

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2022-L4 (A)
Lupus Anticoagulant
Labcode 1492

Date of Issue : 25-January-2023
Survey : 2022-L4 (A)
Report : Lupus Anticoagulant

Note:

In the Survey Manual 2022 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2022 should be considered as an integral part of this survey report.

Please notice the information regarding the homogeneity of samples used and the between-laboratory variation on page 21 of the Survey Manual.

General Information**(A) = Amended Survey Report**

This is an amended survey report 2022-L4 (A) (version 2.0.0) and replaces Survey Report 2022-L4 dated 20 January 2022 (version 1.0.0). The report of 20 January 2022 is not valid anymore.

The reason for the amended report is the fact that a modification scheduled to be included from 2023 by accident already was included into Survey Report 2022-L4. As a result the antiphospholipid antibody parameters were not correctly presented in the report. This error is now corrected in this amended report. We apologise for the inconvenience.

Complaints

Any complaints regarding this survey report should be reported to the ECAT before **March 7th, 2023**. Complaints received after this date will not be taken into consideration.

Exclusion of results

Results < [value] or > [value] are excluded from the statistical analysis. When other results are excluded in the statistical analysis, these results are placed between brackets.

Modified report

Because of the changes in the online result report form we have also modified the survey report. For the screening, mixing and confirmation test now also an evaluation of the ratio ECAT plasma over the Mean of the Reference Interval (MRI) is included. This is done for those participants that selected as a unit "seconds" and also provided a clotting time for the MRI or when the participant indicated that the result for the ECAT plasma was expressed as a ratio MRI. Furthermore, a new section about the interpretation of the Lupus Anticoagulant results has been included. This includes the evaluation of the Delta Seconds, the Ratio Screen/Confirmation and the Percentage Correction. The section about the Final Conclusion now includes also a table where the conclusion of each test panel is compared to the testing strategy used.

Lupus Anticoagulant

When selecting the unit seconds; all results should be reported in seconds and not partly in ratios; e.g. the result for the ECAT sample, the result for normal plasma and the result for MRI.

Antiphospholipid Antibodies

Please be aware of the selection of the correct unit for the method group "IL Acustar / INOVA Quanta Flash". Since there is a difference in the order of magnitude between the results of the "IL Acustar / INOVA Quanta Flash" method group and the other methods, it is expressed in the report as CU/mL instead of U/mL.

This report is authorized by:

Dr. P. Meijer
Director

Note: A printed version of the actual Survey Manual is provided to all participants once a year. This manual can also be downloaded from the member section of the ECAT website.

ECAT Foundation

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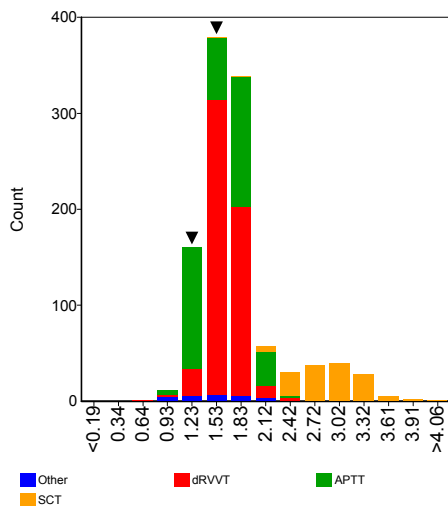
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Appendices are an integral part of the total report.

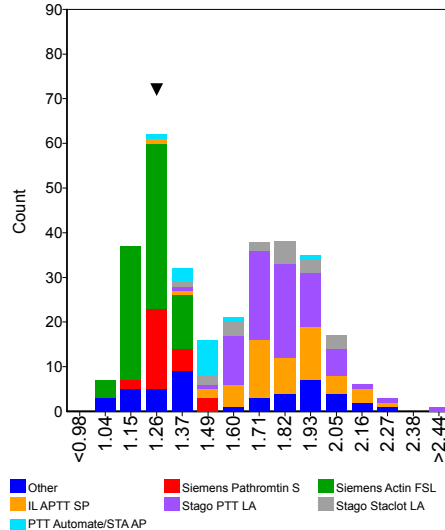
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	368	1.59	21.6	1.03 - 2.49	1	1.23	-1.04	1.29	-0.86		
Hyphen-Biomed Cephen LS	8	1.90		1.70 - 2.01							
IL APTT SP	50	1.81	10.2	1.24 - 2.22							
IL HemosIL SynthAsil	41	1.82	7.8	1.47 - 2.49							
IL MixCon	14	1.69	7.1	1.39 - 1.87							
Siemens Actin FS	5	1.11		1.03 - 1.13							
Siemens Actin FSL	83	1.22	6.7	1.04 - 1.39	1			1.29	0.85		
Siemens Pathromtin SL	28	1.29	4.4	1.11 - 1.53	1	1.23	-1.07				
Stago CKPrest / APTT Kaolin	5	1.27		1.24 - 1.36							
Stago PTT Automate/STA APTT	14	1.47	6.8	1.23 - 1.93							
Stago PTT LA	75	1.79	8.3	1.38 - 2.49							
Stago Staclot LA	19	1.76	12.8	1.36 - 2.06							
Tcoag TriniClot APTT-HS	6	1.82		1.42 - 2.04							
Tcoag TriniClot Automated APTT	6	1.37		1.34 - 1.41							
Technoclone Lupus Anticoagulant Test	5	1.78		1.61 - 2.07							
dAPTT	9	1.82		1.38 - 1.96							
Stago PTT LA	6	1.84		1.50 - 1.91							
dPT	8	1.50		1.20 - 2.14							
dRVVT	552	1.64	10.1	0.68 - 2.95	1					1.47	-1.00
Hyphen Biomed Hemoclot LA-S	9	1.88		1.69 - 2.04							
I.L. HemosIL dRVVT screen	209	1.72	7.8	0.80 - 2.95							
Precision Biologic LA check	6	1.94		1.60 - 1.99							
Roche Lupus S	5	1.69		1.41 - 1.81							
Siemens LA1 screen	222	1.58	7.5	0.68 - 2.36	1					1.47	-0.92
Stago DRVVT screen	84	1.56	11.6	1.21 - 2.27							
Technoclone LA Screen	7	1.37		1.26 - 1.58							
PT	7	1.07		1.00 - 1.11							
SCT	145	2.87	13.8	1.64 - 5.06							
Haematex SACT Reagent	6	3.09		2.73 - 5.06							
IL SCT screen	139	2.86	13.8	1.64 - 3.79							

