

External Quality Assessment Scheme

Phospholipid antibodies Round 1, 2023

Specimens

Please find enclosed 2 human plasma or serum 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

Anti-Cardiolipin antibodies (ACA Screen)
Anti-Cardiolipin antibodies (ACA), IgG
Anti-Cardiolipin antibodies (ACA), IgM
Anti-β2-Glycoprotein I antibodies, IgG
Anti-β2-Glycoprotein I antibodies, IgM

Storage and use

After arrival, the samples should be stored at +2...8°C, and used as soon as possible, preferably within a week. The samples are ready for use. Analyse 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. Report only the results of examinations that are in use in your laboratory.

S001



S002



2023-05-09

INSTRUCTIONS

Product no. 5937
LQ717323011-012/FI

Subcontracting: Sample pretesting

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**.

The expected results of the round are published in LabScala in the View Reports section by June 7, 2023.

Inquiries

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ACA (screen)

Sample S001

Methodics	Positive	Total
ELISA, Euroimmun	2	2
ELISA, Inova Diagnostics	1	1
ELISA, Orgentec	2	2
Total	5	5

ACA (screen)

Sample S002

Methodics	Negative	Total
ELISA, Demeditec Cardiolipin Screen	1	1
ELISA, Euroimmun	1	1
ELISA, Inova Diagnostics	1	1
ELISA, Orgentec	2	2
Total	5	5

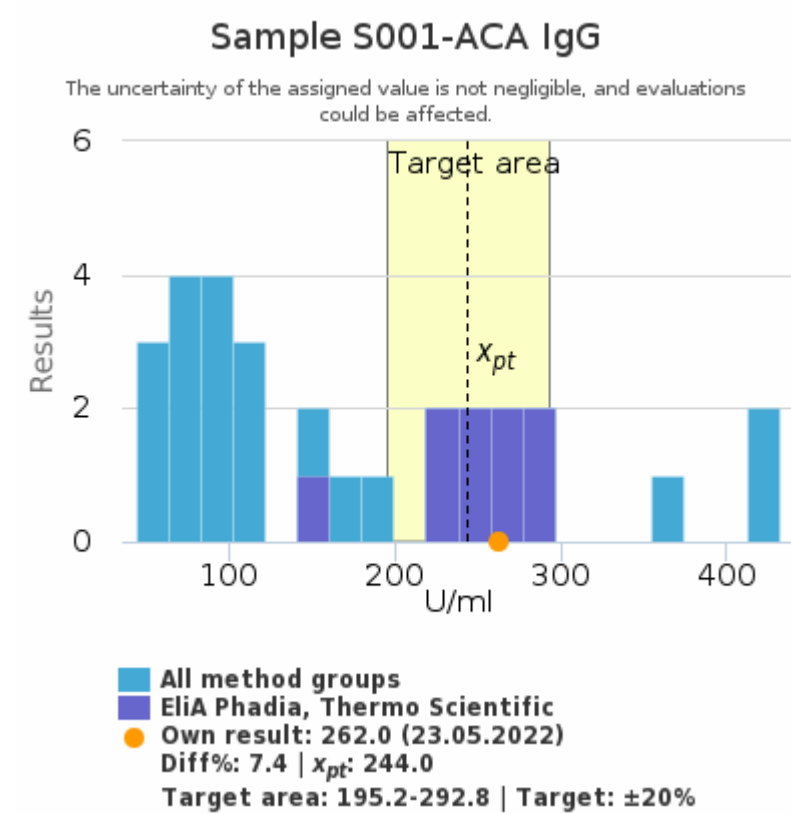
ACA IgG

Sample S001

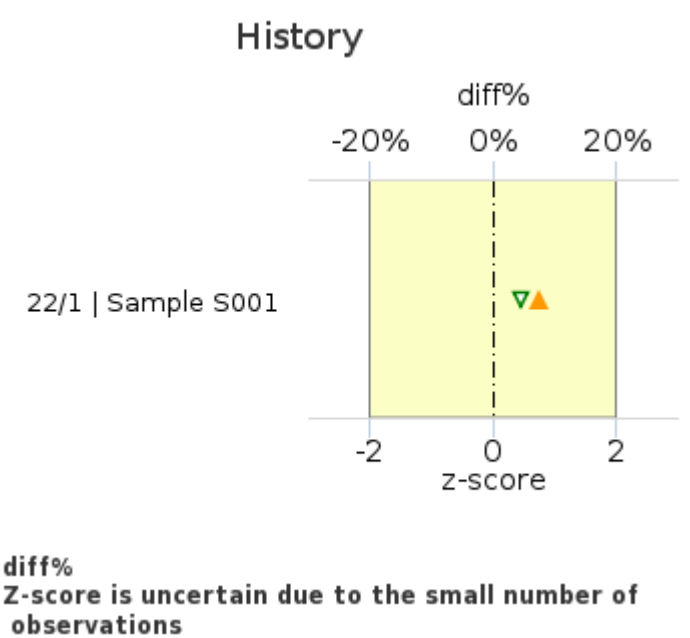
Methodics	Positive	Total
AESKULISA Cardiolipin-GM	1	1
Chorus CARDIOLIPIN-G, Diesse	2	2
EliA Phadia, Thermo Scientific	9	9
ELISA, Aesku Diagnostics	1	1
ELISA, Demeditec Cardiolipin Ab IgG/IgM	1	1
ELISA, Diamedix	1	1
ELISA, Euroimmun	5	5
ELISA, Generic Assays Anti-Cardiolipin	1	1
ELISA, Inova Diagnostics	1	1
ELISA, Orgentec	11	11
Inova Quanta Flash aCL IgG	3	3
Total	36	36

Sample S002

Methodics	Negative	Total
AESKULISA Cardiolipin-GM	1	1
Chorus CARDIOLIPIN-G, Diesse	2	2
EliA Phadia, Thermo Scientific	9	9
ELISA, Aesku Diagnostics	1	1
ELISA, Demeditec Cardiolipin Ab IgG/IgM	1	1
ELISA, Diamedix	1	1
ELISA, Euroimmun	5	5
ELISA, Generic Assays Anti-Cardiolipin	1	1
ELISA, Inova Diagnostics	1	1
ELISA, Orgentec	11	11
Inova Quanta Flash aCL IgG	3	3
Total	36	36



	x_{pt}	sd	SEM	CV%	n
EliA Phadia, Thermo Scientific	244.0 U/ml	40.0	13.3	16.4	9
All methods	176.4 U/ml	111.0	20.6	62.9	29



Round	Sample	x_{pt}	Result	diff%	z-score
22/1	Sample S001	244.0	262.0	7.4%	0.45

ACA IgM

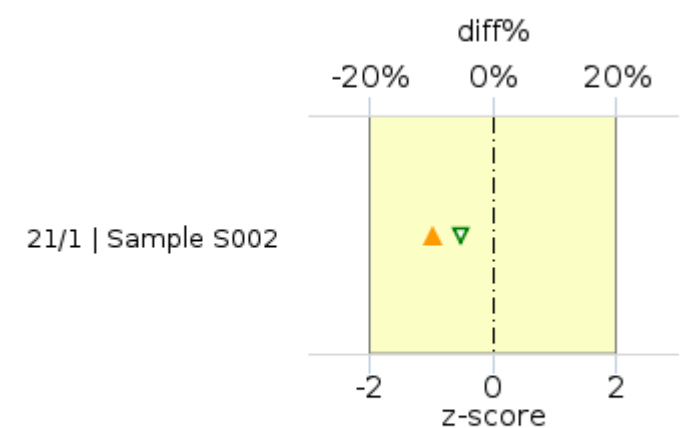
Sample S001

Methodics	Negative	Borderline	Weak positive	Positive	Total
AESKULISA Cardiolipin-GM	1	-	-	-	1
Chorus CARDIOLIPIN-M, Diesse	1	-	-	-	1
ELiA Phadia, Thermo Scientific	7	-	1	-	8
ELISA, Aesku Diagnostics	1	-	-	-	1
ELISA, Demeditec Cardiolipin Ab IgG/IgM	1	-	-	-	1
ELISA, Diamedix	-	1	-	-	1
ELISA, Euroimmun	4	-	1	-	5
ELISA, Generic Assays Anti-Cardiolipin	1	-	-	-	1
ELISA, Inova Diagnostics	1	-	-	-	1
ELISA, Orgentec	9	-	-	2	11
Inova Quanta Flash IgM	3	-	-	-	3
Total	29	1	2	2	34

Sample S002

Methodics	Negative	Total
AESKULISA Cardiolipin-GM	1	1
Chorus CARDIOLIPIN-M, Diesse	1	1
ELiA Phadia, Thermo Scientific	8	8
ELISA, Aesku Diagnostics	1	1
ELISA, Demeditec Cardiolipin Ab IgG/IgM	1	1
ELISA, Diamedix	1	1
ELISA, Euroimmun	5	5
ELISA, Generic Assays Anti-Cardiolipin	1	1
ELISA, Inova Diagnostics	1	1
ELISA, Orgentec	11	11
Inova Quanta Flash IgM	3	3
Total	34	34

History



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

Round	Sample	x_{pt}	Result	diff%	z-score
21/1	Sample S002	25.5	23.0	-9.6%	-0.51

2-Glycoprotein IgG

Sample S001

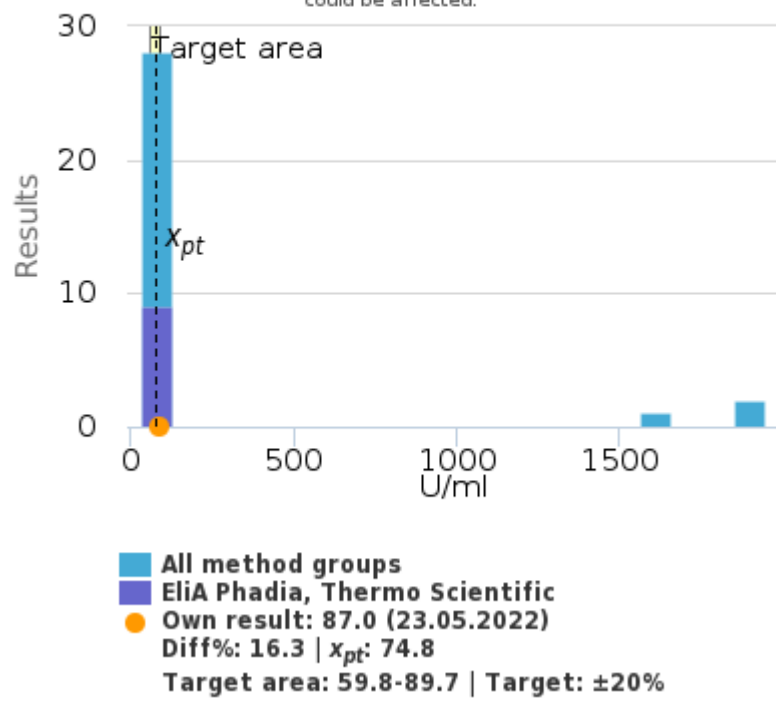
Methodics	Positive	Total
AESKULISA b2-Glyco-GM	1	1
Chorus BETA 2-GLYCOPROTEIN-G, Diesse	2	2
EliA Phadia, Thermo Scientific	9	9
ELISA, Aesku Diagnostics	1	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	1	1
ELISA, Diamedix	1	1
ELISA, Euroimmun	6	6
ELISA, Inova Diagnostics	1	1
ELISA, Orgentec	10	10
Inova Quanta Flash B2GP1 IgG	3	3
Total	35	35

Sample S002

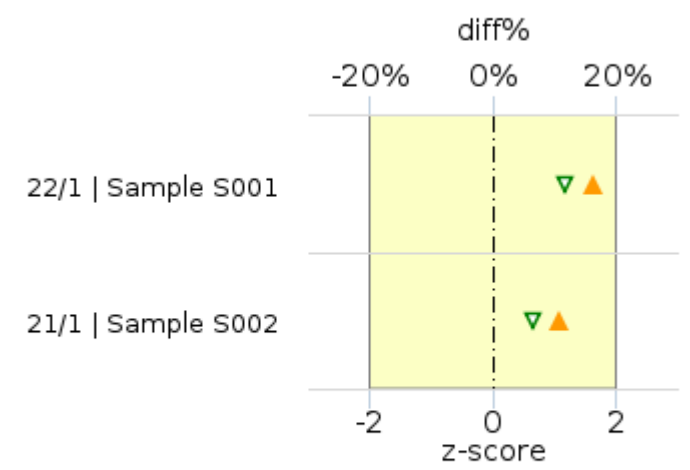
Methodics	Negative	Total
AESKULISA b2-Glyco-GM	1	1
Chorus BETA 2-GLYCOPROTEIN-G, Diesse	2	2
EliA Phadia, Thermo Scientific	9	9
ELISA, Aesku Diagnostics	1	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	1	1
ELISA, Diamedix	1	1
ELISA, Euroimmun	6	6
ELISA, Inova Diagnostics	1	1
ELISA, Orgentec	10	10
Inova Quanta Flash B2GP1 IgG	3	3
Total	35	35

Sample S001-β2-Glycoprotein IgG

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



History



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

	x_{pt}	sd	SEM	CV%	n
EliA Phadia, Thermo Scientific	74.8 U/ml	10.5	3.5	14.0	9
All methods	129.5 U/ml	284.5	52.8	219.7	31

Round	Sample	x_{pt}	Result	diff%	z-score
22/1	Sample S001	74.8	87.0	16.3%	1.17
21/1	Sample S002	5.9	6.5	10.7%	0.65

2-Glycoprotein IgM

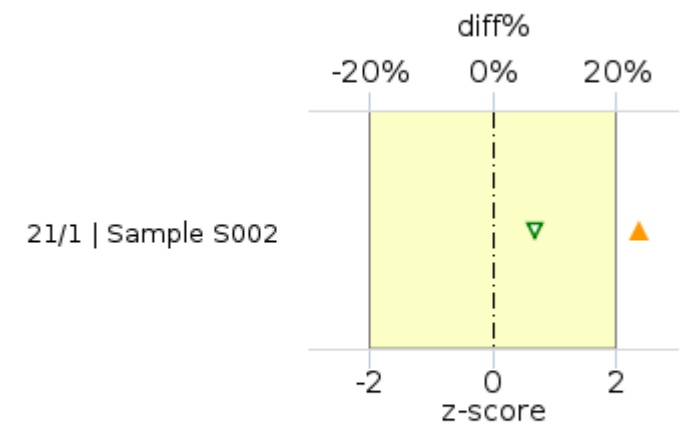
Sample S001

Methodics	Negative	Borderline	Positive	Total
AESKULISA b2-Glyco-GM	1	-	-	1
Chorus BETA 2-GLYCOPROTEIN-M, Diesse	1	-	-	1
EliA Phadia, Thermo Scientific	4	2	1	7
ELISA, Aesku Diagnostics	1	-	-	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	1	-	-	1
ELISA, Diamedix	1	-	-	1
ELISA, Euroimmun	1	-	5	6
ELISA, Inova Diagnostics	1	-	-	1
ELISA, Orgentec	8	-	-	8
Inova Quanta Flash IgM	3	-	-	3
Total	22	2	6	30

Sample S002

Methodics	Negative	Total
AESKULISA b2-Glyco-GM	1	1
Chorus BETA 2-GLYCOPROTEIN-M, Diesse	1	1
EliA Phadia, Thermo Scientific	7	7
ELISA, Aesku Diagnostics	1	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	1	1
ELISA, Diamedix	1	1
ELISA, Euroimmun	6	6
ELISA, Inova Diagnostics	1	1
ELISA, Orgentec	8	8
Inova Quanta Flash IgM	3	3
Total	30	30

History



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

Round	Sample	x_{pt}	Result	diff%	z-score
21/1	Sample S002	12.1	15.0	23.7%	0.67

Report info**Participants**

41 participants from 11 countries.

Report info

Qualitative and quantitative results are presented in the same report. Always compare your results to those obtained with the same test kit.

The qualitative results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green colour and laboratory's own result with a black radio button .

The quantitative results from the positive specimens are presented as histograms. Quantitative results reported with < or > -signs are not processed. Results reported as ratios, titres, absorbances and without a unit are manually removed and not statistically processed.

Assigned values (target values) are mean 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 participant specific report your own result is shown with an orange dot. The target area is presented as a yellow area in the picture. In the history graphs you are able to see your performance graphically with both against the assigned value (xpt) and the z-score area of -2 ... +2.

If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EOA Coordinator.

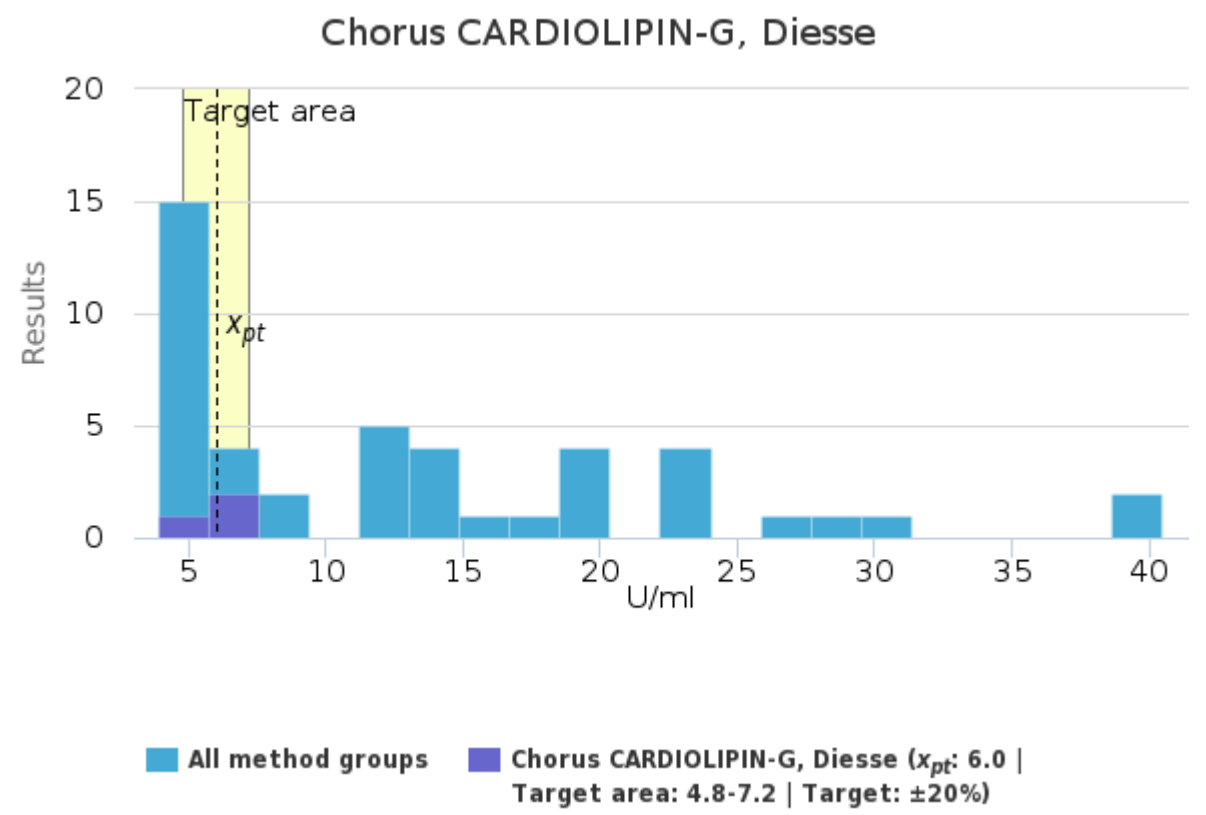
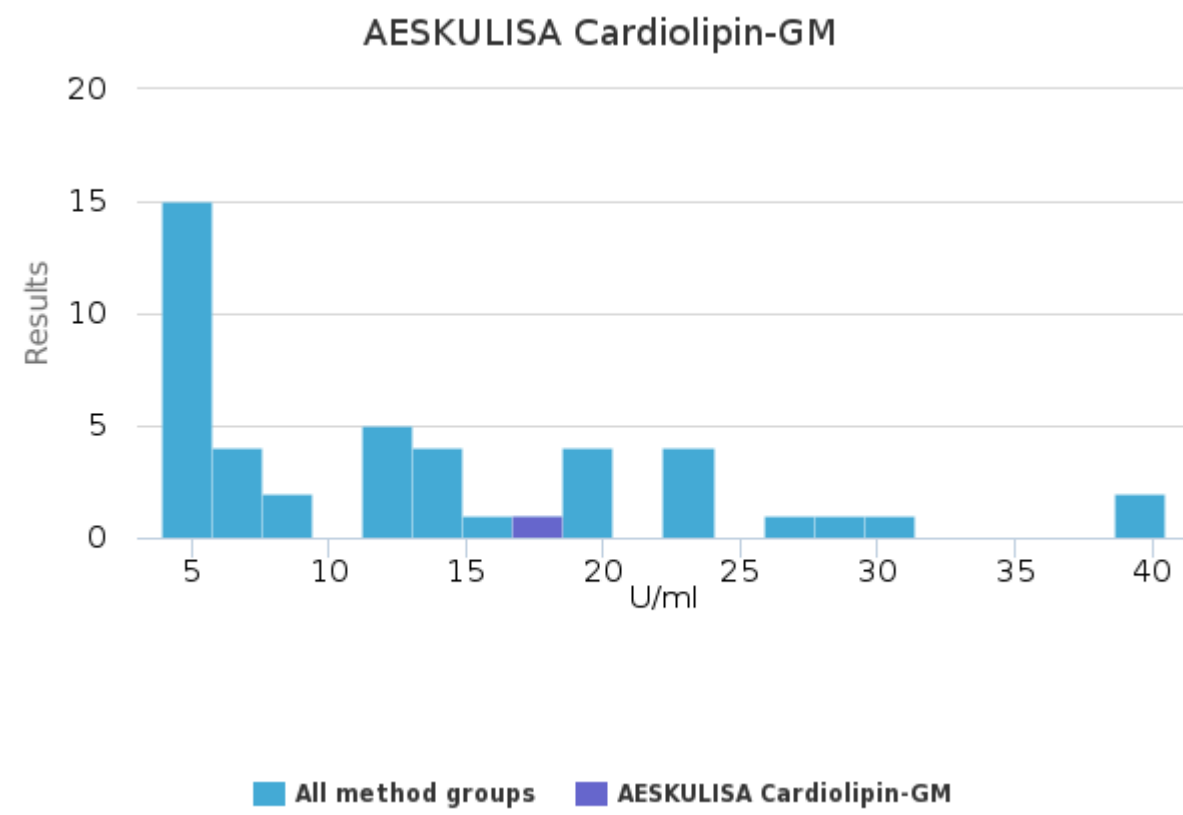
Sample S001 | ACA (screen), --

