

External Quality Assessment Scheme

ANCA and GbmAb 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

ANCA	Anti-neutrophilic cytoplasmic antibodies and Immunofluorescent test for ANCA (atypical, cytoplasmic or perinuclear)
MPOAb	Myeloperoxidase antibodies
Pr3Ab	Proteinase-3 antibodies
GbmAb	Glomerular basement membrane antibodies

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 reagent from the registry, please contact the EQA Coordinator. Report only the results of examinations that are in use in your laboratory.

S001



S002



2023-02-21

INSTRUCTIONS

Product no. 5935
LQ717223011-012/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 **March 16, 2023**.

The expected results of the round are published in LabScala in the View Reports section by March 21, 2023.

Inquiries

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ANCA

Sample S001

Methodics	Positive	Total
IFA (Aesku Diagnostics)	1	1
IFA Zenit (Menarini Diagnostics)	1	1
IFA (Euroimmun)	13	13
IFA (Inova)	4	4
ELISA (Euroimmun)	1	1
ELISA (Orgentec)	3	3
Total	23	23

Sample S002

Methodics	Positive	Total
IFA (Aesku Diagnostics)	1	1
IFA Zenit (Menarini Diagnostics)	1	1
IFA (Euroimmun)	13	13
IFA (Inova)	4	4
ELISA (Euroimmun)	1	1
ELISA (Orgentec)	3	3
Total	23	23

Fluorescence pattern

Sample S001

Methodics	P-ANCA	Total
Fluorescence pattern	20	20
Total	20	20

Sample S002

Methodics	P-ANCA	Total
Fluorescence pattern	20	20
Total	20	20

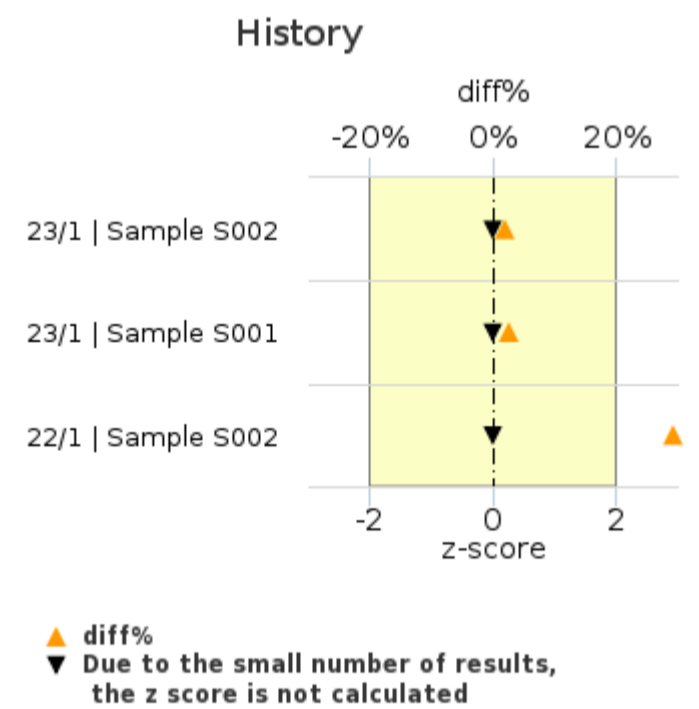
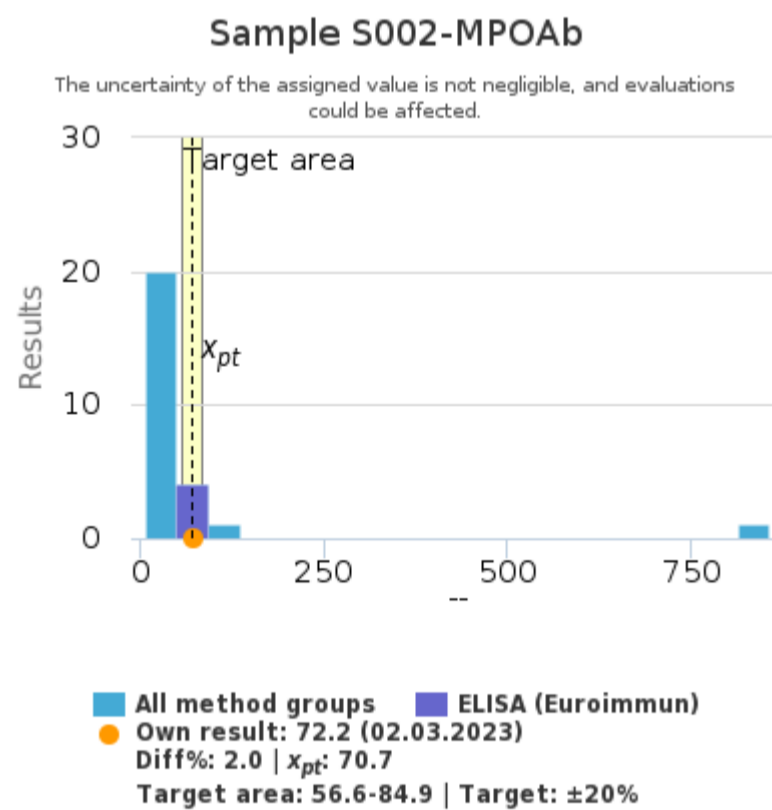
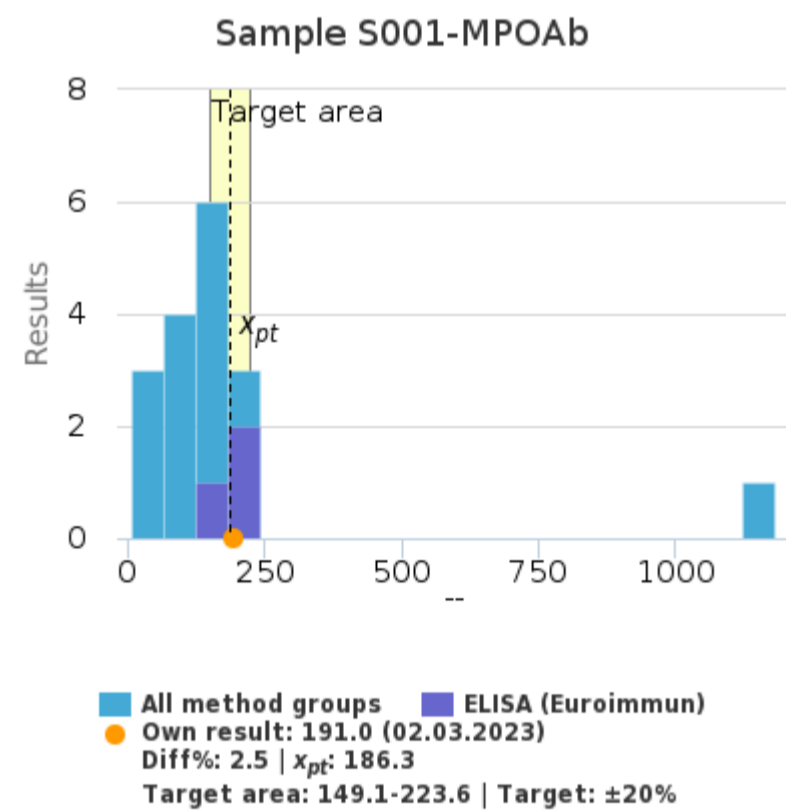
MPOAb

Sample S001

Methodics	Negative	Positive	Total
CIA (Inova)	-	1	1
ELISA (Euroimmun)	-	4	4
ELISA (Inova)	-	1	1
ELISA (Orgentec)	1	2	3
ELISA Chorus (Diesse)	-	1	1
Immunoblot (Aesku Diagnostics)	-	1	1
Euroline immunoblot (Euroimmun)	-	4	4
Phadia EliA (ThermoScientific)	-	16	16
ELISA (ZEUS Scientific)	-	1	1
BioPlex 2200 (BIO-RAD)	-	1	1
CLIA (Immunodiagnostic Systems)	-	1	1
Total	1	33	34