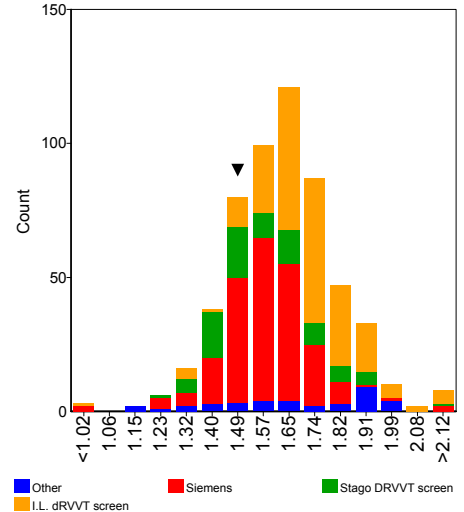
Assays



APTT



DRVVT



Lupus Anticoagulant

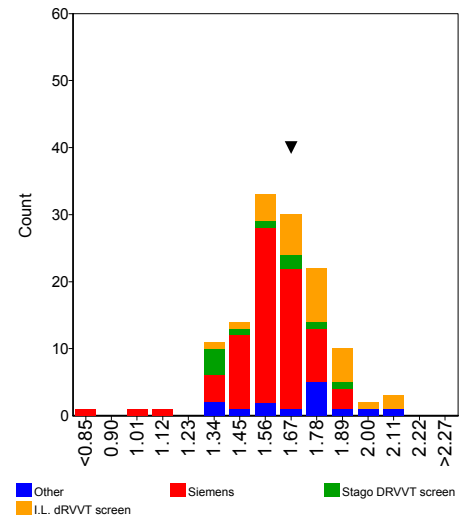
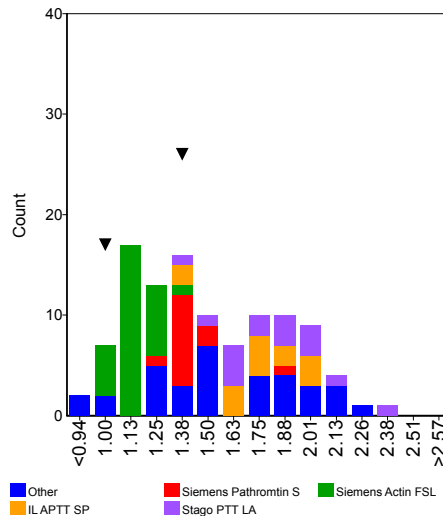
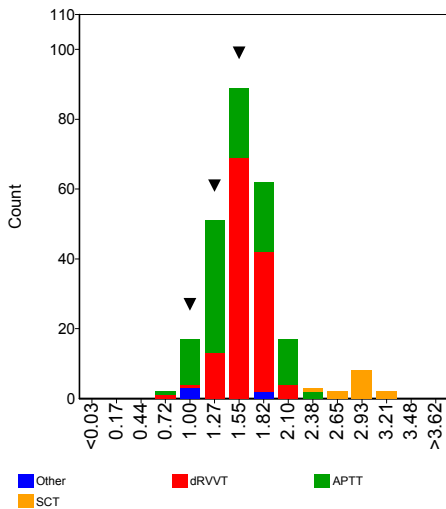
Screening

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	107	1.50	25.1	0.71 - 2.40	1	1.36	-0.36	0.99	-1.35		
IL APTT SP	14	1.75	13.6	1.34 - 2.03							
IL HemosIL SynthAsil	7	1.92		1.75 - 2.30							
Siemens Actin FSL	30	1.16	6.4	0.99 - 1.39	1			0.99	-2.30		
Siemens Pathromtin SL	13	1.40	6.2	1.24 - 1.91	1	1.36	-0.41				
Stago PTT Automate/STA APTT	8	1.48		1.29 - 1.52							
Stago PTT LA	16	1.81	13.9	1.43 - 2.40							
dRVVT	128	1.63	10.6	0.75 - 2.08	1					1.63	0.00
I.L. HemosIL dRVVT screen	28	1.74	10.1	1.36 - 2.08							
Roche Lupus S	5	1.78		1.46 - 1.85							
Siemens LA1 screen	76	1.59	8.5	0.75 - 1.87	1					1.63	0.25
Stago DRVVT screen	10	1.53	14.7	1.31 - 1.88							
SCT	13	2.89	8.5	2.26 - 3.32							
IL SCT screen	13	2.89	8.5	2.26 - 3.32							

Assays

APTT

DRVVT



Comments

Several participants selected the wrong unit, e.g. ratio while the result was likely to be in seconds. Other participants reported their result for the ECAT plasma in seconds while the result for their reference plasma or the mean of the reference interval was reported as a ratio or vice versa. One participant reported a negative result for their reference plasma. In all these cases the ratio between the ECAT plasma and the laboratories own reference plasma and/or the mean of the reference interval could not be correctly calculated. Therefore all these results were excluded in the statistical analysis.

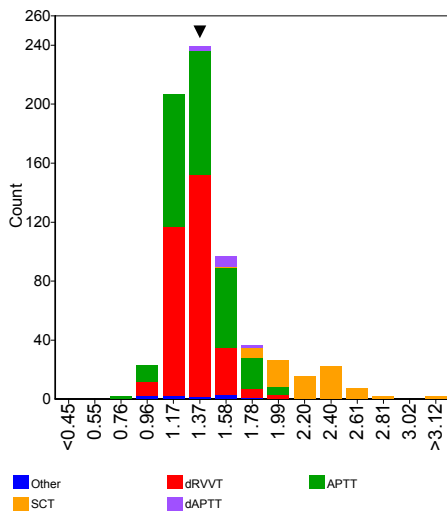
The vast majority of performed screening tests (> 94%) were classified as elevated.

In general, comparable results were observed for the ratio ECAT plasma over Normal Plasma and ratio ECAT plasma over Mean Reference Interval (MRI).

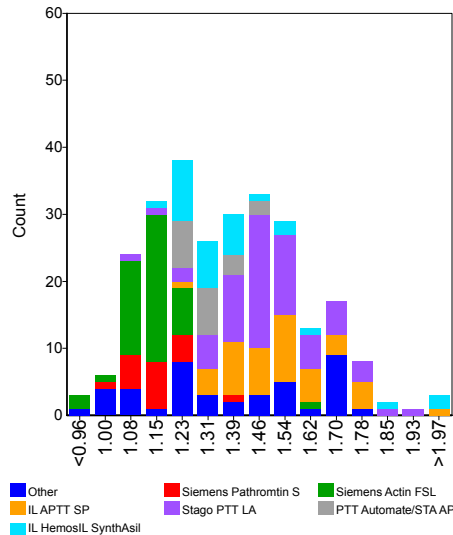
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	267	1.36	16.7	0.83 - 1.99							
Hyphen-Biomed Cephen LS	6	1.61		1.26 - 1.81							
IL APTT SP	43	1.52	10.0	1.21 - 1.98							
IL HemosIL SynthAsil	30	1.36	9.5	1.19 - 1.99							
IL MixCon	9	1.54		0.97 - 1.70							
Siemens Actin FSL	47	1.13	4.9	0.83 - 1.60							
Siemens Pathromtin SL	18	1.15	5.4	1.02 - 1.38							
Stago PTT Automate/STA APTT	19	1.30	5.8	1.22 - 1.48							
Stago PTT LA	66	1.49	9.8	1.06 - 1.92							
Tcoag TriniClot APTT-HS	5	1.45		1.31 - 1.57							
Tcoag TriniClot Automated APTT	6	1.23		1.22 - 1.28							
dAPTT	12	1.55	7.7	1.43 - 1.74							
Stago PTT LA	5	1.48		1.43 - 1.61							
dRVVT	316	1.32	9.4	0.89 - 2.08	1					1.33	0.11
I.L. HemosIL dRVVT screen	90	1.41	8.0	1.01 - 2.03							
Siemens LA1 screen	142	1.27	5.6	0.89 - 2.08	1					1.33	0.89
Siemens LA2 confirmation	11	1.13	10.5	1.04 - 1.58							
Stago DRVVT screen	47	1.32	9.1	1.06 - 1.55							
Technoclone LA Screen	5	1.21		1.08 - 1.31							
SCT	74	2.22	13.5	1.60 - 5.06							
IL SCT screen	70	2.21	13.3	1.60 - 3.36							