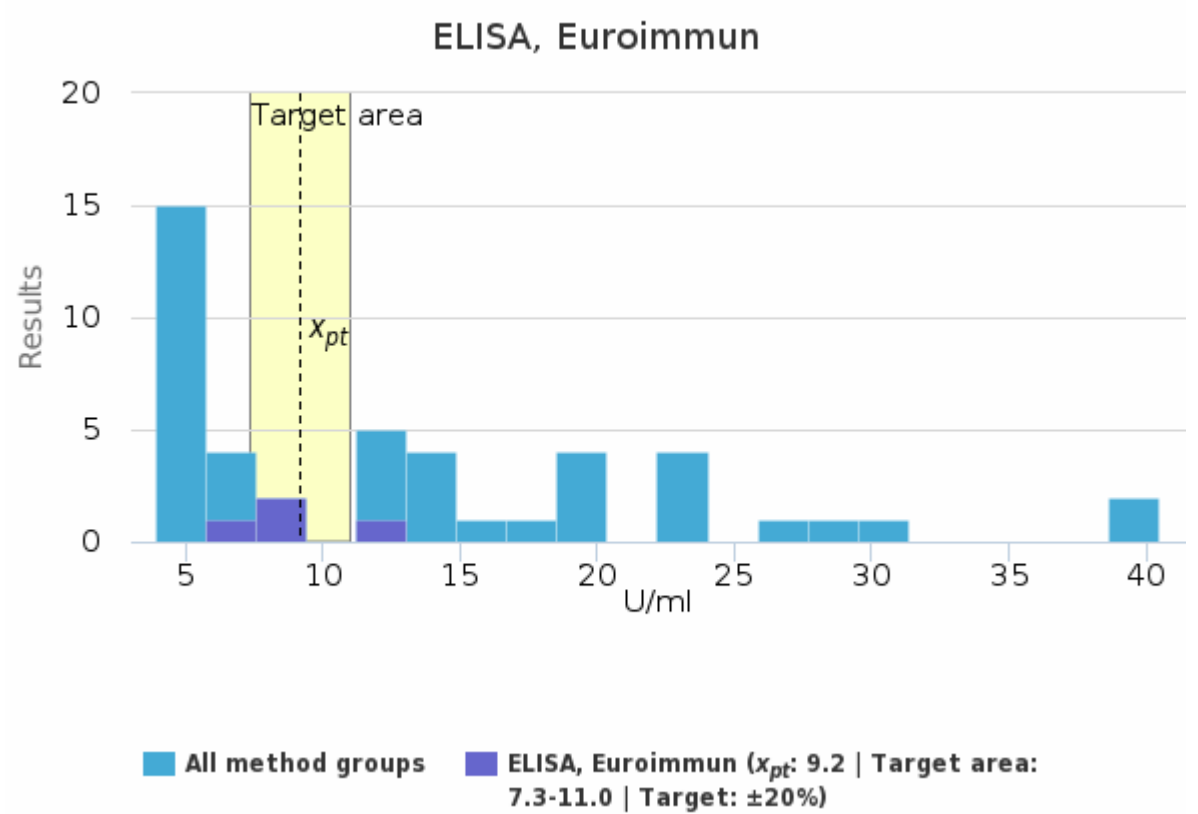
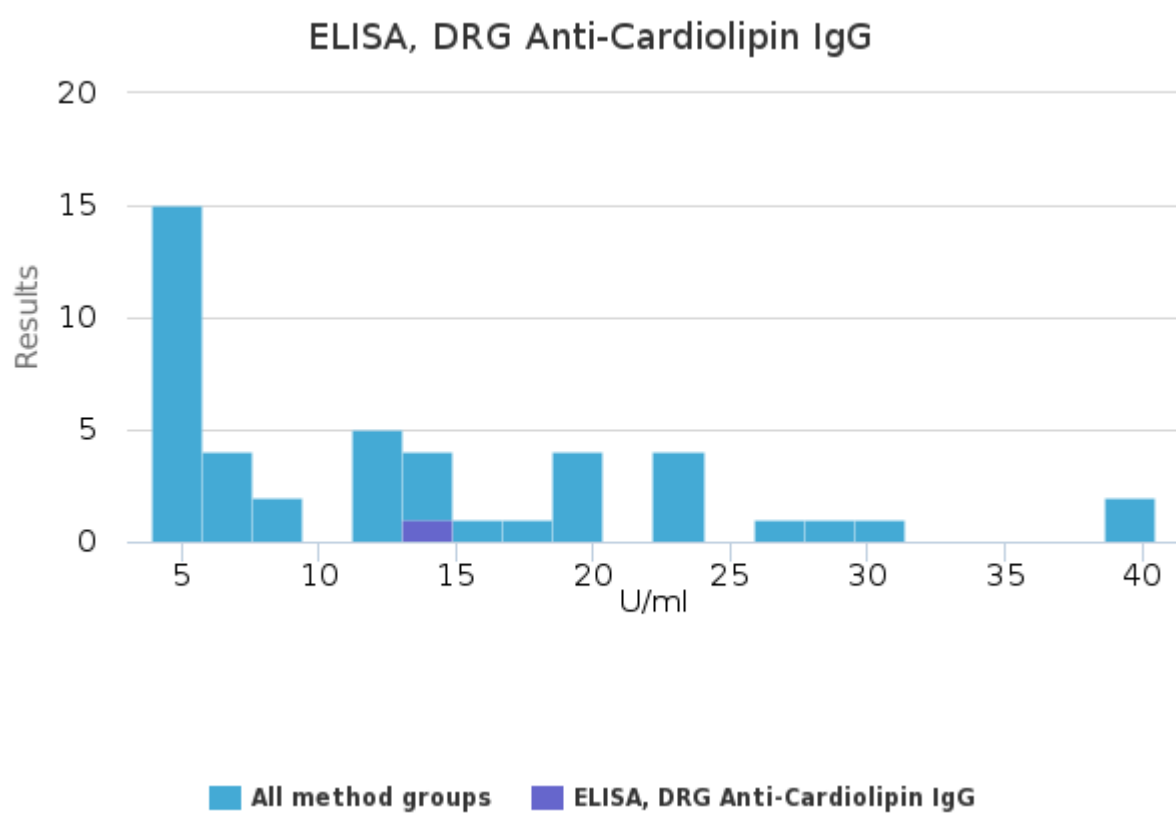
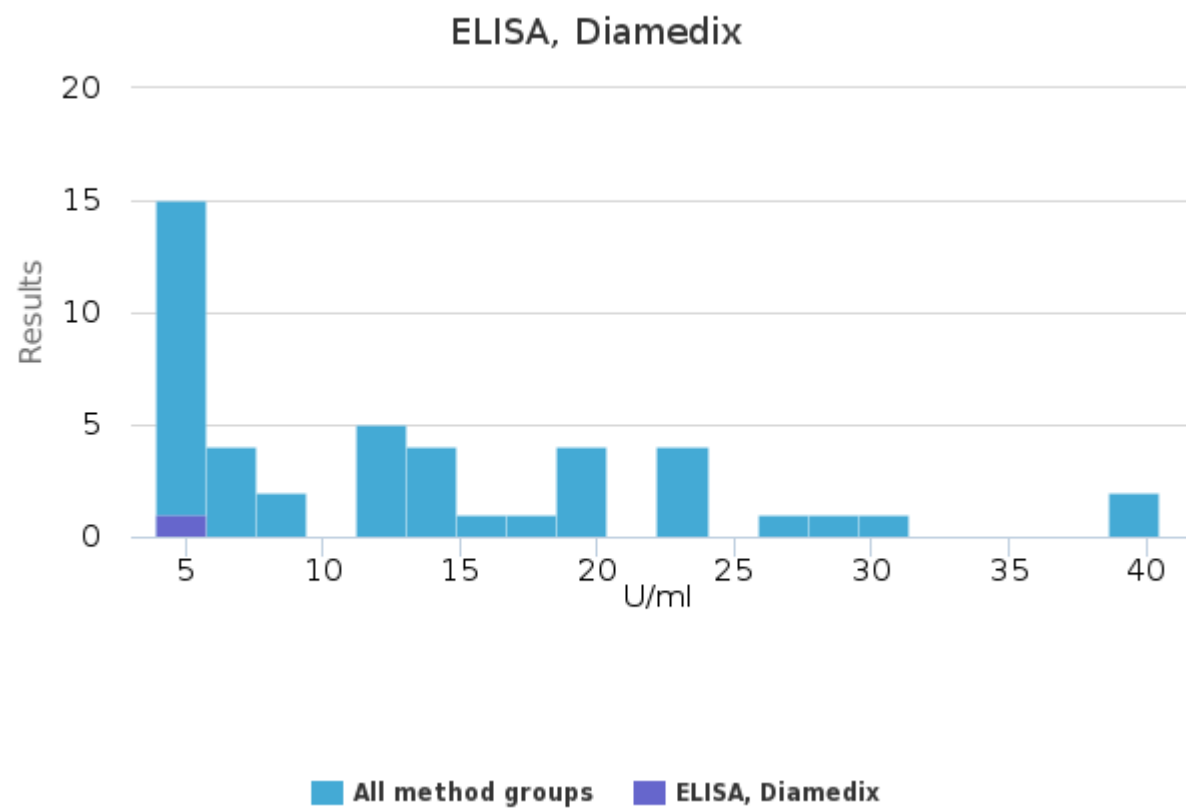
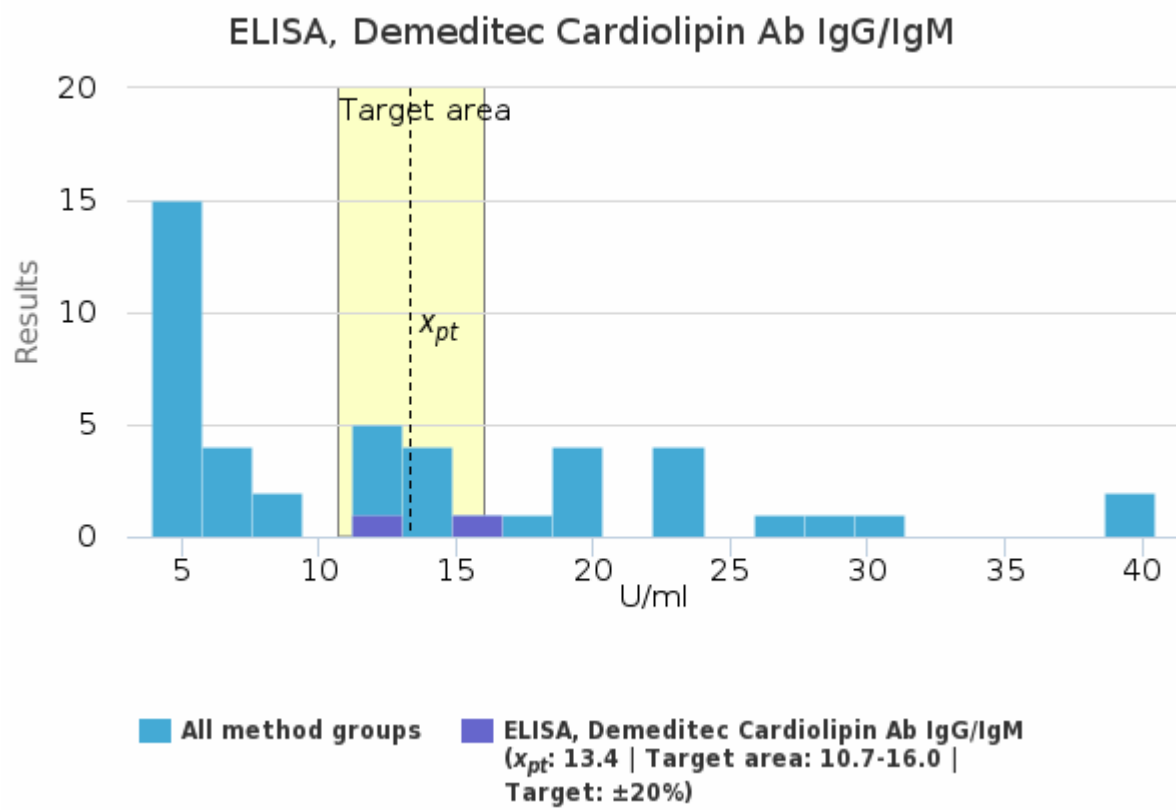
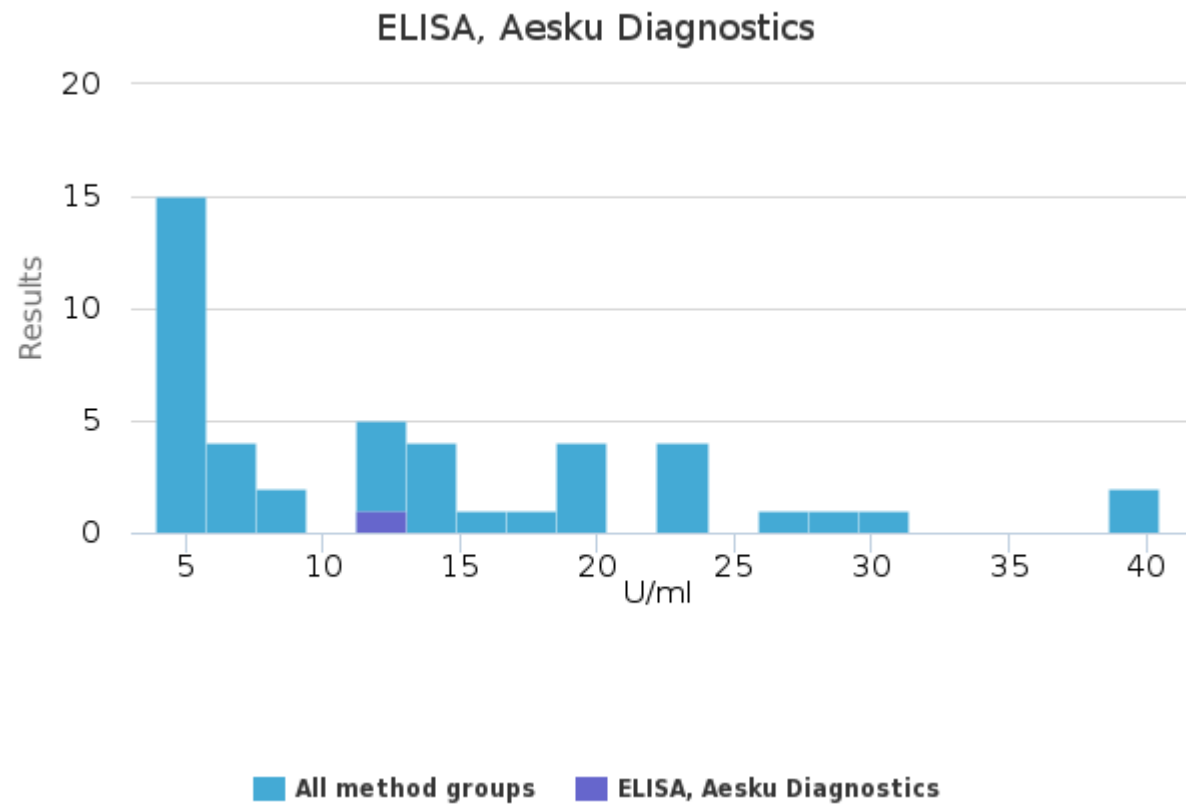
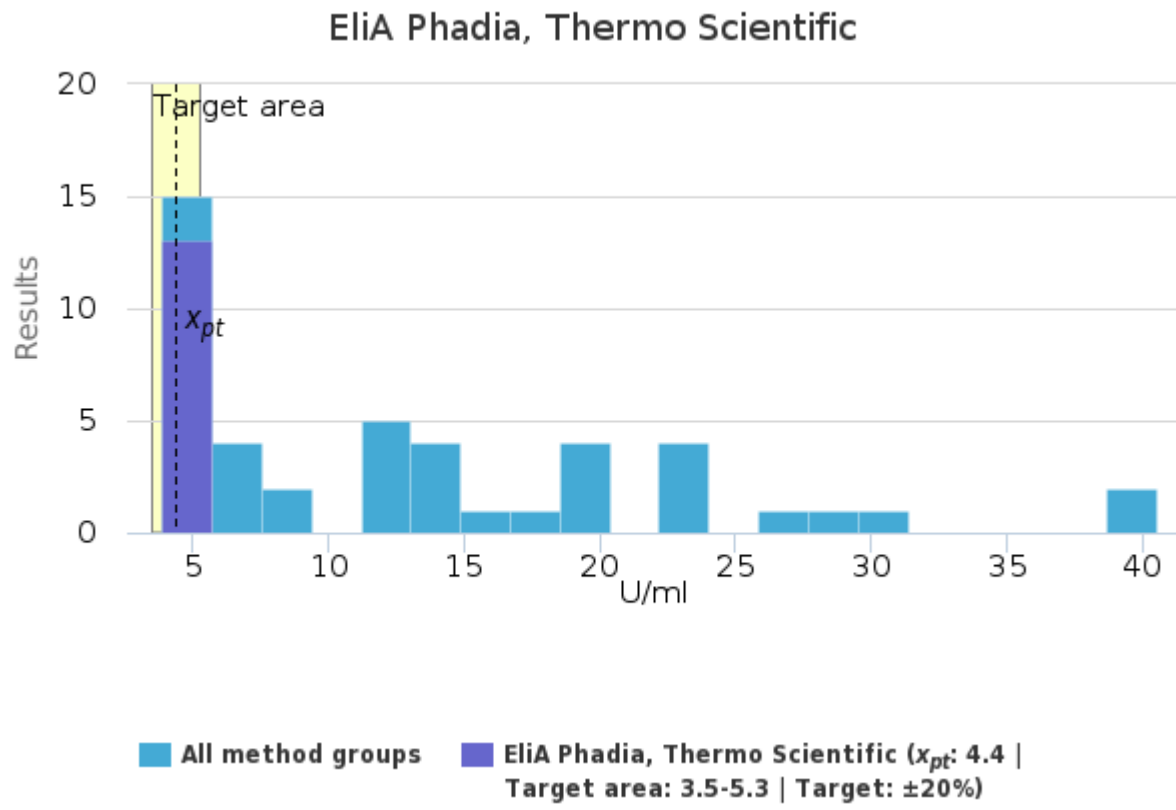
Methodics	Positive	Total
ELISA, Euroimmun	1	1
ELISA, Orgentec	2	2
Inova Quanta Lite ACA Screen III	1	1
Total	4	4

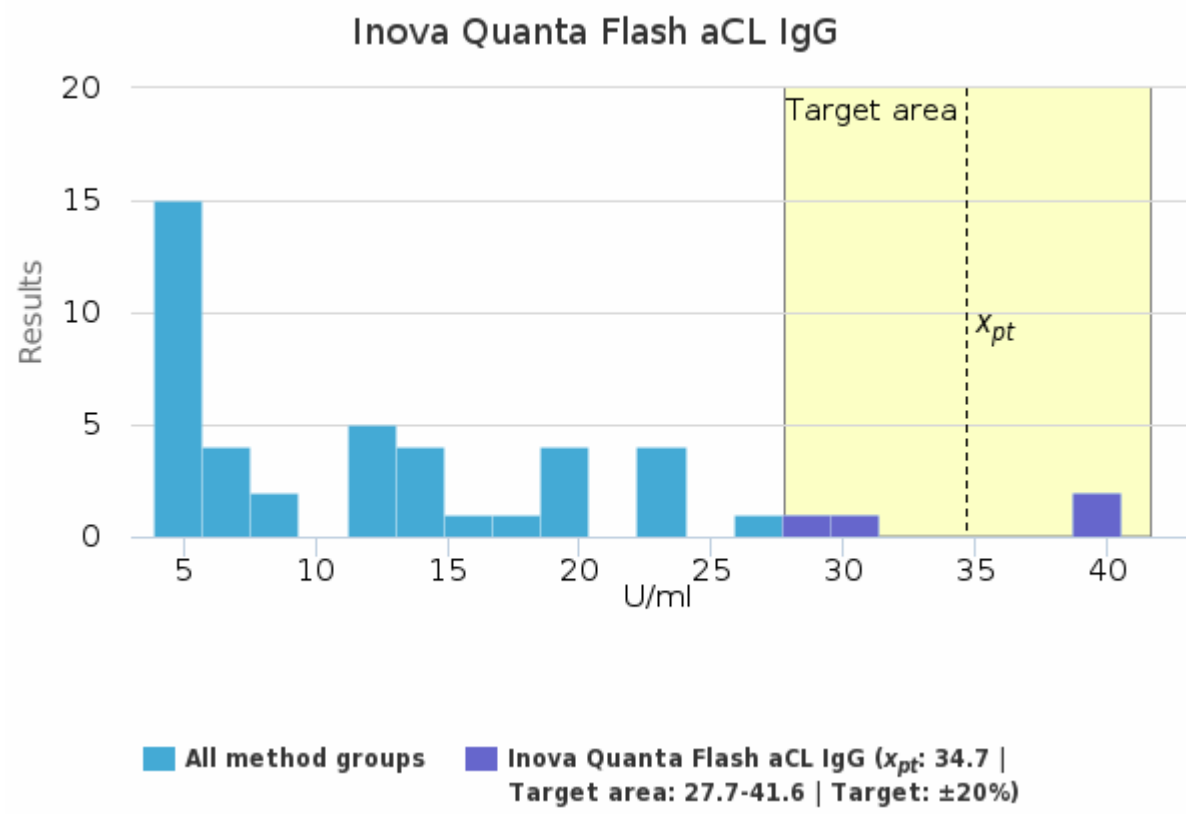
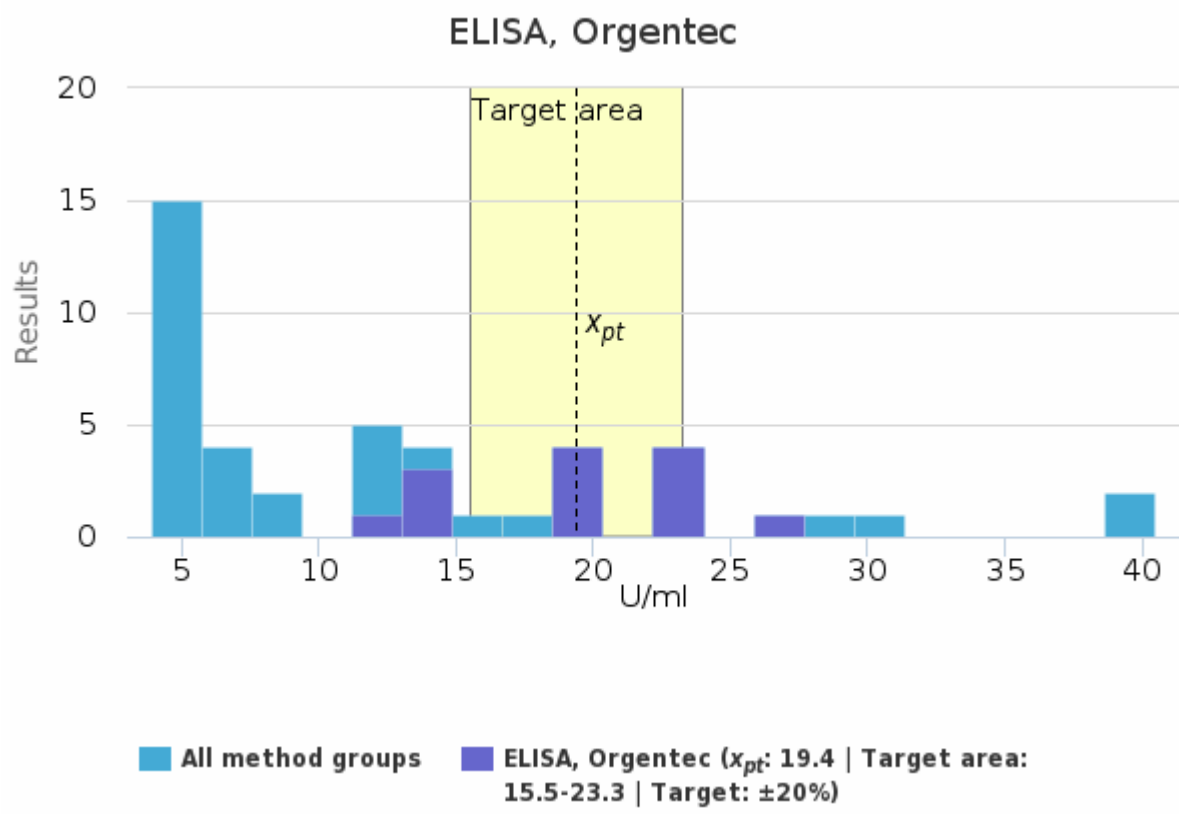
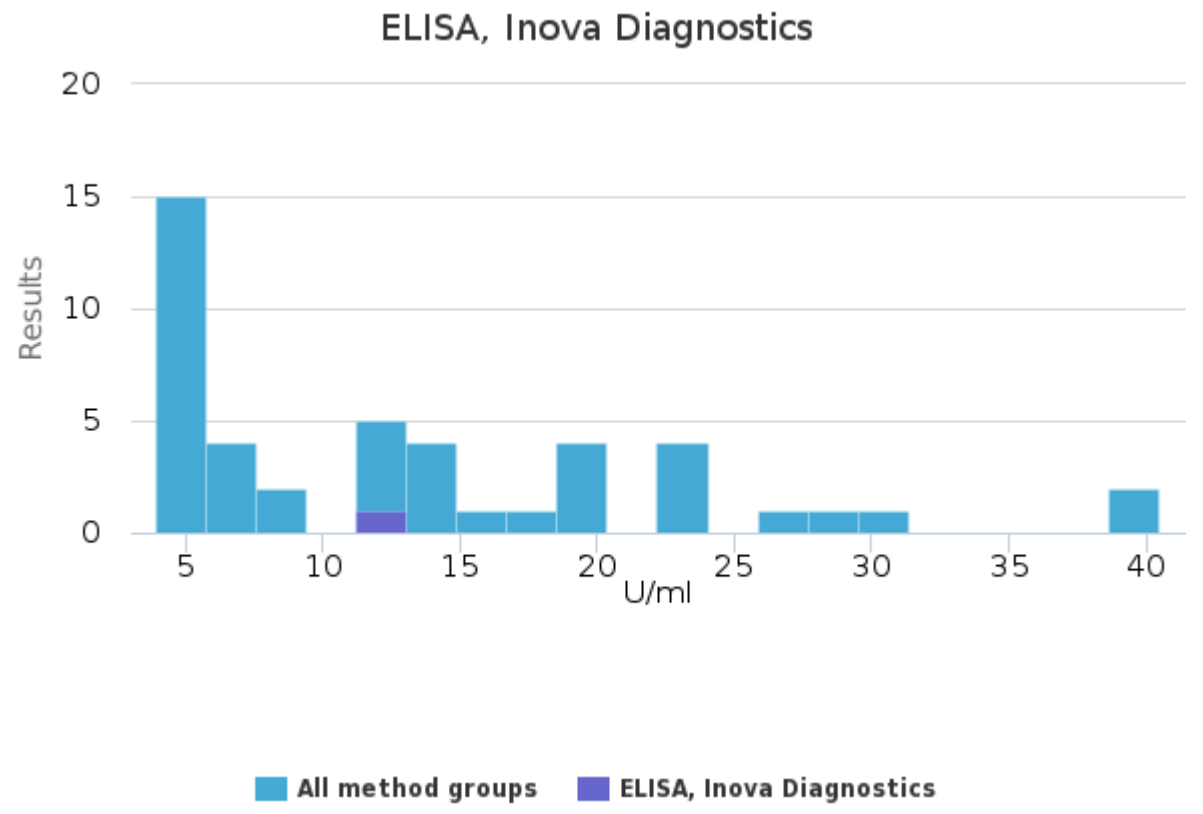
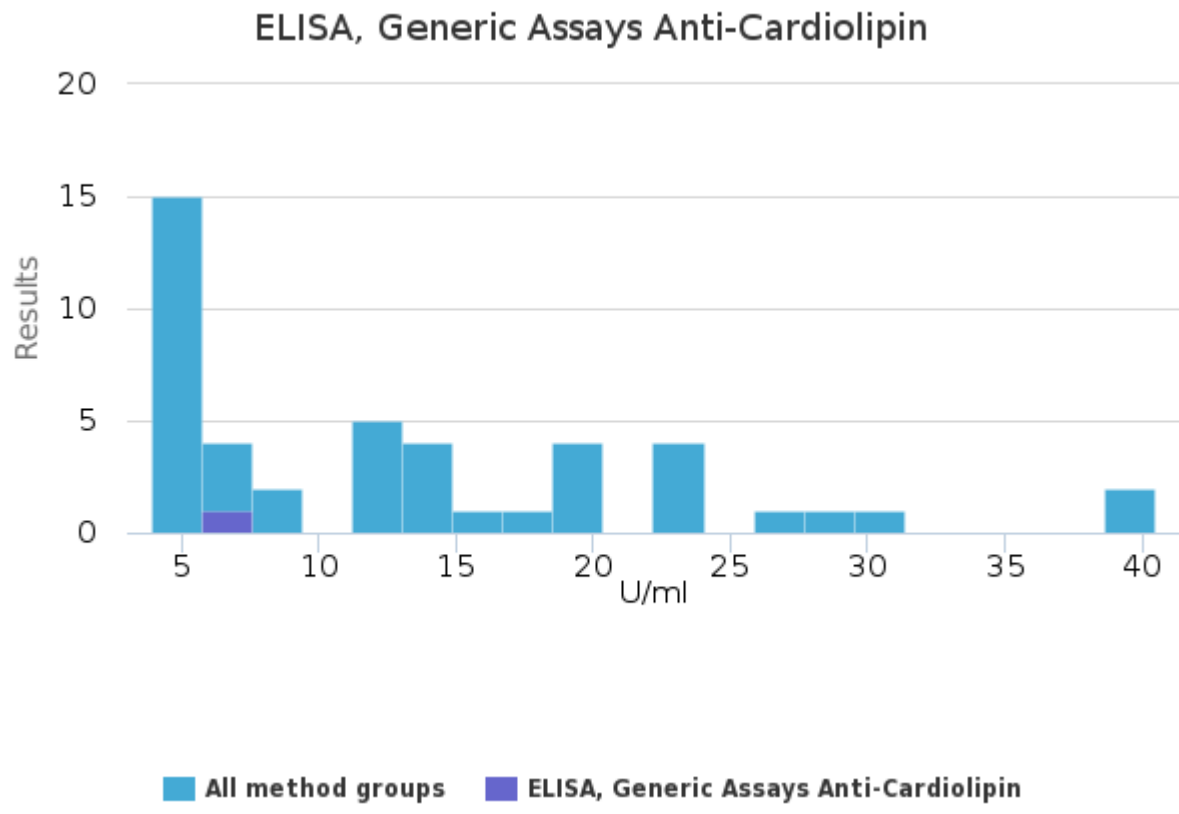
Sample S001 | ACA IgG, U/ml

Methodics	Negative	Borderline	Weak positive	Positive	Total
AESKULISA Cardioliipin-GM	-	1	-	-	1
Chorus CARDIOLIPIN-G, Diesse	3	-	-	-	3
EliA Phadia, Thermo Scientific	13	-	-	-	13
ELISA, Aesku Diagnostics	-	1	-	-	1
ELISA, Demeditec Cardioliipin Ab IgG/IgM	-	-	2	-	2
ELISA, Diamedix	1	-	-	-	1
ELISA, DRG Anti-Cardioliipin IgG	-	-	1	-	1
ELISA, Euroimmun	4	1	-	-	5
ELISA, Generic Assays Anti-Cardioliipin	1	-	-	-	1
ELISA, Inova Diagnostics	1	-	-	-	1
ELISA, Orgentec	-	-	2	11	13
Inova Quanta Flash aCL IgG	-	-	-	4	4
Total	23	3	5	15	46

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
AESKULISA Cardioliipin-GM	-	-	-	-	-	17.8	17.8	-	1
Chorus CARDIOLIPIN-G, Diesse	6.0	6.7	1.2	20.6	0.7	4.6	6.8	-	3
EliA Phadia, Thermo Scientific	4.4	4.3	0.5	11.6	0.1	3.9	5.7	-	13
ELISA, Aesku Diagnostics	-	-	-	-	-	12.1	12.1	-	1
ELISA, Demeditec Cardioliipin Ab IgG/IgM	13.4	13.4	2.3	17.5	1.7	11.7	15.0	-	2
ELISA, Diamedix	-	-	-	-	-	5.4	5.4	-	1
ELISA, DRG Anti-Cardioliipin IgG	-	-	-	-	-	14.3	14.3	-	1
ELISA, Euroimmun	9.2	9.0	1.7	18.4	0.8	7.2	11.4	-	4
ELISA, Generic Assays Anti-Cardioliipin	-	-	-	-	-	6.3	6.3	-	1
ELISA, Inova Diagnostics	-	-	-	-	-	12.2	12.2	-	1
ELISA, Orgentec	19.4	19.4	4.7	24.1	1.3	11.9	27.2	-	13
Inova Quanta Flash aCL IgG	34.7	34.6	6.0	17.3	3.0	29.0	40.5	-	4
All	13.3	11.7	9.6	72.6	1.4	3.9	40.5	-	45