Sample S002

Methodics	Negative	Borderline	Positive	Total
CIA (Inova)	-	-	1	1
ELISA (Euroimmun)	-	-	4	4
ELISA (Inova)	-	-	1	1
ELISA (Orgentec)	1	-	2	3
ELISA Chorus (Diesse)	-	-	1	1
Immunoblot (Aesku Diagnostics)	-	-	1	1
Euroline immunoblot (Euroimmun)	-	-	4	4
Phadia EliA (ThermoScientific)	1	-	15	16
ELISA (ZEUS Scientific)	-	-	1	1
BioPlex 2200 (BIO-RAD)	-	-	1	1
CLIA (Immunodiagnostic Systems)	-	1	-	1
Total	2	1	31	34



	x_{pt}	sd	SEM	CV%	n
ELISA (Euroimmun)	186.3 --	4.5	2.6	2.4	3
All methods	129.7 --	58.9	14.7	45.4	17

	x_{pt}	sd	SEM	CV%	n
ELISA (Euroimmun)	70.7 --	12.8	6.4	18.2	4
All methods	40.0 --	21.6	4.3	54.0	26

Round	Sample	x_{pt}	Result	diff%	z-score
23/1	Sample S002	70.7	72.2	2.0%	-
23/1	Sample S001	186.3	191.0	2.5%	-
22/1	Sample S002	282.5	365.0	29.2%	-

Pr3Ab

Sample S001

Methodics	Negative	Positive	Total
CIA (Inova)	1	-	1
ELISA (Euroimmun)	4	-	4
ELISA (Inova)	1	-	1
ELISA (Orgentec)	3	-	3
ELISA Chorus (Diesse)	1	-	1
Immunoblot (Aesku Diagnostics)	1	-	1
Euroline immunoblot (Euroimmun)	4	-	4
Phadia EliA (ThermoScientific)	15	1	16
ELISA (ZEUS Scientific)	1	-	1
BioPlex 2200 (BIO-RAD)	1	-	1
CLIA (Immunodiagnostic Systems)	1	-	1
Total	33	1	34

Sample S002

Methodics	Negative	Positive	Total
CIA (Inova)	1	-	1
ELISA (Euroimmun)	4	-	4
ELISA (Inova)	1	-	1
ELISA (Orgentec)	3	-	3
ELISA Chorus (Diesse)	1	-	1
Immunoblot (Aesku Diagnostics)	1	-	1
Euroline immunoblot (Euroimmun)	4	-	4
Phadia EliA (ThermoScientific)	16	-	16
ELISA (ZEUS Scientific)	1	-	1
BioPlex 2200 (BIO-RAD)	1	-	1
CLIA (Immunodiagnostic Systems)	1	-	1
Total	34	0	34

GbmAb

Sample S001

Methodics	Negative	Total
IFA (Euroimmun)	3	3
ELISA (Euroimmun)	1	1
ELISA (Inova)	1	1
ELISA (Orgentec)	2	2
Immunoblot (Aesku Diagnostics)	1	1
Euroline immunoblot (Euroimmun)	4	4
Phadia EliA (ThermoScientific)	12	12
Total	24	24

Sample S002

Methodics	Negative	Positive	Total
IFA (Euroimmun)	3	-	3
ELISA (Euroimmun)	-	1	1
ELISA (Inova)	1	-	1
ELISA (Orgentec)	2	-	2
Immunoblot (Aesku Diagnostics)	1	-	1
Euroline immunoblot (Euroimmun)	4	-	4
Phadia EliA (ThermoScientific)	12	-	12
Total	23	1	24

Report info**Participants**

35 participants from 12 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 | ANCA

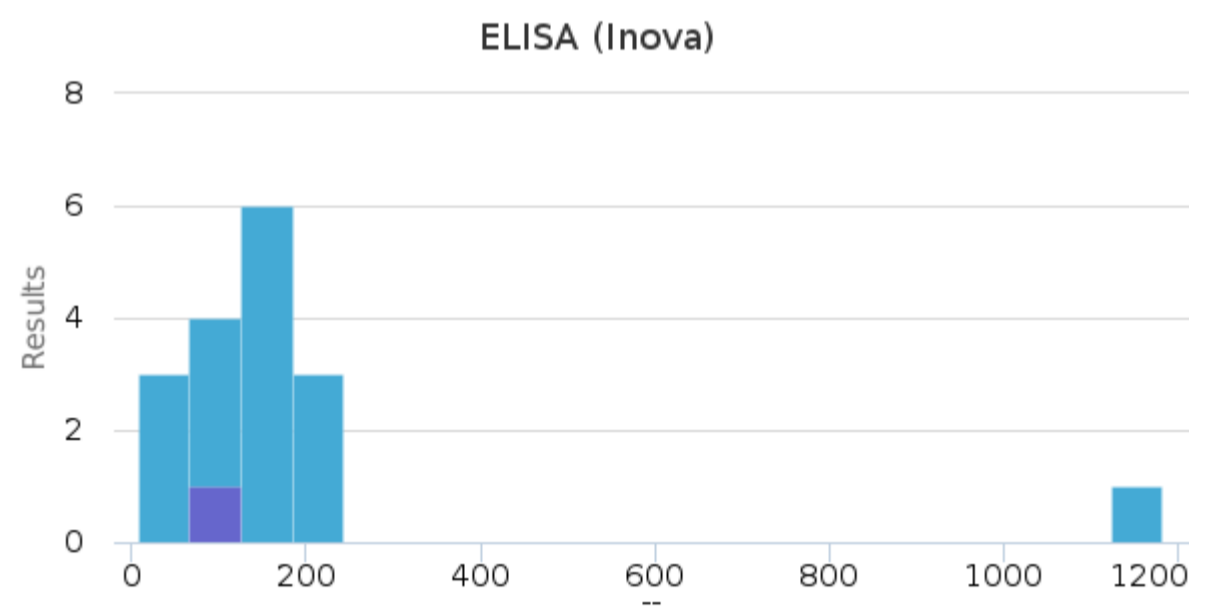
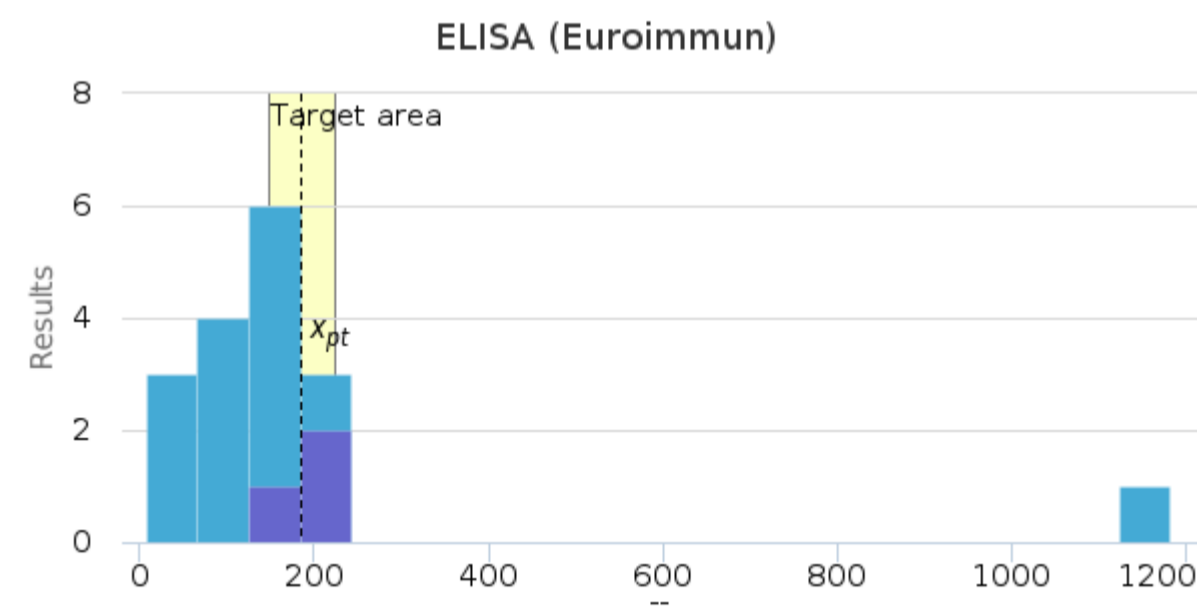
Methodics	Positive	Total
ELISA (Euroimmun)	1	1
ELISA (Orgentec)	3	3
IFA (Aesku Diagnostics)	1	1
IFA (Euroimmun)	13	13
IFA (Inova)	4	4
IFA Zenit (Menarini Diagnostics)	1	1
Total	23	23