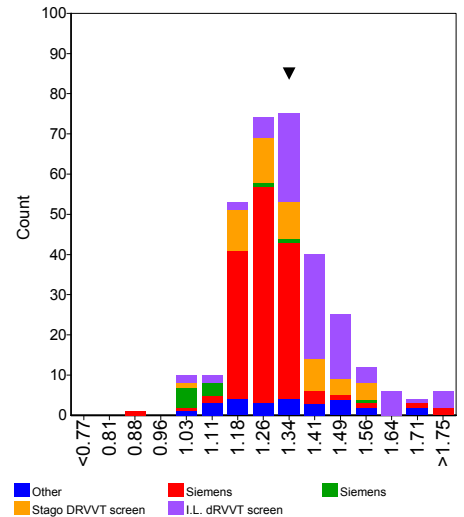
Assays



APTT



DRVVT

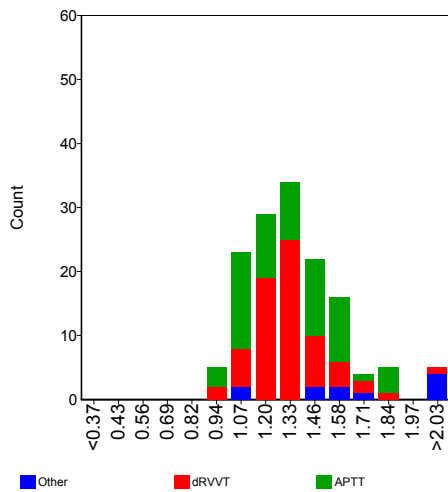


Lupus Anticoagulant

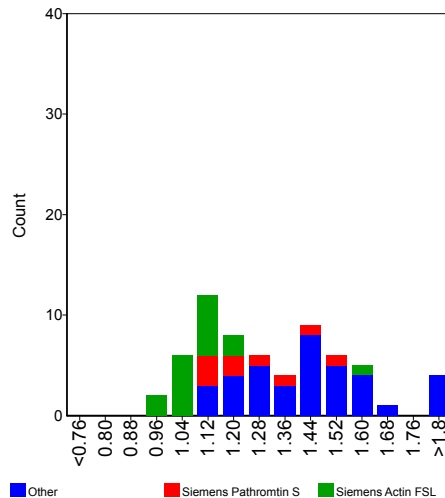
Mixing

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	64	1.32	18.1	0.97 - 1.89							
IL APTT SP	8	1.48		1.19 - 1.71							
IL HemosIL SynthAsil	7	1.55		1.28 - 1.89							
Siemens Actin FSL	17	1.09	7.5	0.97 - 1.60							
Siemens Pathromtin SL	10	1.28	13.6	1.08 - 1.55							
Stago PTT Automate/STA APTT	6	1.30		1.18 - 1.39							
Stago PTT LA	9	1.45		1.31 - 1.87							
dRVVT	68	1.30	11.9	0.93 - 2.21							
I.L. HemosIL dRVVT screen	9	1.48		1.11 - 2.21							
Siemens LA1 screen	42	1.27	9.2	0.93 - 1.64							
Stago DRVVT screen	5	1.31		1.06 - 1.46							
SCT	5	2.33		1.04 - 3.36							

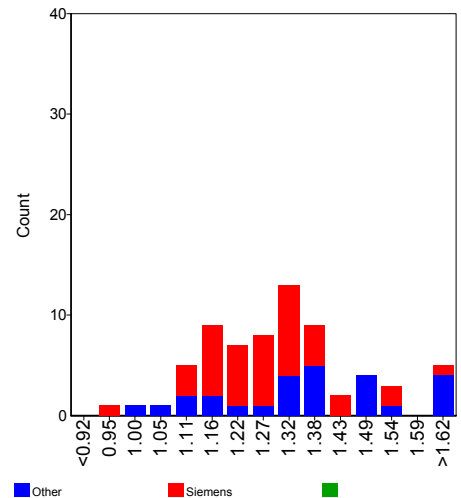
Assays



APTT



DRVVT



Comments

Several participants selected the wrong unit, e.g. ratio while the result was likely to be in seconds or vice versa. Other participants reported their result for the ECAT plasma in seconds while the result for their reference plasma or the mean of the reference interval was reported as a ratio or vice versa. In all these cases the ratio between the ECAT plasma and the laboratories own reference plasma and/or the mean of the reference interval could not be correctly calculated. Therefore all these results were excluded in the statistical analysis.

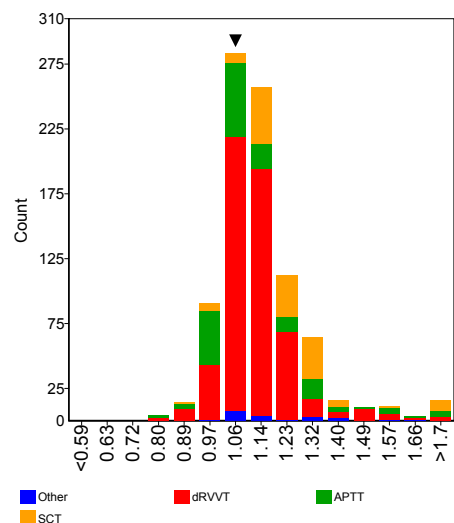
The majority of performed mixing tests (> 84%) were classified as elevated.

In general, comparable results were observed for the ratio ECAT plasma over Normal Plasma and ratio ECAT plasma over Mean Reference Interval (MRI).