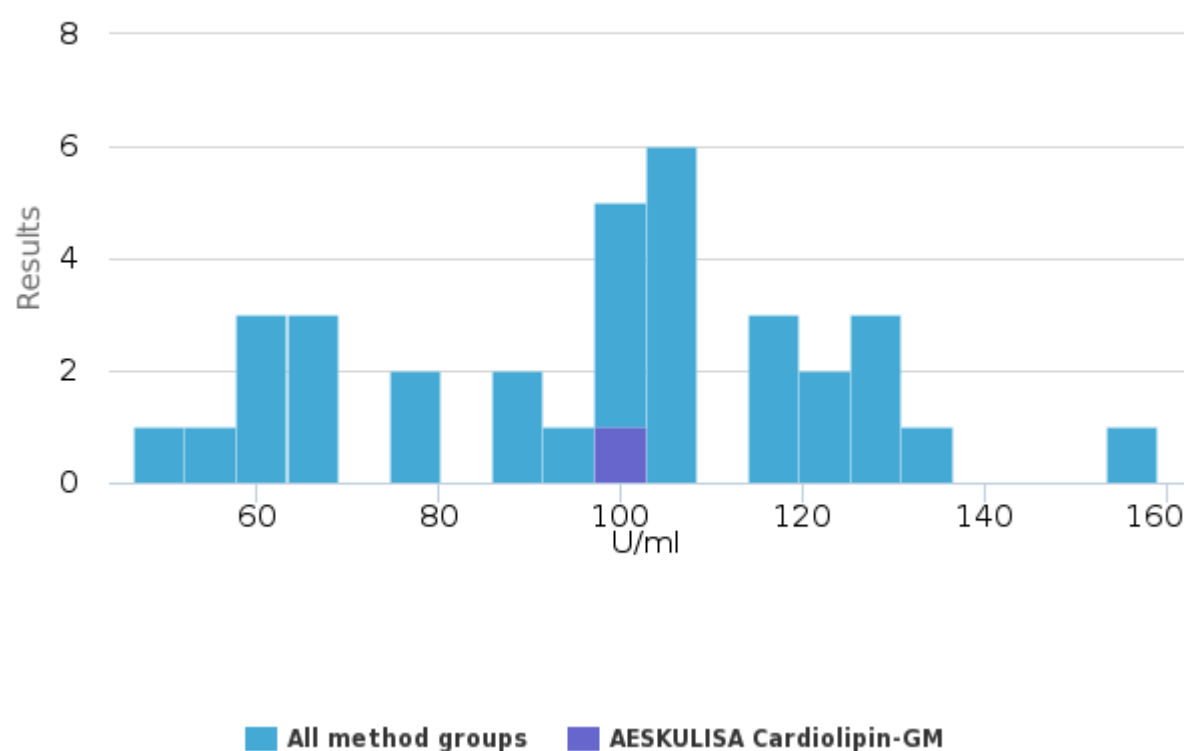


Sample S001 | ACA IgM, U/ml

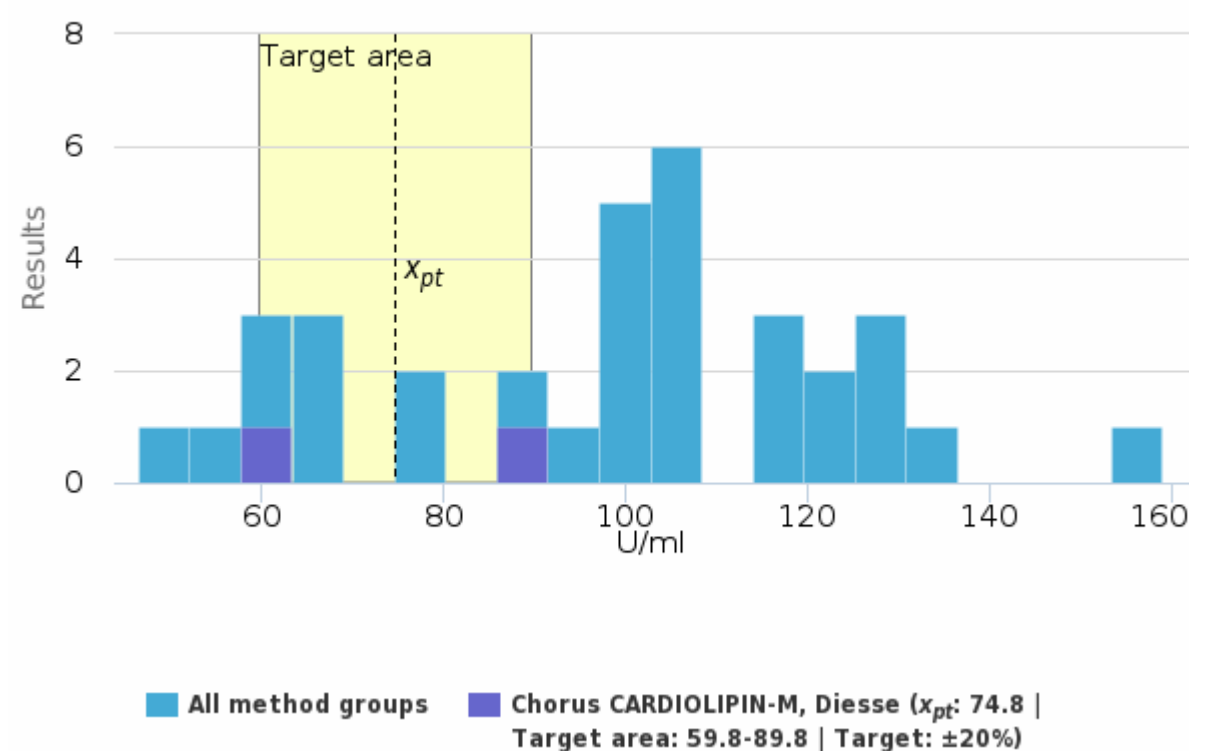
Methodics	Positive	Total
AESKULISA Cardioliipin-GM	1	1
Chorus CARDIOLIPIN-M, Diesse	2	2
EliA Phadia, Thermo Scientific	13	13
ELISA, Aesku Diagnostics	1	1
ELISA, Demeditec Cardioliipin Ab IgG/IgM	2	2
ELISA, Diamedix	1	1
ELISA, DRG Anti-Cardioliipin IgM	1	1
ELISA, Euroimmun	5	5
ELISA, Generic Assays Anti-Cardioliipin	1	1
ELISA, Orgentec	13	13
Inova Quanta Flash aCL IgM	4	4
Total	44	44

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
AESKULISA Cardioliipin-GM	-	-	-	-	-	98.2	98.2	-	1
Chorus CARDIOLIPIN-M, Diesse	74.8	74.8	19.1	25.5	13.5	61.3	88.3	-	2
EliA Phadia, Thermo Scientific	110.6	105.0	18.1	16.4	5.0	86.4	159.0	-	13
ELISA, Aesku Diagnostics	-	-	-	-	-	91.7	91.7	-	1
ELISA, Demeditec Cardioliipin Ab IgG/IgM	49.9	49.9	4.7	9.5	3.4	46.5	53.2	-	2
ELISA, Diamedix	-	-	-	-	-	131.4	131.4	-	1
ELISA, DRG Anti-Cardioliipin IgM	-	-	-	-	-	108.0	108.0	-	1
ELISA, Euroimmun	113.3	113.3	7.4	6.5	5.2	108.1	118.6	-	2
ELISA, Generic Assays Anti-Cardioliipin	-	-	-	-	-	66.1	66.1	-	1
ELISA, Orgentec	68.4	66.7	7.9	11.5	3.2	60.3	80.0	-	6
Inova Quanta Flash aCL IgM	122.4	123.4	5.6	4.6	2.8	115.1	127.7	-	4
All	97.3	101.5	26.4	27.1	4.5	46.5	159.0	-	34

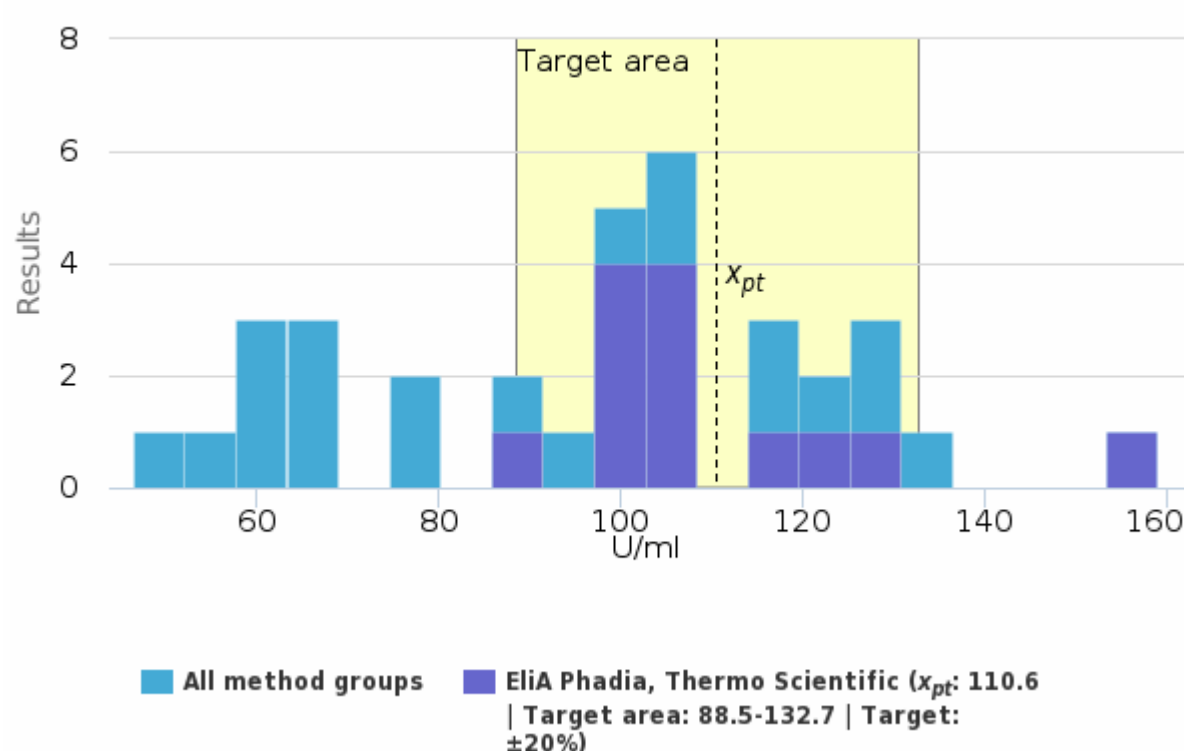
AESKULISA Cardioliipin-GM



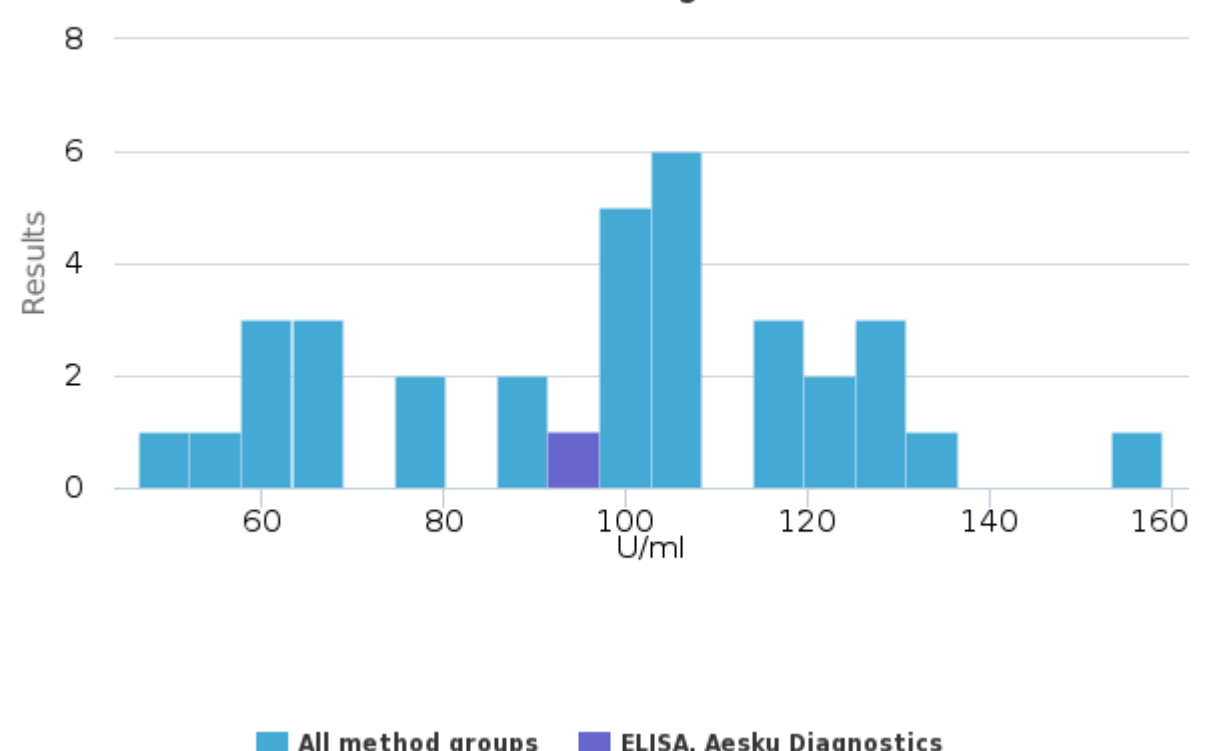
Chorus CARDIOLIPIN-M, Diesse

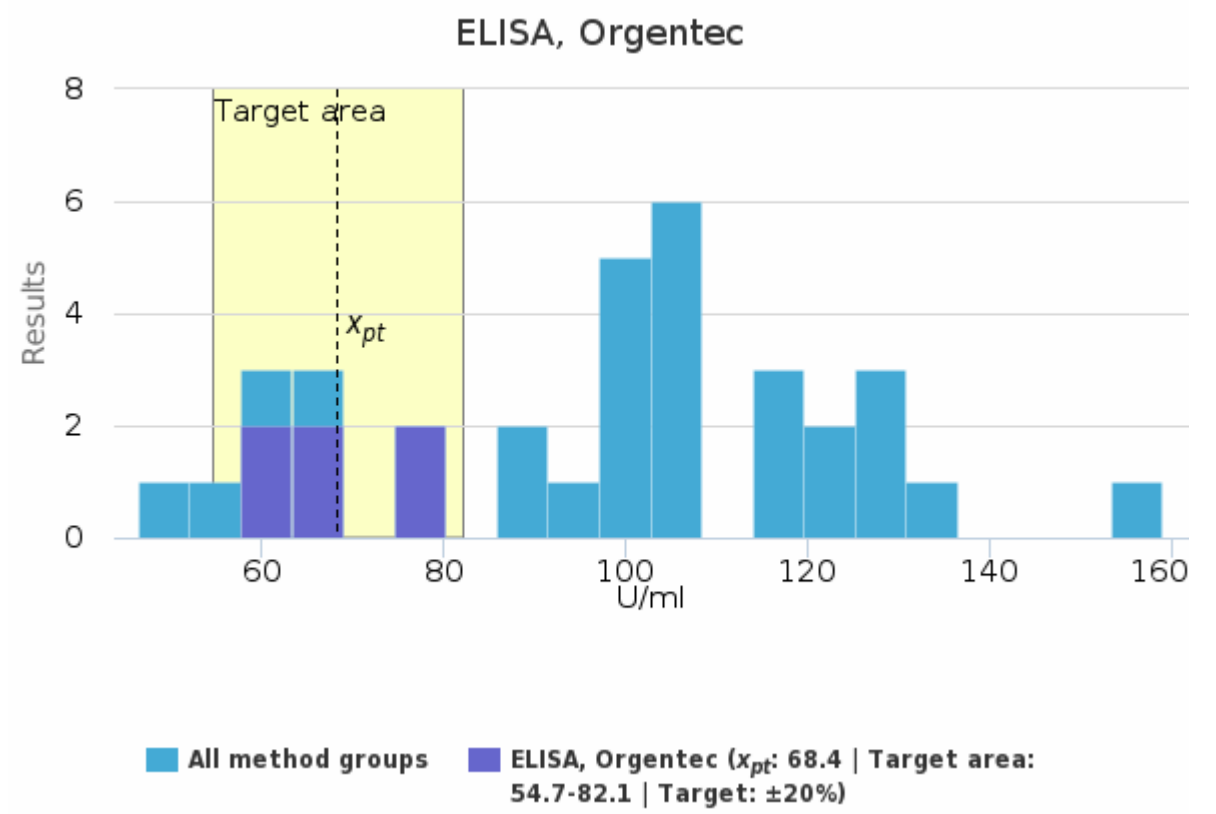
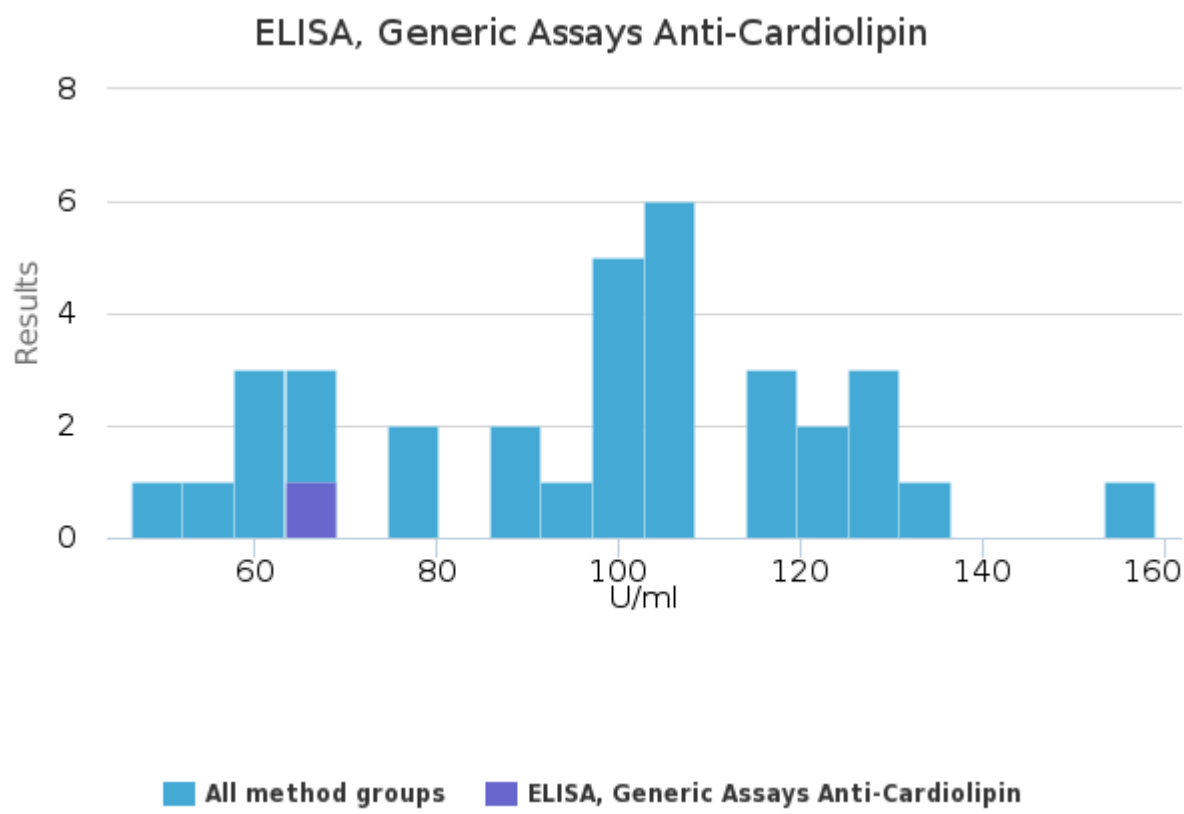
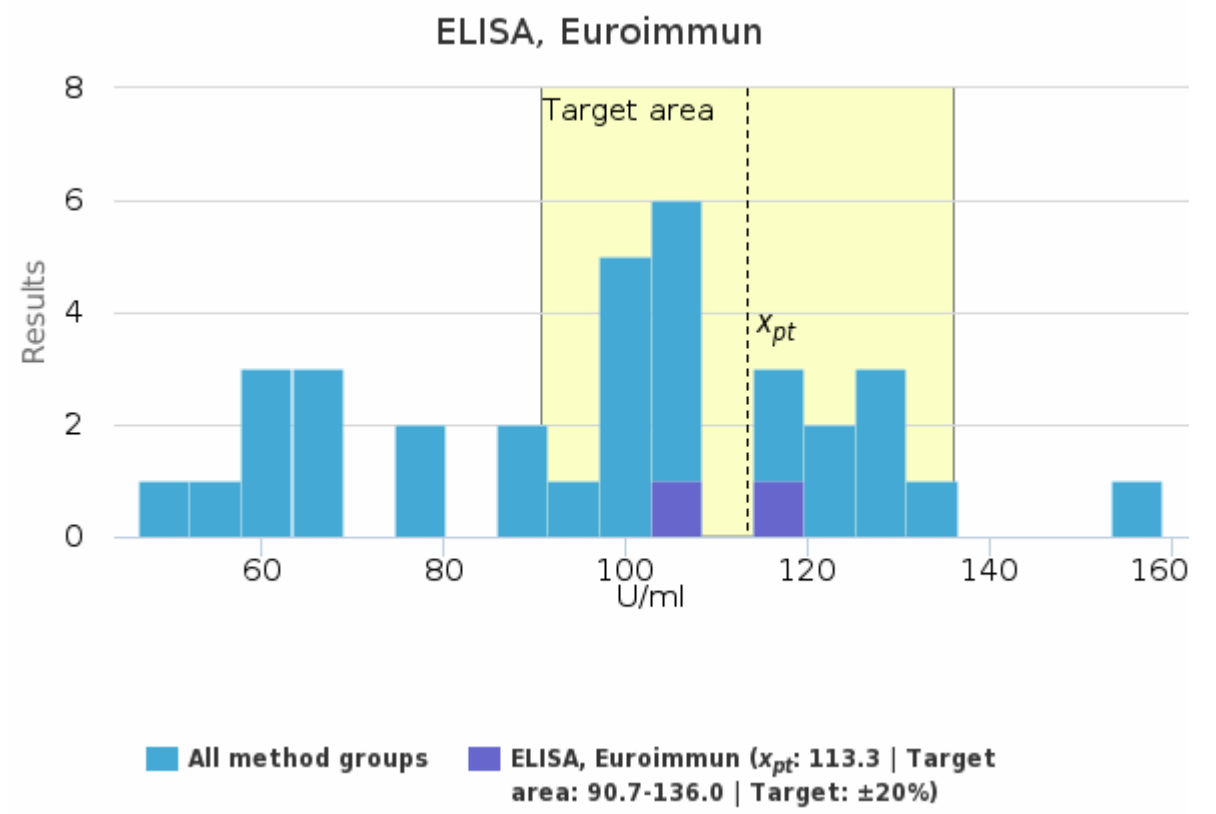
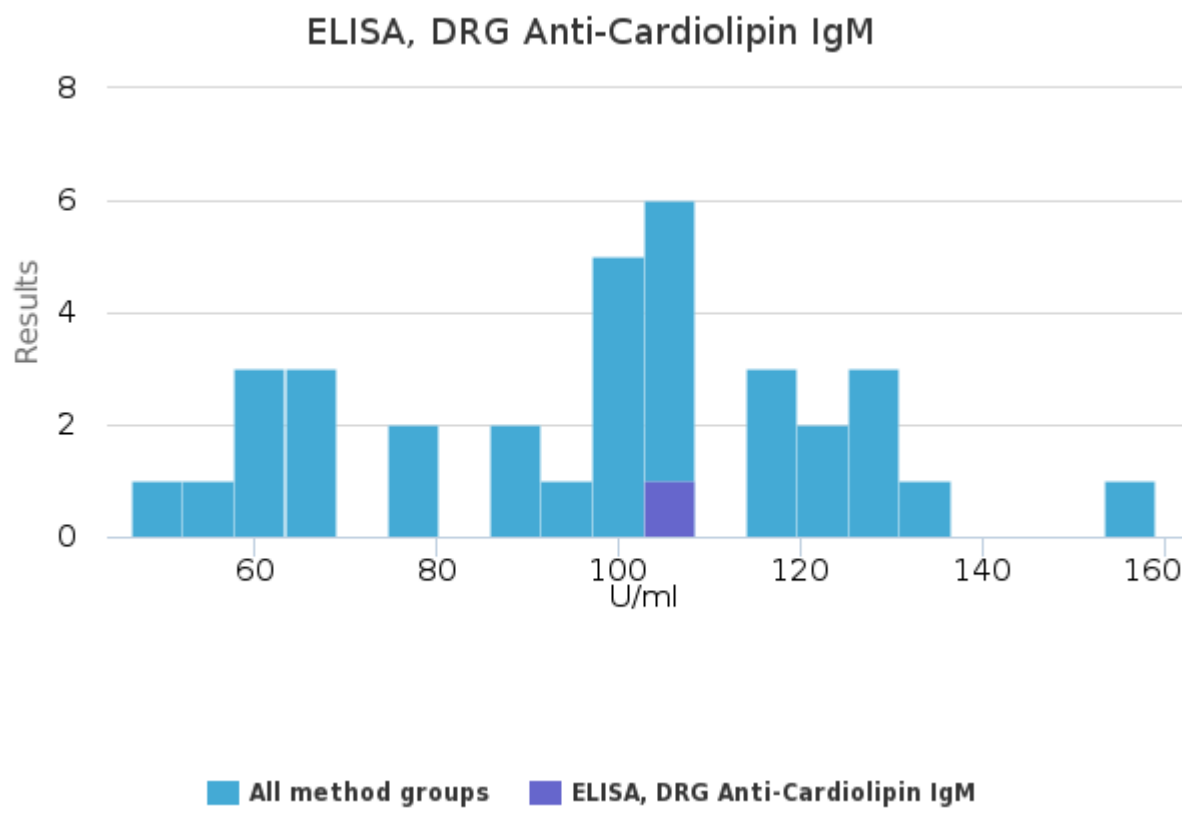
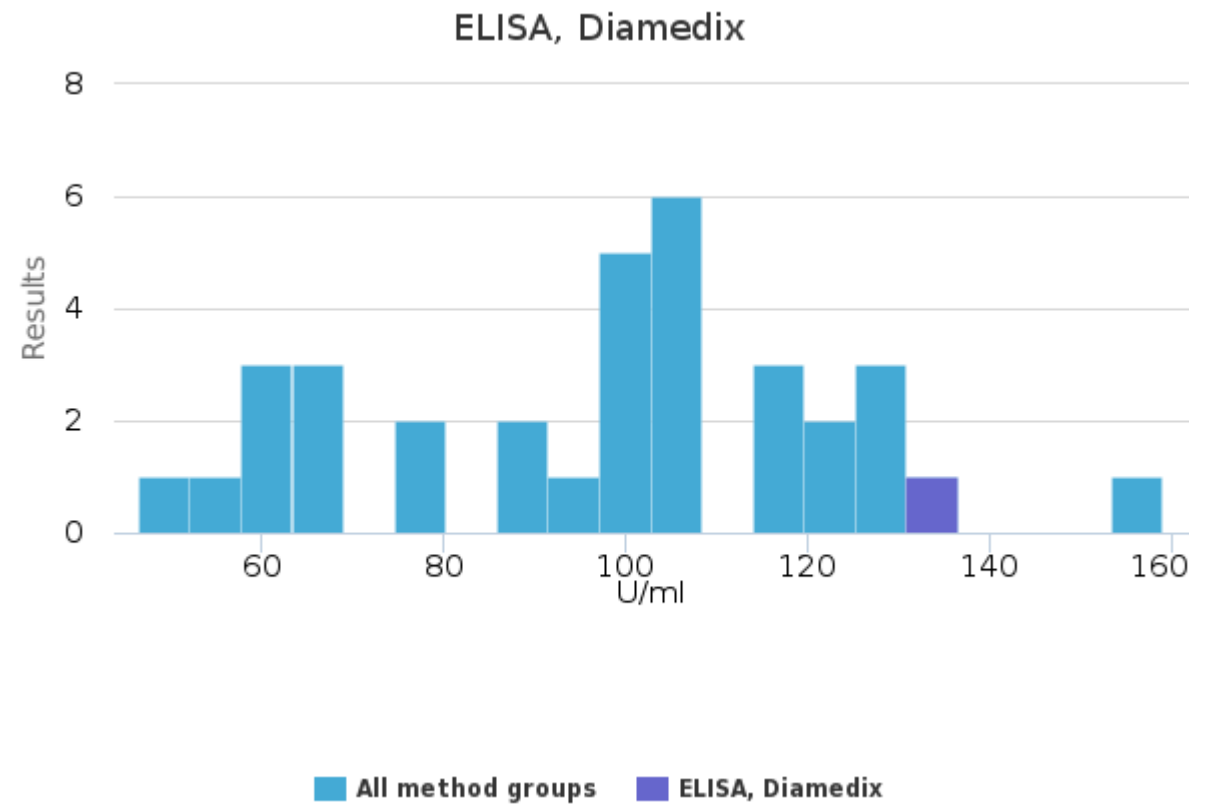
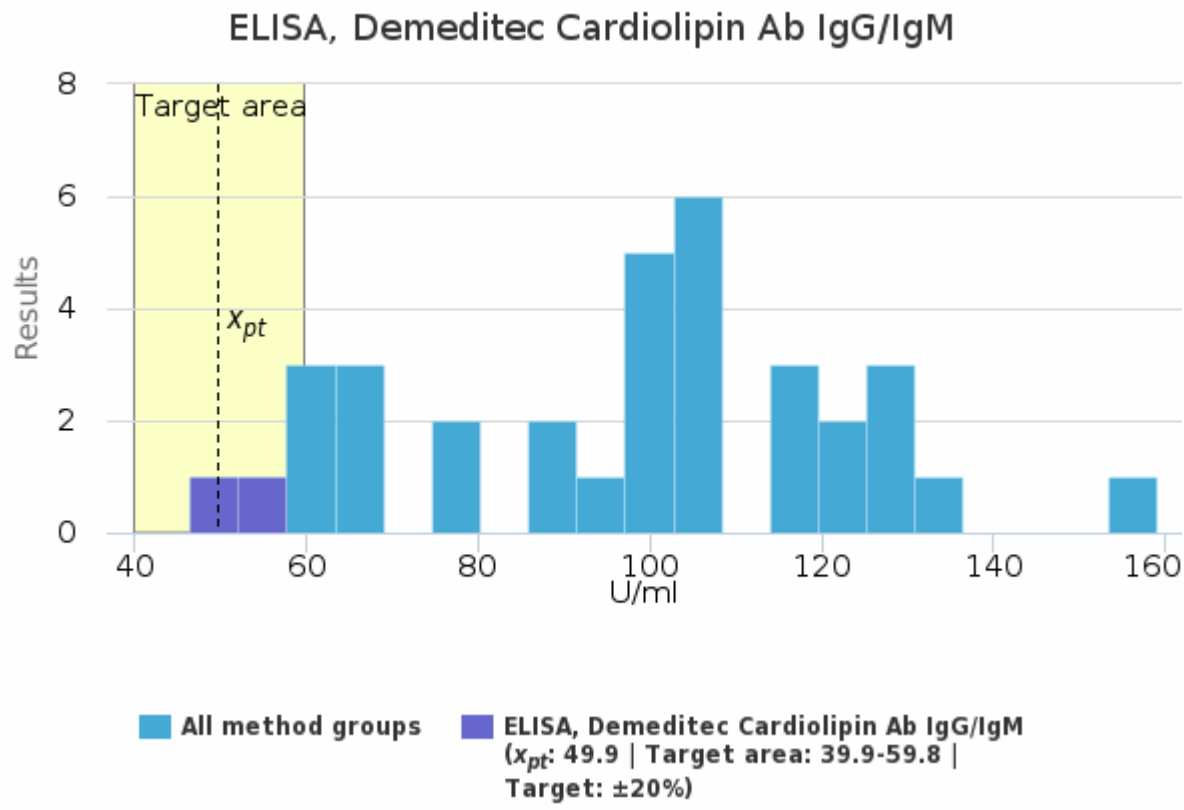