Methodics	P-ANCA	Total
Fluorescence pattern	20	20

Sample S001 | MPOAb

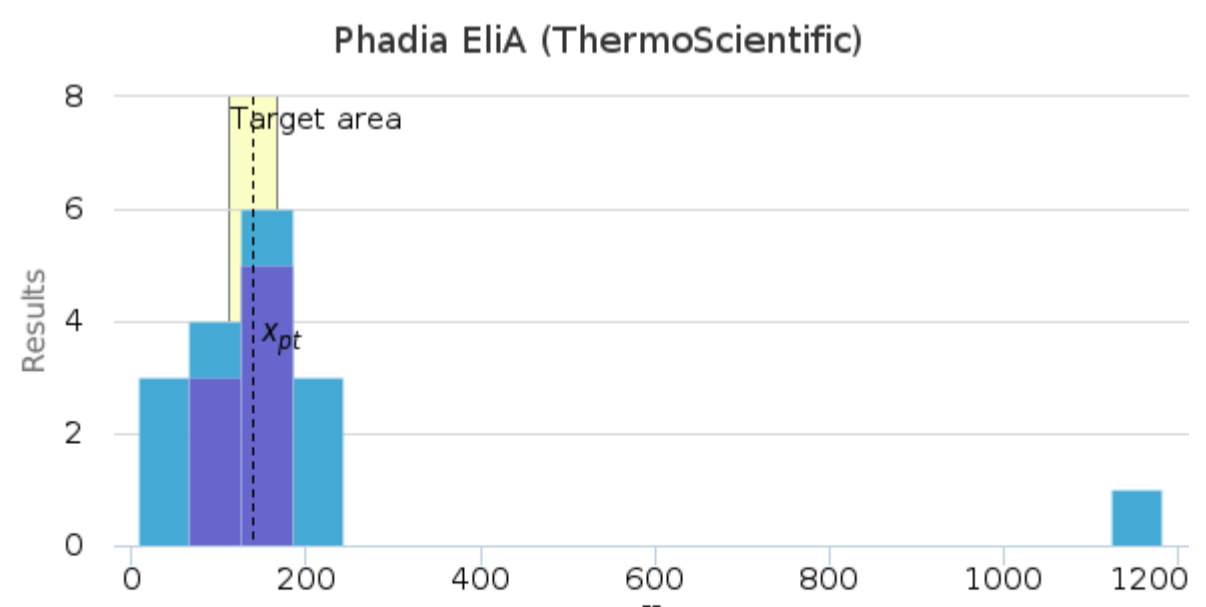
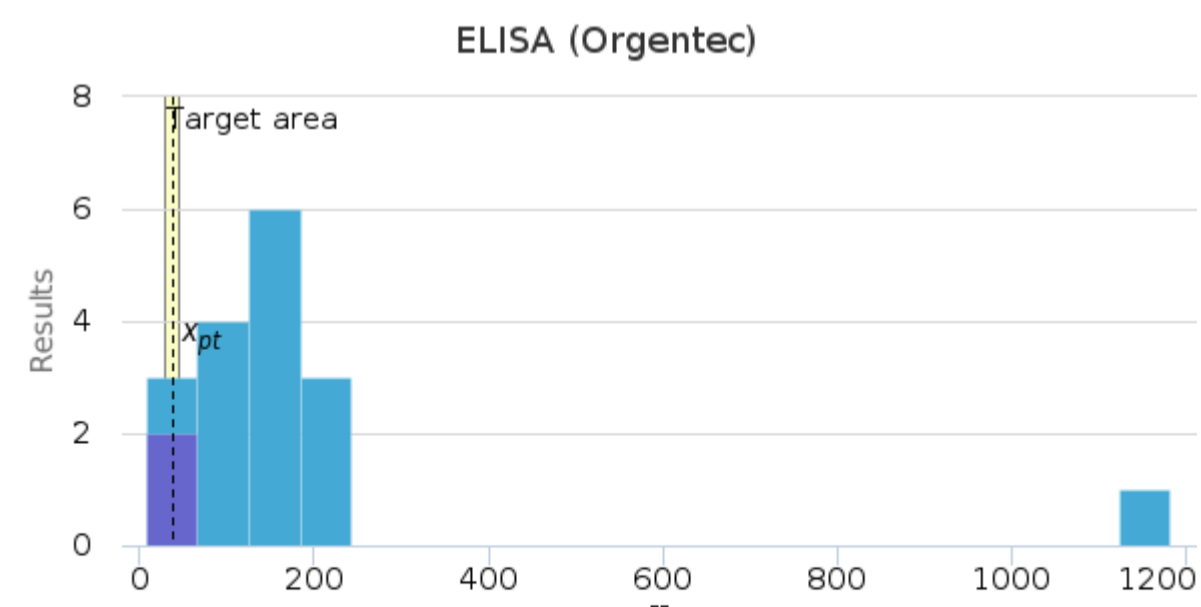
Methodics	Negative	Positive	Total
BioPlex 2200 (BIO-RAD)	-	1	1
CIA (Inova)	-	1	1
CLIA (Immunodiagnostic Systems)	-	1	1
ELISA Chorus (Diesse)	-	1	1
ELISA (Euroimmun)	-	4	4
ELISA (Inova)	-	1	1
ELISA (Orgentec)	1	2	3
ELISA (ZEUS Scientific)	-	1	1
Euroline immunoblot (Euroimmun)	-	4	4
Immunoblot (Aesku Diagnostics)	-	1	1
Phadia EliA (ThermoScientific)	-	16	16
Total	1	33	34

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
ELISA (Euroimmun)	186.3	185.9	4.5	2.4	2.6	182.1	191.0	-	3
ELISA (Inova)	-	-	-	-	-	108.2	108.2	-	1
ELISA (Orgentec)	37.4	37.4	3.5	9.4	2.5	34.9	39.9	-	2
Phadia EliA (ThermoScientific)	138.9	134.0	18.3	13.2	6.5	120.0	171.0	-	8
ELISA (ZEUS Scientific)	-	-	-	-	-	1182.0	1182.0	-	1
BioPlex 2200 (BIO-RAD)	-	-	-	-	-	8.0	8.0	-	1
CLIA (Immunodiagnostic Systems)	-	-	-	-	-	214.0	214.0	-	1
All	129.7	134.0	58.9	45.4	14.7	8.0	214.0	1	17



