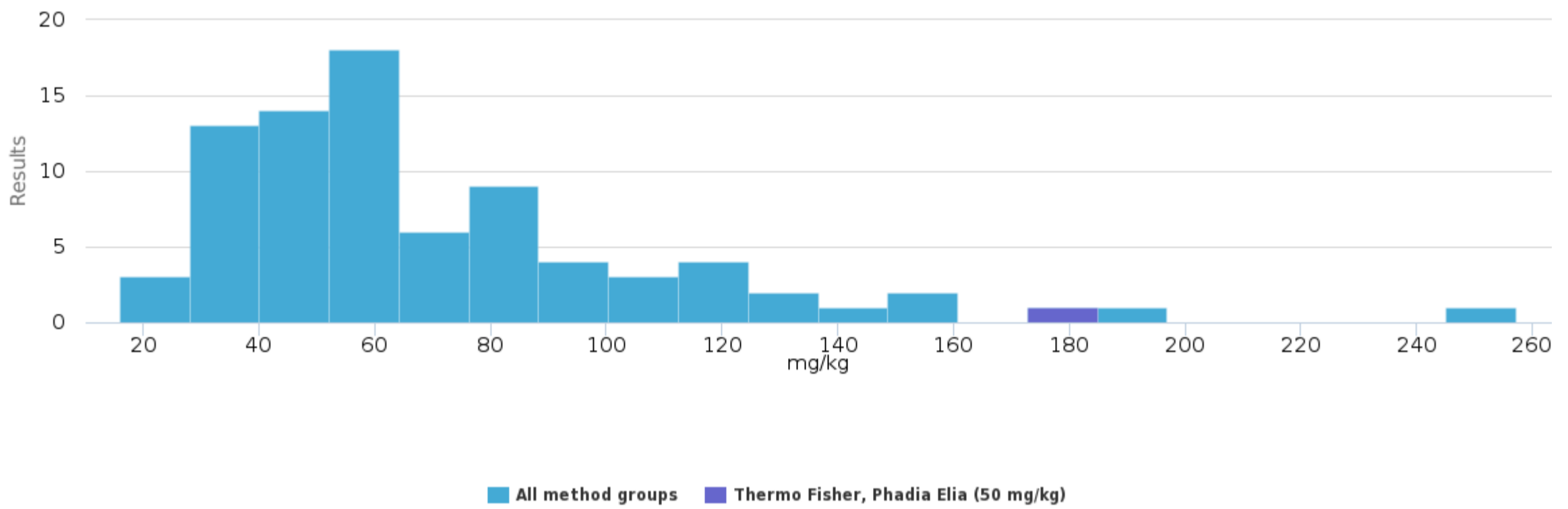




Thermo Fisher, Phadia Elia 2 (50 mg/kg)



Thermo Fisher, Phadia Elia (50 mg/kg)



Specimen S001 | Calprotectin, qualitative, -

Methodics	Negative	Positive	Total
ACRO Biotech, Rapid Test (50 mg/kg)	-	1	1
CerTest Biotec CLIA Calprotectin Ag (50 mg/kg)	-	1	1
CerTest Biotec (50 mg/kg)	-	1	1
Hangzhou AllTest Biotech (50 mg/kg)	-	1	1
Medix Biochemica, Actim Calprotectin (50 mg/kg)	-	1	1
Nal von Minden, Nadal calprotectin (50 mg/kg)	1	1	2
Vedalab Calprotectin-Check-1 (50 mg/kg)	1	-	1
Vitassay Calprotectin Single Card (50 mg/kg)	-	1	1
Total	2	7	9

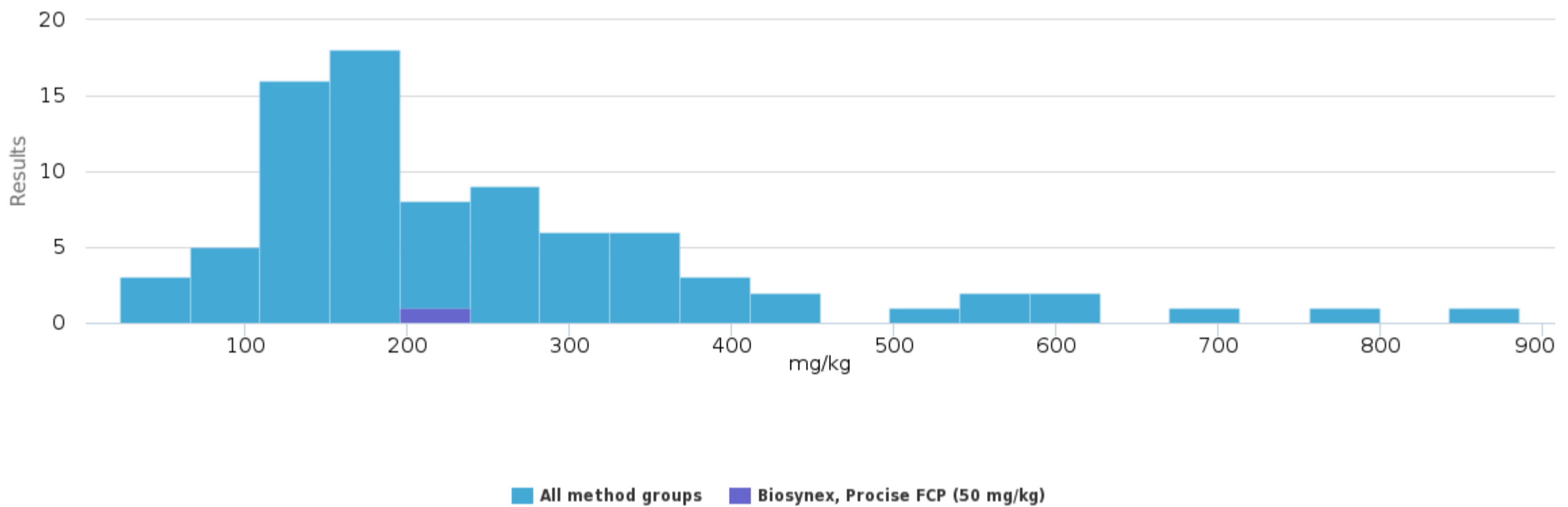
Specimen S001 | Extraction methods, -

Extraction methods	Number of results
CerTest Turbilatex Sample Collection Tube	1
LIAISON Calprotectin Stool Extraction Device	6
LIAISON Q.S.E.T Device	18
EasyCal	1
EasyCal Turbo	2
Easy Extract	1
Smart-Prep	1
CALEX Cap Device	19
EliA Stool Extraction Kit 2	12
EliA Stool Extraction Kit Plus	7
Roche Faecal sample preparation kit	1
Weighing with scale	3
Other type extraction method	25
CALiaGold pierce Tube	2
Total	99