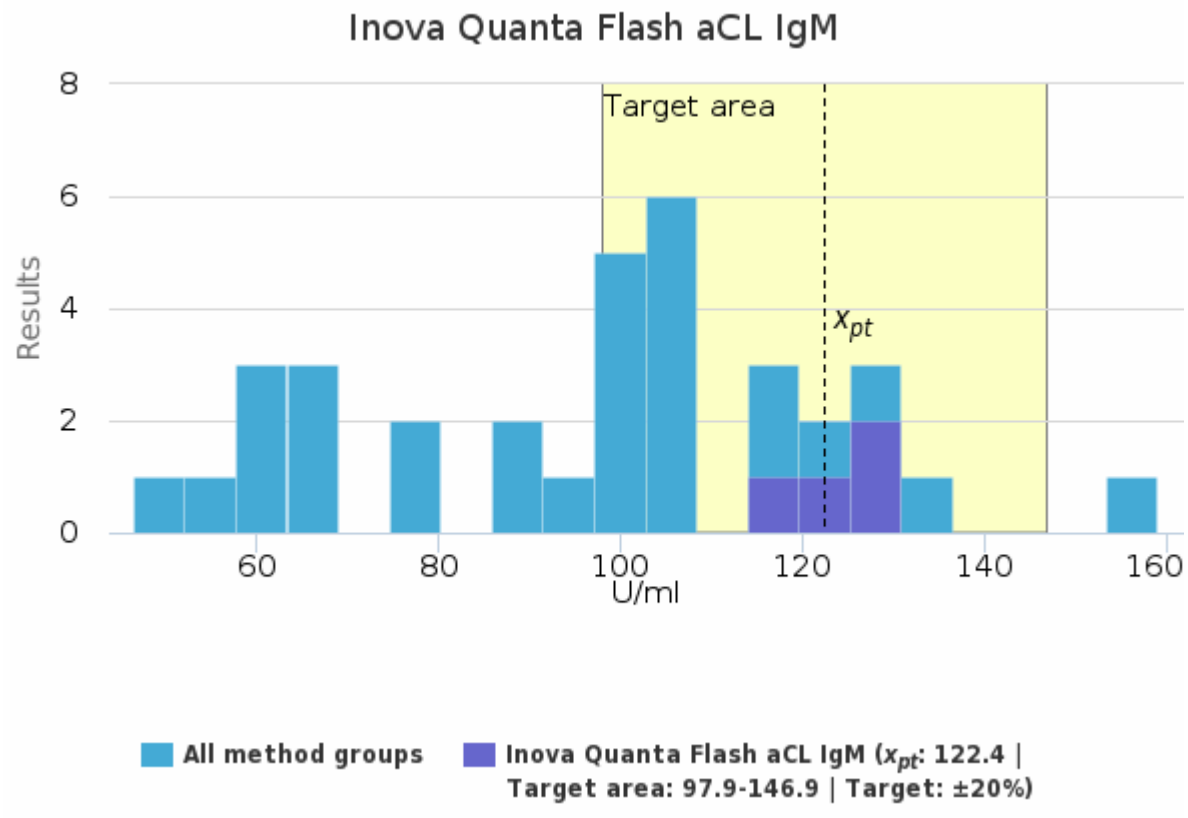
EliA Phadia, Thermo Scientific



ELISA, Aesku Diagnostics



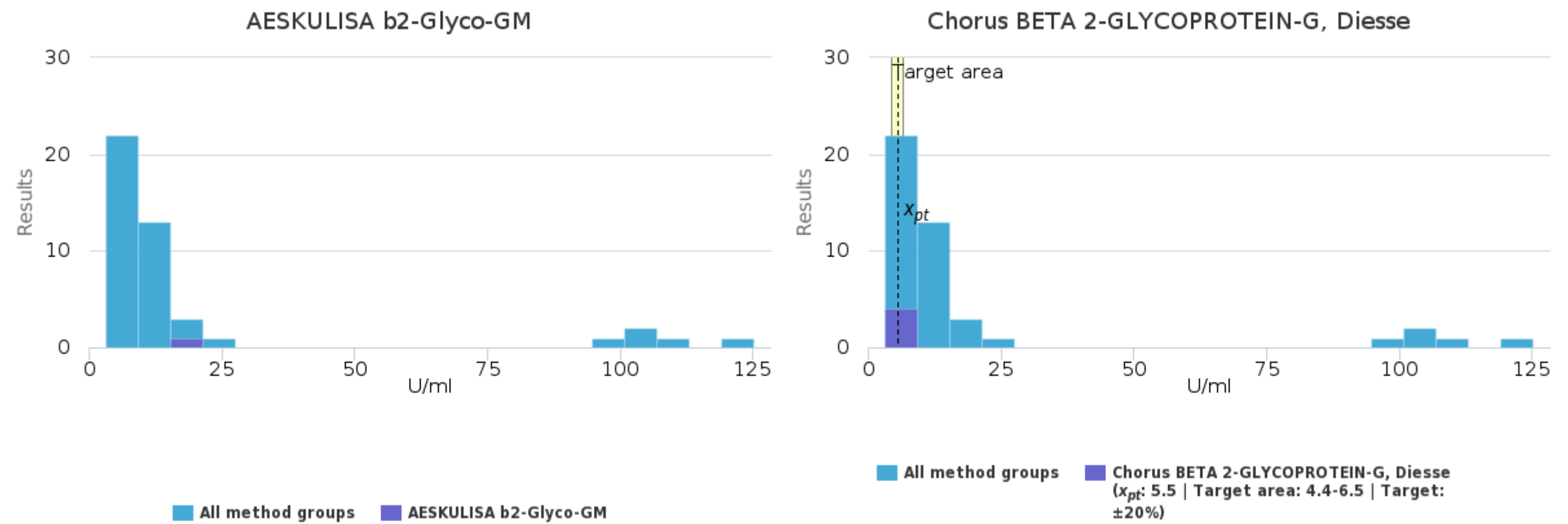


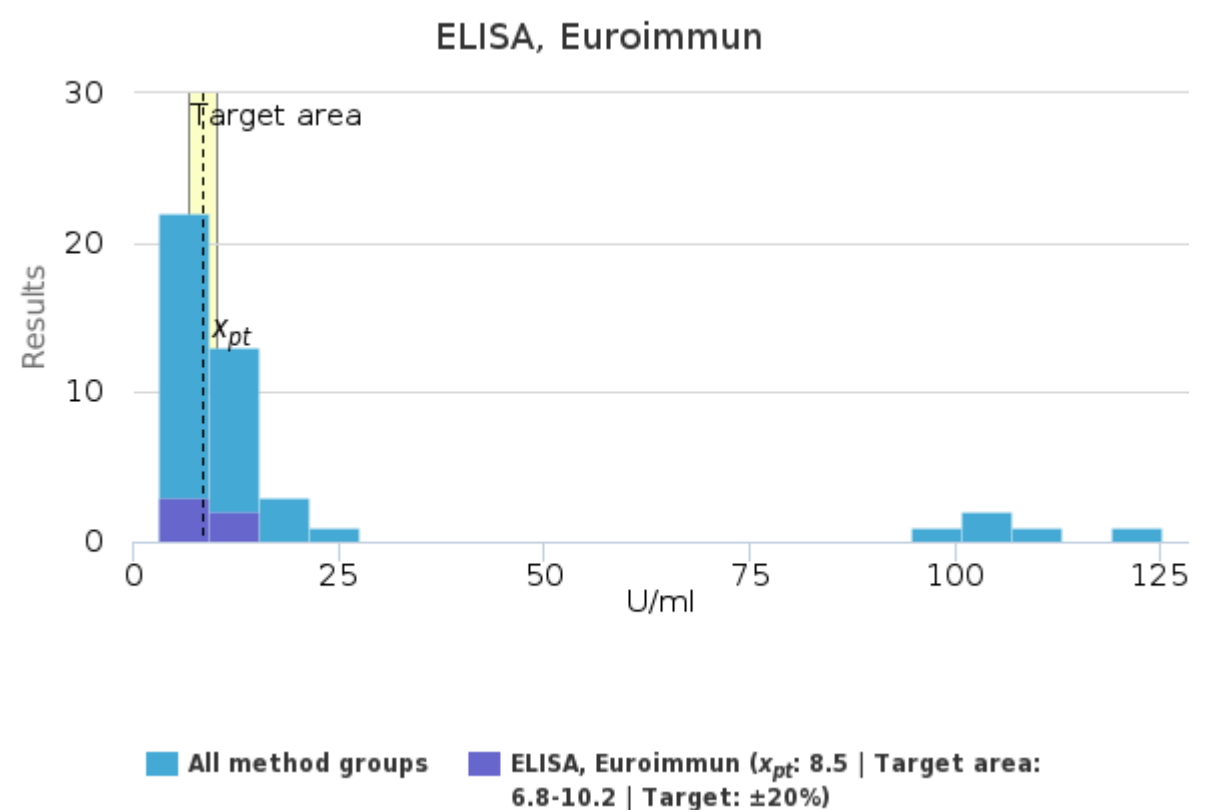
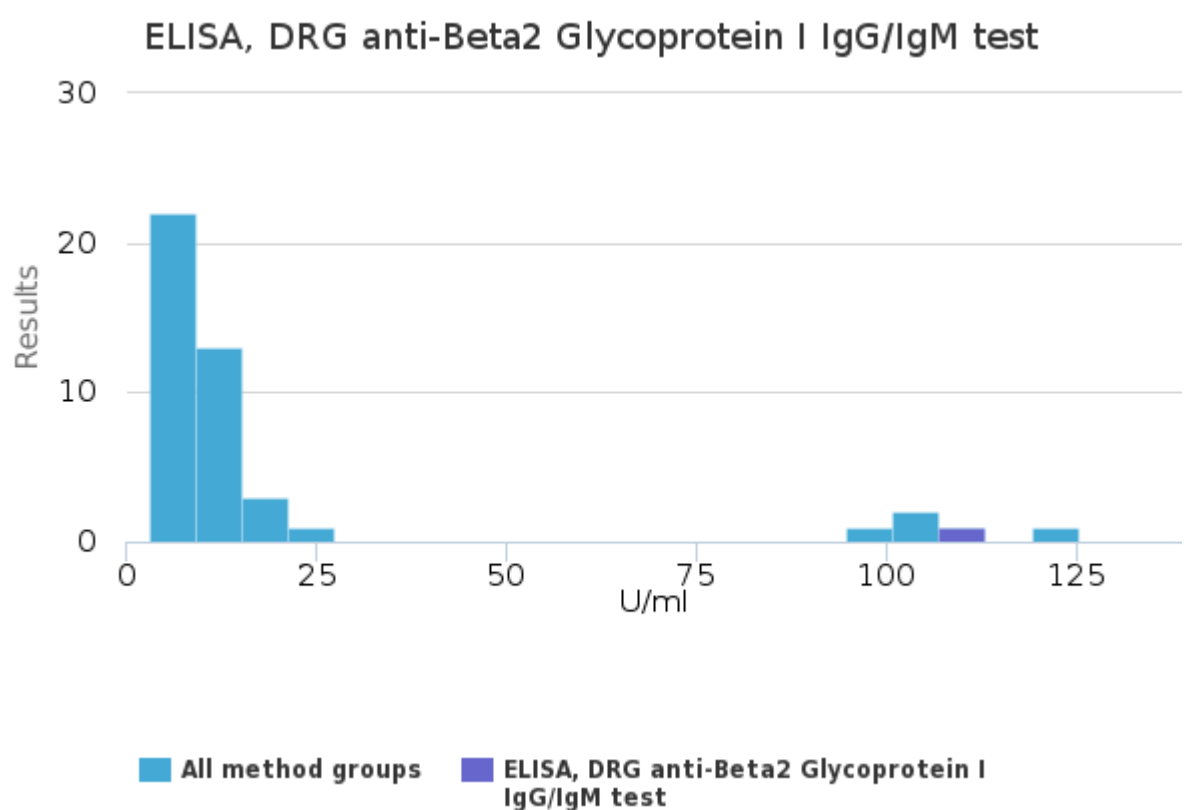
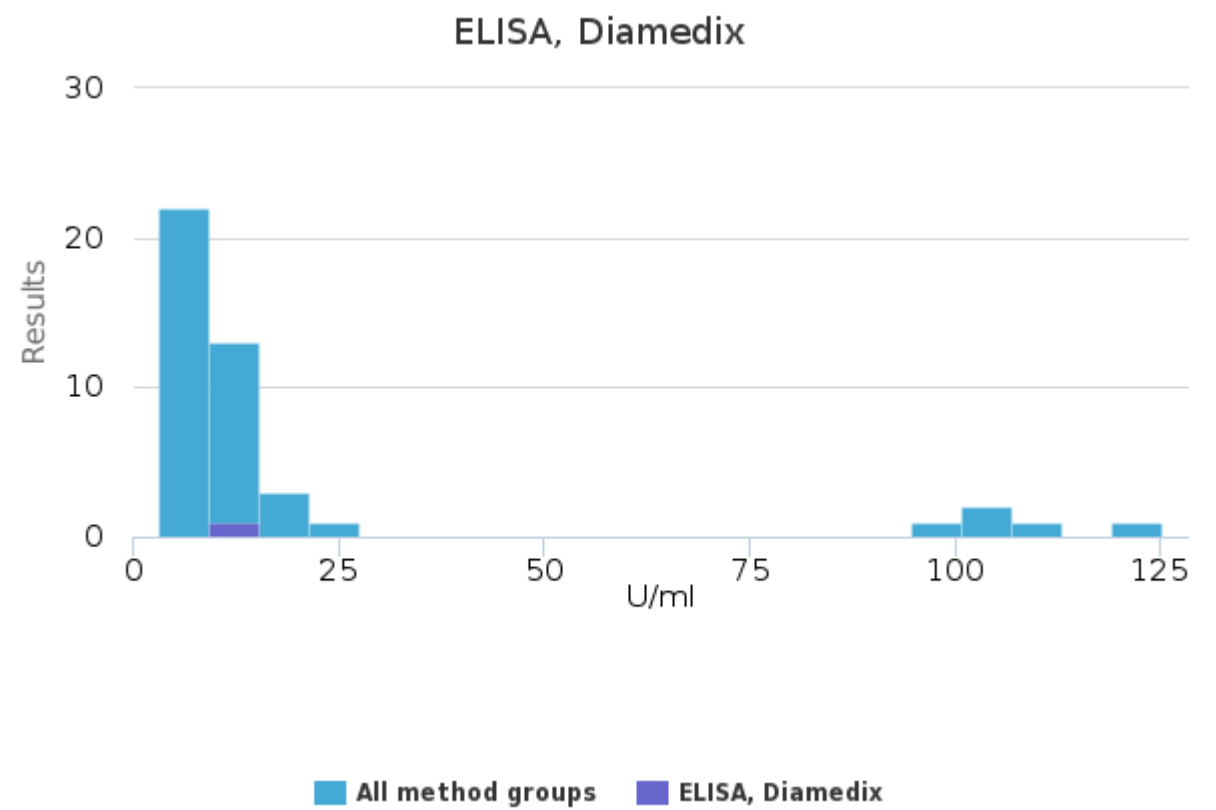
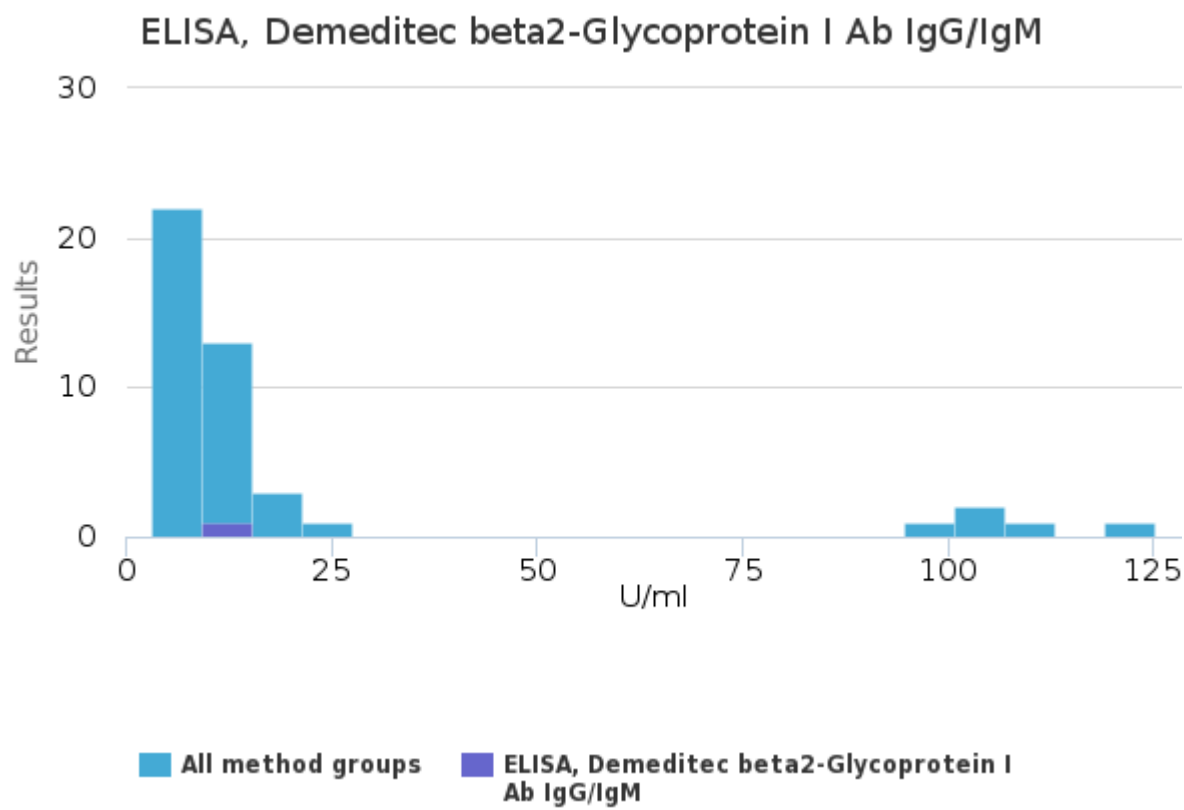
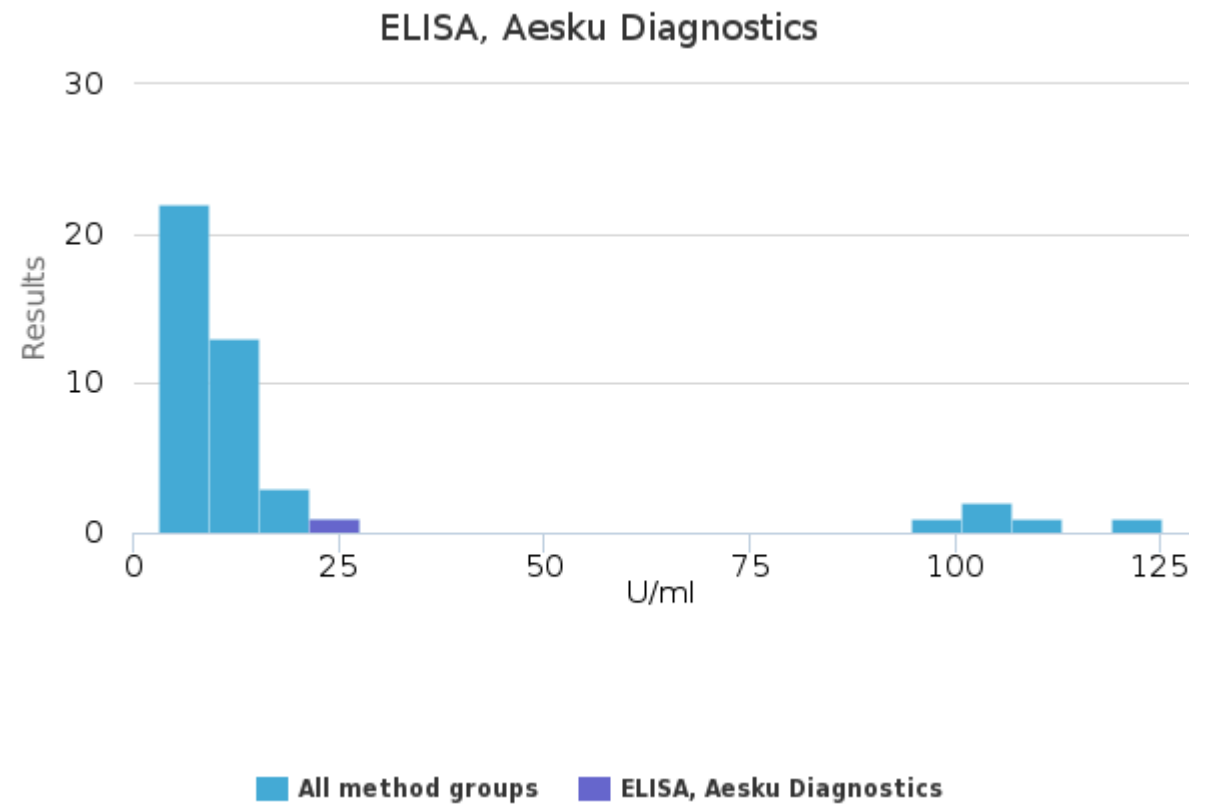
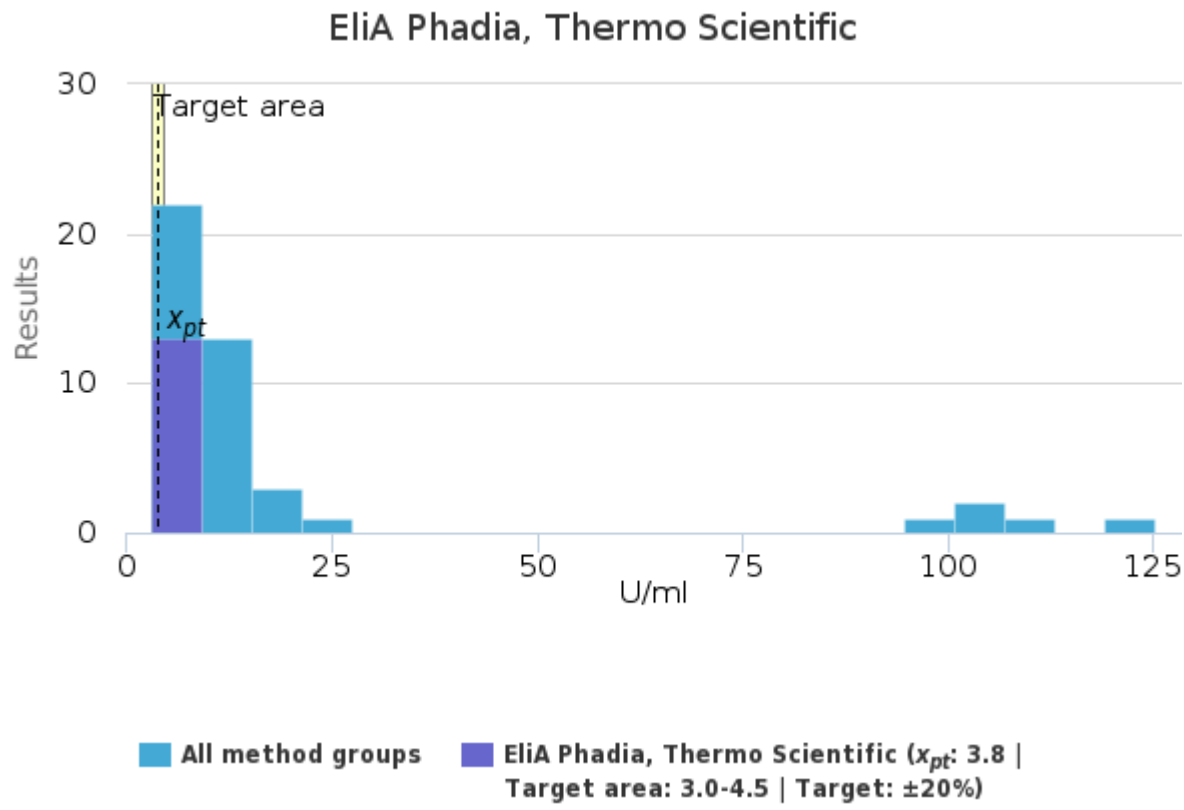