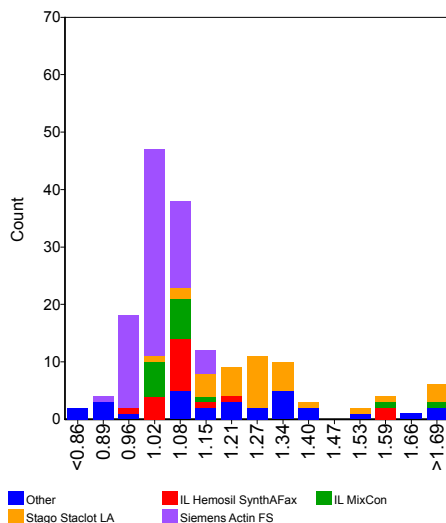
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	167	1.10	12.8	0.78 - 3.35							
IL Hemosil SynthAFax	18	1.08	5.7	0.96 - 1.59							
IL MixCon	16	1.08	4.6	1.00 - 1.70							
Siemens Actin FS	72	1.02	4.7	0.91 - 1.15							
Stago Staclot LA	32	1.27	10.8	1.00 - 3.35							
Technoclone Lupus Anticoagulant Test	5	1.33		1.28 - 2.00							
dAPTT	9	1.11		1.04 - 1.65							
dPT	5	1.11		1.01 - 1.22							
dRVVT	558	1.11	7.3	0.84 - 2.02	1					1.05	-0.77
Hyphen Biomed Hemoclot LA-C	9	1.10		1.03 - 1.21							
IL Hemosil dRVVT confirm	197	1.16	7.7	0.84 - 1.67							
IL Hemosil LAC confirm	19	1.14	7.8	0.90 - 1.75							
Precision Biologic LA sure	5	1.02		0.92 - 1.13							
Siemens LA2 confirmation	229	1.09	5.7	0.84 - 1.73	1					1.05	-0.64
Stago DRVVT Confirm	75	1.08	6.0	0.94 - 2.02							
Technoclone LA Confirm	8	1.03		0.98 - 1.16							
PNP	5	1.28		1.04 - 1.39							
SCT	136	1.22	8.8	0.85 - 2.90							
IL Hemosil SCT confirm	135	1.22	8.7	0.85 - 2.90							

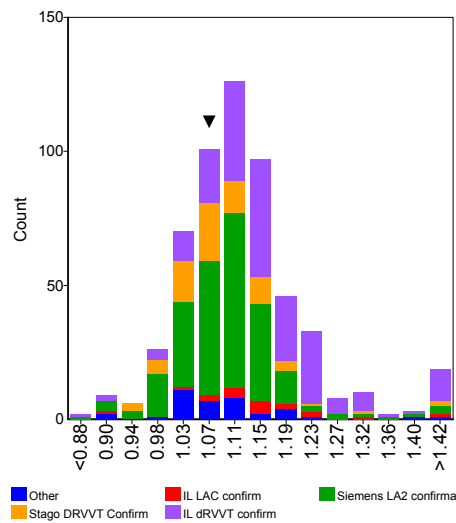
Assays



APTT



DRVVT

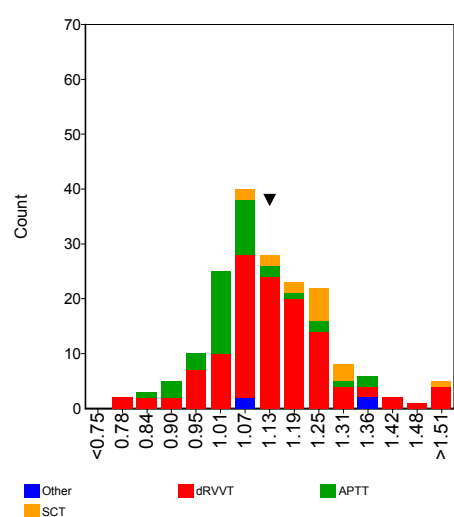


Lupus Anticoagulant

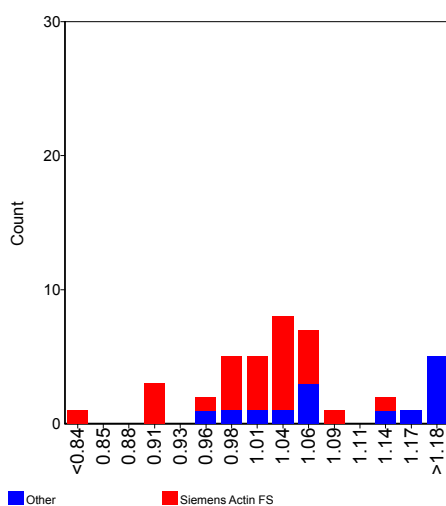
Confirmation

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	40	1.04	8.5	0.83 - 1.37							
Siemens Actin FS	26	1.01	5.5	0.83 - 1.15							
dRVVT	120	1.13	10.0	0.80 - 1.76	1					1.14	0.08
IL HemosIL dRVVT confirm	21	1.17	9.1	0.80 - 1.50							
IL HemosIL LAC confirm	7	1.24		0.99 - 1.76							
Siemens LA2 confirmation	72	1.11	9.5	0.84 - 1.38	1					1.14	0.28
Stago DRVVT Confirm	10	1.09	6.0	0.80 - 1.23							
SCT	16	1.22	6.7	1.05 - 1.93							
IL HemosIL SCT confirm	16	1.22	6.7	1.05 - 1.93							

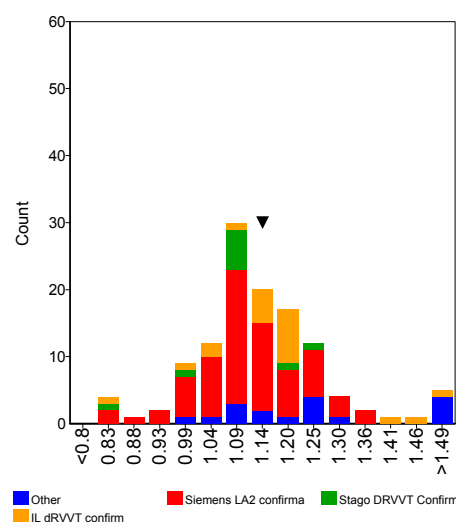
Assays



APTT



DRVVT



Comments

Several participants selected the wrong unit, e.g. ratio while the result was likely to be in seconds or vice versa. Other participants reported their result for the ECAT plasma in seconds while the result for their reference plasma or the mean of the reference interval was reported as a ratio or vice versa. In all these cases the ratio between the ECAT plasma and the laboratories own reference plasma and/or the mean of the reference interval could not be correctly calculated. Several participants reported also a confirmation result in Delta Seconds. However the difference in clotting time between the screen and confirmation test (or reagent 1 and reagent 2) should be reported in the Interpretation section. All these results were excluded in the statistical analysis.