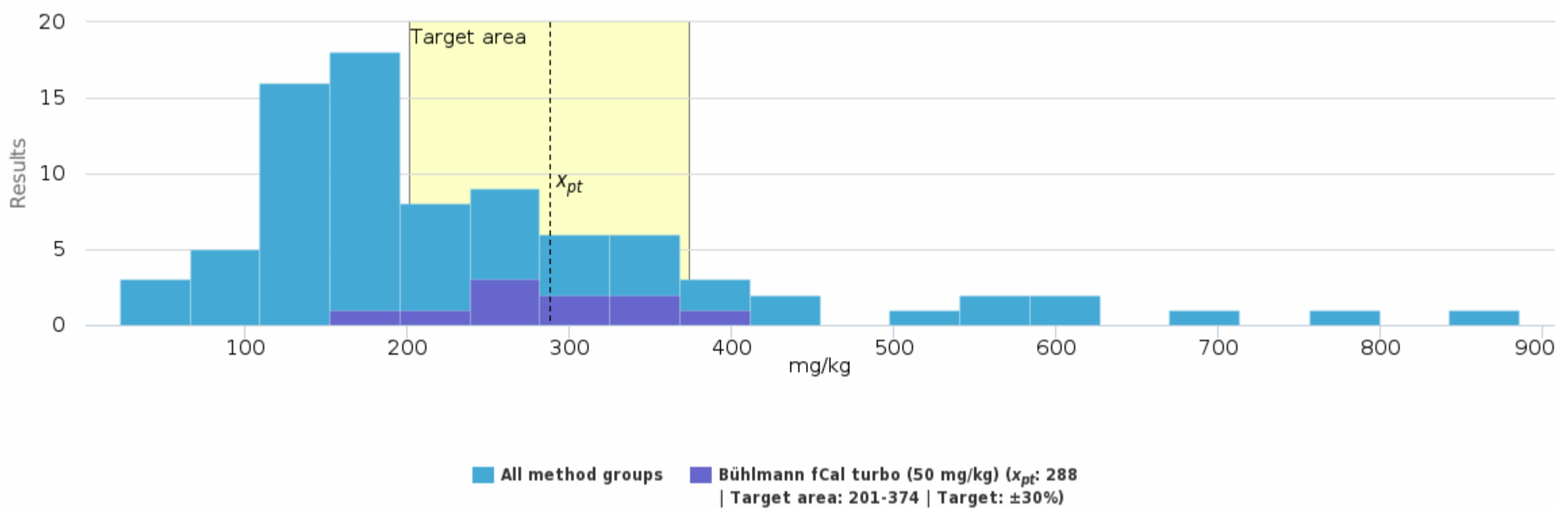
Specimen S002 | Calprotectin, quantitative, mg/kg

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Biosynex, Procise FCP (50 mg/kg)	-	-	-	-	-	213	213	-	1
Bühlmann fCal turbo (50 mg/kg)	288	284	67	23.2	21	164	378	-	10
Bühlmann Quantum Blue fCal (50 mg/kg)	254	272	85	33.6	30	140	363	-	8
Calpro, CalproLab Elisa (ALP) (50 mg/kg)	145	145	33	23.0	24	122	169	-	2
CerTest Biotec Turbilatex (50 mg/kg)	-	-	-	-	-	157	157	-	1
DiaSorin, Liaison Clia (50 mg/kg)	164	157	34	20.9	7	107	258	-	24
Euroimmun, ELISA (50 mg/kg)	138	111	69	49.9	40	87	217	-	3
Eurospital, CalFast, ELISA (70 mg/kg)	-	-	-	-	-	155	155	-	1
Eurospital, Calprest, ELISA (50 mg/kg)	-	-	-	-	-	43	43	-	1
Eurospital, Calprest, TURBO (50 mg/kg)	-	-	-	-	-	23	23	-	1
Inova Diagnostics, QUANTA Flash (50 mg/kg)	91	87	35	38.3	17	55	133	-	4
Orgentec, ELISA (50 mg/kg)	564	545	245	43.4	100	287	886	-	6
R-Biopharm, Ridascreen (50 mg/kg)	-	-	-	-	-	607	607	-	1
Sentinel Diagnostics, CALiaGold (50 mg/kg)	515	536	87	16.8	50	420	589	-	3
Thermo Fisher, Phadia Elia 2 (50 mg/kg)	267	239	121	45.3	29	88	569	-	17
Thermo Fisher, Phadia Elia (50 mg/kg)	-	-	-	-	-	562	562	-	1
All	232	195	127	54.9	14	23	607	3	84

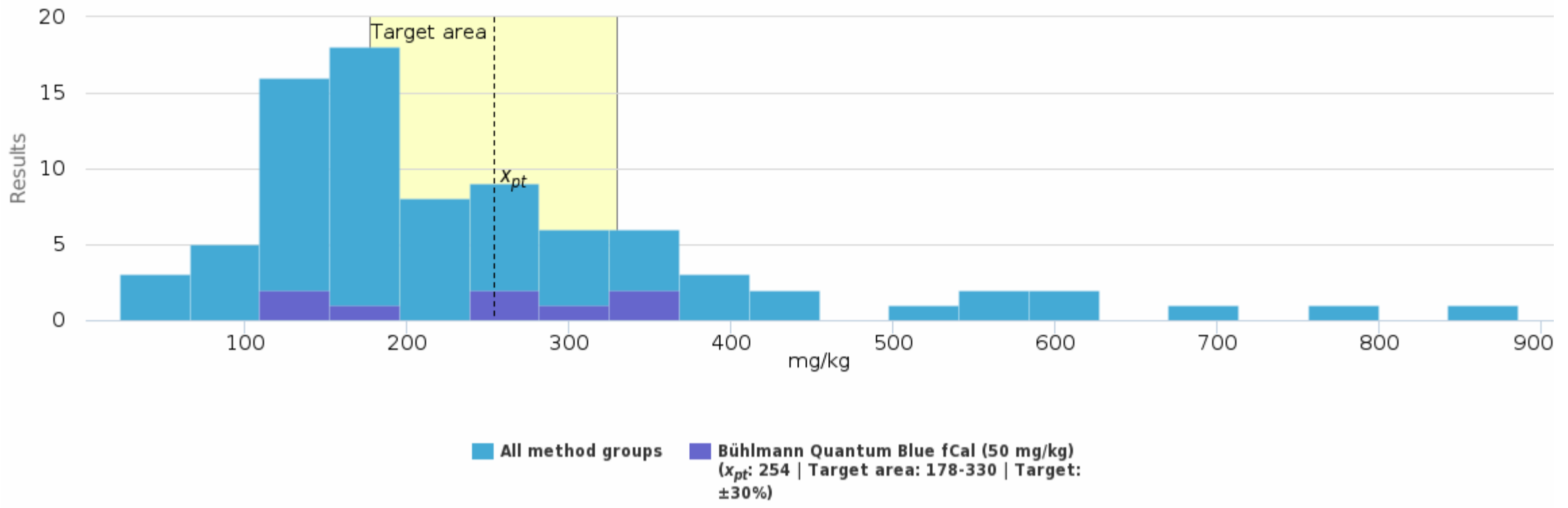
Biosynex, Procise FCP (50 mg/kg)