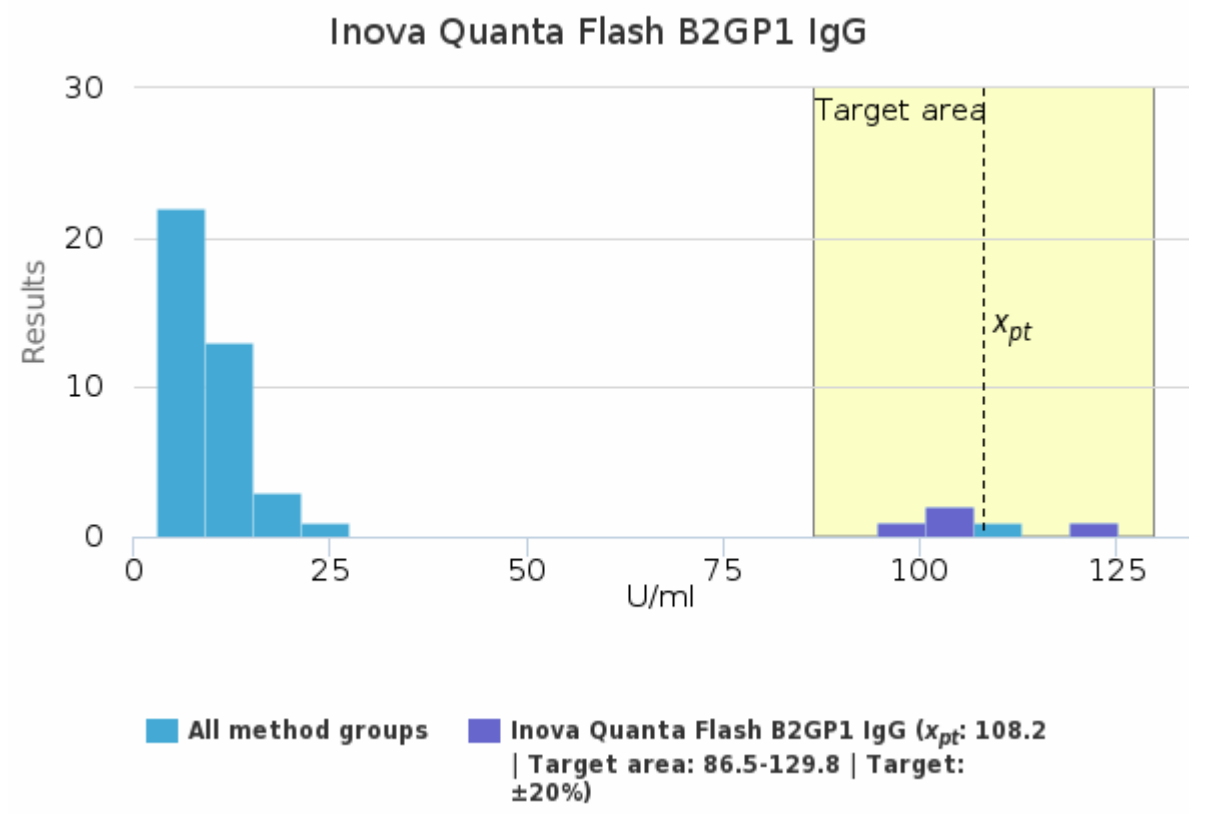
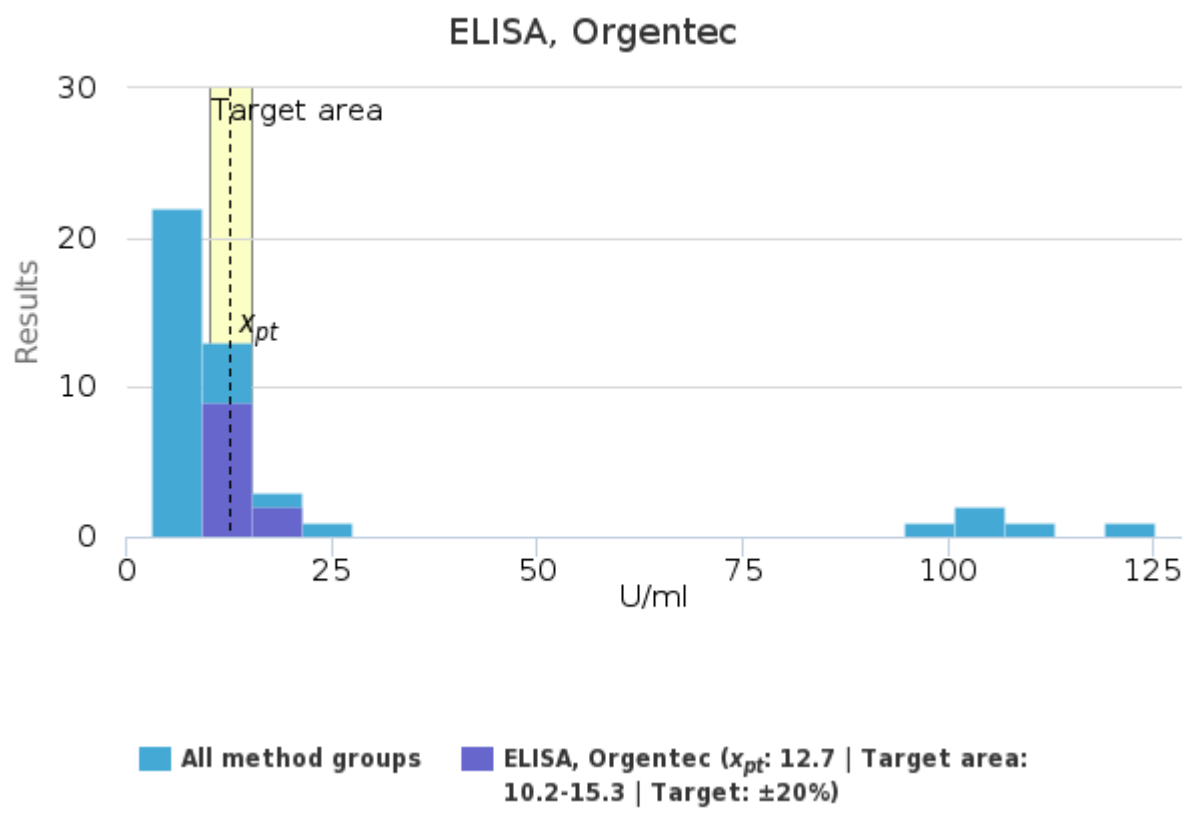
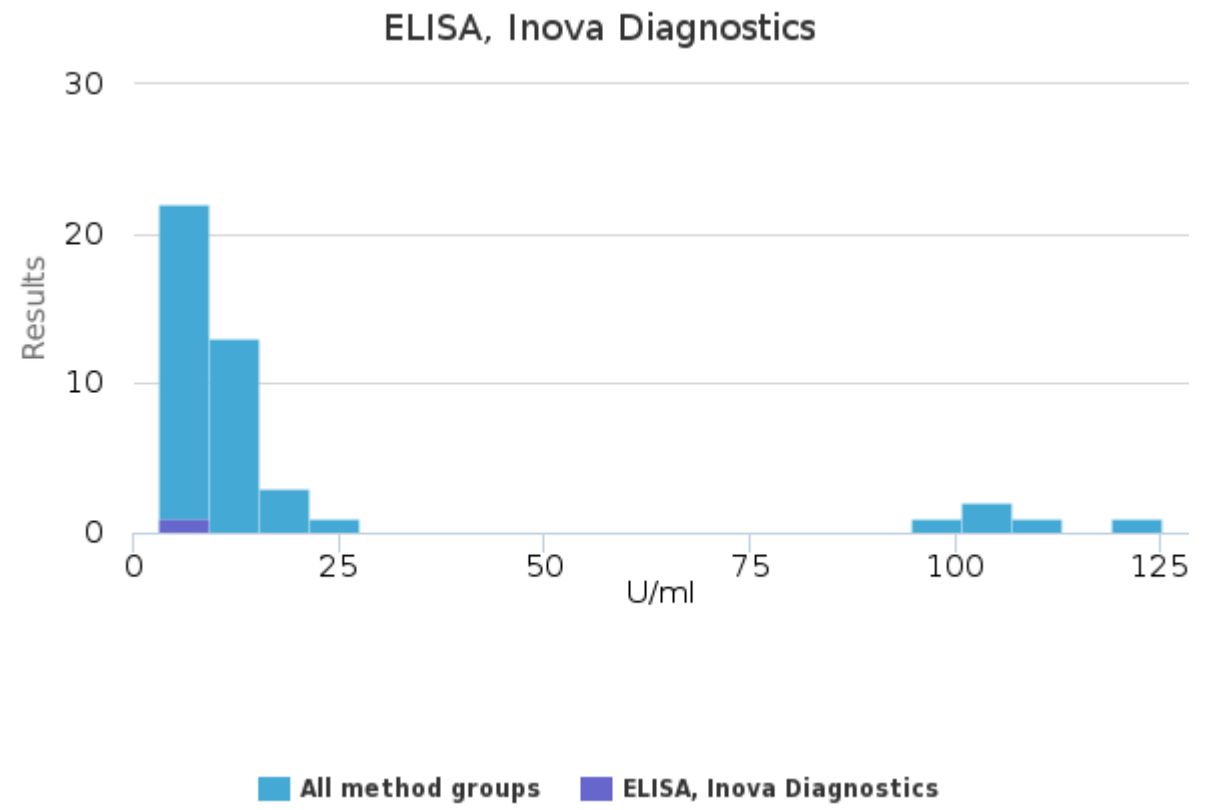
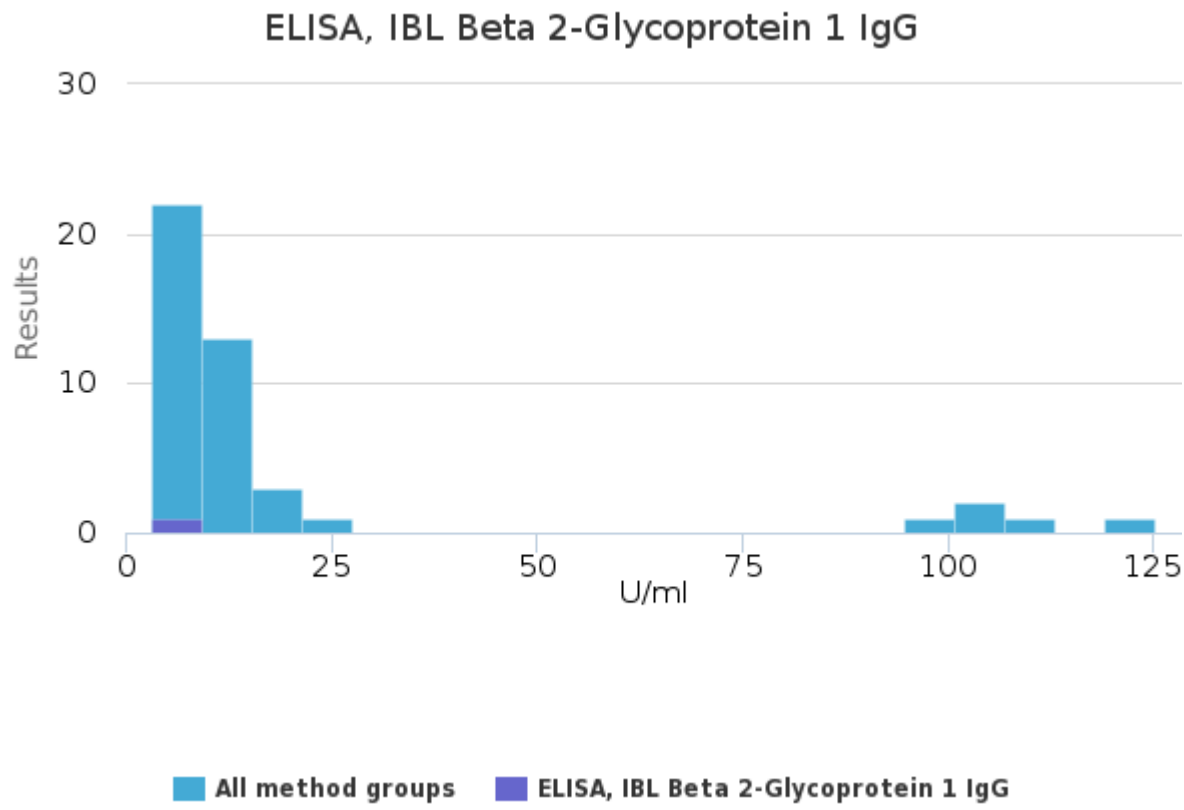
Sample S001 | 2-Glycoprotein IgG, U/ml

Methodics	Negative	Borderline	Weak positive	Positive	Total
AESKULISA b2-Glyco-GM	-	1	-	-	1
Chorus BETA 2-GLYCOPROTEIN-G, Diesse	4	-	-	-	4
EliA Phadia, Thermo Scientific	13	-	-	-	13
ELISA, Aesku Diagnostics	-	-	1	-	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	-	-	1	-	1
ELISA, Diamedix	1	-	-	-	1
ELISA, DRG anti-Beta2 Glycoprotein I IgG/IgM test	-	-	-	1	1
ELISA, Euroimmun	5	-	-	-	5
ELISA, IBL Beta 2-Glycoprotein 1 IgG	1	-	-	-	1
ELISA, Inova Diagnostics	1	-	-	-	1
ELISA, Orgentec	-	-	4	8	12
Inova Quanta Flash B2GP1 IgG	-	-	-	4	4
Total	25	1	6	13	45

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
AESKULISA b2-Glyco-GM	-	-	-	-	-	17.9	17.9	-	1
Chorus BETA 2-GLYCOPROTEIN-G, Diesse	5.5	5.1	1.7	31.7	0.9	4.0	7.6	-	4
EliA Phadia, Thermo Scientific	3.8	3.8	0.4	11.3	0.1	3.0	4.6	-	13
ELISA, Aesku Diagnostics	-	-	-	-	-	22.3	22.3	-	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	-	-	-	-	-	9.5	9.5	-	1
ELISA, Diamedix	-	-	-	-	-	15.2	15.2	-	1
ELISA, DRG anti-Beta2 Glycoprotein I IgG/IgM test	-	-	-	-	-	112.0	112.0	-	1
ELISA, Euroimmun	8.5	8.3	1.6	18.5	0.7	6.6	10.8	-	5
ELISA, IBL Beta 2-Glycoprotein 1 IgG	-	-	-	-	-	7.1	7.1	-	1
ELISA, Inova Diagnostics	-	-	-	-	-	8.9	8.9	-	1
ELISA, Orgentec	12.7	12.1	2.9	23.1	0.9	10.2	19.5	-	11
Inova Quanta Flash B2GP1 IgG	108.2	103.3	11.6	10.7	5.8	100.8	125.3	-	4
All	15.3	8.6	24.9	163.3	3.8	3.0	104.9	2	44



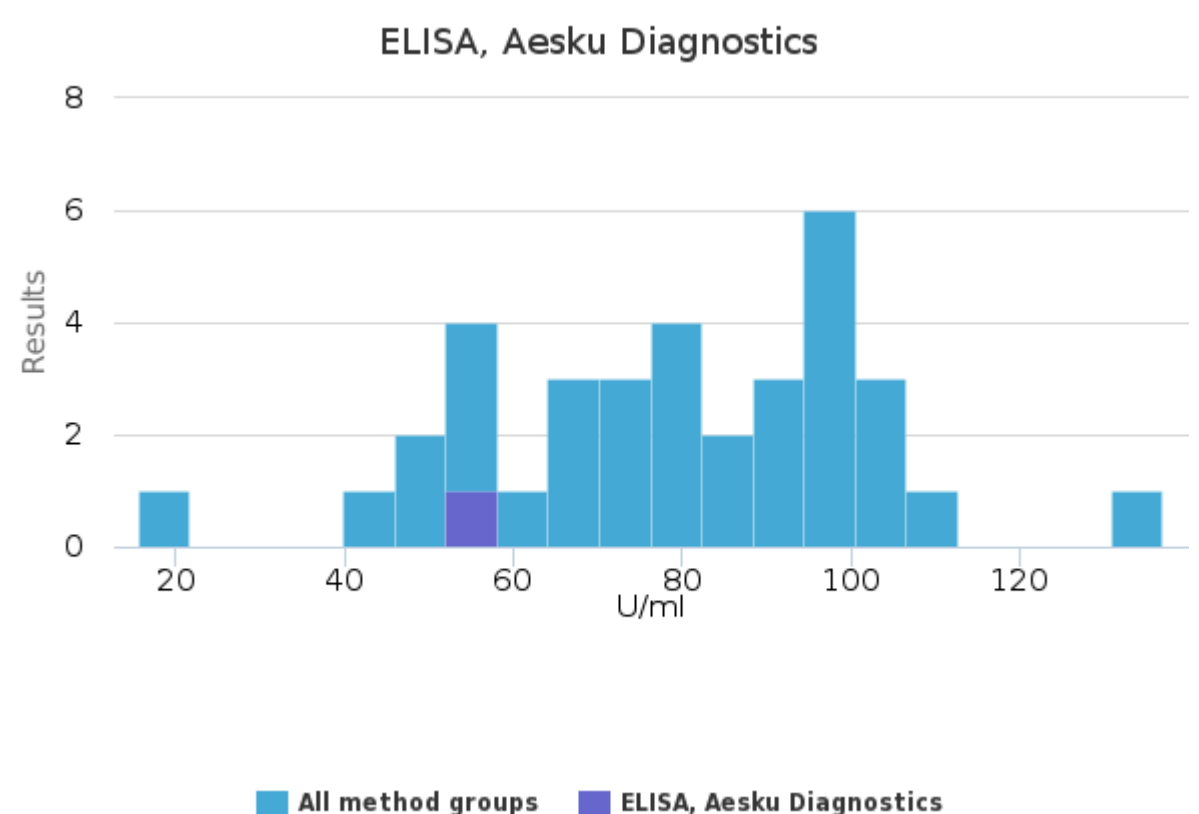
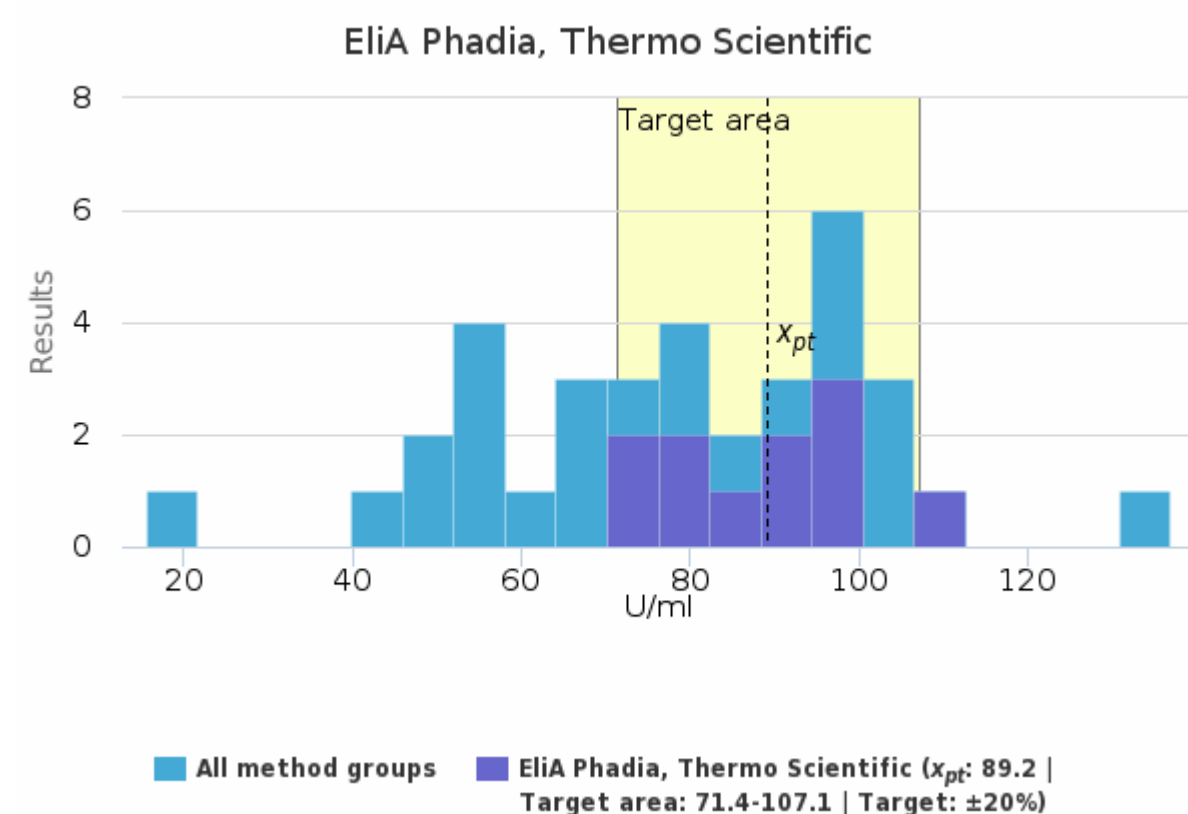
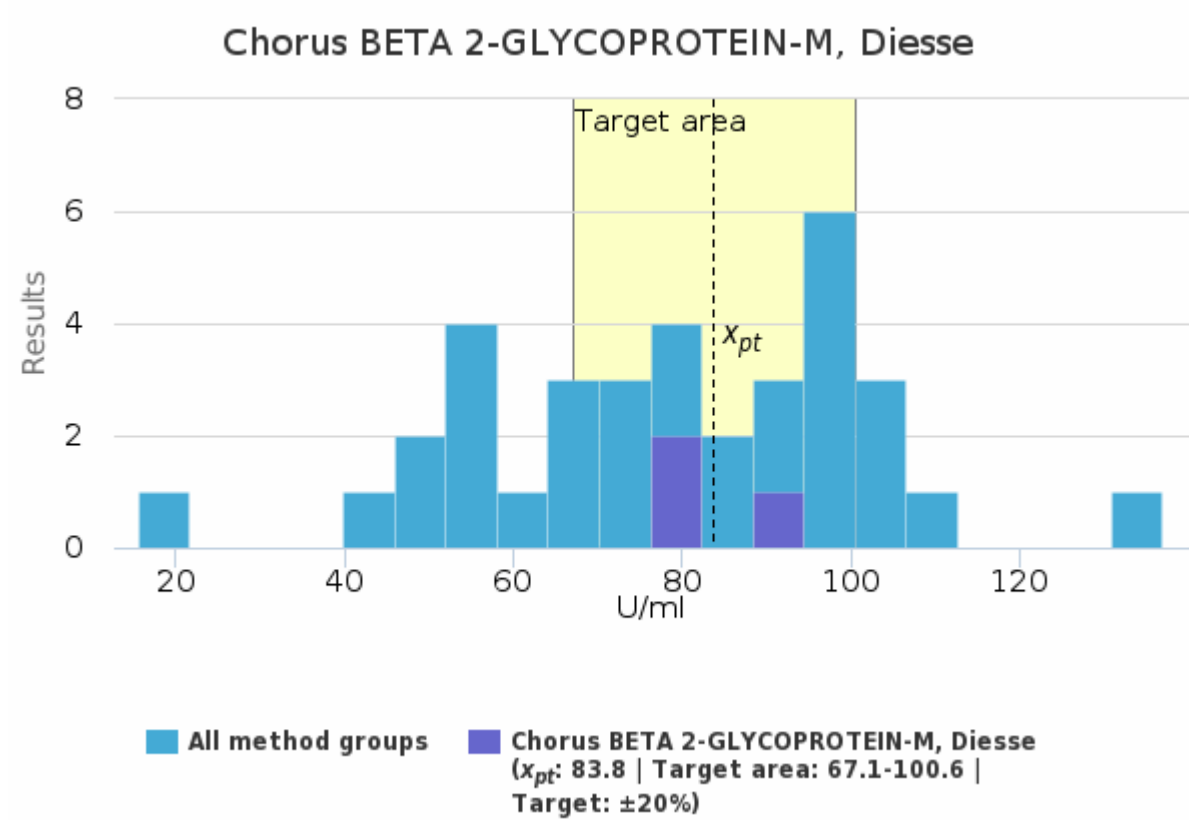
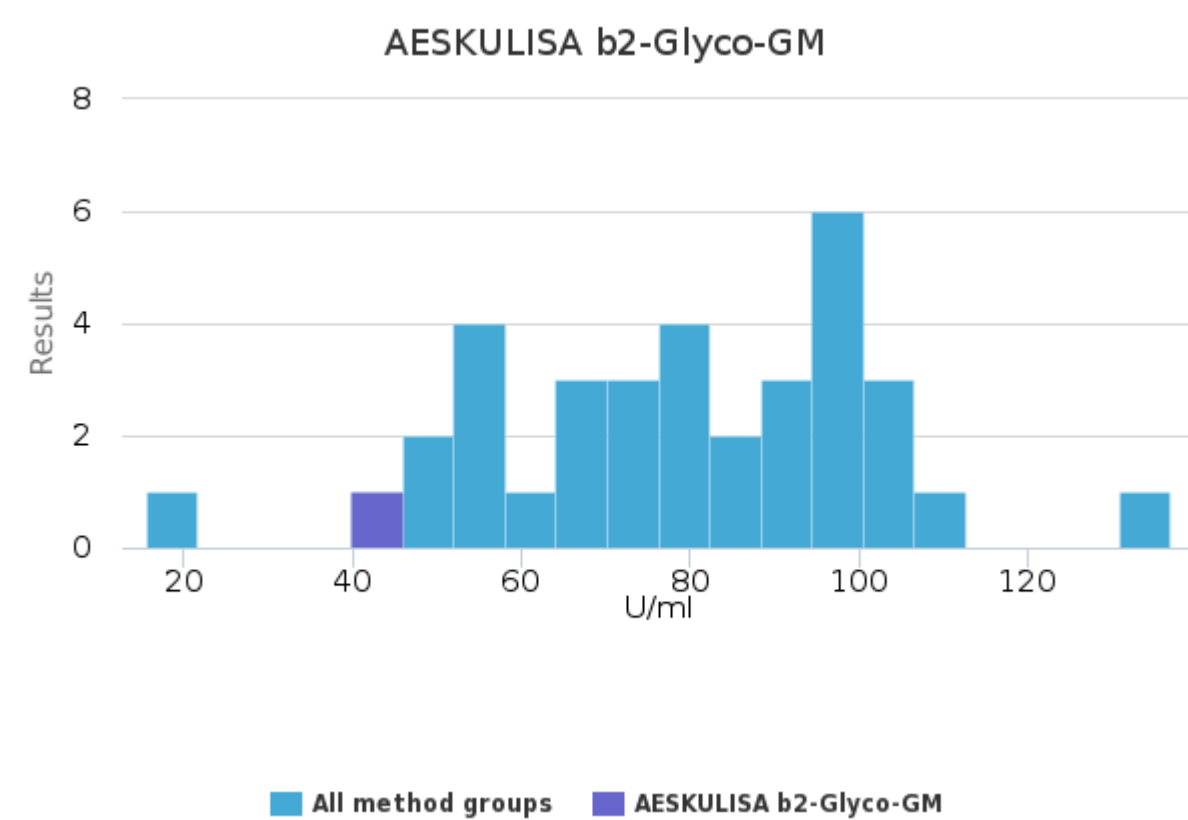