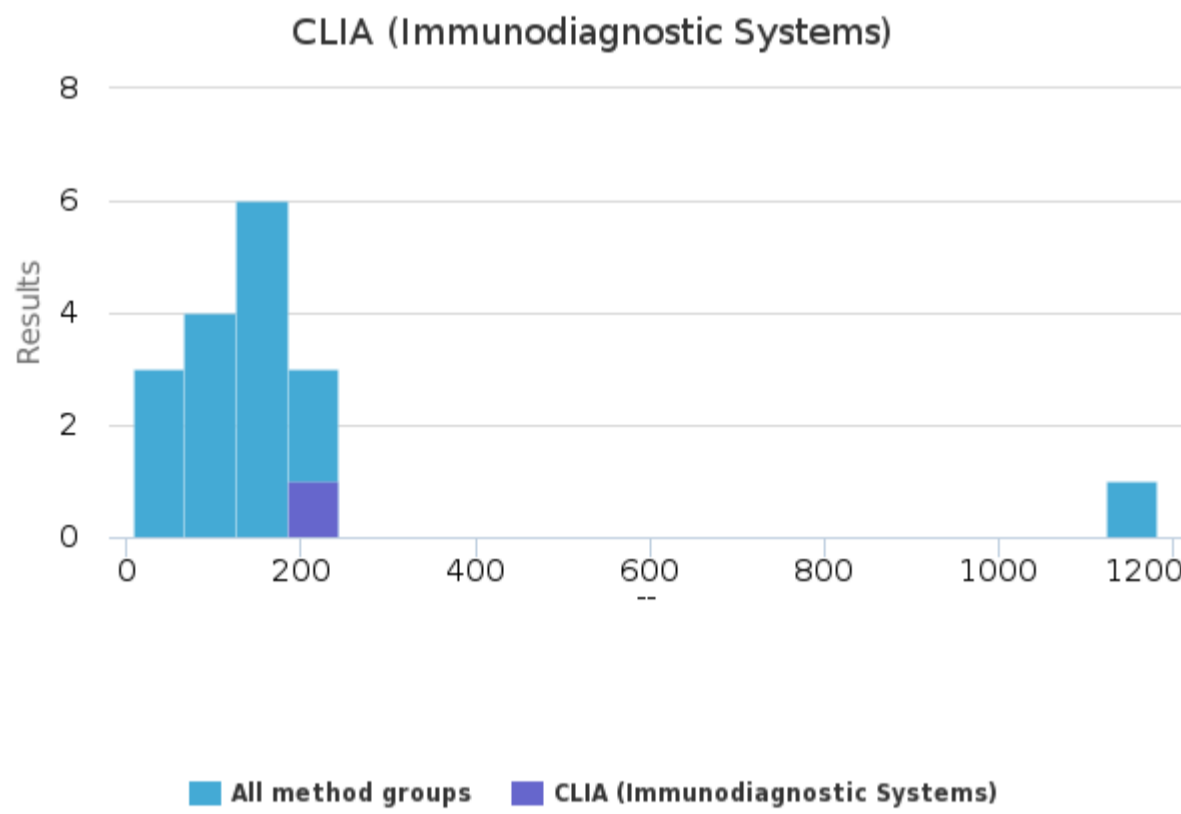
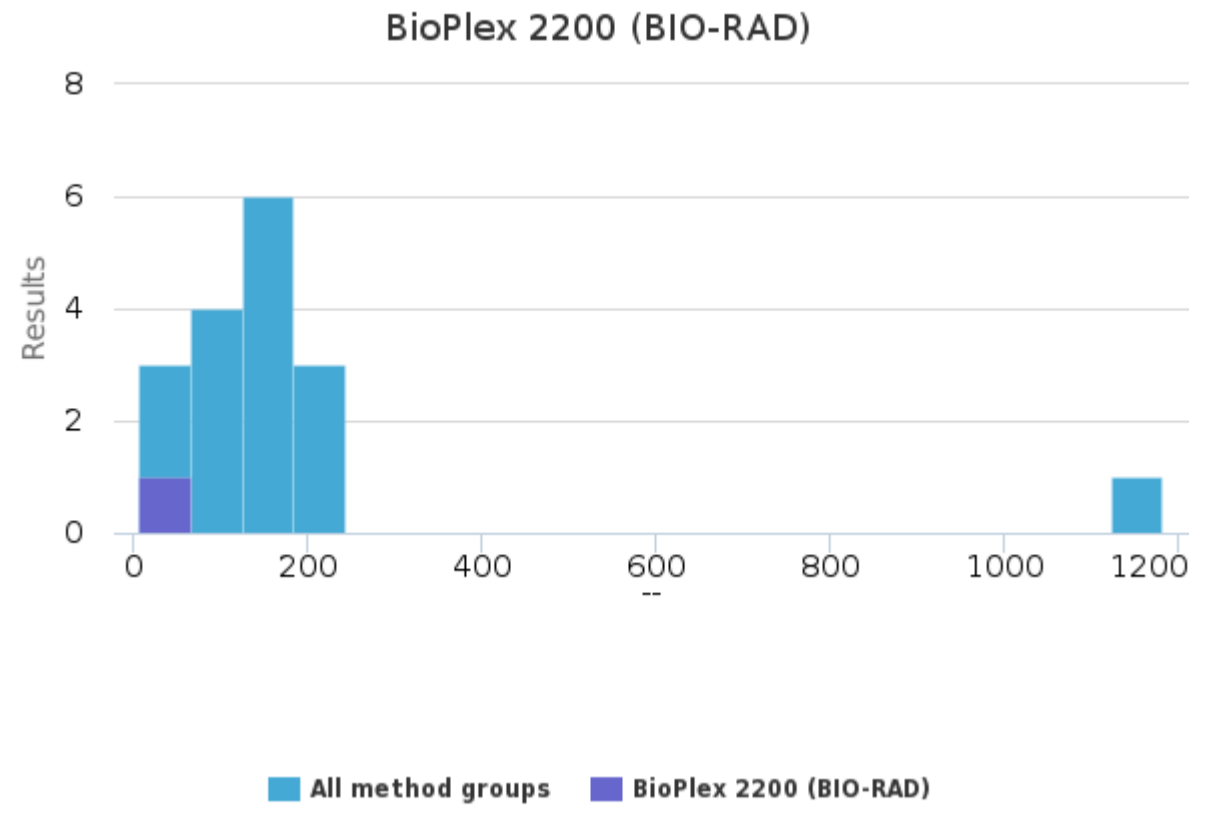
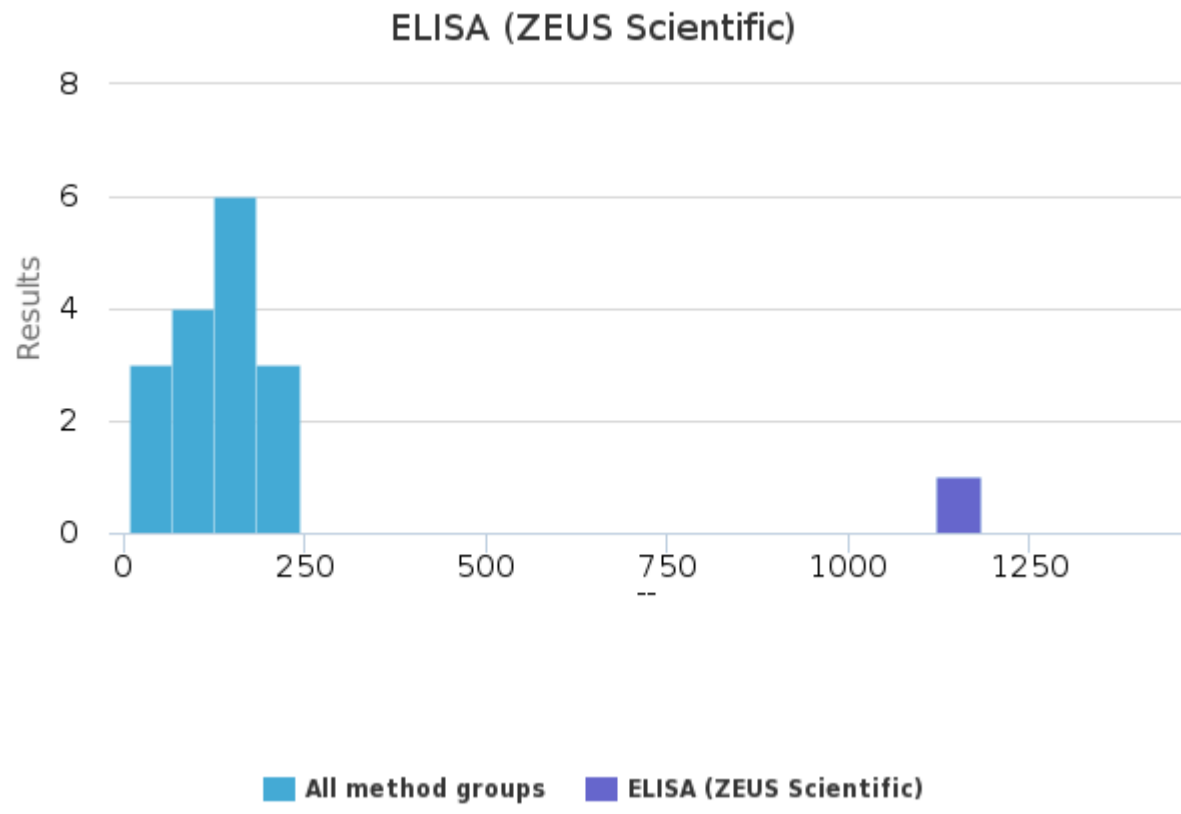
■ All method groups ■ ELISA (Euroimmun) (x_{pt} : 186.3 | Target area: 149.1-223.6 | Target: $\pm 20\%$)