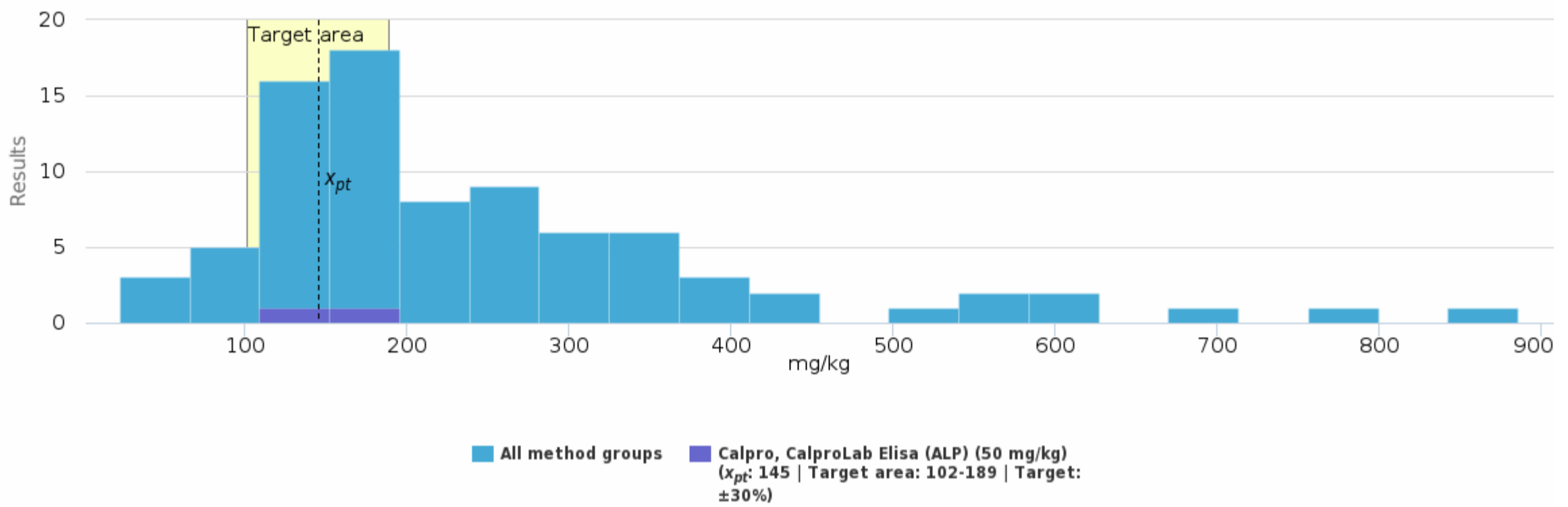
Bühlmann fCal turbo (50 mg/kg)



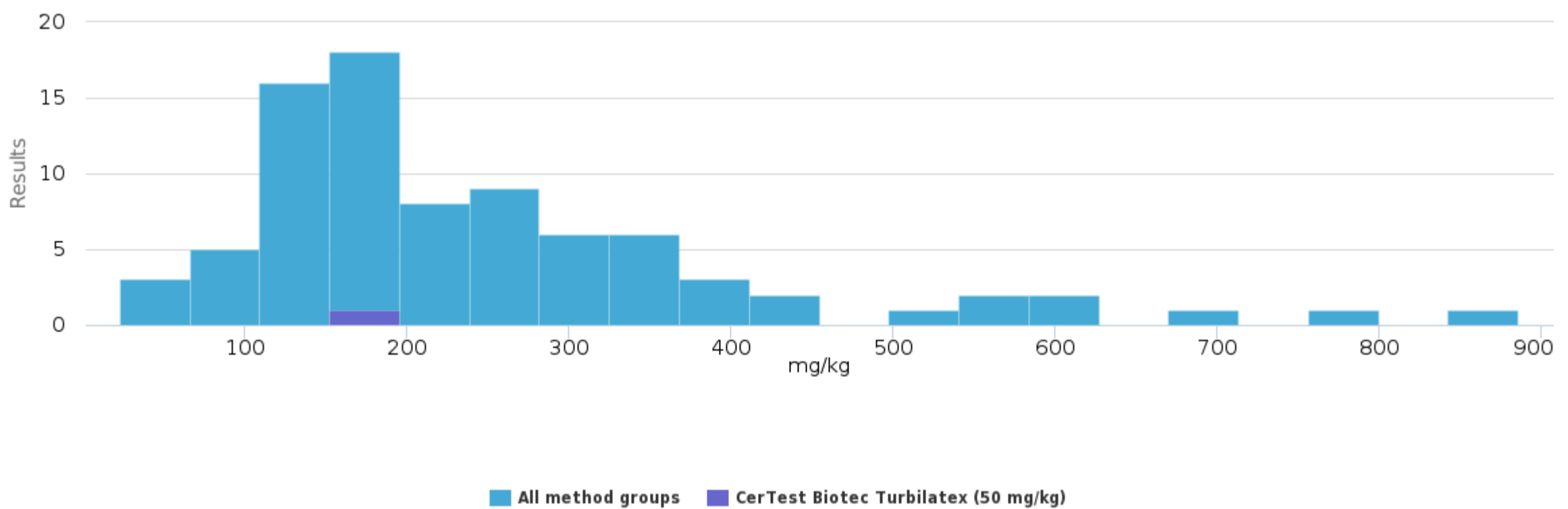
Bühlmann Quantum Blue fCal (50 mg/kg)