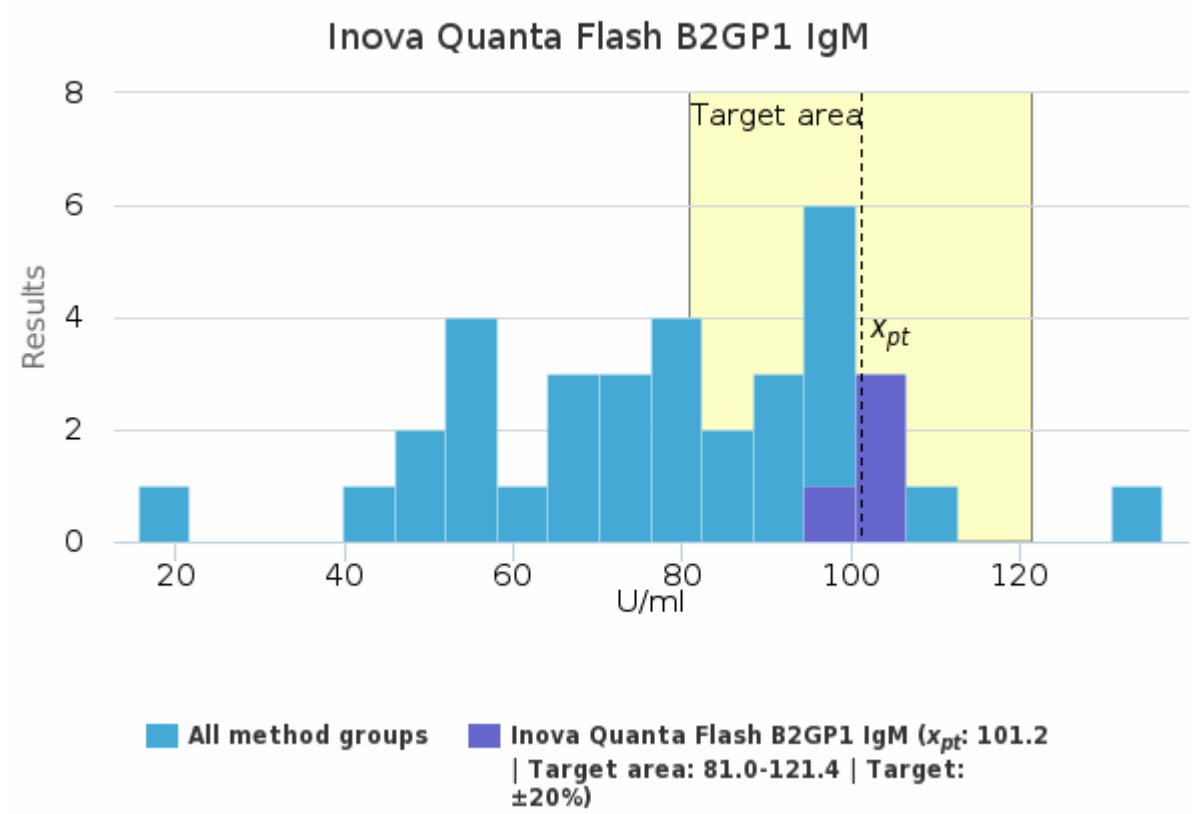
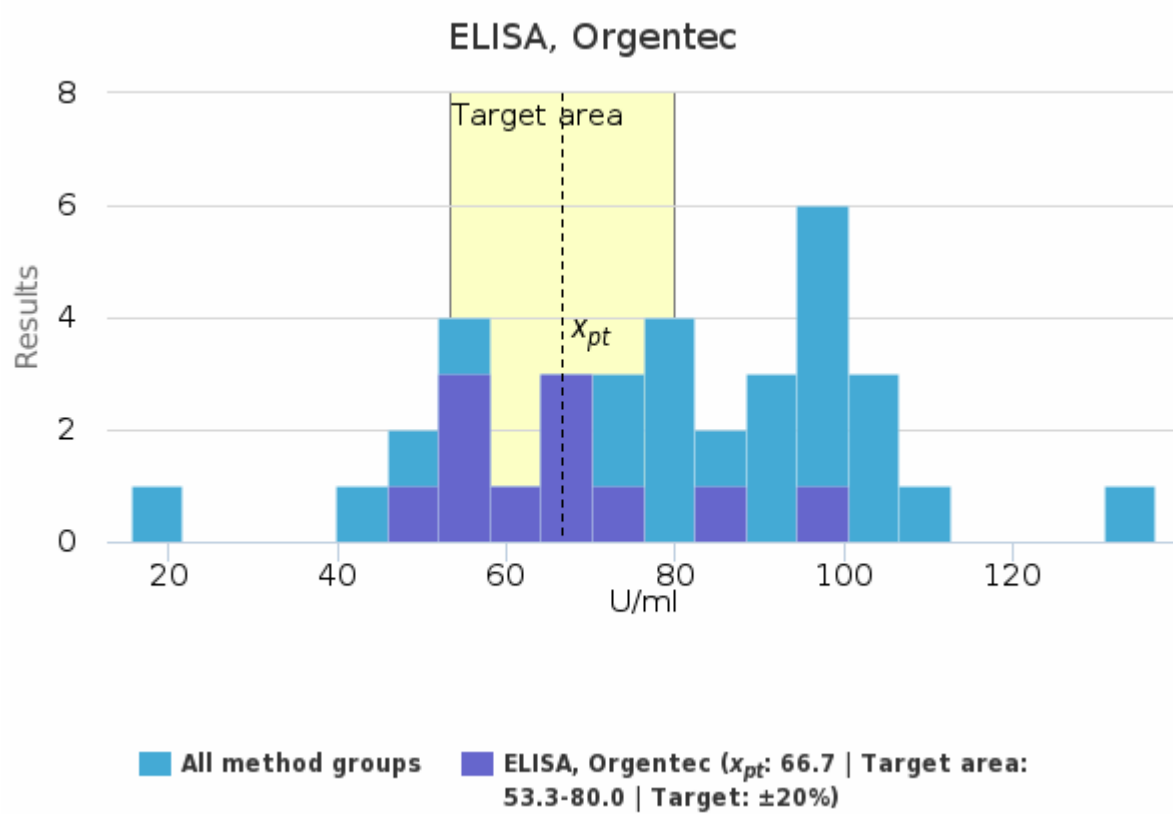
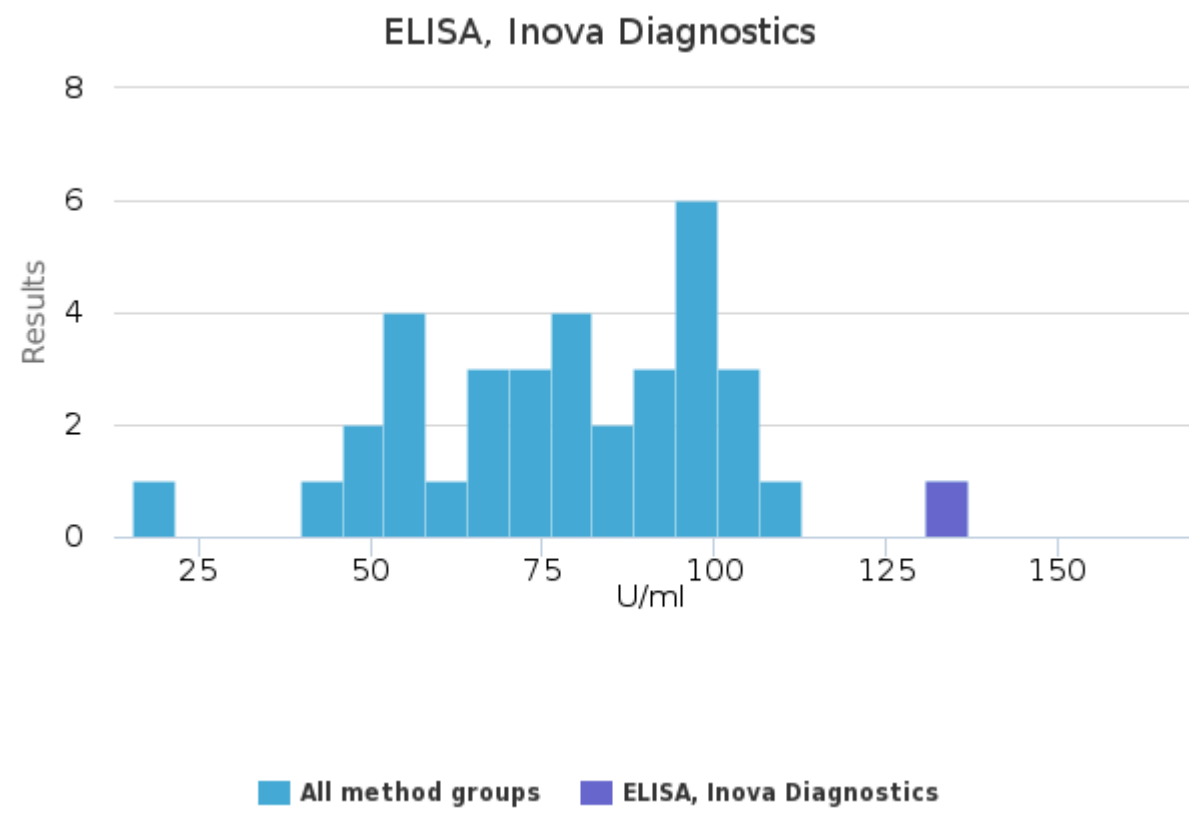
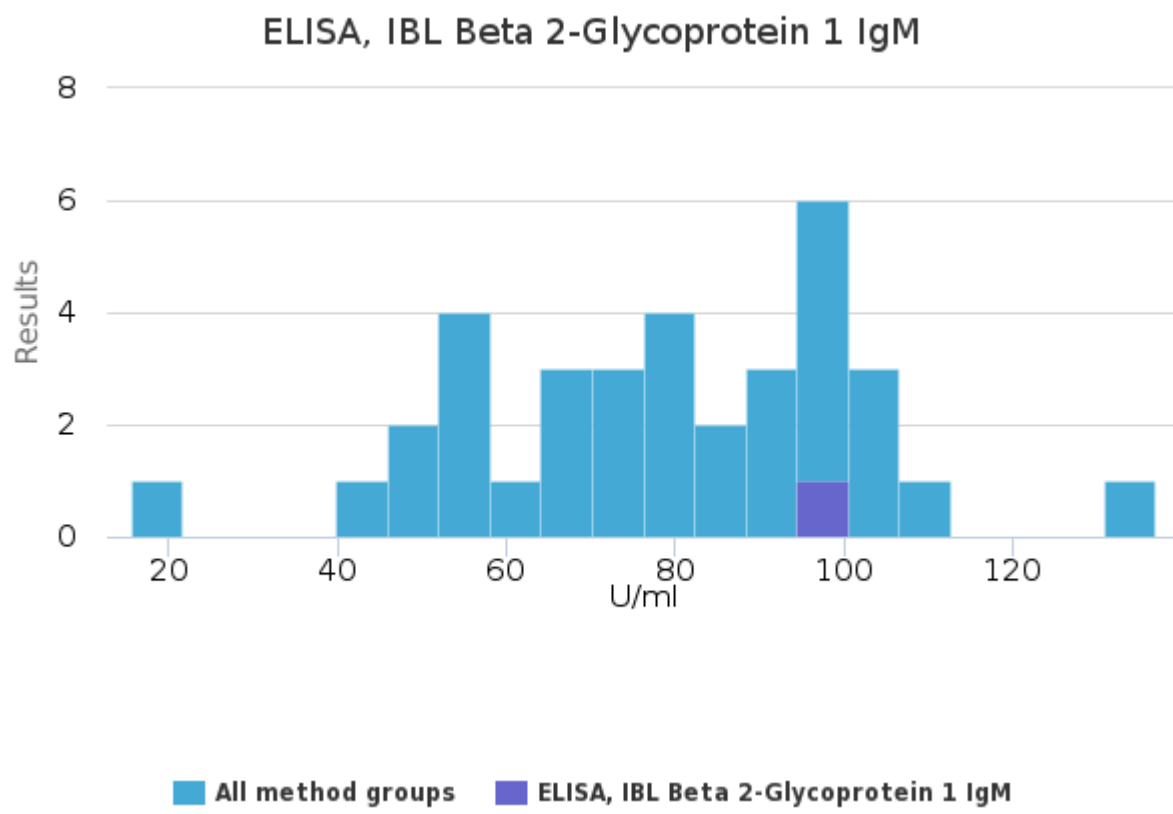
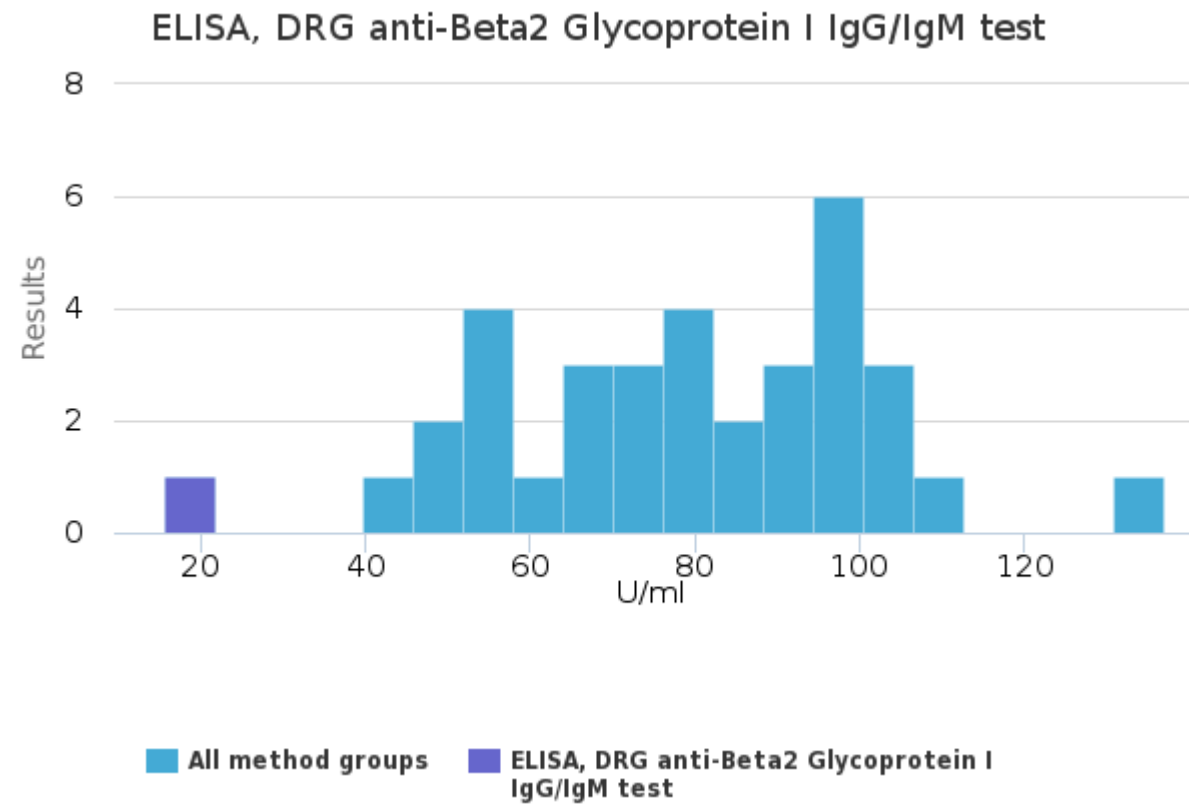
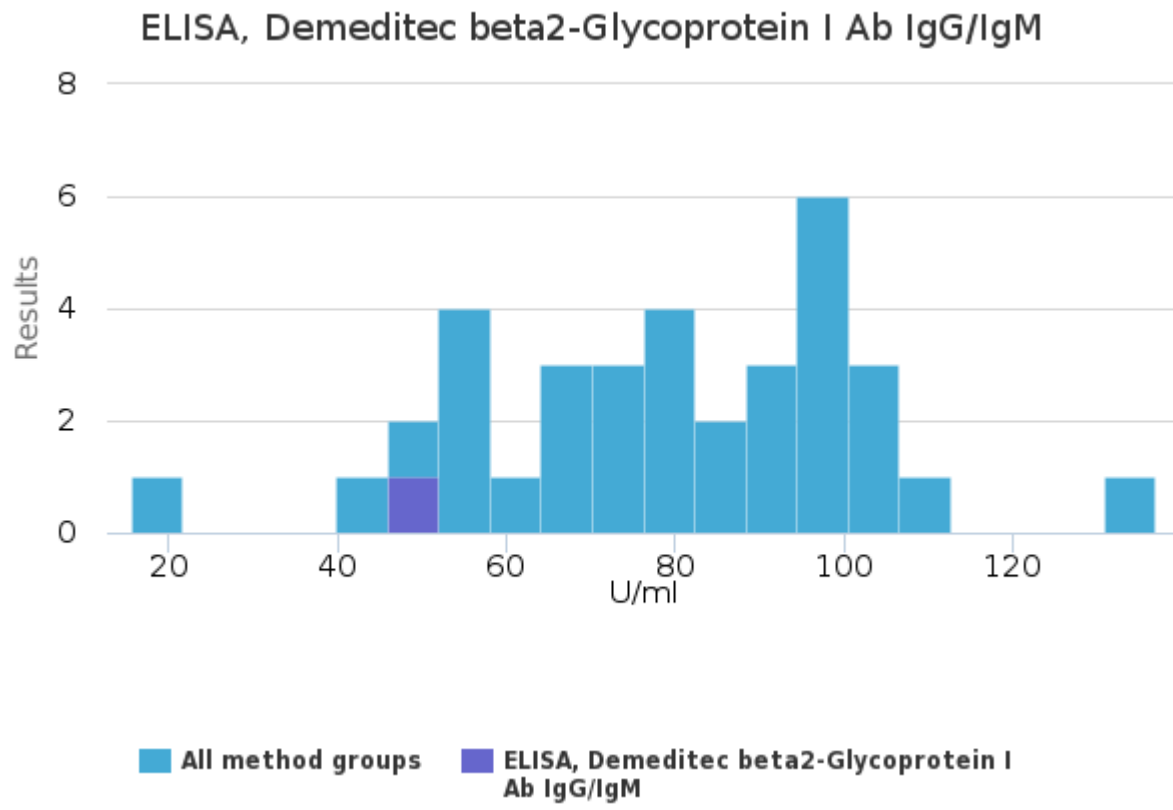


Sample S001 | 2-Glycoprotein IgM, U/ml

Methodics	Weak positive	Positive	Total
AESKULISA b2-Glyco-GM	-	1	1
Chorus BETA 2-GLYCOPROTEIN-M, Diesse	-	3	3
EliA Phadia, Thermo Scientific	-	11	11
ELISA, Aesku Diagnostics	-	1	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	-	1	1
ELISA, Diamedix	-	1	1
ELISA, DRG anti-Beta2 Glycoprotein I IgG/IgM test	1	-	1
ELISA, Euroimmun	-	5	5
ELISA, IBL Beta 2-Glycoprotein 1 IgM	-	1	1
ELISA, Inova Diagnostics	-	1	1
ELISA, Orgentec	-	11	11
Inova Quanta Flash B2GP1 IgM	-	4	4
Total	1	40	41

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
AESKULISA b2-Glyco-GM	-	-	-	-	-	44.8	44.8	-	1
Chorus BETA 2-GLYCOPROTEIN-M, Diesse	83.8	80.7	9.0	10.8	5.2	76.8	94.0	-	3
EliA Phadia, Thermo Scientific	89.2	90.6	12.3	13.8	3.7	72.0	111.0	-	11
ELISA, Aesku Diagnostics	-	-	-	-	-	54.2	54.2	-	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	-	-	-	-	-	50.2	50.2	-	1
ELISA, DRG anti-Beta2 Glycoprotein I IgG/IgM test	-	-	-	-	-	15.6	15.6	-	1
ELISA, IBL Beta 2-Glycoprotein 1 IgM	-	-	-	-	-	95.0	95.0	-	1
ELISA, Inova Diagnostics	-	-	-	-	-	136.9	136.9	-	1
ELISA, Orgentec	66.7	66.3	13.8	20.7	4.2	48.5	95.1	-	11
Inova Quanta Flash B2GP1 IgM	101.2	102.9	3.5	3.5	1.8	95.9	103.2	-	4
All	79.1	80.7	23.5	29.7	4.0	15.6	136.9	-	35





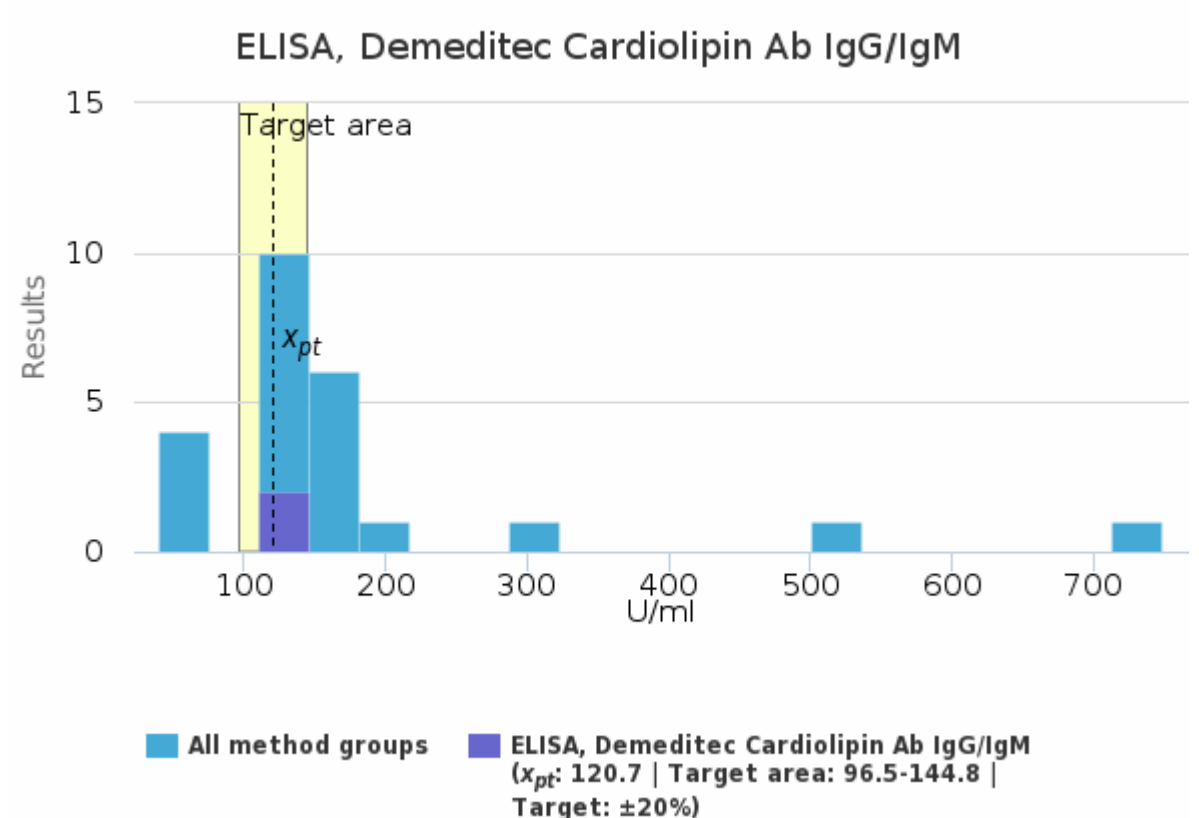
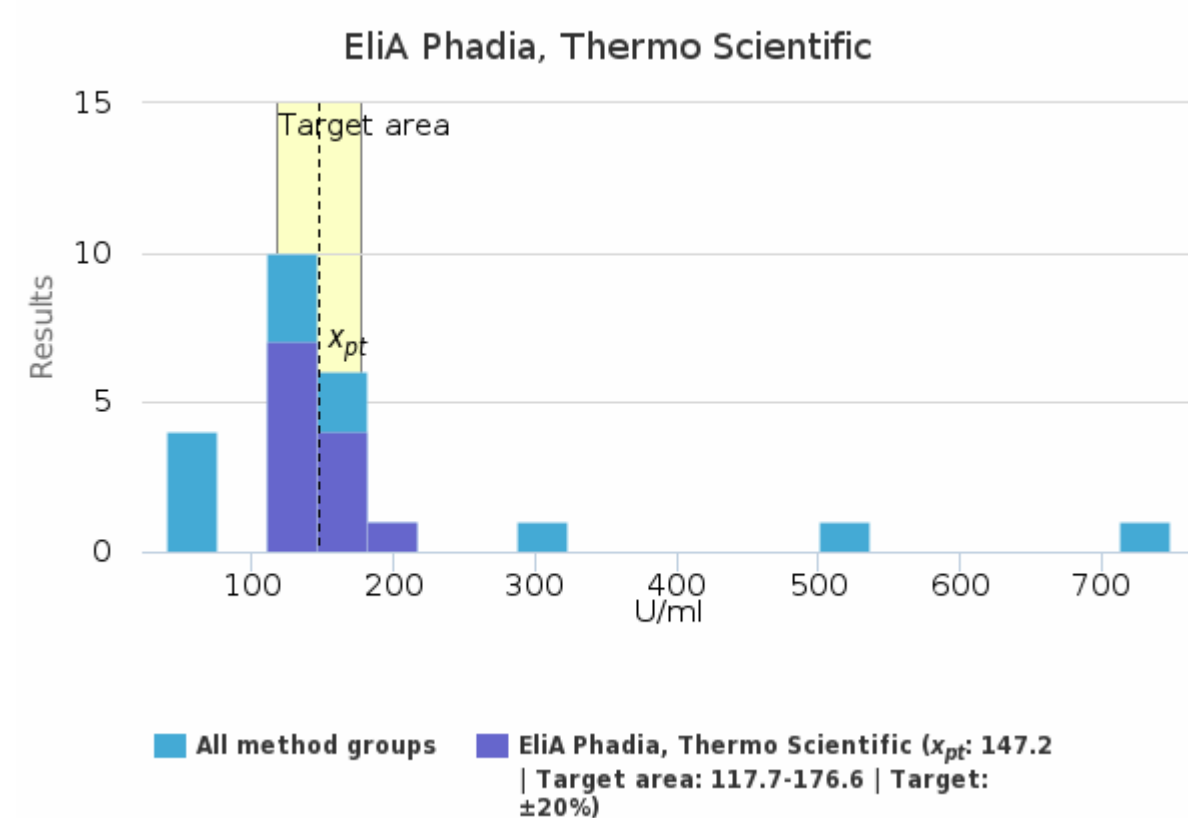
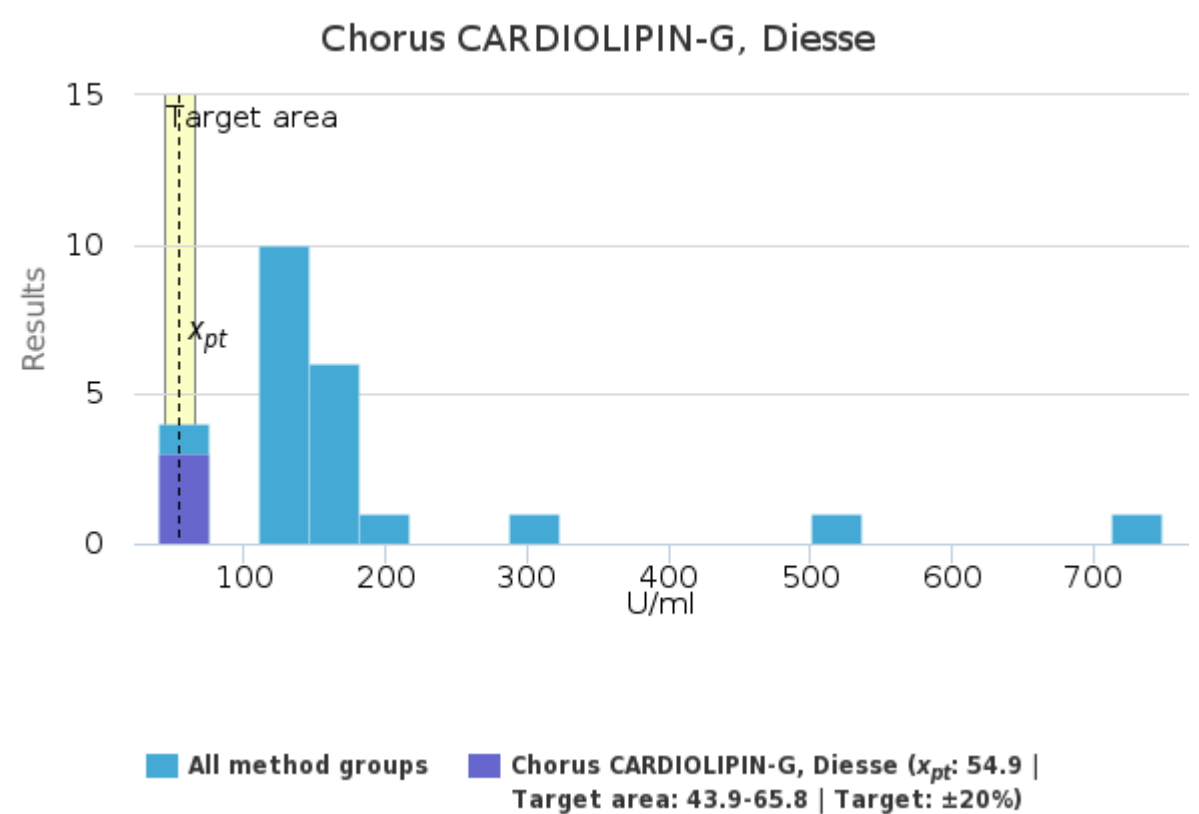
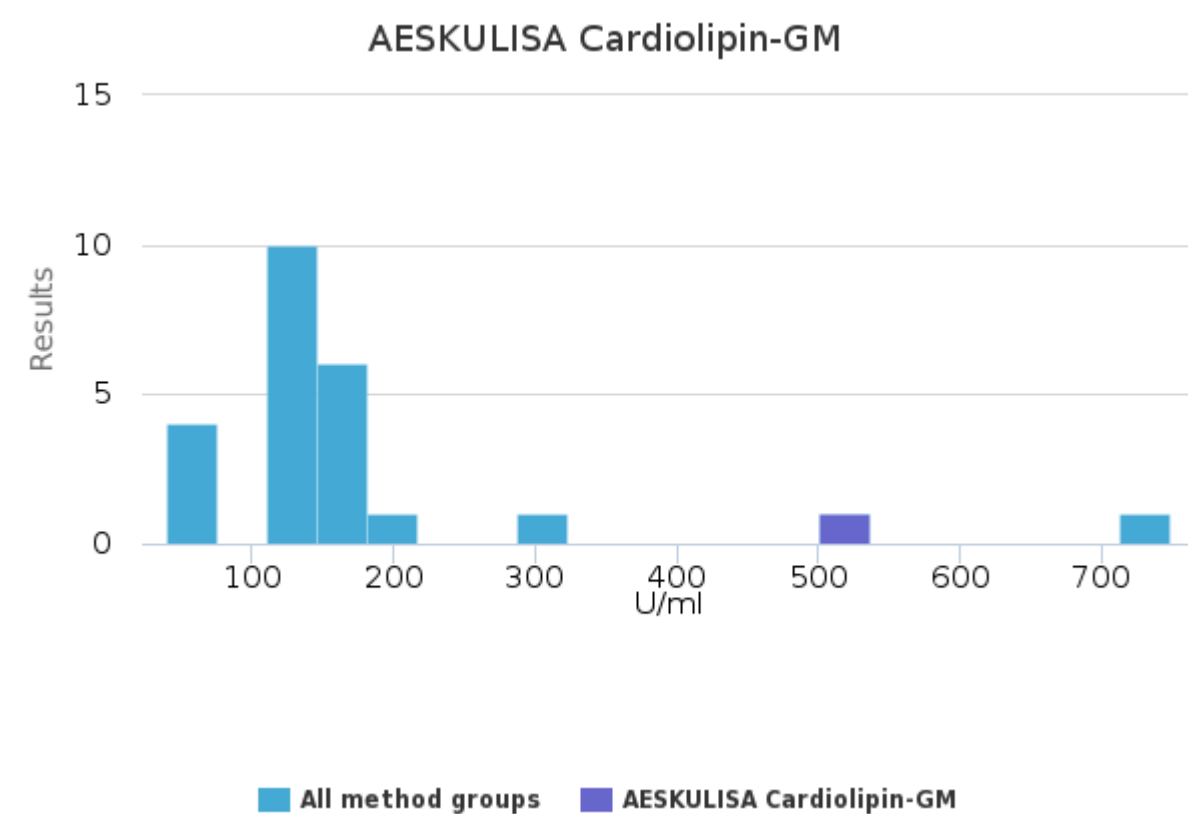
Sample S002 | ACA (screen), --

