

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2022-L1 Lupus Anticoagulant Labcode 1492

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Date of Issue : 18-May-2022
Survey : 2022-L1
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**Complaints**

Any complaints regarding this survey report should be reported to the ECAT before **July 1st, 2022**.

Complaints received after this date will not be taken into consideration.

Exclusion of results

Results < [value] or > [value] are excluded in the statistical analysis.

When other results are excluded in the statistical analysis, these results are placed between brackets.

Use of units

We observed several issue of improper use of units during this survey.

Lupus Anticoagulant

See comments in the respective sections.

Antiphospholipid Antibodies

Please be aware of the proper use of units. We have frequently observed the use of different units by participants using the same method while their results are comparable. For now we have harmonised the units. However it is the responsibility of the participant to use the correct units!

This report is authorized by:

Dr. M.J. van Essen-Hollestelle
Programme Expert

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 .

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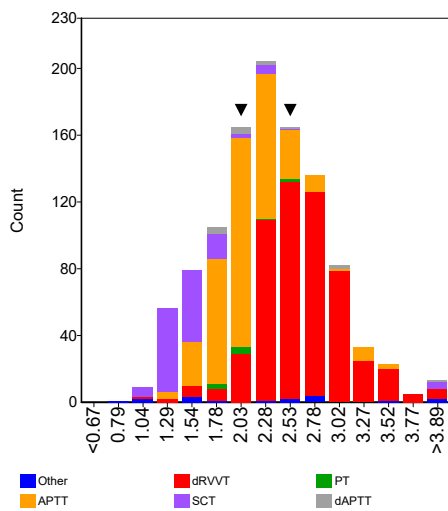
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Appendices are an integral part of the total report.

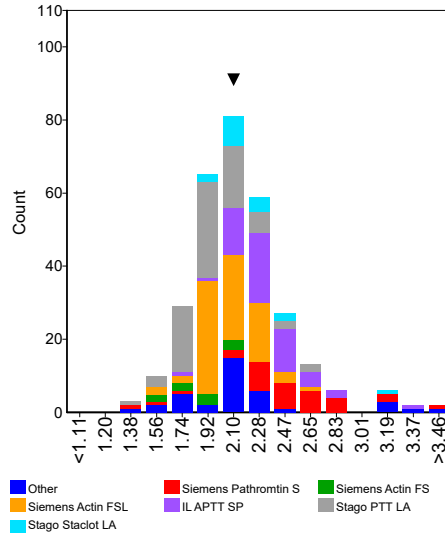
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	368	2.08	14.8	1.30 - 3.50	1	2.15	0.26	2.11	0.10		
Hyphen-Biomed Cephen LS	9	2.14		1.87 - 2.31							
IL APTT SP	53	2.32	8.7	1.82 - 3.28							
IL HemosIL SynthAsil	36	1.68	11.3	1.30 - 3.22							
IL MixCon	14	2.23	8.6	1.44 - 2.84							
Siemens Actin FS	10	1.86	13.2	1.52 - 2.11							
Siemens Actin FSL	78	2.06	8.6	1.49 - 2.60	1			2.11	0.26		
Siemens Pathromtin SL	33	2.47	13.3	1.37 - 3.50	1	2.15	-0.97				
Stago PTT Automate/STA APTT	15	1.88	7.2	1.70 - 2.19							
Stago PTT LA	75	1.95	9.9	1.37 - 2.67							
Stago Staclot LA	17	2.18	8.9	1.90 - 3.20							
Tocoag TriniClot Automated APTT	8	2.13		2.03 - 2.22							
dAPTT	14	2.24	23.4	1.78 - 4.25							
Stago PTT LA	6	1.94		1.78 - 2.31							
dPT	8	1.69		0.89 - 2.86							
dRVVT	540	2.63	14.7	1.00 - 5.85	1					2.43	-0.52
Hyphen Biomed Hemoclot LA-S	6	2.78		2.28 - 4.55							
I.L. HemosIL dRVVT screen	194	2.65	14.6	1.50 - 5.85							
Precision Biologic LA check	6	2.56		2.46 - 3.09							
Siemens LA1 screen	217	2.73	13.2	1.00 - 3.96	1					2.43	-0.82
Stago DRVVT screen	89	2.38	10.7	1.37 - 3.54							
Technoclone LA Screen	7	2.66		2.27 - 3.17							
KCT	7	2.84		2.44 - 4.25							
Homemade Kaolin	5	3.45		2.49 - 4.25							
PT	10	2.08	14.9	1.80 - 2.58							
IL HemosIL Recombiplastin (2nd gen.)	6	1.94		1.80 - 2.58							
SCT	127	1.47	16.9	1.07 - 7.73							
IL SCT screen	123	1.46	15.9	1.07 - 2.44							