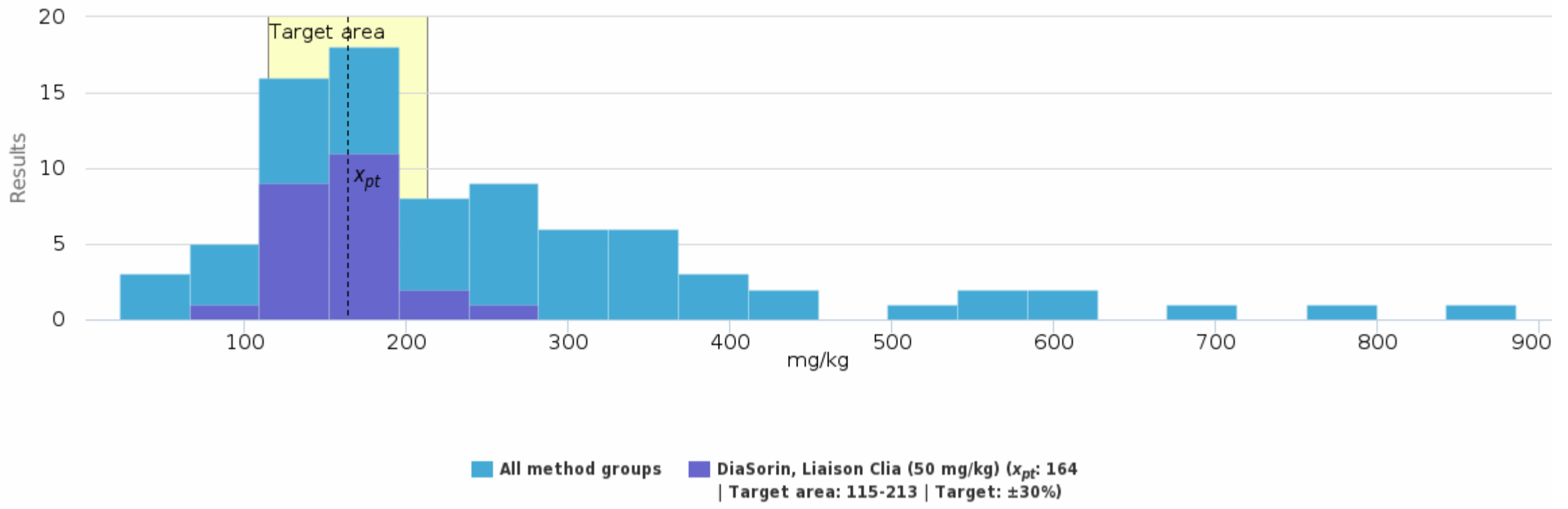
Calpro, CalproLab Elisa (ALP) (50 mg/kg)



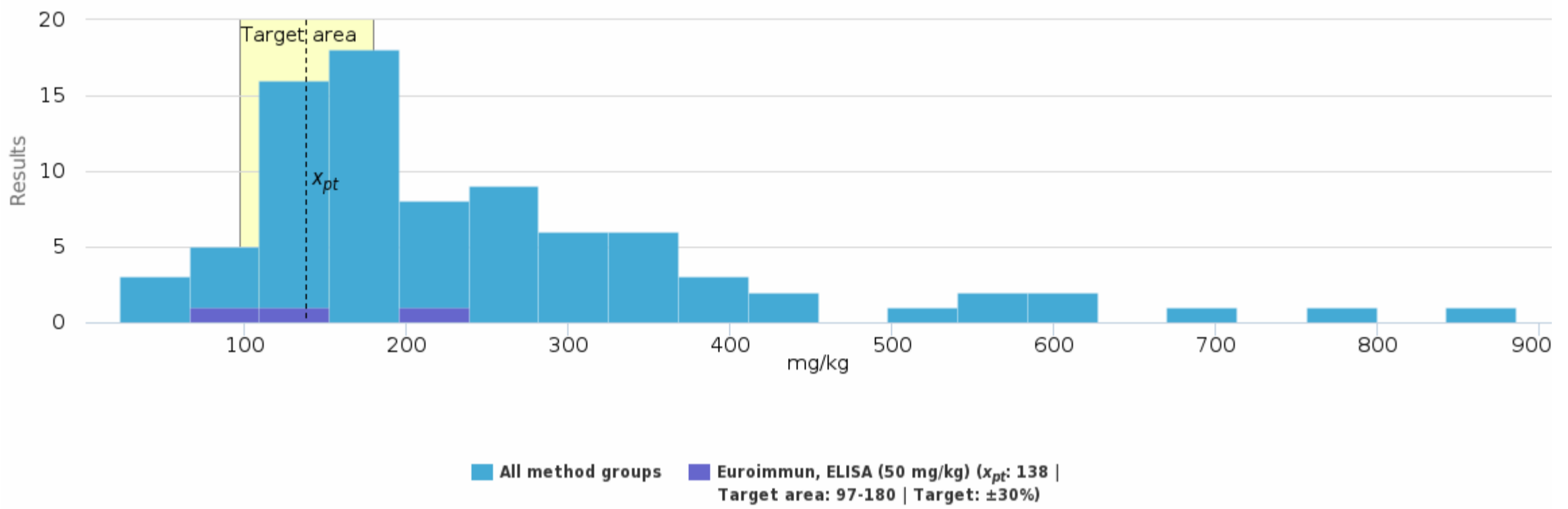
CerTest Biotec Turbilatex (50 mg/kg)