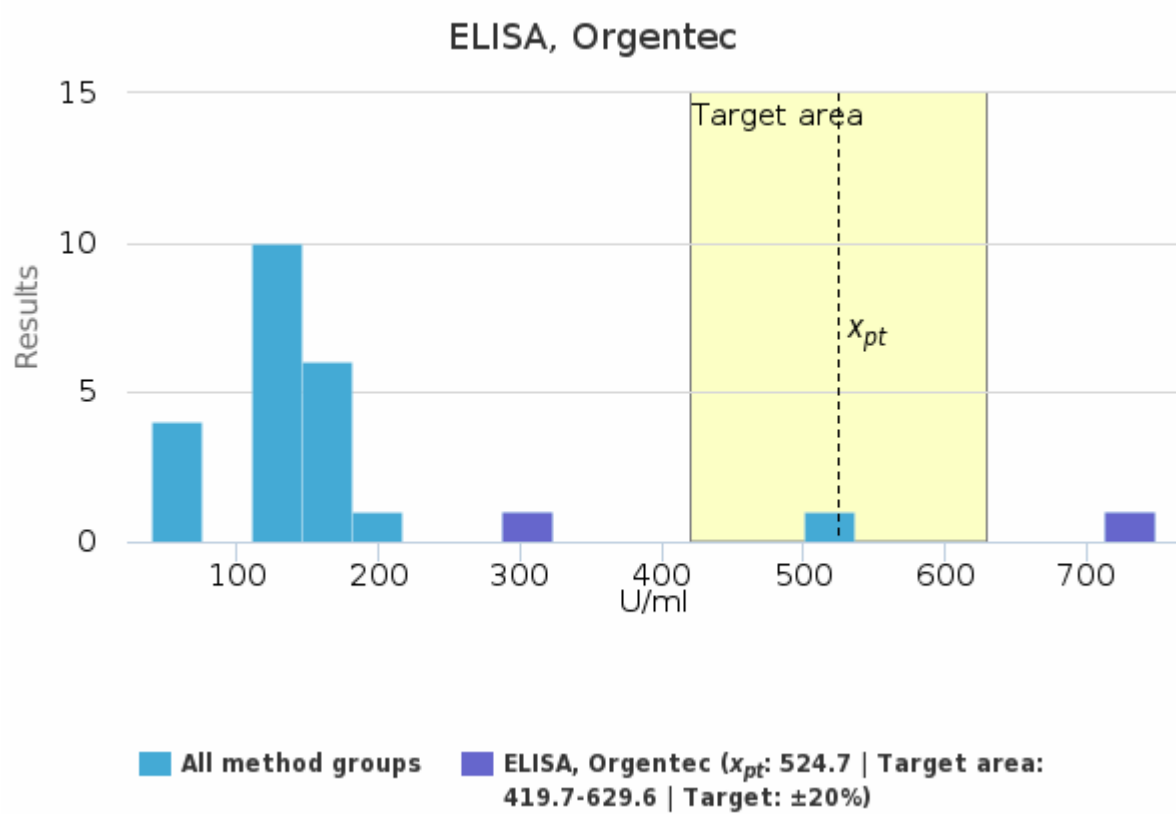
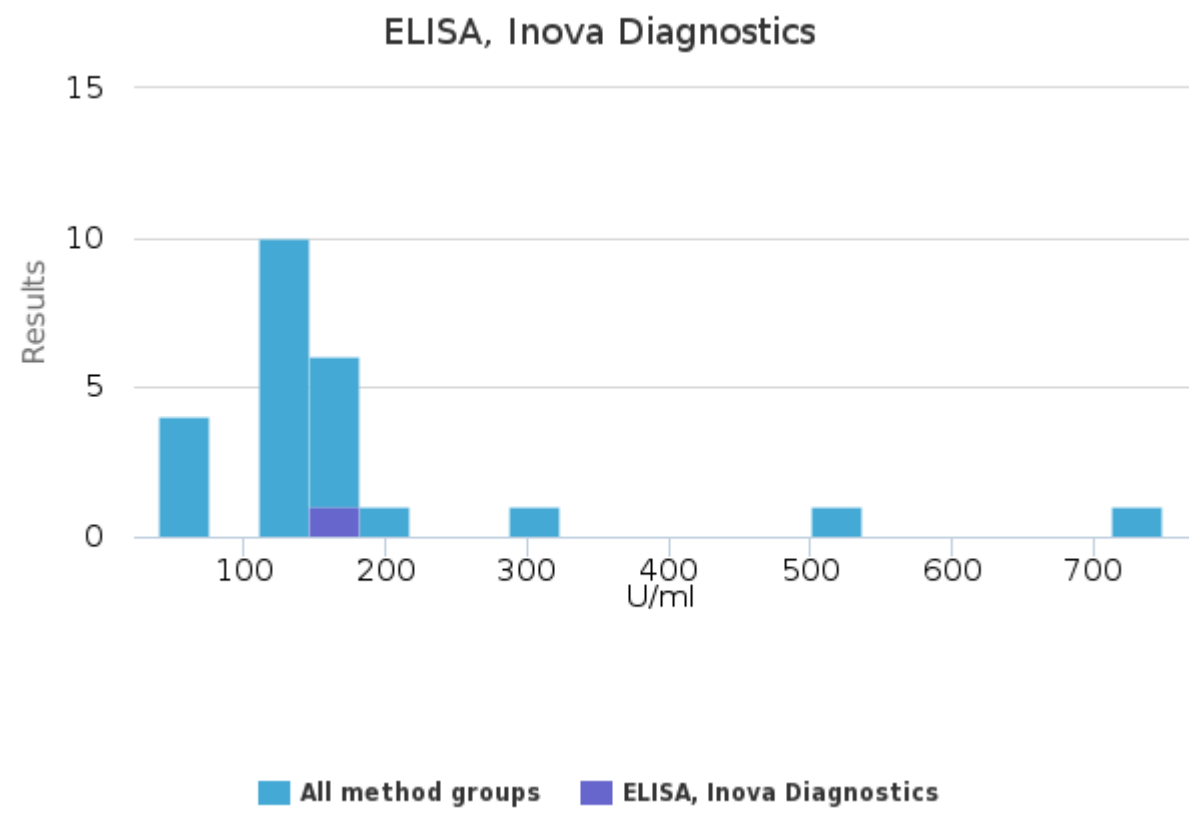
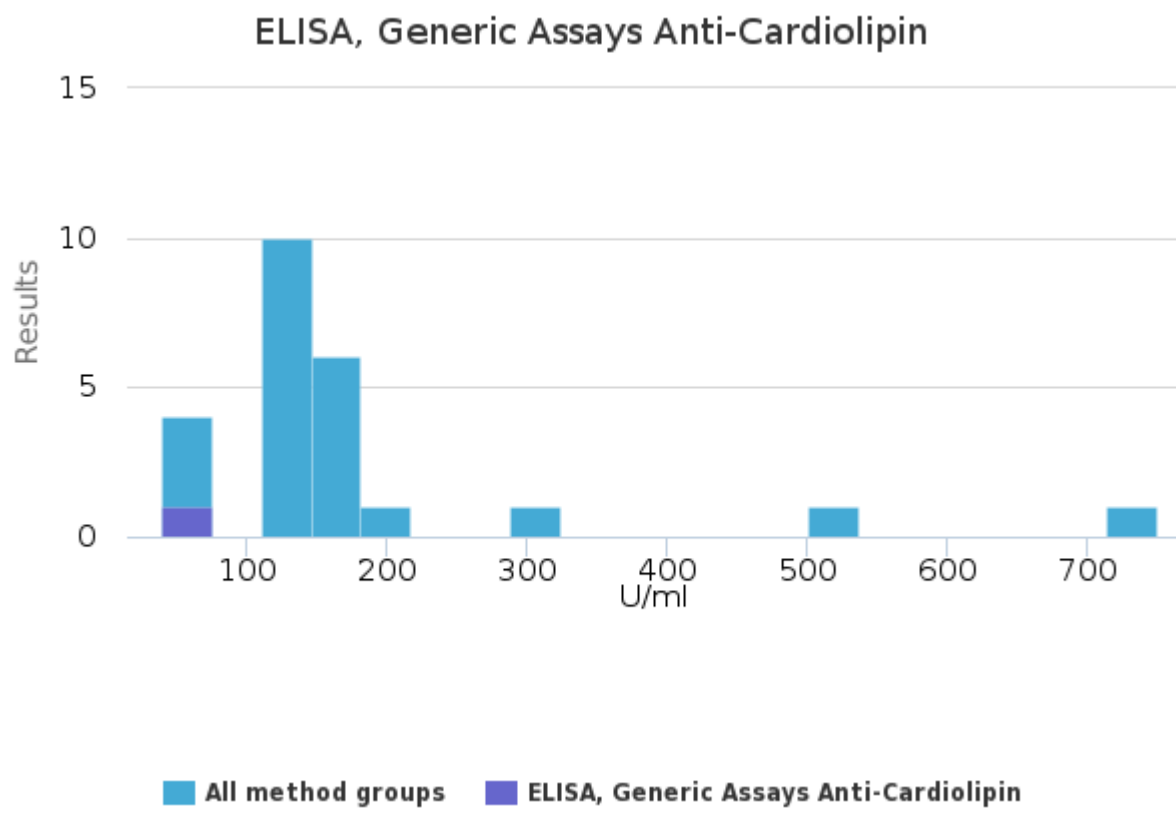
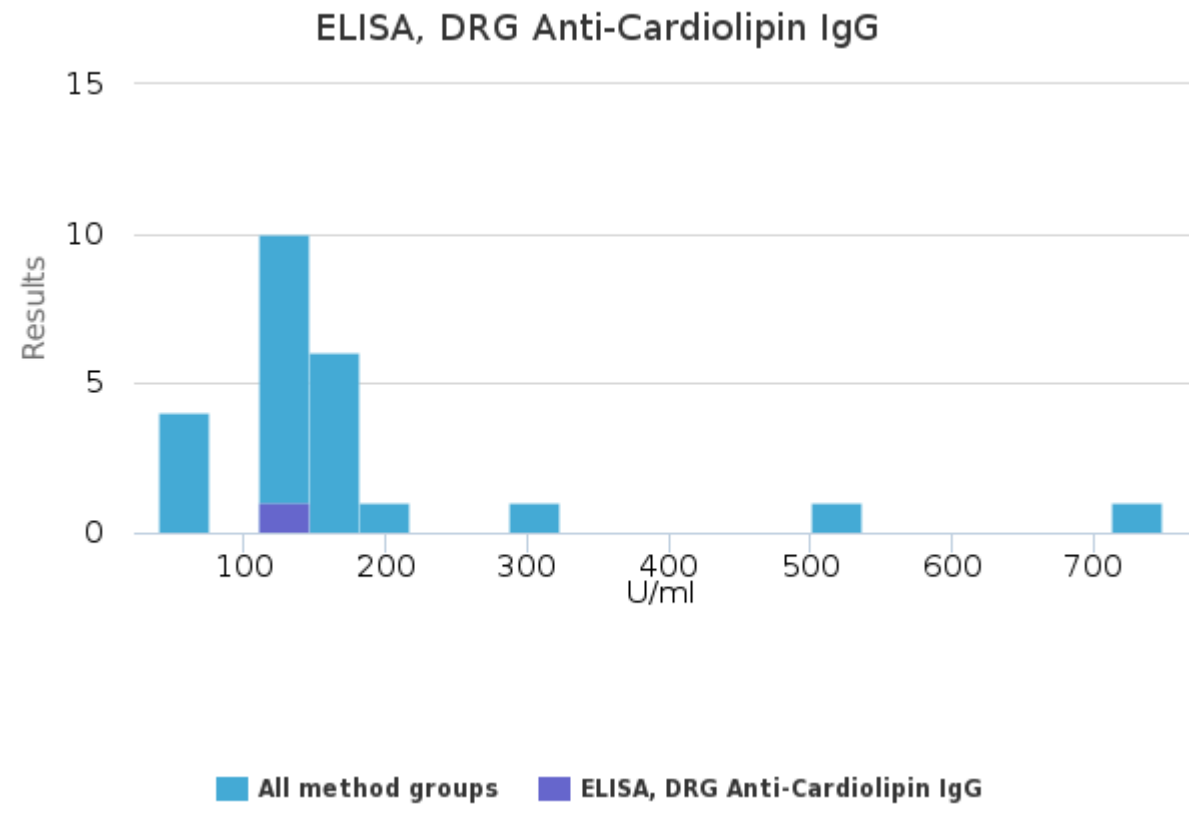
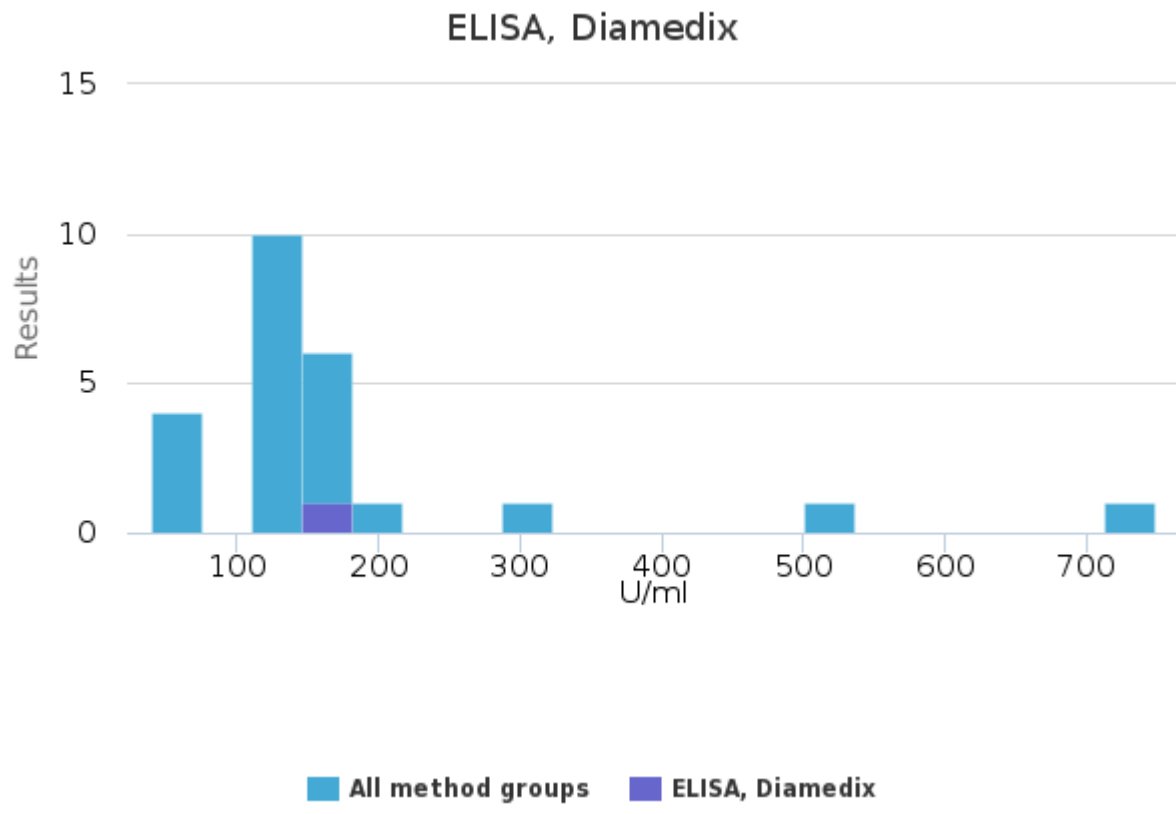
Methodics	Positive	Total
ELISA, Euroimmun	1	1
ELISA, Orgentec	2	2
Inova Quanta Lite ACA Screen III	1	1
Total	4	4

Sample S002 | ACA IgG, U/ml

Methodics	Weak positive	Positive	Total
AESKULISA Cardioliipin-GM	-	1	1
Chorus CARDIOLIPIN-G, Diesse	-	3	3
EliA Phadia, Thermo Scientific	1	12	13
ELISA, Aesku Diagnostics	-	1	1
ELISA, Demeditec Cardioliipin Ab IgG/IgM	-	2	2
ELISA, Diamedix	-	1	1
ELISA, DRG Anti-Cardioliipin IgG	-	1	1
ELISA, Euroimmun	-	5	5
ELISA, Generic Assays Anti-Cardioliipin	-	1	1
ELISA, Inova Diagnostics	-	1	1
ELISA, Orgentec	-	13	13
Inova Quanta Flash aCL IgG	-	4	4
Total	1	45	46

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
AESKULISA Cardioliipin-GM	-	-	-	-	-	503.4	503.4	-	1
Chorus CARDIOLIPIN-G, Diesse	54.9	57.1	9.2	16.7	5.3	44.8	62.7	-	3
EliA Phadia, Thermo Scientific	147.2	140.5	22.8	15.5	6.6	122.0	208.0	-	12
ELISA, Demeditec Cardioliipin Ab IgG/IgM	120.7	120.7	8.7	7.2	6.2	114.5	126.8	-	2
ELISA, Diamedix	-	-	-	-	-	154.4	154.4	-	1
ELISA, DRG Anti-Cardioliipin IgG	-	-	-	-	-	118.0	118.0	-	1
ELISA, Generic Assays Anti-Cardioliipin	-	-	-	-	-	39.5	39.5	-	1
ELISA, Inova Diagnostics	-	-	-	-	-	155.9	155.9	-	1
ELISA, Orgentec	524.7	524.7	317.3	60.5	224.4	300.3	749.0	-	2
All	149.7	139.0	94.3	63.0	19.7	39.5	503.4	1	24





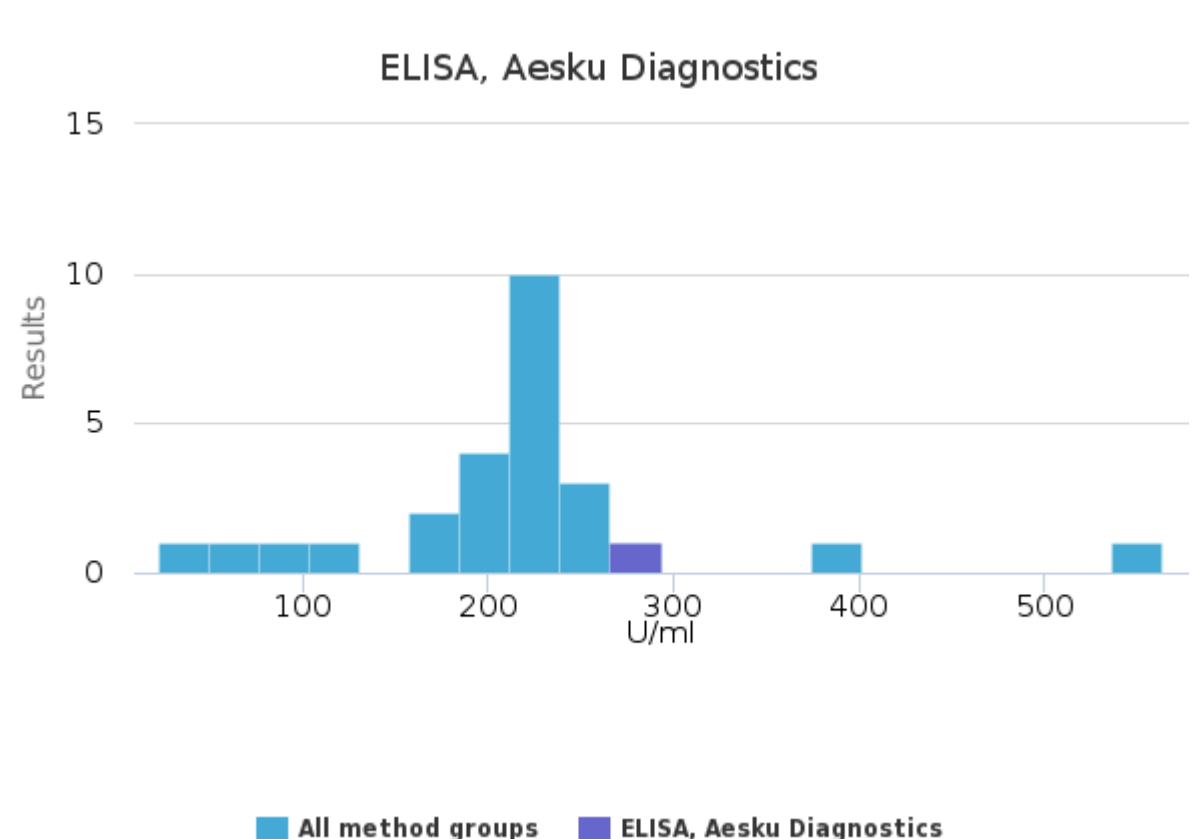
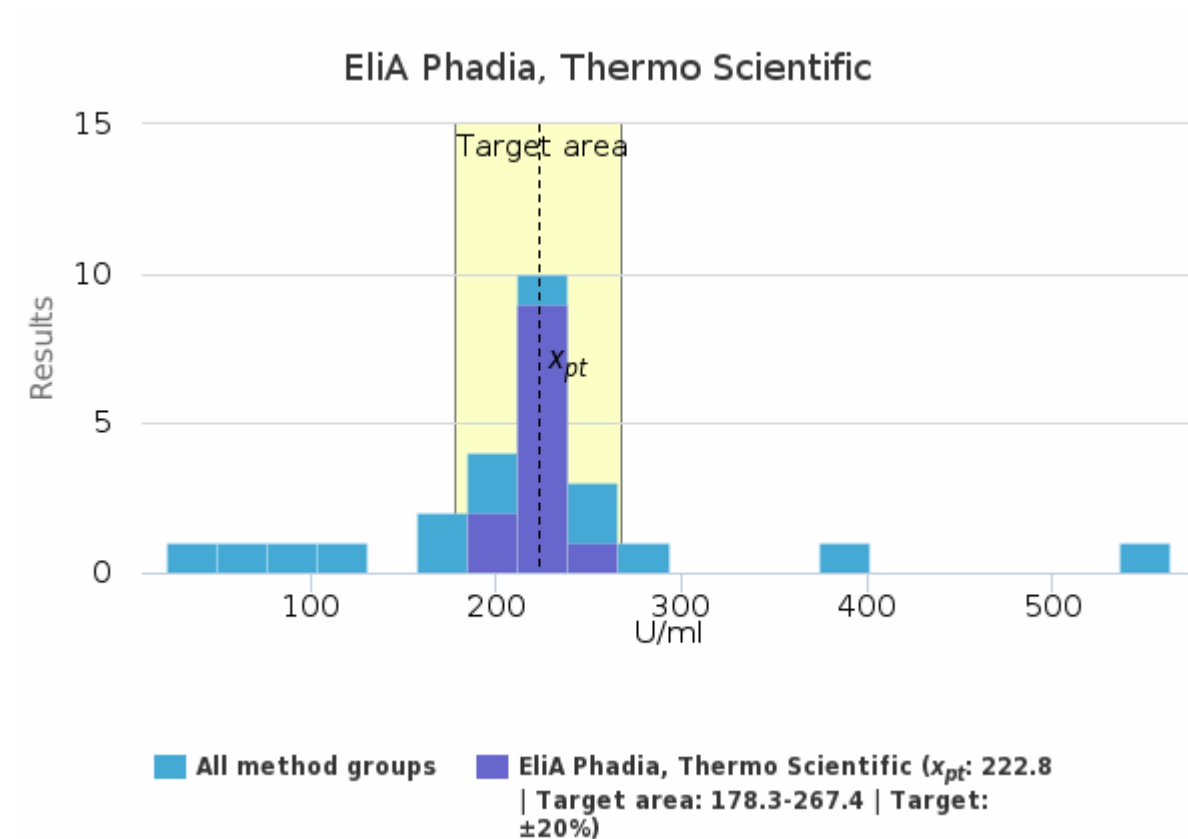
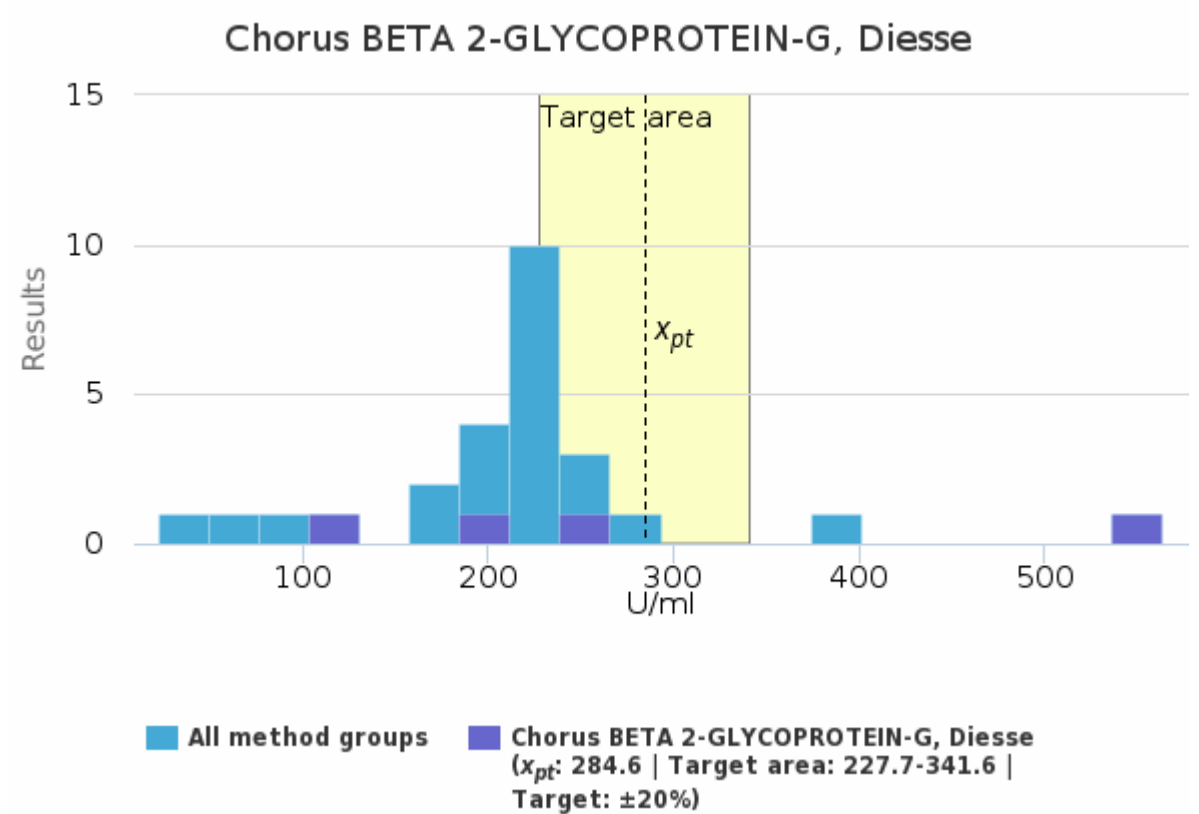
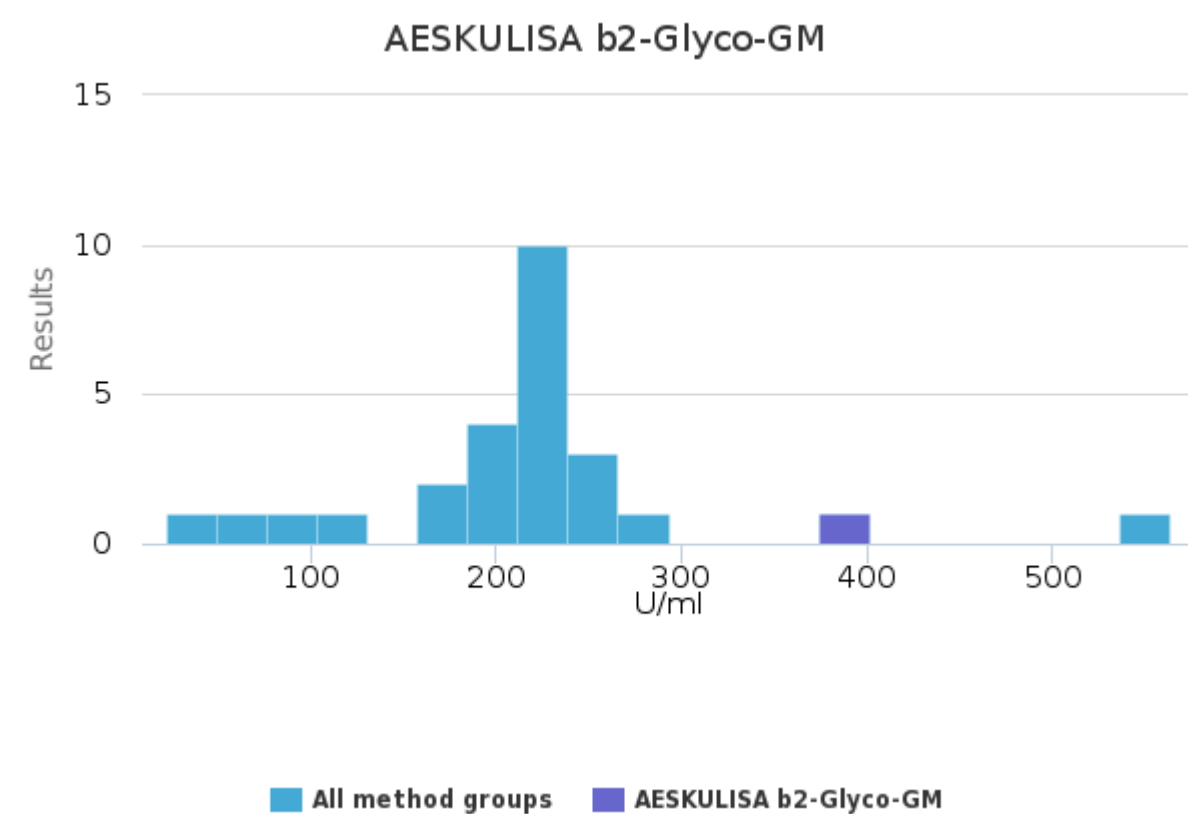
Sample S002 | ACA IgM, U/ml