A part of the performed confirmation tests (41%) were classified as elevated. For a positive Lupus Anticoagulant plasma in the range of a LA ratio of 1.7, it is expected that the test result is slightly elevated or (almost) normalised in the confirmation test.

In general, comparable results were observed for the ratio ECAT plasma over Normal Plasma and ratio ECAT plasma over Mean Reference Interval (MRI).

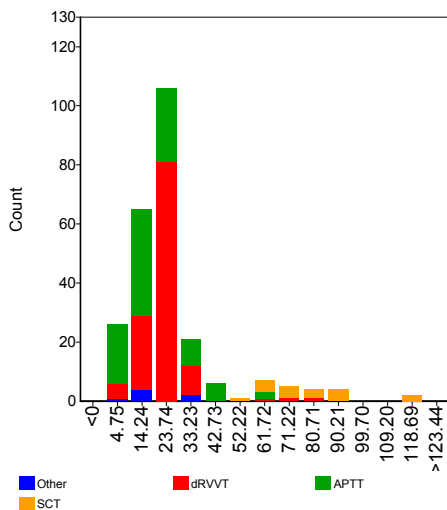
Lupus Anticoagulant

Interpretation

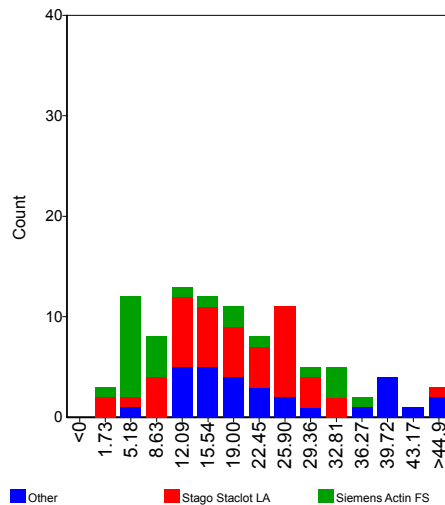
Delta Seconds

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	98	18.54	59.1	2.70 - 66.10							
IL Hemosil SynthAFax	5	15.50		11.28 - 23.70							
Siemens Actin FS	25	13.00	81.8	2.70 - 35.20							
Stago Staclot LA	44	18.91	45.1	3.00 - 46.10							
dRVVT	125	21.82	23.8	0.00 - 76.80							
IL HemosIL dRVVT confirm	36	25.90	20.0	3.50 - 76.80							
IL HemosIL LAC confirm	6	23.05		1.53 - 28.20							
Siemens LA2 confirmation	69	20.25	16.2	0.00 - 27.20							
Stago DRVVT Confirm	8	19.35		11.50 - 65.20							
SCT	18	77.96	19.4	56.00 - 119.90							
IL HemosIL SCT confirm	17	76.40	17.9	56.00 - 119.90							

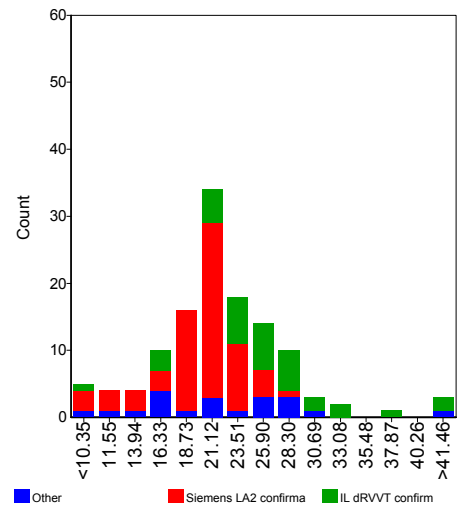
Assays



APTT



DRVVT



Comments

It is not clear whether all results submitted for Delta Seconds are really the difference in clotting time between the screen and confirmation test (or reagent 1 and reagent 2).

Please submit for Delta Seconds only the value which is the absolute difference in clotting time between the screen and confirmation test (or difference between reagent 1 and reagent 2).

Some participants reported their result for Delta Seconds as a negative result. Please, report in future surveys the result without the negative prefix.

A few participants reported a result, which was a delta ratio instead of a delta seconds and therefore were excluded in the statistical analysis.

The following participants reported deviating results which were excluded in the statistical evaluation:

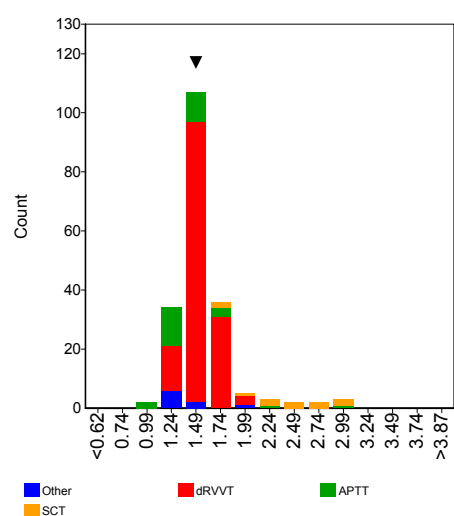
1376 : 0
66606872 : 0

Lupus Anticoagulant	Interpretation
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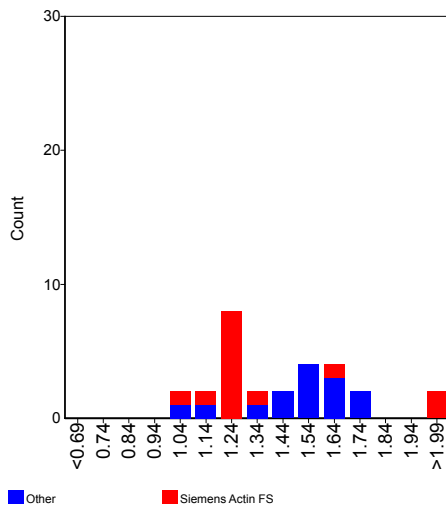
Ratio Screen/Confirmation - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	30	1.41	17.0	1.03 - 2.88							
Siemens Actin FS	15	1.34	16.2	1.03 - 2.88							
Stago Staclot LA	6	1.46		1.18 - 1.61							
dRVVT	144	1.55	7.5	1.20 - 2.03	1					1.52	-0.25
IL HemosIL dRVVT confirm	18	1.56	9.9	1.20 - 2.03							
Siemens LA2 confirmation	91	1.56	5.1	1.22 - 1.79	1					1.52	-0.52
Stago DRVVT Confirm	18	1.44	8.9	1.29 - 1.69							
SCT	11	2.37	20.2	1.76 - 3.04							
IL HemosIL SCT confirm	10	2.43	18.2	1.83 - 3.04							

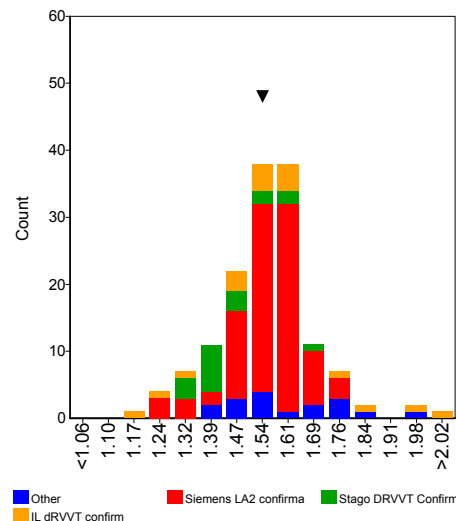
Assays



APTT



DRVVT



Comments

Some participants did not indicate which type of ratio screen/confirmation they reported (standard ratio or normalised ratio). These results have been excluded in the evaluation. **Don't forget to select the type of ratio in the next survey.**

A few participants reported a result, which was not a ratio and therefore were excluded in the statistical analysis.