■ All method groups ■ ELISA (Inova)



■ All method groups ■ ELISA (Orgentec) (x_{pt} : 37.4 | Target area: 29.9-44.9 | Target: $\pm 20\%$)

■ All method groups ■ Phadia EliA (ThermoScientific) (x_{pt} : 138.9 | Target area: 111.1-166.6 | Target: $\pm 20\%$)



Sample S001 | Pr3Ab

Methodics	Negative	Positive	Total
BioPlex 2200 (BIO-RAD)	1	-	1
CIA (Inova)	1	-	1
CLIA (Immunodiagnostic Systems)	1	-	1
ELISA Chorus (Diesse)	1	-	1
ELISA (Euroimmun)	4	-	4
ELISA (Inova)	1	-	1
ELISA (Orgentec)	3	-	3
ELISA (ZEUS Scientific)	1	-	1
Euroline immunoblot (Euroimmun)	4	-	4
Immunoblot (Aesku Diagnostics)	1	-	1
Phadia EliA (ThermoScientific)	15	1	16
Total	33	1	34

Sample S001 | GbmAb

Methodics	Negative	Total
ELISA (Euroimmun)	1	1
ELISA (Inova)	1	1
ELISA (Orgentec)	2	2
Euroline immunoblot (Euroimmun)	4	4
IFA (Euroimmun)	3	3
Immunoblot (Aesku Diagnostics)	1	1
Phadia EliA (ThermoScientific)	12	12
Total	24	24

Sample S002 | ANCA

Methodics	Positive	Total
ELISA (Euroimmun)	1	1
ELISA (Orgentec)	3	3
IFA (Aesku Diagnostics)	1	1
IFA (Euroimmun)	13	13
IFA (Inova)	4	4
IFA Zenit (Menarini Diagnostics)	1	1
Total	23	23

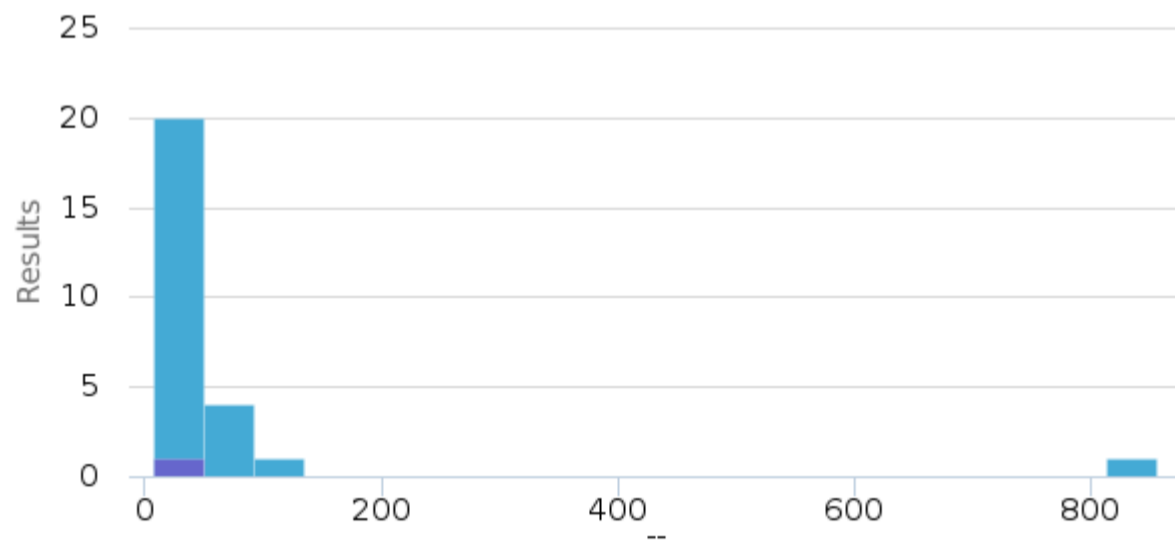
Methodics	P-ANCA	Total
Fluorescence pattern	20	20

Sample S002 | MPOAb

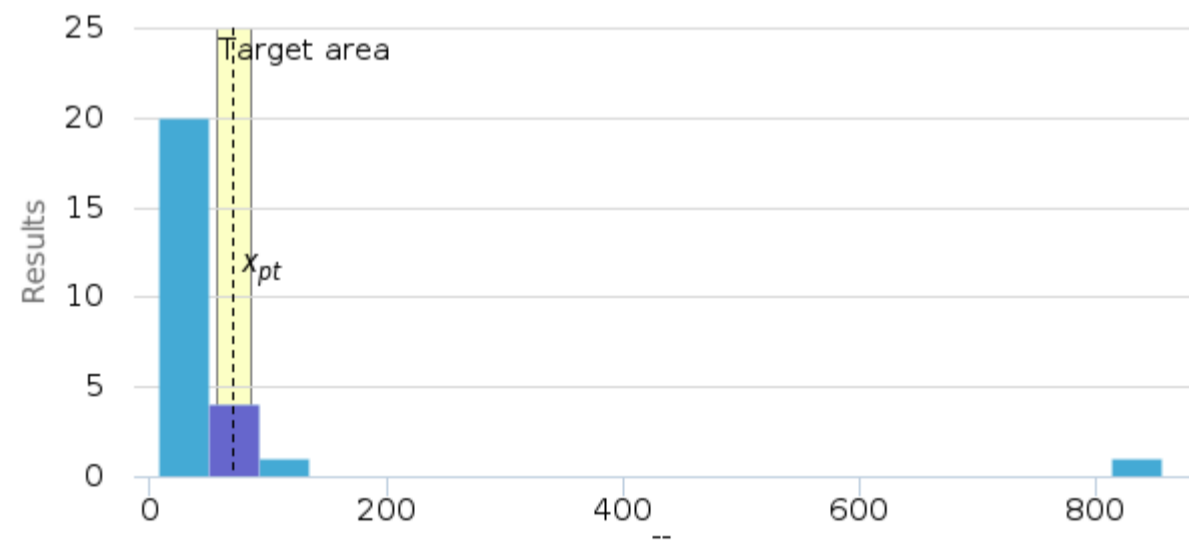
Methodics	Negative	Borderline	Positive	Total
BioPlex 2200 (BIO-RAD)	-	-	1	1
CIA (Inova)	-	-	1	1
CLIA (Immunodiagnostic Systems)	-	1	-	1
ELISA Chorus (Diesse)	-	-	1	1
ELISA (Euroimmun)	-	-	4	4
ELISA (Inova)	-	-	1	1
ELISA (Orgentec)	1	-	2	3
ELISA (ZEUS Scientific)	-	-	1	1
Euroline immunoblot (Euroimmun)	-	-	4	4
Immunoblot (Aesku Diagnostics)	-	-	1	1
Phadia EliA (ThermoScientific)	1	-	15	16
Total	2	1	31	34