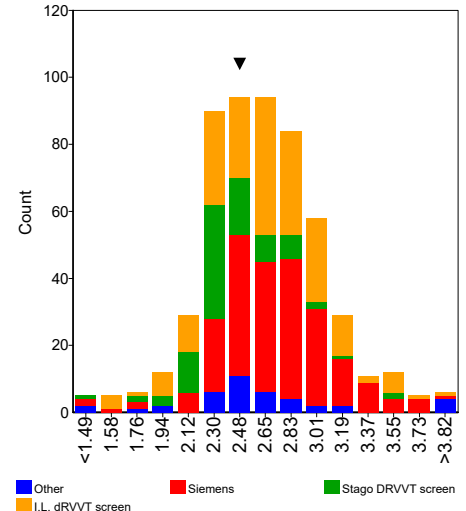
Assays



APTT



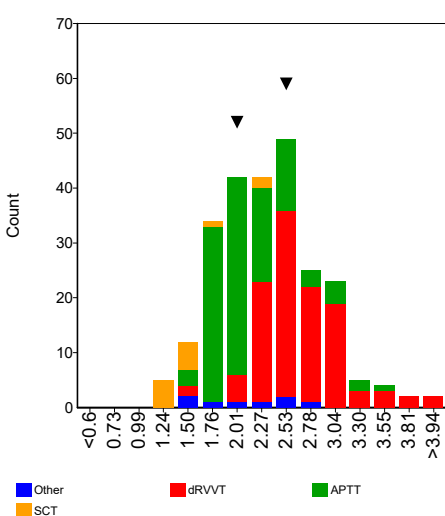
DRVVT



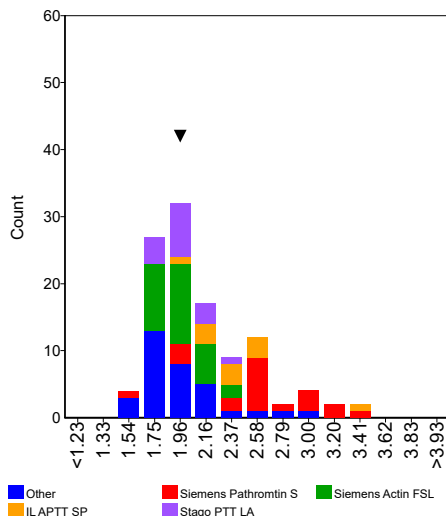
Lupus Anticoagulant **Screening**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	111	2.09	17.0	1.49 - 3.43	1	2.04	-0.14	2.03	-0.17		
IL APTT SP	11	2.34	11.3	2.01 - 3.43							
IL HemosIL SynthAsil	8	1.78		1.49 - 2.76							
Siemens Actin FSL	30	1.95	8.9	1.71 - 2.39	1			2.03	0.41		
Siemens Pathromtin SL	21	2.58	17.4	1.59 - 3.32	1	2.04	-1.22				
Stago PTT Automate/STA APTT	7	1.79		1.72 - 1.92							
Stago PTT LA	16	1.96	9.1	1.68 - 2.32							
Stago Staclot LA	5	2.39		1.75 - 3.09							
dRVVT	113	2.64	14.7	1.45 - 4.75	1					2.48	-0.41
I.L. HemosIL dRVVT screen	22	2.69	15.5	2.17 - 3.79							
Siemens LA1 screen	70	2.62	13.7	1.45 - 4.75	1					2.48	-0.39
Stago DRVVT screen	10	2.58	12.4	2.19 - 3.00							
SCT	13	1.45	14.7	1.22 - 2.19							
IL SCT screen	13	1.45	14.7	1.22 - 2.19							

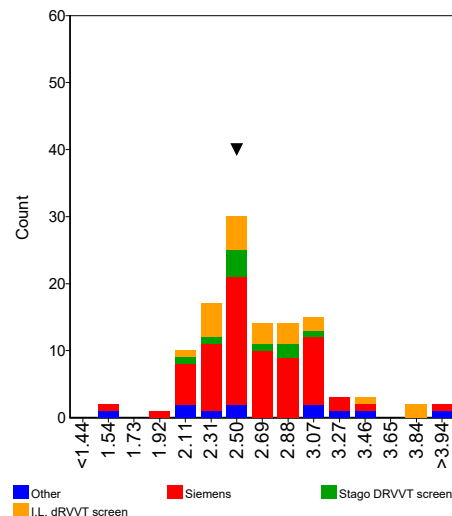
Assays



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.