The average ratio screen / confirmation is in general in line with the expected LA ratio (approx. 1.7).

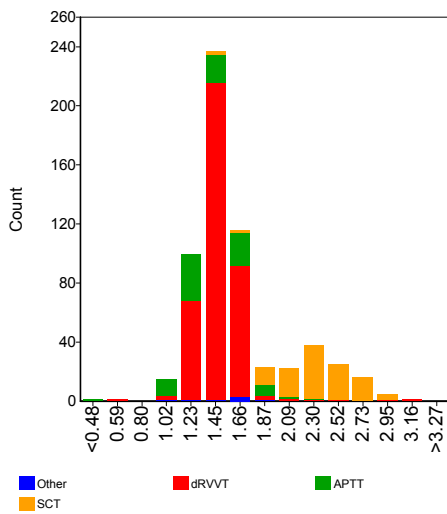
Lupus Anticoagulant

Interpretation

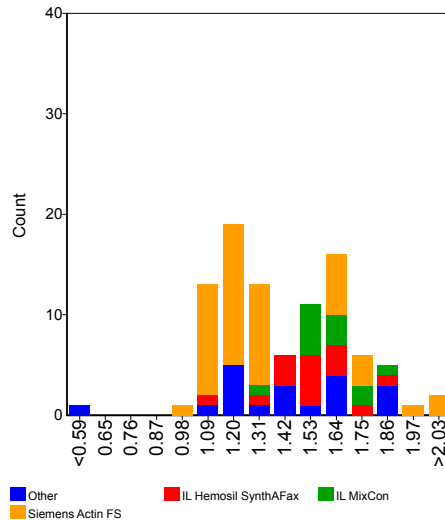
Ratio Screen/Confirmation - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	94	1.41	19.5	0.11 - 2.20							
IL Hemosil SynthAFax	15	1.53	9.7	1.13 - 1.85							
IL MixCon	12	1.59	8.3	1.34 - 1.81							
Siemens Actin FS	48	1.31	18.4	1.02 - 2.20							
dRVVT	384	1.47	9.5	0.62 - 3.18							
IL Hemosil dRVVT confirm	168	1.49	9.5	0.62 - 3.18							
IL Hemosil LAC confirm	16	1.45	6.9	1.08 - 2.45							
Siemens LA2 confirmation	132	1.44	8.9	1.10 - 1.69							
Stago DRVVT Confirm	53	1.47	11.3	1.22 - 1.73							
SCT	115	2.34	13.3	1.48 - 2.99							
IL Hemosil SCT confirm	115	2.34	13.3	1.48 - 2.99							

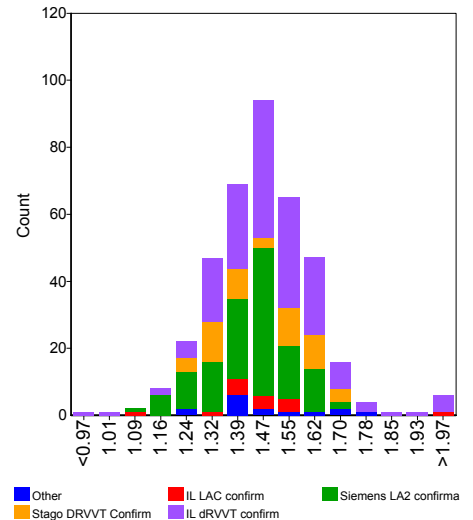
Assays



APTT



DRVVT



Comments

Some participants did not indicate which type of ratio screen/confirmation they reported (standard ratio or normalised ratio). These results have been excluded in the evaluation. **Don't forget to select the type of ratio in the next survey.**

A few participants reported a result, which was not a ratio and therefore were excluded in the statistical analysis.

The average ratio screen / confirmation is in general in line with the expected LA ratio (approx. 1.7).

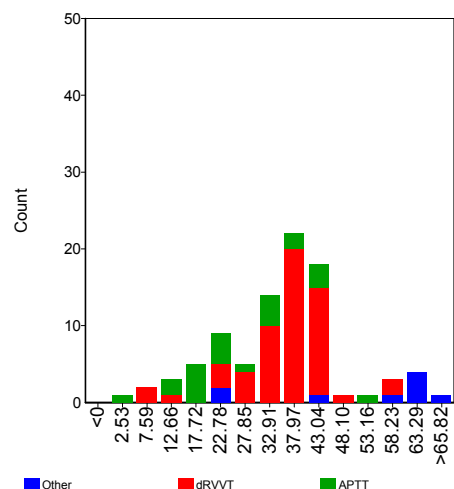
Lupus Anticoagulant

Interpretation

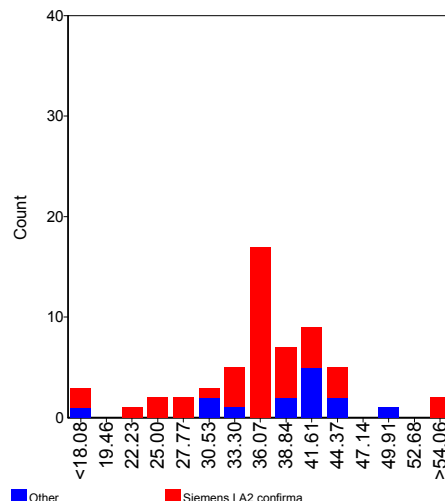
Percentage Correction - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	23	26.83	48.4	4.90 - 53.00							
Siemens Actin FS	9	21.30		13.70 - 43.00							
Stago Staclot LA	5	23.70		16.00 - 34.00							
dRVVT	57	36.76	17.1	9.38 - 59.00							
IL HemosIL dRVVT confirm	5	42.12		39.10 - 49.00							
Siemens LA2 confirmation	43	36.07	16.6	9.38 - 59.00							
Stago DRVVT Confirm	6	34.09		9.92 - 43.12							
SCT	7	62.50		43.10 - 66.30							
IL HemosIL SCT confirm	6	63.50		58.01 - 66.30							

Assays



DRVVT



Comments

Some participants did not indicate which type of correction they have reported (standard correction or normalised correction). These results have been excluded in the evaluation. **Don't forget to select the type of correction in the next survey.**

One participant reported a result, which was a ratio instead of a percentage correction and therefore was excluded in the statistical analysis.