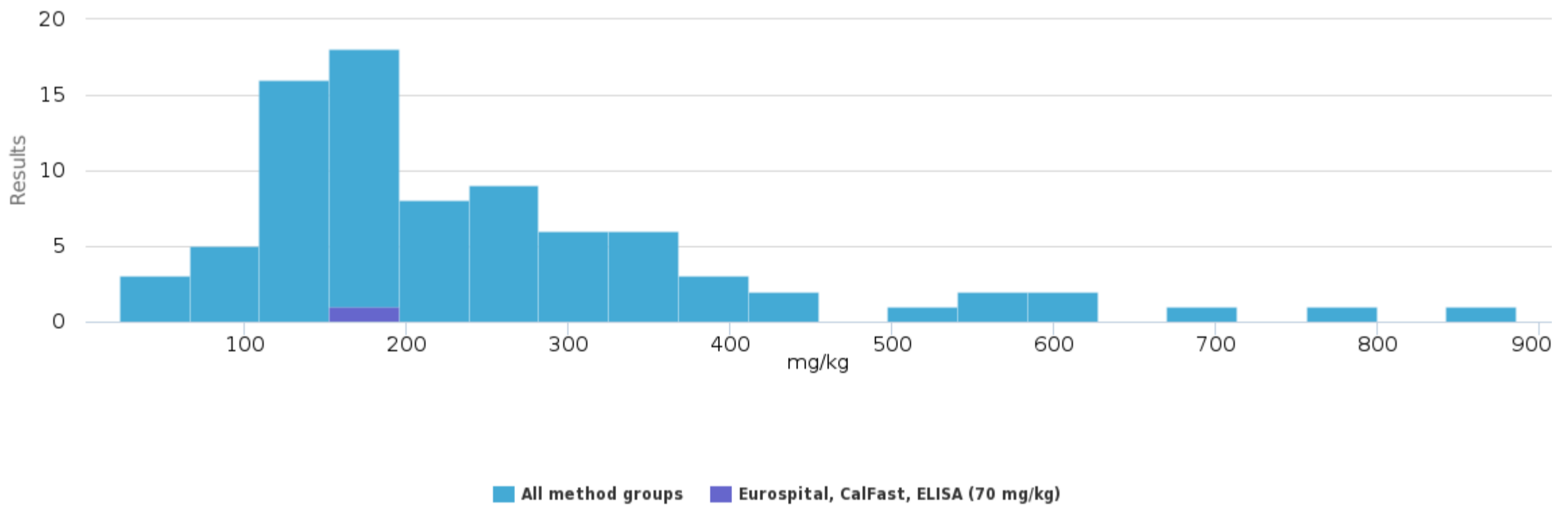
DiaSorin, Liaison Clia (50 mg/kg)



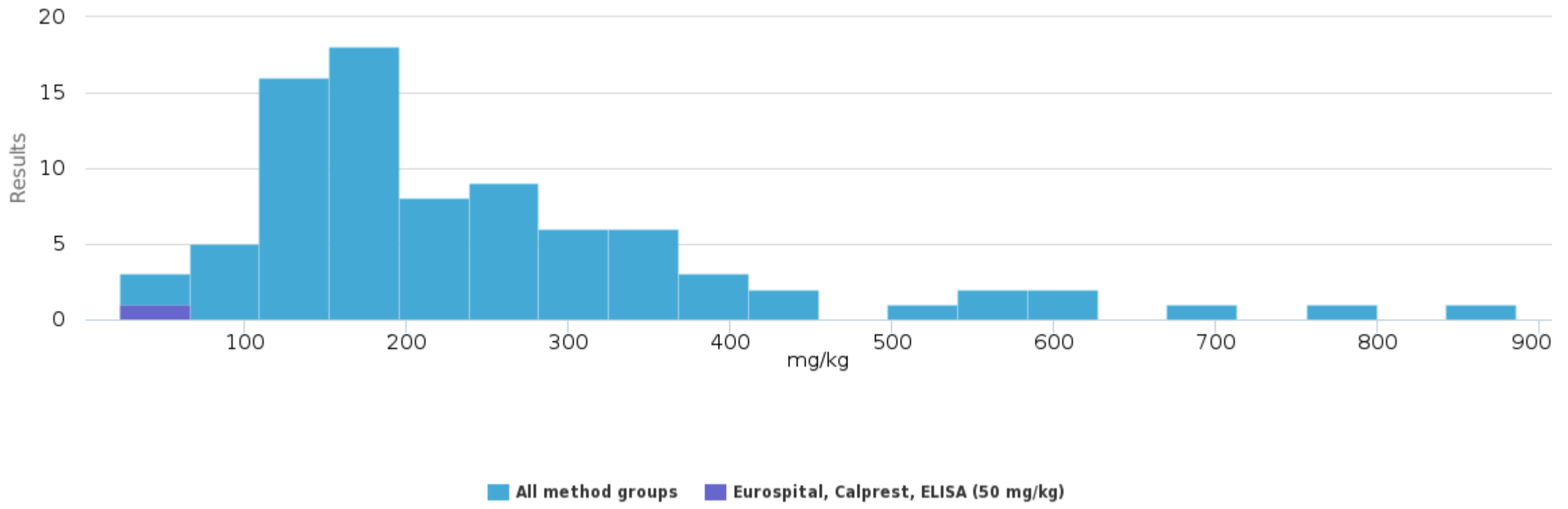
Euroimmun, ELISA (50 mg/kg)



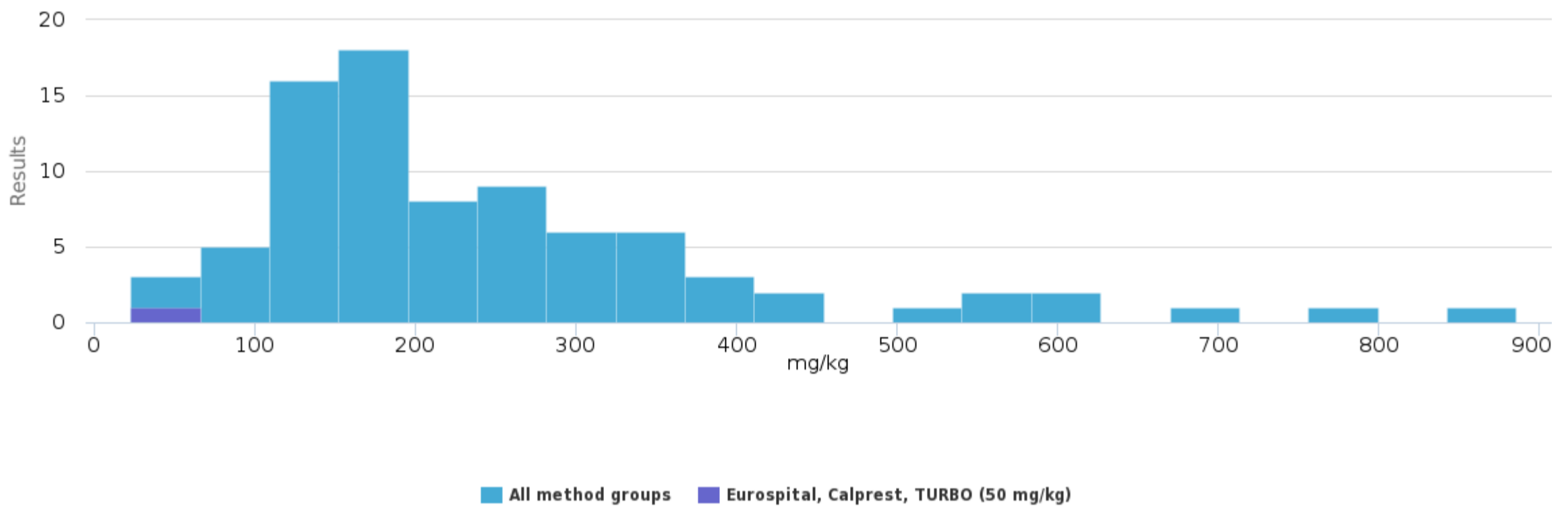
Eurospital, CalFast, ELISA (70 mg/kg)