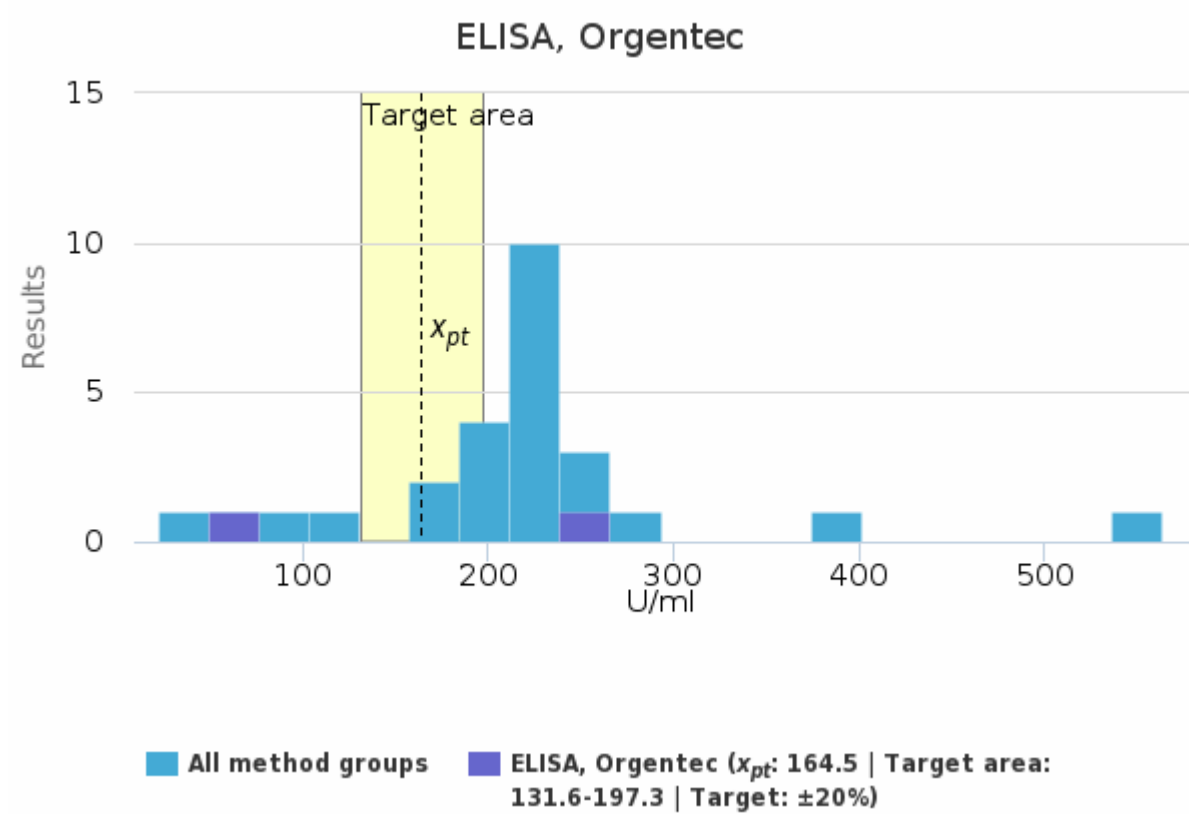
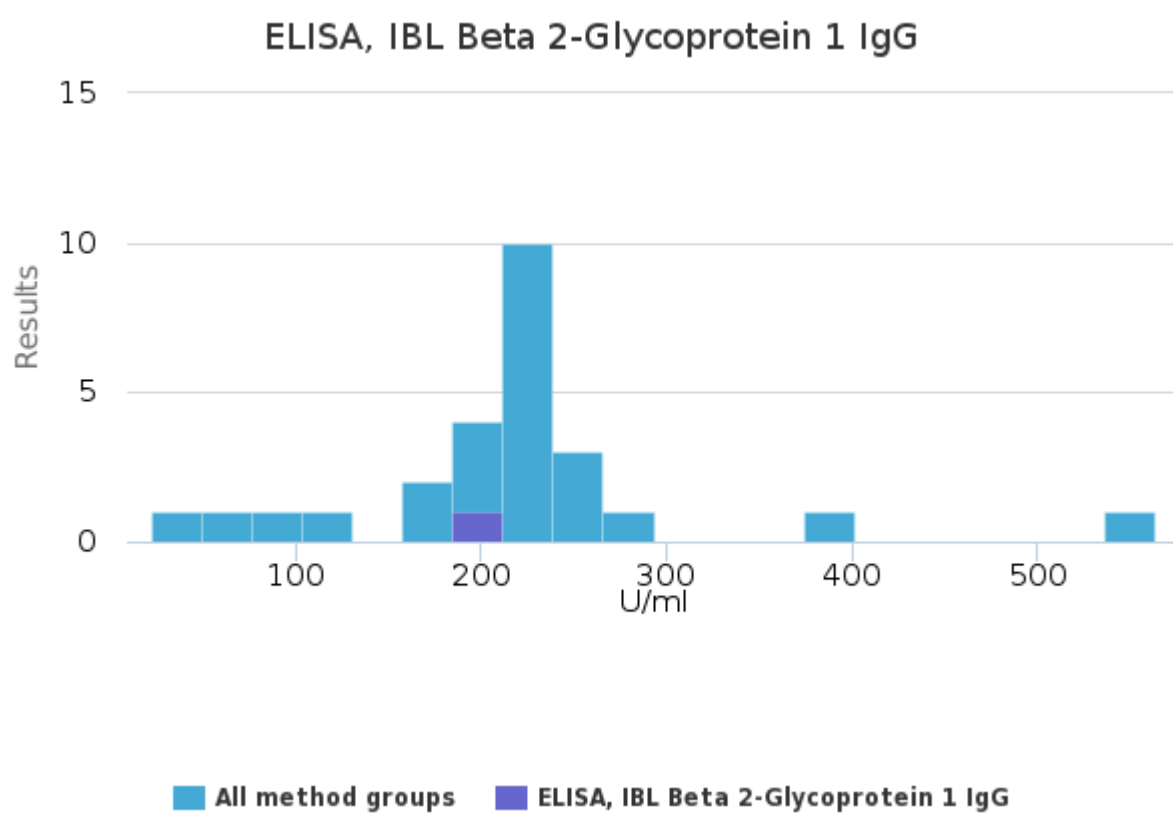
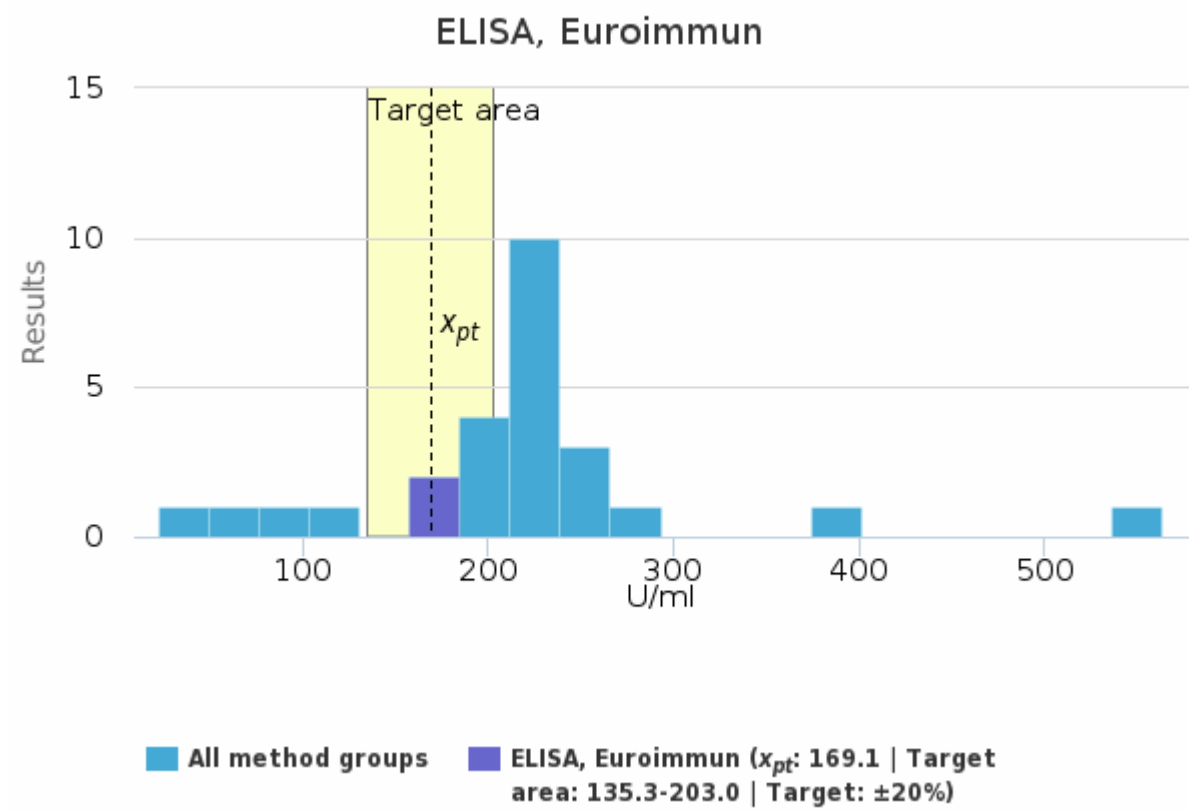
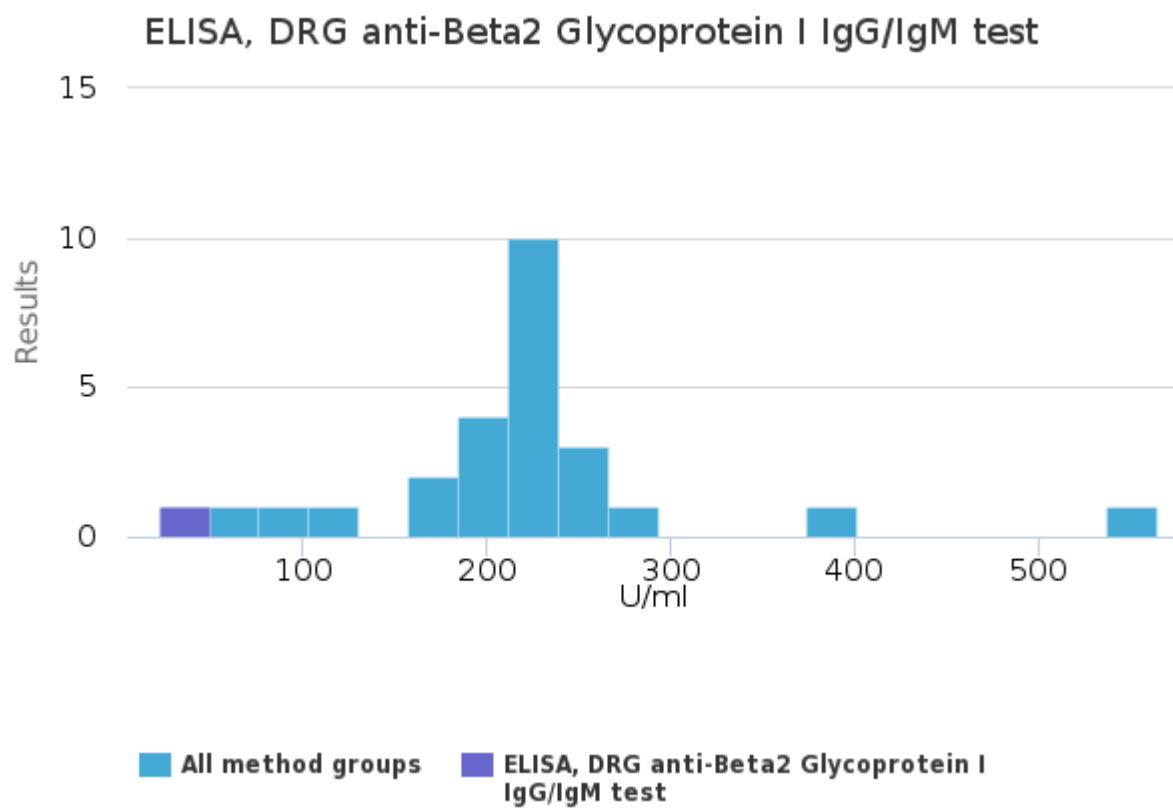
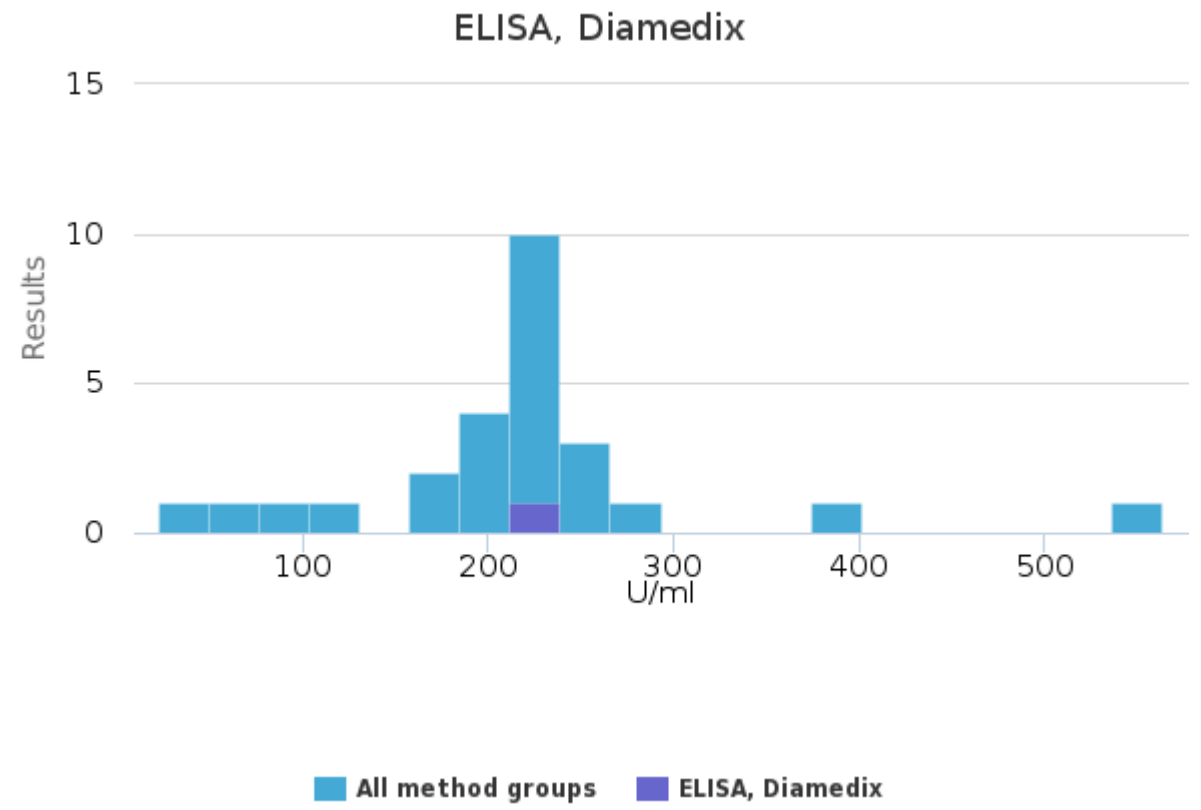
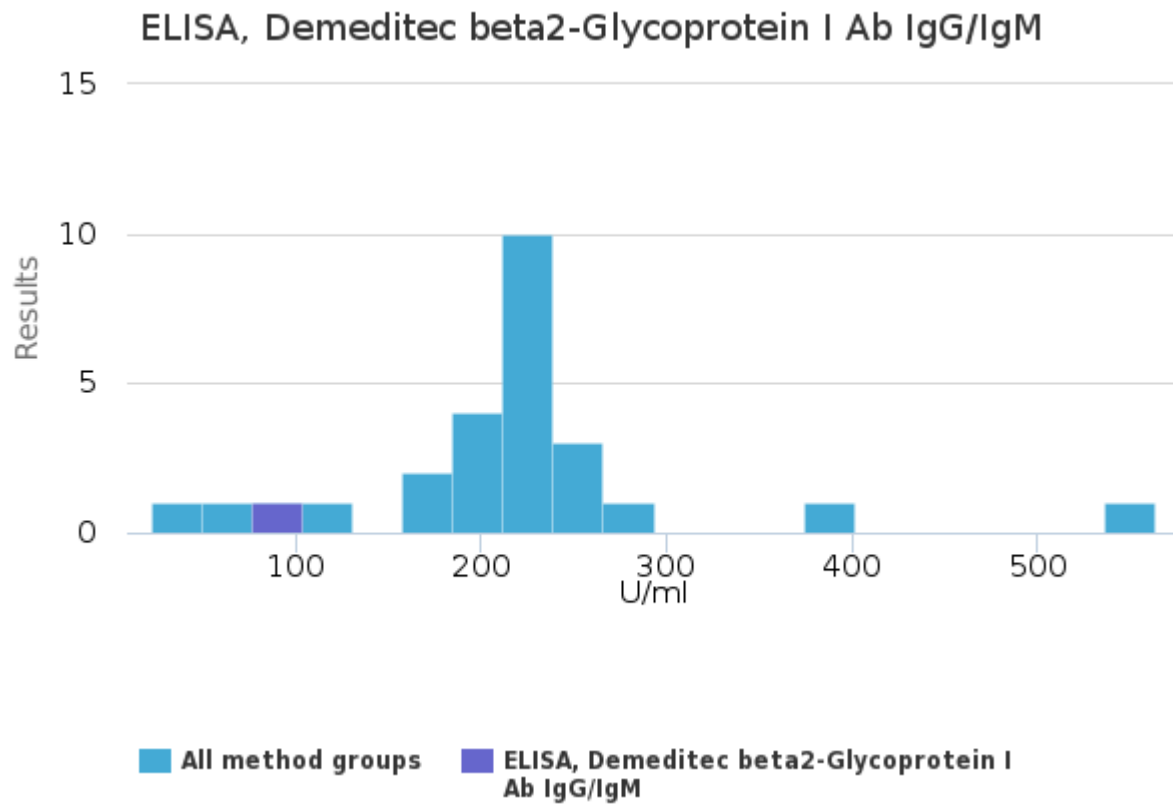
Methodics	Negative	Weak positive	Total
AESKULISA Cardioliipin-GM	1	-	1
Chorus CARDIOLIPIN-M, Diesse	2	-	2
EliA Phadia, Thermo Scientific	13	-	13
ELISA, Aesku Diagnostics	1	-	1
ELISA, Demeditec Cardioliipin Ab IgG/IgM	2	-	2
ELISA, Diamedix	1	-	1
ELISA, DRG Anti-Cardioliipin IgM	-	1	1
ELISA, Euroimmun	5	-	5
ELISA, Generic Assays Anti-Cardioliipin	1	-	1
ELISA, Inova Diagnostics	1	-	1
ELISA, Orgentec	13	-	13
Inova Quanta Flash aCL IgM	4	-	4
Total	44	1	45

Sample S002 | 2-Glycoprotein IgG, U/ml

Methodics	Weak positive	Positive	Total
AESKULISA b2-Glyco-GM	-	1	1
Chorus BETA 2-GLYCOPROTEIN-G, Diesse	-	4	4
EliA Phadia, Thermo Scientific	-	13	13
ELISA, Aesku Diagnostics	-	1	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	-	1	1
ELISA, Diamedix	-	1	1
ELISA, DRG anti-Beta2 Glycoprotein I IgG/IgM test	1	-	1
ELISA, Euroimmun	-	5	5
ELISA, IBL Beta 2-Glycoprotein 1 IgG	-	1	1
ELISA, Orgentec	-	12	12
Inova Quanta Flash B2GP1 IgG	-	4	4
Total	1	43	44

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
AESKULISA b2-Glyco-GM	-	-	-	-	-	374.9	374.9	-	1
Chorus BETA 2-GLYCOPROTEIN-G, Diesse	284.6	225.1	193.9	68.1	97.0	124.4	564.0	-	4
EliA Phadia, Thermo Scientific	222.8	220.5	15.6	7.0	4.5	205.0	265.0	-	12
ELISA, Aesku Diagnostics	-	-	-	-	-	288.8	288.8	-	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	-	-	-	-	-	80.6	80.6	-	1
ELISA, Diamedix	-	-	-	-	-	215.8	215.8	-	1
ELISA, DRG anti-Beta2 Glycoprotein I IgG/IgM test	-	-	-	-	-	22.0	22.0	-	1
ELISA, Euroimmun	169.1	169.1	12.8	7.6	9.1	160.1	178.2	-	2
ELISA, IBL Beta 2-Glycoprotein 1 IgG	-	-	-	-	-	186.8	186.8	-	1
ELISA, Orgentec	164.5	164.5	126.6	77.0	89.5	74.9	254.0	-	2
All	203.4	215.0	71.6	35.2	14.3	22.0	374.9	1	26





Sample S002 | 2-Glycoprotein IgM, U/ml

Methodics	Negative	Positive	Total
AESKULISA b2-Glyco-GM	1	-	1
Chorus BETA 2-GLYCOPROTEIN-M, Diesse	3	-	3
EliA Phadia, Thermo Scientific	11	-	11
ELISA, Aesku Diagnostics	1	-	1
ELISA, Demeditec beta2-Glycoprotein I Ab IgG/IgM	1	-	1
ELISA, Diamedix	1	-	1
ELISA, DRG anti-Beta2 Glycoprotein I IgG/IgM test	-	1	1
ELISA, Euroimmun	5	-	5
ELISA, IBL Beta 2-Glycoprotein 1 IgM	1	-	1
ELISA, Inova Diagnostics	1	-	1
ELISA, Orgentec	11	-	11
Inova Quanta Flash B2GP1 IgM	4	-	4
Total	40	1	41

Report info**Participants**

46 participants from 16 countries.

Report info

Qualitative and quantitative results are presented in the same report. Always compare your results to those obtained with the same test kit.

The qualitative results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green colour and laboratory's own result with a black radio button .

The quantitative results from the positive specimens are presented as histograms. Quantitative results reported with < or > -signs are not processed. Results reported as ratios, titres, absorbances and without a unit are manually removed and not statistically processed.

Assigned values (target values) are mean 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 participant specific report your own result is shown with an orange dot. The target area is presented as a yellow area in the picture. In the history graphs you are able to see your performance graphically with both against the assigned value (xpt) and the z-score area of -2 ... +2.

If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EOA Coordinator.

External Quality Assessment Scheme

Phospholipid antibodies Round 1, 2023

Specimens

Samples of this EQA round were human plasma or serum. Based on the pre-testing and the results obtained in the round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

The expected results were as follows:

Sample S001 (LQ717323011)

Anti-Cardiolipin antibodies (ACA Screen)	Positive
Anti-Cardiolipin antibodies (ACA), IgG	Negative (no consensus)
Anti-Cardiolipin antibodies (ACA), IgM	Positive
Anti-β2-Glycoprotein I antibodies, IgG	Negative (no consensus)
Anti-β2-Glycoprotein I antibodies, IgM	Positive

Sample S002 (LQ717323012)

Anti-Cardiolipin antibodies (ACA Screen)	Positive
Anti-Cardiolipin antibodies (ACA), IgG	Positive
Anti-Cardiolipin antibodies (ACA), IgM	Negative
Anti-β2-Glycoprotein I antibodies, IgG	Positive
Anti-β2-Glycoprotein I antibodies, IgM	Negative

Pre-test methods: EliA Cardiolipin IgG, EliA Cardiolipin IgM, EliA β2-Glycoprotein I IgG, EliA β2-Glycoprotein I IgM.

Report info

Please see the description of the data analysis on the last page of the laboratory-specific reports and global 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

For sample S001, no consensus was reached on IgG cardiolipin and IgG B2GPI antibodies. Interestingly, two tests with highest participant number had distinct results: the other reported the sample to be anti-cardiolipin and anti-B2GPI IgG negative while the participants using the other method reported the sample to be positive. Anyhow, the antibody levels reported were low. We must remember that even though cardiolipin and B2GPI IgG autoantibodies are important criterion for APS, the antibodies alone are not diagnostic. The quantitative levels on antibodies detected from the sample S001 were also very low in case of IgM antibodies, but there were no discrepancies in results.

Sample S002 was clearer and there were no major difficulties. Anyhow, because the antibody levels were high, some participants probably diluted the sample. It should be noticed that dilution is not required for quality samples. It's acceptable to report the results "over" detection level.

Exceptions

No consensus was reached for IgG cardiolipin and IgG B2GPI antibodies in sample S001.

Annex

The numbers of results reported in the round that exceed the upper limit of the method's measurement range are shown by method and analyte in Annex 1.

2023-06-16

FINAL REPORT

Product no. 5937

Subcontracting: Sample pretesting

Samples sent	2023-05-09
Round closed	2023-06-02
Expected results	2023-06-07
Final report	2023-06-16

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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End of report

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Annex 1. Number of results exceeding the upper limit of the measuring range by method and analyte.

	S001	S001	S002	S002
	Analyte	Analyte	Analyte	Analyte
Method	B2GPAbM	KardAbM	B2GPAbG	KardAbG
ELISA, Euroimmun	5/5 of the results	3/5 of the results	3/5 of the results	5/5 of the results
ELISA, Orgentec		7/12 of the results	7/12 of the results	7/13 of the results
Inova Quanta Flash B2GP1 IgG			3/4 of the results	
ELISA, Aesku Diagnostics				1/1 of the results
Inova Quanta Flash aCL IgG				3/4 of the results