Some participants reported their result for Percentage Correction as a negative result. Please, report in future surveys the result without the negative prefix.

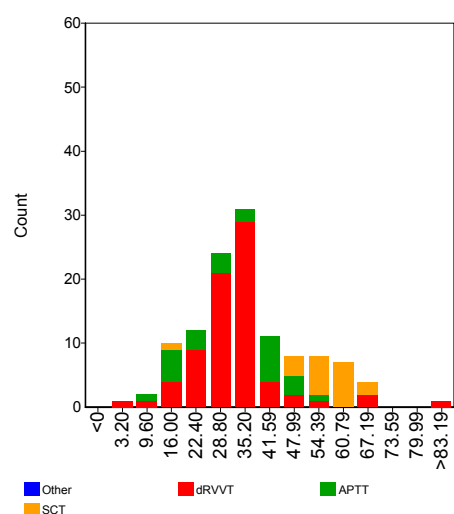
Lupus Anticoagulant

Interpretation

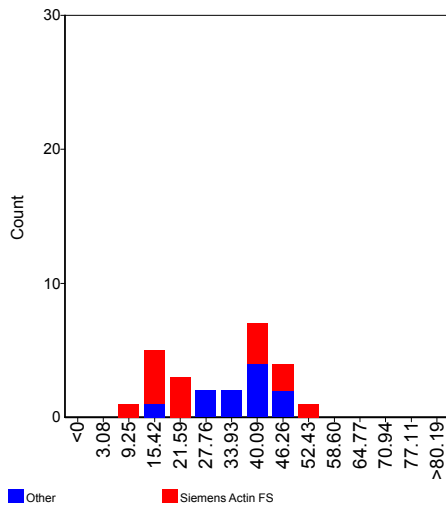
Percentage Correction - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	25	31.79	44.7	6.42 - 54.20							
Siemens Actin FS	14	28.79	59.5	6.42 - 54.20							
dRVVT	75	31.65	20.8	4.63 - 100.00							
IL HemosIL dRVVT confirm	29	32.78	22.7	4.63 - 100.00							
Siemens LA2 confirmation	29	30.90	20.3	10.80 - 69.40							
Stago DRVVT Confirm	9	35.80		19.00 - 50.00							
SCT	19	56.31	12.4	16.00 - 65.50							
IL HemosIL SCT confirm	19	56.31	12.4	16.00 - 65.50							

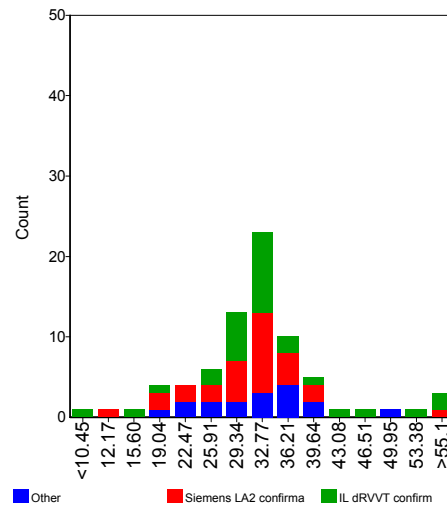
Assays



APTT



DRVVT



Comments

Some participants did not indicate which type of correction they have reported (standard correction or normalised correction). These results have been excluded in the evaluation. **Don't forget to select the type of correction in the next survey.**

A few participants reported a result, which was a ratio instead of a percentage correction and therefore were excluded in the statistical analysis.

Some participants reported their result for Percentage Correction as a negative result. Please, report in future surveys the result without the negative prefix.

Lupus Anticoagulant

Final Conclusion

Testing Strategies	Classification				Your Classification			
	Equivocal	LA detected	LA not detected	No conclusion	Test System	Panel 1	Panel 2	Panel 3
Screen test only	1	7	5	9	1			
					2			
					3			
Screen and mixing test	6	59	10	12	1			
					2			
					3			
Screen and confirm test	10	452	21	4	1			
					2			
					3			
Screen, mixing and confirm test	4	266	16	3	1			LA detected
					2			
					3			
Screen, confirm, mixing test	8	134	5	2	1			
					2			
					3			
Mixing - confirmation	2	29		3	1			
					2			
					3			

Final Conclusion				Your Results		
Counts				Test System 1	Test System 2	Test System 3
LA detected	LA not detected	Equivocal	No Conclusion			
497	7	11	3	LA detected		

Comments

The sample used in this survey was plasma from a patient diagnosed with Lupus Anticoagulant (LA Ratio = approx. 1.7). No other types of inhibitors were present.

In total 515 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 96% classified the sample as positive. Two percent classified the sample as equivocal. Thus, the vast majority of the participants correctly classified this sample as positive.

Several participants stated that there is an indication that this sample is positive for lupus anticoagulant but in real clinical practice this should be confirmed in a new sample after 12 weeks.

Lupus Anticoagulant

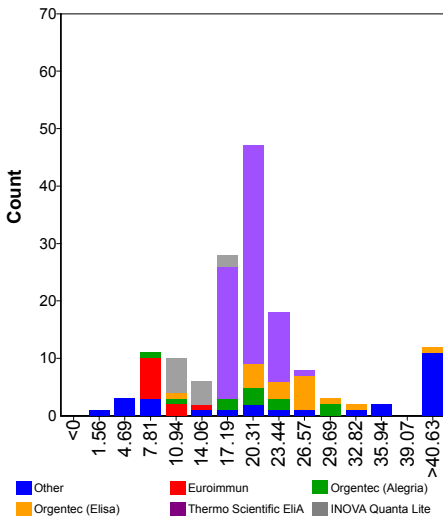
AntiCardiolipin Antibodies IgG

Sample No	22.209		
Sample Details	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.7)		
Prior Use	Prior Use: None		
Unit	GPL, U/mL, µg/mL, CU/mL		
Expiry Date	30-April-2025		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	622		
Number of Responders	239	Response Rate	38 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	37	19	66	48	70	1

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U/mL, µg/mL, GPL/MPL	151	19.6	32.9	2.0 - 540.0						
Aeskulisa Diagnostic GmbH	8	36.4		5.0 - 117.0						
Euroimmun	10	9.3	23.0	6.5 - 13.0						
INOVA Quanta Lite	12	13.2	23.9	9.8 - 18.5						
Orgentec (Alegria)	11	19.7	35.3	9.0 - 28.7						
Orgentec (Elisa)	17	25.2	18.9	12.4 - 45.4						
Other	5	8.0		3.5 - 19.0						
Thermo Scientific EliA	74	19.7	10.3	16.0 - 26.0						
CU/mL	77	121.3	11.0	97.7 - 145.0						
I.L. Acustar / INOVA Quanta Flash	76	121.2	11.1	97.7 - 145.0						

GPL, U/mL, µg/mL



Comments

A heterogeneous pattern in the classification has been observed.