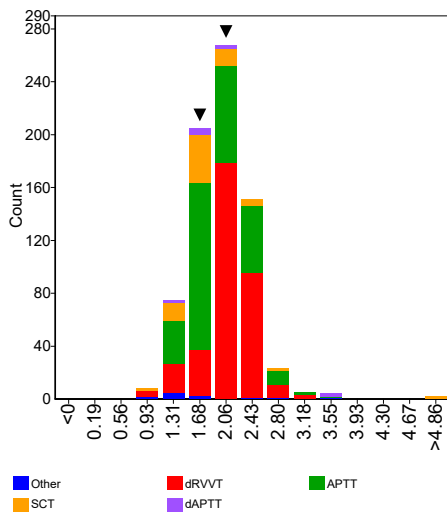
The vast majority of performed screening tests (> 98%) were classified as elevated.

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

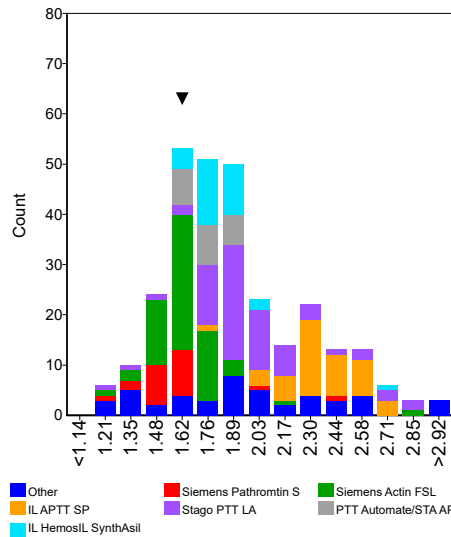
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	295	1.89	19.5	1.17 - 3.53	1			1.63	-0.70		
Hyphen-Biomed Cephen LS	7	2.36		1.87 - 3.34							
IL APTT SP	42	2.36	8.0	1.73 - 2.74							
IL Hemosil SynthAFax	5	1.69		1.58 - 2.05							
IL Hemosil SynthAsil	30	1.80	6.7	1.66 - 2.74							
IL MixCon	6	2.35		1.17 - 2.58							
Siemens Actin FS	8	1.34		1.17 - 1.78							
Siemens Actin FSL	62	1.63	8.0	1.24 - 2.90	1			1.63	-0.01		
Siemens Pathromtin SL	22	1.55	8.9	1.26 - 2.48							
Stago PTT Automate/STA APTT	21	1.75	7.5	1.57 - 1.94							
Stago PTT LA	68	1.96	10.9	1.17 - 2.89							
Tocoag TriniClot Automated APTT	9	1.90		1.85 - 2.23							
dAPTT	13	2.12	43.2	1.31 - 3.59							
dRVVT	347	2.11	13.2	0.84 - 3.29	1					2.23	0.42
I.L. Hemosil dRVVT confirm	7	1.21		1.14 - 2.11							
I.L. Hemosil dRVVT screen	91	2.16	12.9	1.41 - 3.23							
Precision Biologic LA check	5	2.42		2.27 - 2.47							
Siemens LA1 screen	154	2.18	10.9	0.84 - 2.99	1					2.23	0.21
Siemens LA2 confirmation	11	1.16	5.1	1.00 - 2.11							
Stago DRVVT screen	55	2.00	7.3	1.60 - 2.53							
Technoclone LA Screen	6	2.21		1.91 - 2.27							
PT	5	1.15		1.03 - 1.75							
SCT	74	1.73	19.5	1.06 - 7.73							
IL SCT screen	68	1.73	17.0	1.28 - 2.87							