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
CIA (Inova)	-	-	-	-	-	41.4	41.4	-	1
ELISA (Euroimmun)	70.7	68.4	12.8	18.2	6.4	58.1	88.0	-	4
ELISA (Inova)	-	-	-	-	-	42.4	42.4	-	1
ELISA (Orgentec)	9.4	9.4	3.5	37.1	2.5	6.9	11.8	-	2
ELISA Chorus (Diesse)	-	-	-	-	-	93.8	93.8	-	1
Phadia EliA (ThermoScientific)	35.3	36.0	5.4	15.4	1.4	27.0	47.0	-	14
ELISA (ZEUS Scientific)	-	-	-	-	-	857.0	857.0	-	1
BioPlex 2200 (BIO-RAD)	-	-	-	-	-	8.0	8.0	-	1
CLIA (Immunodiagnostic Systems)	-	-	-	-	-	19.1	19.1	-	1
All	40.0	37.0	21.6	54.0	4.3	6.9	93.8	1	26

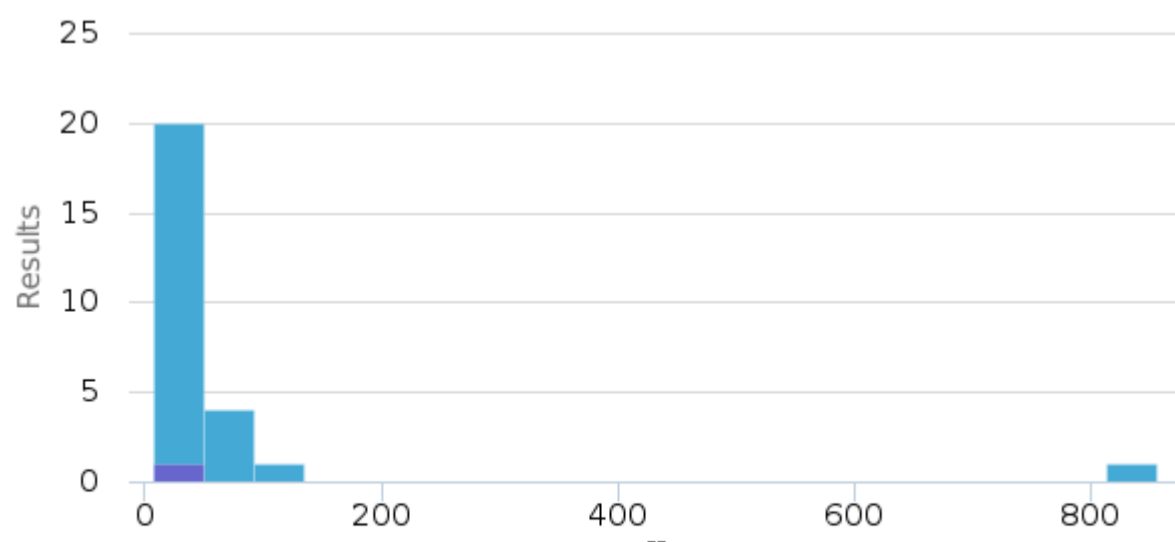
CIA (Inova)



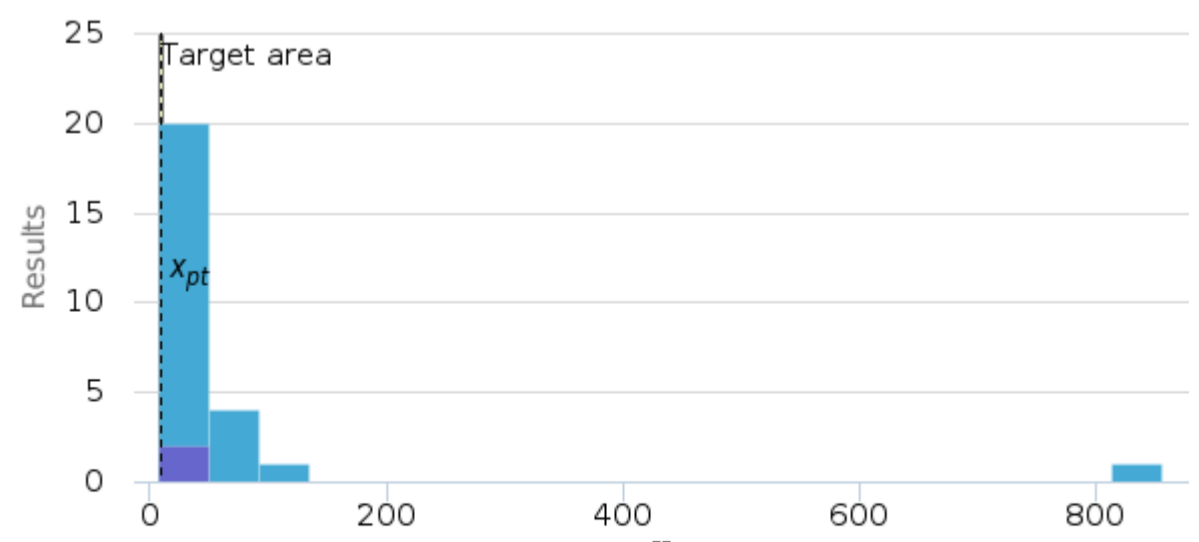
ELISA (Euroimmun)