The following participant reported a deviating result within their method group I.L. Acustar / INOVA Quanta Flash which was excluded in the statistical evaluation:

167 : 6.8 CU/mL

One participant (**1353**) reported the result as a ratio instead of one of the above mentioned units and was therefore excluded in the statistical evaluation.

Lupus Anticoagulant

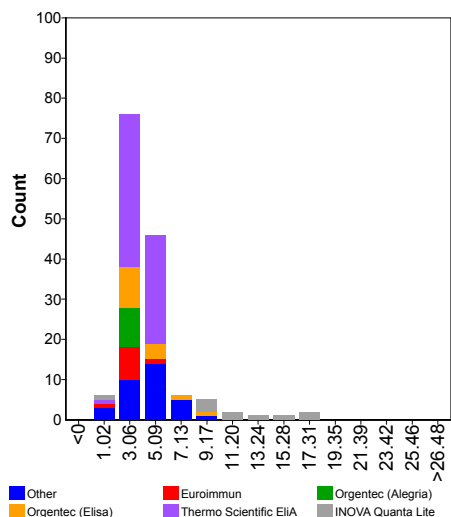
AntiCardiolipin Antibodies IgM

Sample No	22.209		
Sample Details	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.7)		
Prior Use	Prior Use: None		
Unit	MPL, U/mL, µg/mL, CU/mL		
Expiry Date	30-April-2025		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	622		
Number of Responders	226	Response Rate	36 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	225	1	1	0	0	1

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U/mL, µg/mL, GPL/MPL	145	4.0	27.9	0.0 - 18.0						
Aeskulisa Diagnostic GmbH	8	3.2		2.0 - 6.5						
Biorad Bioplex	9	5.3		4.4 - 6.8						
Euroimmun	10	3.4	19.0	2.0 - 4.1						
INOVA Quanta Lite	10	12.3	38.2	0.0 - 18.0						
Orgentec (Alegria)	10	3.1	15.3	2.4 - 3.7						
Orgentec (Elisa)	16	3.8	34.0	2.1 - 9.4						
Thermo Scientific EliA	66	3.9	12.7	1.1 - 5.3						
CU/mL	72	6.0	11.0	2.2 - 9.0						
I.L. Acustar / INOVA Quanta Flash	72	6.0	11.0	2.2 - 9.0						

MPL, U/mL, µg/mL



Comments

Most of the participants reported a negative classification.

One participant (**1353**) reported the result as a ratio instead of one of the above mentioned units and was therefore excluded in the statistical evaluation.

Lupus Anticoagulant

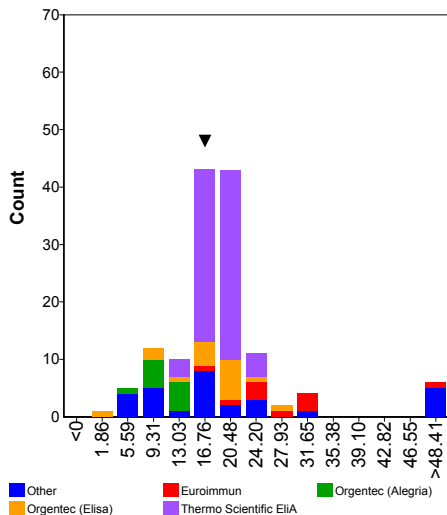
β2-Glycoprotein I Antibodies IgG

Sample No	22.209		
Sample Details	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.7)		
Prior Use	Prior Use: None		
Unit	U, U/mL, µg/mL, CU/mL		
Expiry Date	30-April-2025		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	622		
Number of Responders	223	Response Rate	36 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	22	7	52	46	97	1

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U, U/mL, µg/mL	137	18.2	28.6	2.8 - 604.0	16.6	-0.31				
Aeskulisa Diagnostic GmbH	8	7.7		4.0 - 22.8						
Euroimmun	10	28.0	24.3	18.0 - 162.1						
INOVA Quanta Lite	8	17.7		12.0 - 24.5						
Orgentec (Alegria)	11	10.4	22.0	7.0 - 13.3						
Orgentec (Elisa)	17	17.6	34.9	2.8 - 28.9	16.6	-0.17				
Thermo Scientific EIIA	70	18.7	11.0	14.0 - 25.9						
CU/mL	76	646.2	13.5	312.0 - 899.0						
I.L. Acustar / INOVA Quanta Flash	74	647.6	13.7	312.0 - 899.0						

U, U/mL, µg/mL



Comments

A heterogeneous pattern in the classification has been observed.

Lupus Anticoagulant

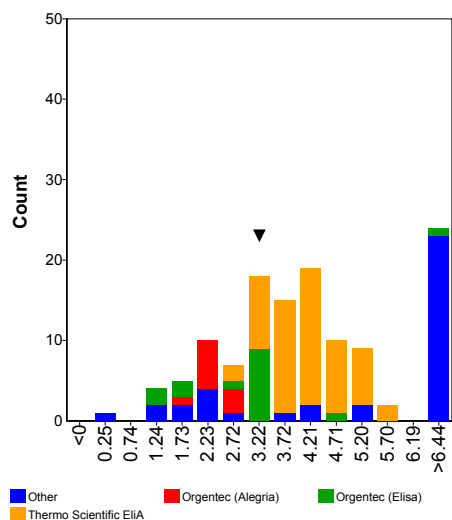
β2-Glycoprotein I Antibodies IgM

Sample No	22.209		
Sample Details	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.7)		
Prior Use	Prior Use: None		
Unit	U, U/mL, µg/mL, CU/mL		
Expiry Date	30-April-2025		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	622		
Number of Responders	198	Response Rate	32 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	196	3	1	0	0	1

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U, U/mL, µg/mL	124	4.2	47.6	0.0 - 20.0	3.3	-0.45				
Aeskulisa Diagnostic GmbH	8	2.0		1.0 - 2.5						
Biorad Bioplex	8	7.7		6.6 - 8.9						
Euroimmun	8	17.5		5.4 - 20.0						
Orgentec (Alegria)	10	2.3	13.4	1.9 - 2.6						
Orgentec (Elisa)	16	2.9	38.2	1.0 - 14.6	3.3	0.35				
Thermo Scientific EliA	60	4.1	19.1	2.6 - 5.6						
CU/mL	68	5.1	13.7	3.5 - 6.4						
I.L. Acustar / INOVA Quanta Flash	68	5.1	13.7	3.5 - 6.4						

U, U/mL, µg/mL



Comments

Most of the participants reported a negative classification.