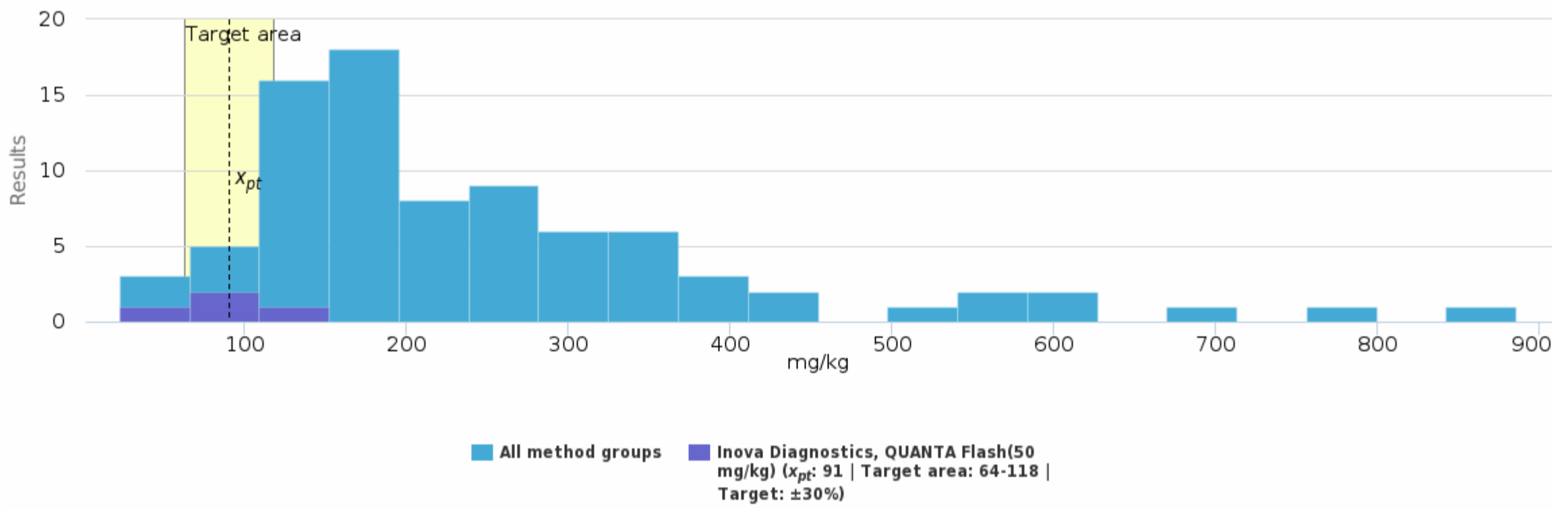
Eurospital, Calprest, ELISA (50 mg/kg)



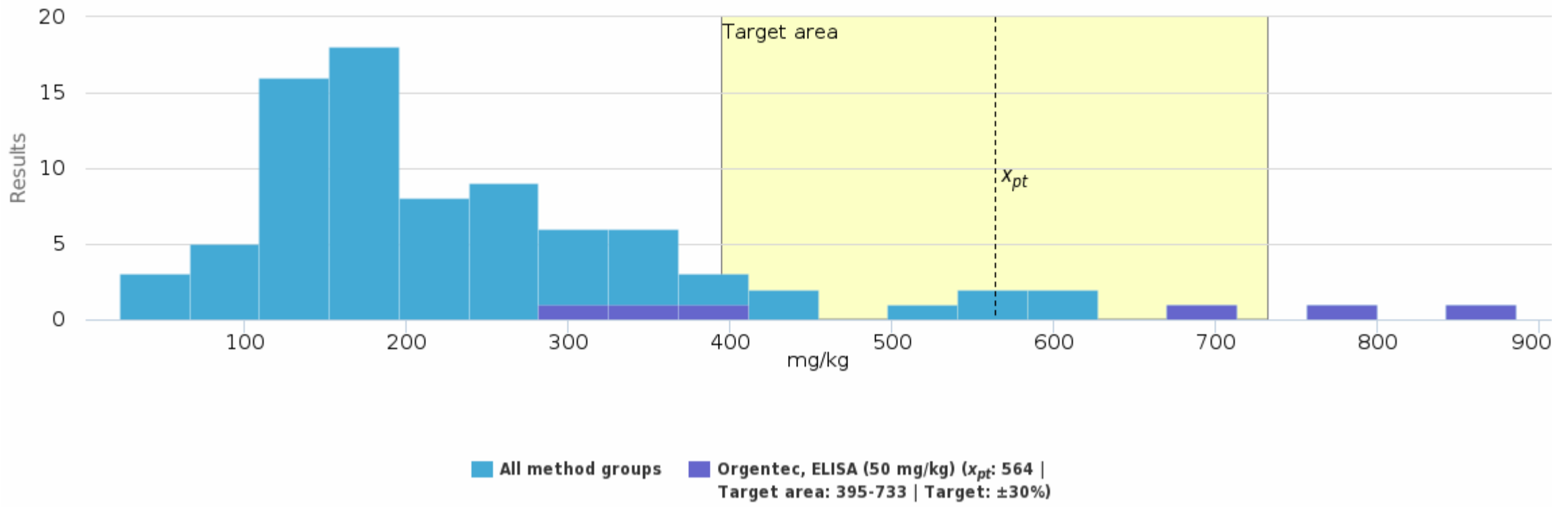
Eurospital, Calprest, TURBO (50 mg/kg)