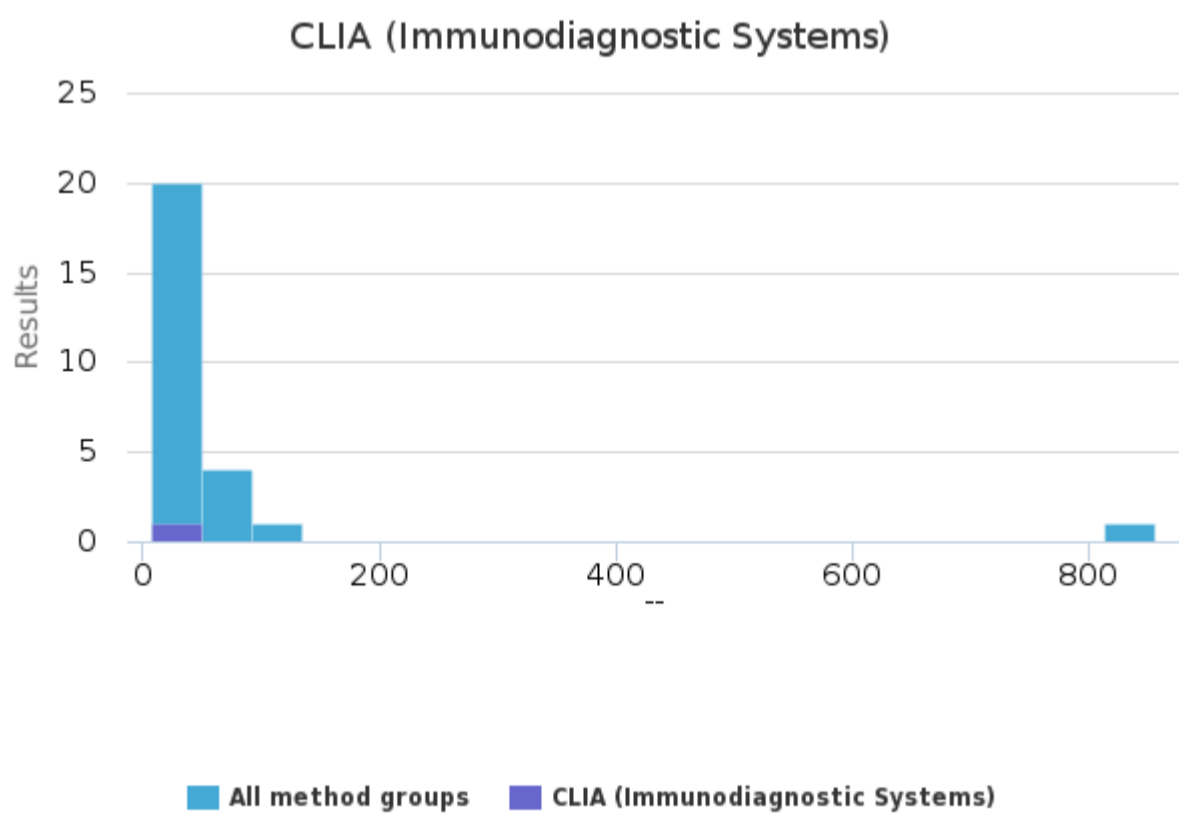
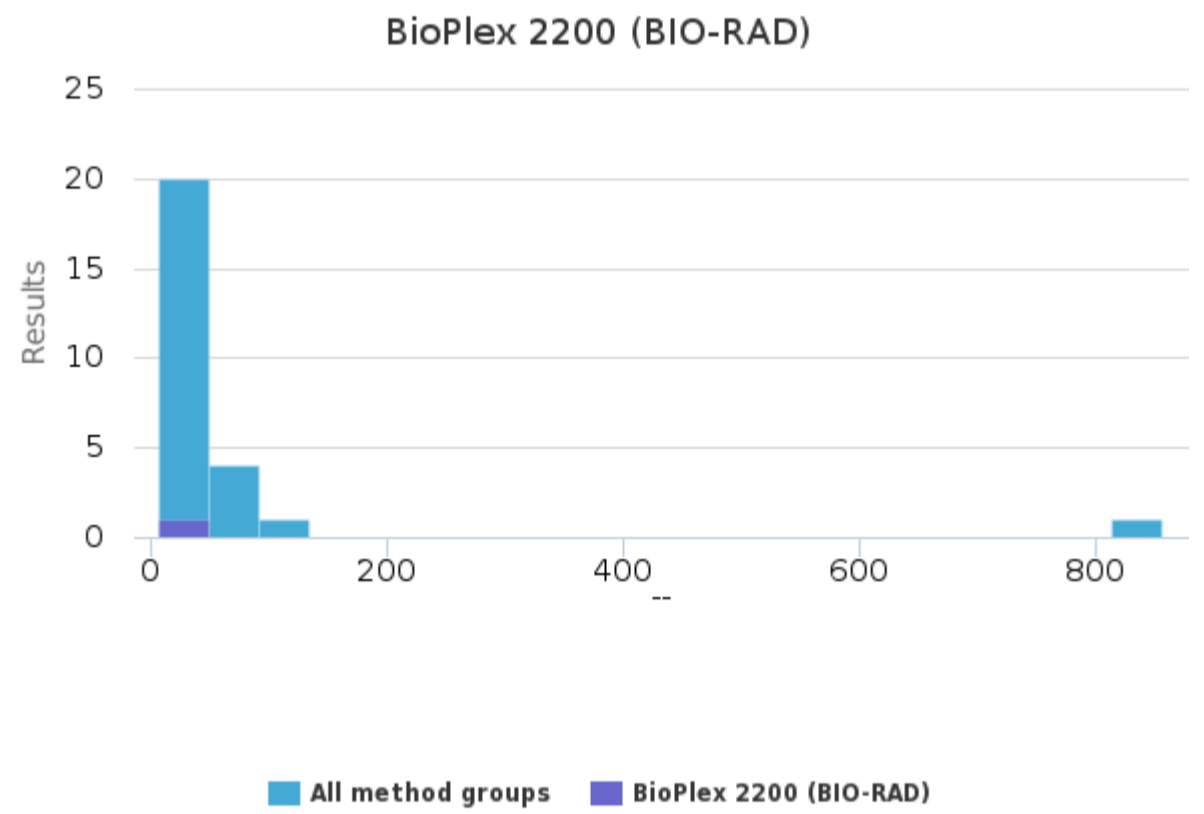
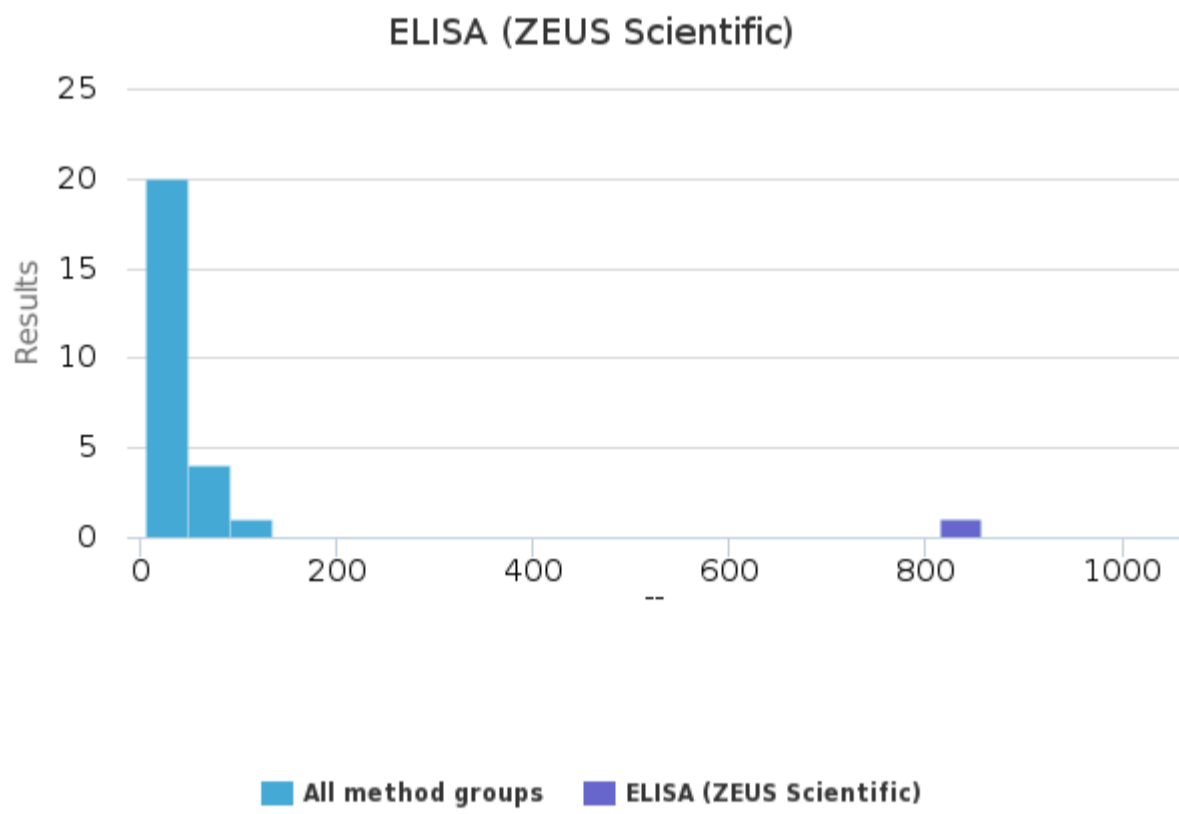
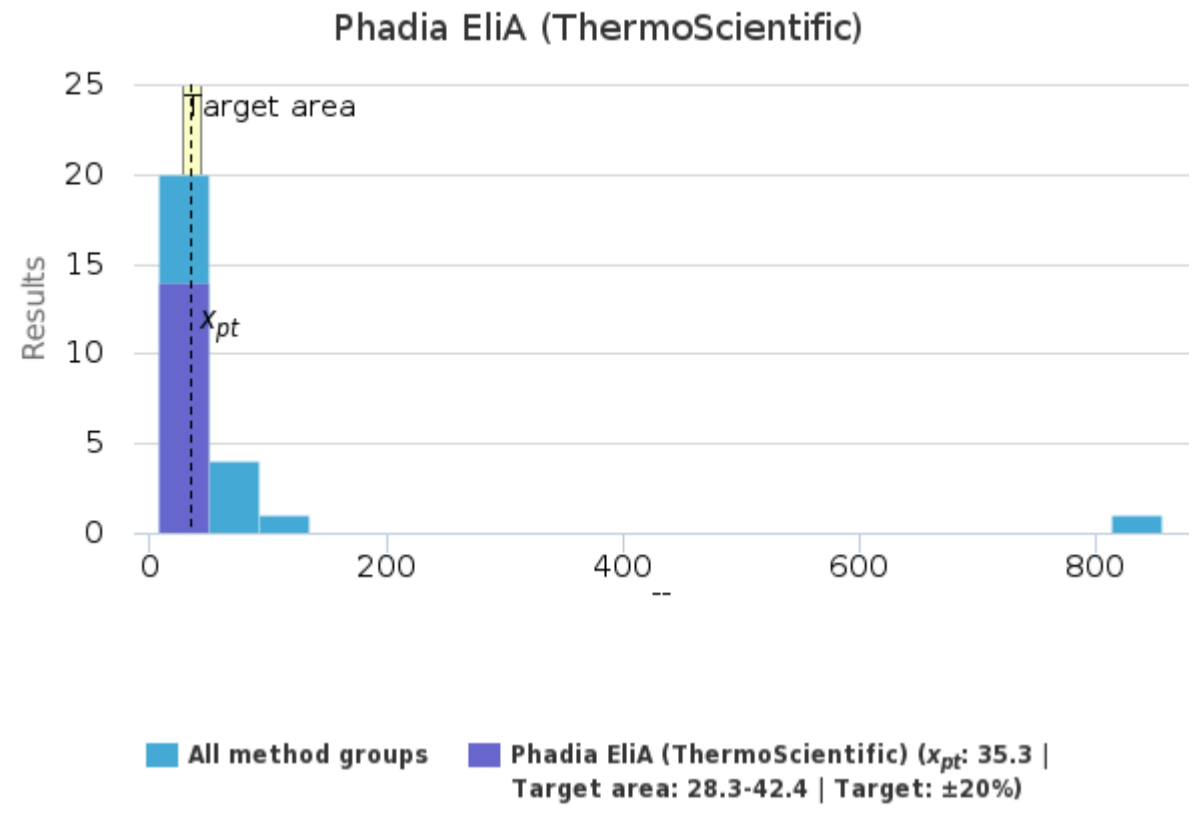
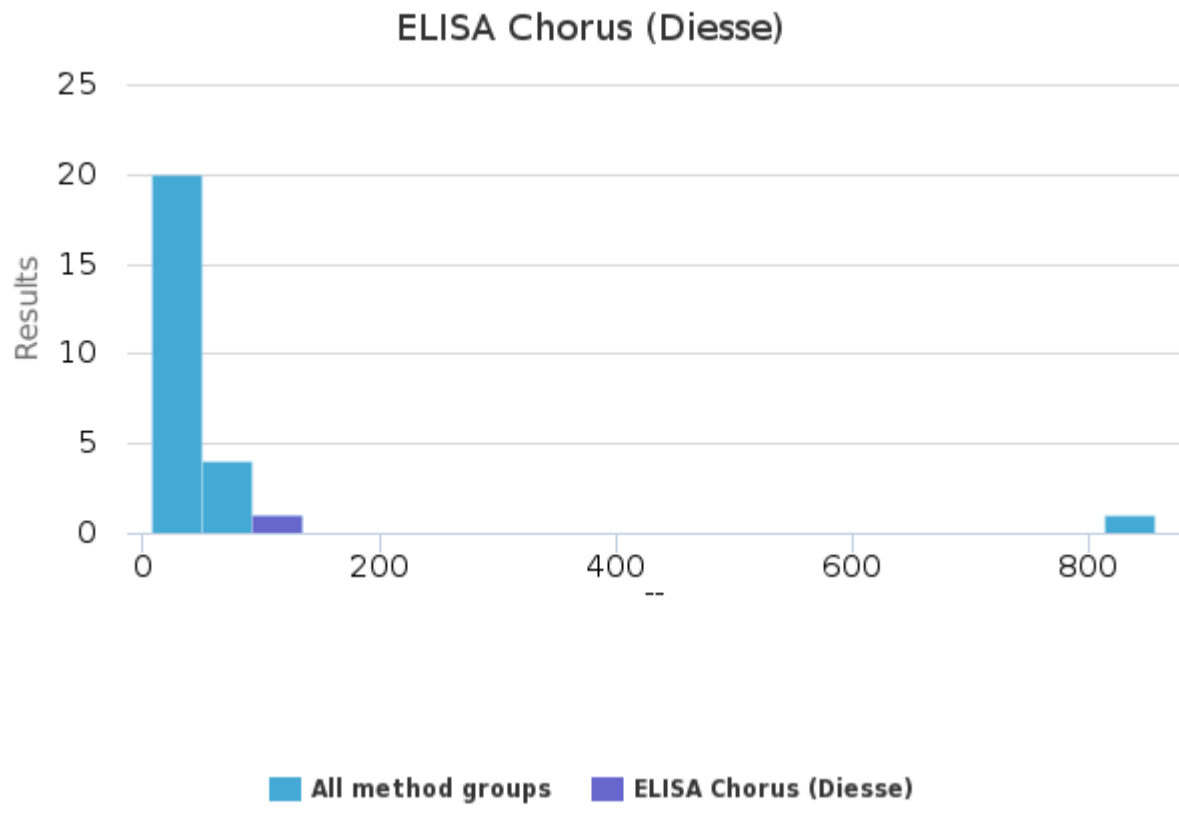