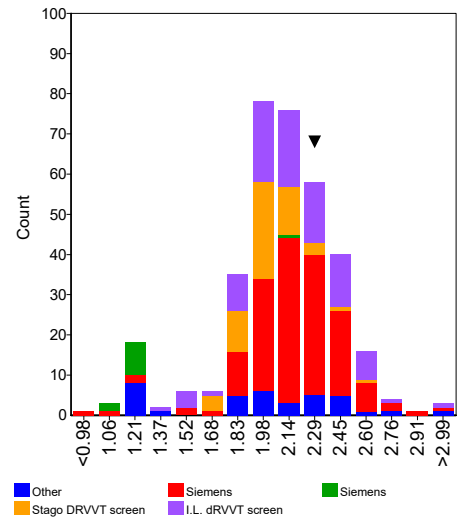
Assays



APTT



DRVVT



Lupus Anticoagulant

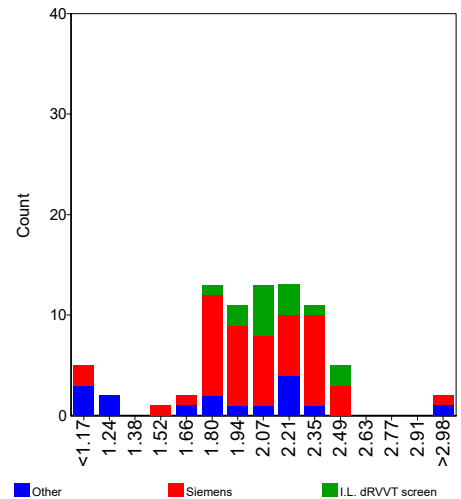
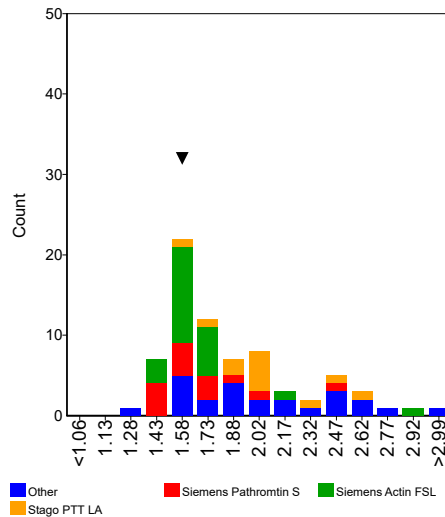
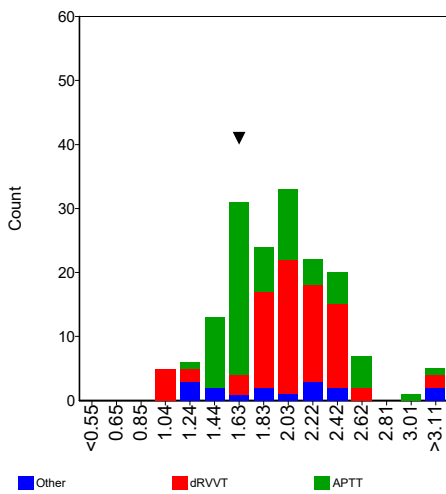
Mixing

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	73	1.83	19.5	1.30 - 3.50	1			1.58	-0.69		
IL APTT SP	8	2.48		1.83 - 2.69							
Siemens Actin FSL	23	1.61	7.4	1.45 - 2.98	1			1.58	-0.26		
Siemens Pathromtin SL	14	1.66	12.0	1.47 - 2.48							
Stago PTT LA	12	2.04	15.4	1.65 - 2.59							
dRVVT	78	2.06	15.2	1.00 - 4.69							
I.L. HemosIL dRVVT screen	14	2.15	9.1	1.80 - 2.55							
Siemens LA1 screen	48	2.08	14.6	1.10 - 4.69							
Stago DRVVT screen	6	2.15		1.86 - 2.36							
SCT	8	1.94		1.51 - 2.31							
IL SCT screen	8	1.94		1.51 - 2.31							

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.

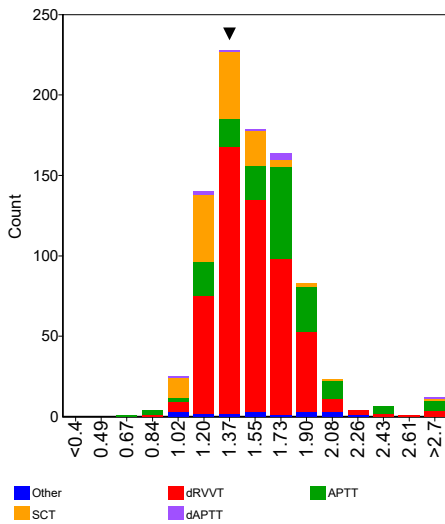
The majority of performed mixing tests (> 97%) were classified as elevated.