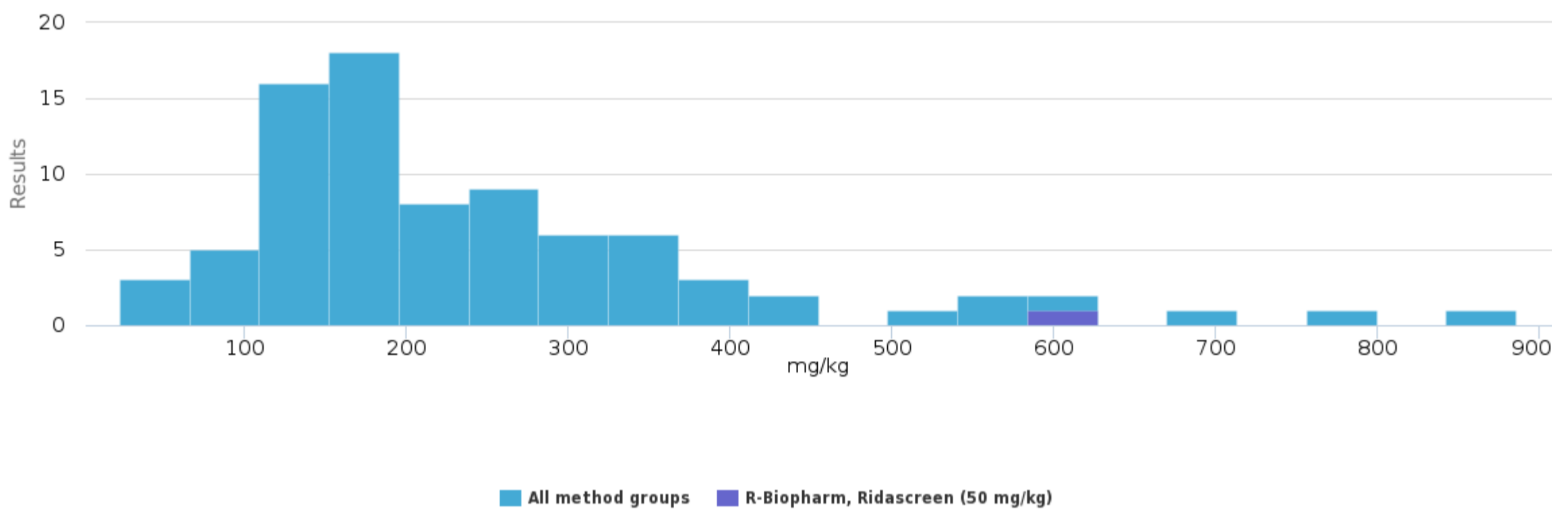
Inova Diagnostics, QUANTA Flash(50 mg/kg)



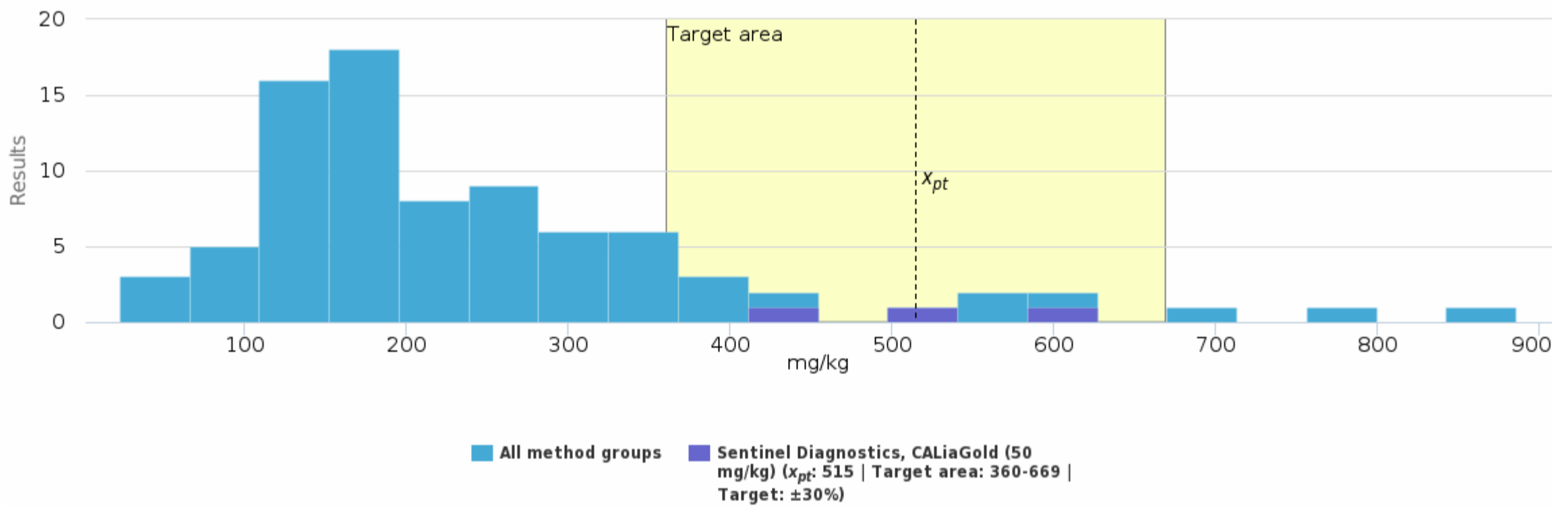
Orgentec, ELISA (50 mg/kg)



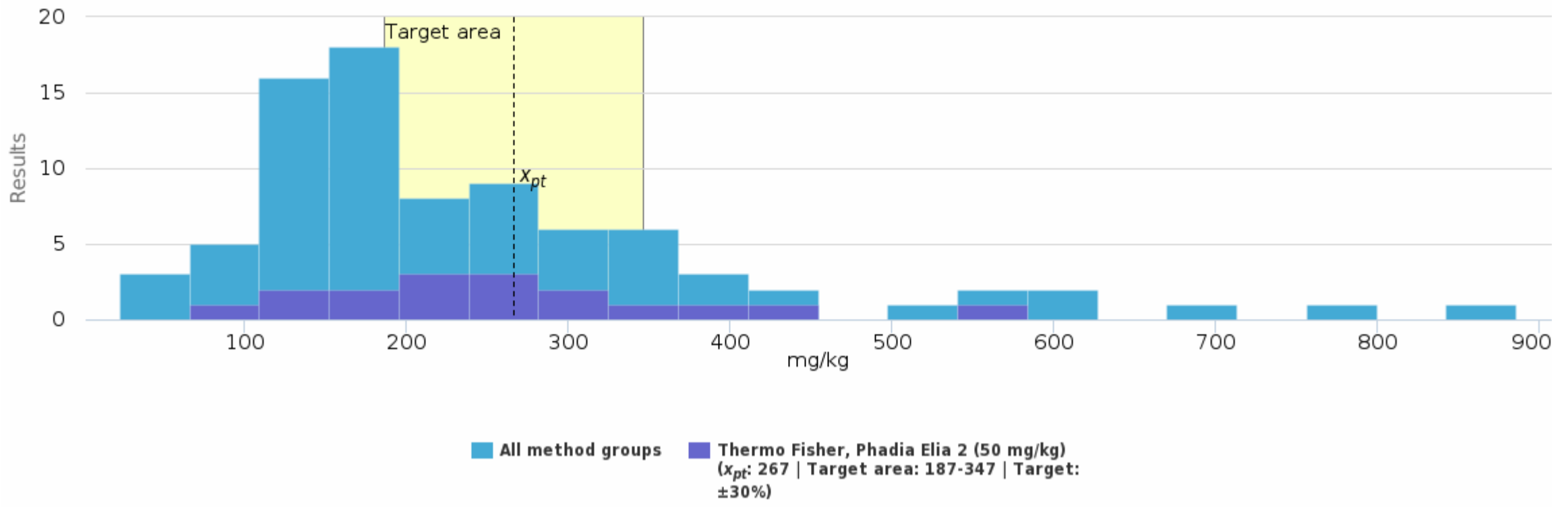
R-Biopharm, Ridascreen (50 mg/kg)