ELISA (Inova)



ELISA (Orgentec)





Sample S002 | Pr3Ab

Methodics	Negative	Total
BioPlex 2200 (BIO-RAD)	1	1
CIA (Inova)	1	1
CLIA (Immunodiagnostic Systems)	1	1
ELISA Chorus (Diesse)	1	1
ELISA (Euroimmun)	4	4
ELISA (Inova)	1	1
ELISA (Orgentec)	3	3
ELISA (ZEUS Scientific)	1	1
Euroline immunoblot (Euroimmun)	4	4
Immunoblot (Aesku Diagnostics)	1	1
Phadia EliA (ThermoScientific)	16	16
Total	34	34

Sample S002 | GbmAb

Methodics	Negative	Positive	Total
ELISA (Euroimmun)	-	1	1
ELISA (Inova)	1	-	1
ELISA (Orgentec)	2	-	2
Euroline immunoblot (Euroimmun)	4	-	4
IFA (Euroimmun)	3	-	3
Immunoblot (Aesku Diagnostics)	1	-	1
Phadia EliA (ThermoScientific)	12	-	12
Total	23	1	24

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External Quality Assessment Scheme

ANCA and GbmAb 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 (LQ717223011)

ANCA	Positive, P-ANCA
MPOAb	Positive
Pr3Ab	Negative
GbmAb	Negative

Sample S002 (LQ717223012)

ANCA	Positive, P-ANCA
MPOAb	Low positive
Pr3Ab	Negative
GbmAb	Negative

Pre-test methods: ANCA IFA (Inova), EliA PR3 Well, EliA MPO Well, EliA GBM Well.

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

The round included two P-ANCA/MPOAb positive samples with different quantitative levels of MPO antibodies. In sample S001 the MPO antibody level was high and in sample S002 the level was low. There were no major difficulties to report expected results and the CV% were also moderate.

Comments – EQA Coordinator

ANCA and GbmAb EQA samples with high concentrations do not need to be diluted, it is sufficient that the result is reported > the upper limit of the method. Of the results reported in this way, we report numbers by analytes and methods in the Final report.

From sample S001, seven >method upper limit MPOAb results were reported by Phadia Elia method. Individual >method upper limit MPOAb results were also reported by ELISA Euroimmun, ELISA DIESSE Chorus and CIA Inova methods. A total of 14/28 Pr3Ab results and 6/15 GbmAb results were reported below (<) the measurement range or reference value of the method.

From sample S002, a total of 13/28 Pr3Ab and 6/15 GbmAb results were reported below (<) the measurement range or reference value of the method.

Exceptions

The borderline MPO antibody result reported from sample S002 was also accepted.

End of report

2023-04-11

FINAL REPORT

Product no. 5935

Subcontracting: Sample pretesting

Samples sent	2023-02-21
Round closed	2023-03-16
Expected results	2023-03-21
Final report	2023-04-11

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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