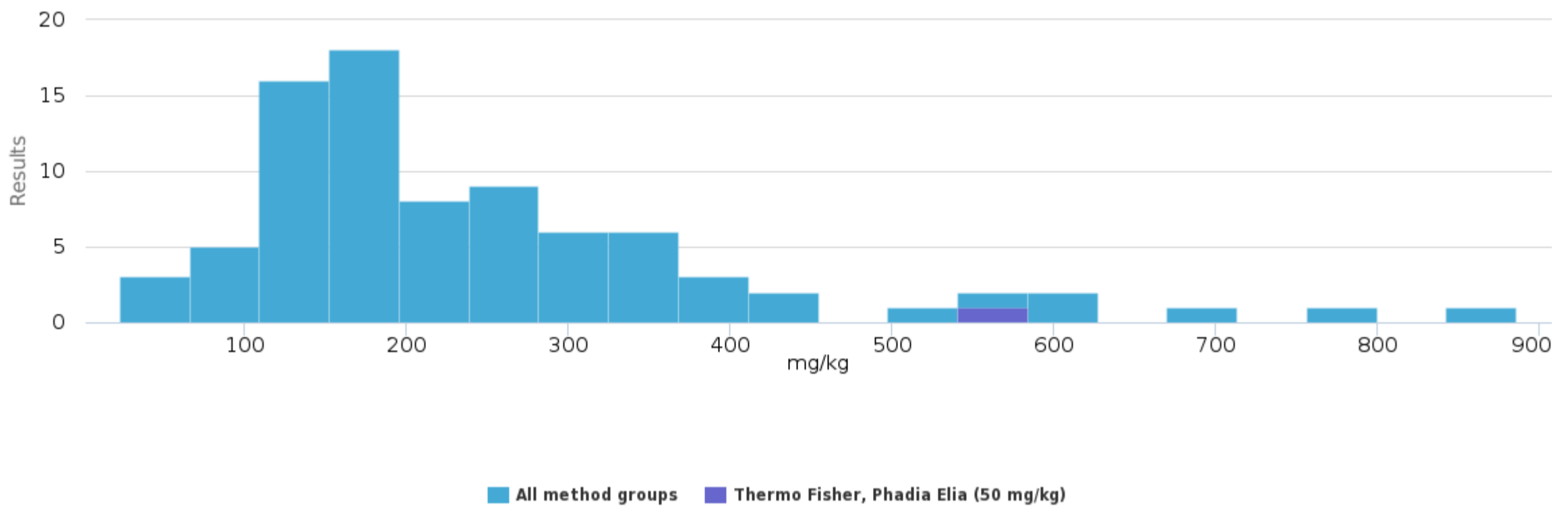
Sentinel Diagnostics, CALiaGold (50 mg/kg)



Thermo Fisher, Phadia Elia 2 (50 mg/kg)



Thermo Fisher, Phadia Elia (50 mg/kg)



Specimen S002 | Calprotectin, qualitative, -

Methodics	Negative	Positive	Total
ACRO Biotech, Rapid Test (50 mg/kg)	-	1	1
CerTest Biotec CLIA Calprotectin Ag (50 mg/kg)	-	1	1
CerTest Biotec (50 mg/kg)	-	1	1
Hangzhou AllTest Biotech (50 mg/kg)	-	1	1
Medix Biochemica, Actim Calprotectin (50 mg/kg)	-	1	1
Nal von Minden, Nadal calprotectin (50 mg/kg)	-	2	2
Vedalab Calprotectin-Check-1 (50 mg/kg)	1	-	1
Vitassay Calprotectin Single Card (50 mg/kg)	-	1	1
Total	1	8	9

Specimen S002 | Extraction methods, -

Extraction methods	Number of results
CerTest Turbilatex Sample Collection Tube	1
LIAISON Calprotectin Stool Extraction Device	6
LIAISON Q.S.E.T Device	18
EasyCal	1
EasyCal Turbo	2
Easy Extract	1
Smart-Prep	1
CALEX Cap Device	19
EliA Stool Extraction Kit 2	13
EliA Stool Extraction Kit Plus	7
Roche Faecal sample preparation kit	1
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External Quality Assessment Scheme

Faecal calprotectin Round 2, 2023

Specimens

Samples S001 (LQ775123021) and S002 (LQ775123022) were lyophilized faecal samples.

Based on the previous tests and the results of this round, the samples were 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 –Expert

The faecal calprotectin round composed of 16 quantitative immunochemical and turbidimetric methods, and 8 qualitative immunochromatographic methods.

Sample S001 represented sample close to calprotectin 50 mg/kg cut-off value. The mean value of all quantitative methods was 67 mg/kg. 4 quantitative methods showed values on both sides of cut-off value and 3 quantitative methods showed values only below cut-off value. In all qualitative methods' results, 2 results were negative, and 7 results were positive.

Sample S002 was positive. The mean value of all quantitative methods was 232 mg/kg. There is seen a clear bias between different method groups. Generally, CV% inside the method groups was high. In all qualitative methods' results, 1 result was negative and 8 results were positive.

When analyzing faecal sample, the preanalytical phase and the sample extraction method used therein, influence the measurement uncertainty considerably. In this round, for the first time, we also collected the information about the sample extraction method used. The participants reported in total using 14 different sample extraction methods. Also, laboratories reported 25/100 results with extraction method outside those listed in the LabScala result submission. In the next round, we kindly ask selecting the right sample extraction method, and if the extraction method used is not available for selection in LabScala, inform that to Labquality.

End of report

2023-06-20

FINAL REPORT

Product no. 2751

Samples sent	2023-05-15
Round closed	2023-06-02
Final report	2023-06-20

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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Expert

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