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

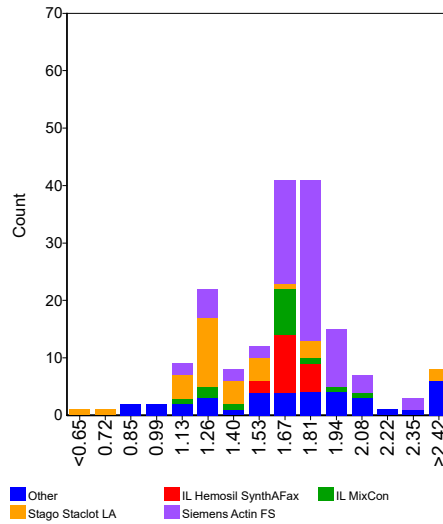
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	173	1.66	18.9	0.58 - 4.40							
IL Hemosil SynthAFax	17	1.69	6.0	1.48 - 1.86							
IL MixCon	15	1.62	16.4	1.09 - 2.06							
Siemens Actin FS	72	1.76	8.9	1.18 - 2.41							
Siemens Pathromtin SL	6	0.99		0.81 - 1.29							
Stago Staclot LA	32	1.39	17.8	0.58 - 2.91							
Technoclone Lupus Anticoagulant Test	5	3.38		1.98 - 3.73							
dAPTT	10	1.53	24.7	1.00 - 3.71							
dPT	6	1.89		1.01 - 2.32							
dRVVT	543	1.52	16.1	0.88 - 3.32	1					1.35	-0.69
Hyphen Biomed Hemoclot LA-C	7	1.42		1.13 - 1.83							
IL Hemosil dRVVT confirm	183	1.71	10.0	1.08 - 3.00							
IL Hemosil LAC confirm	16	1.66	15.7	1.15 - 2.02							
Precision Biologic LA sure	6	1.52		1.21 - 1.80							
Siemens LA2 confirmation	216	1.42	10.9	1.00 - 3.21	1					1.35	-0.44
Stago DRVVT Confirm	84	1.38	7.4	0.88 - 1.79							
Technoclone LA Confirm	9	1.33		1.16 - 1.52							
PNP	6	1.36		1.06 - 1.60							
SCT	127	1.32	13.1	0.93 - 3.56							
IL Hemosil SCT confirm	126	1.32	12.9	0.93 - 2.05							

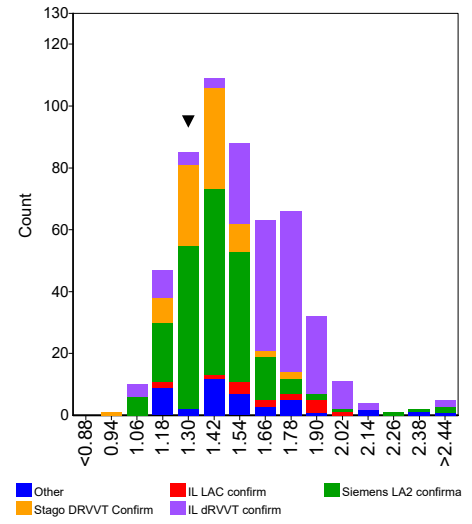
Assays



APTT



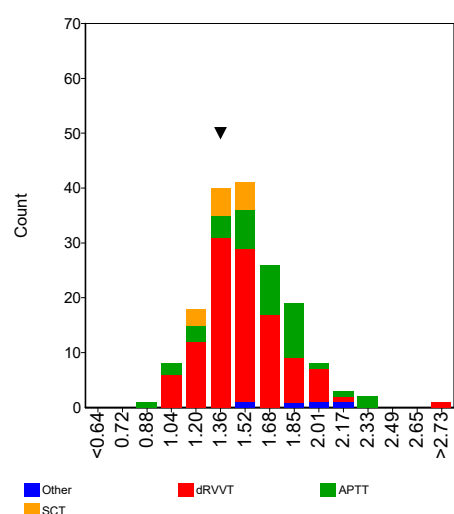
DRVVT



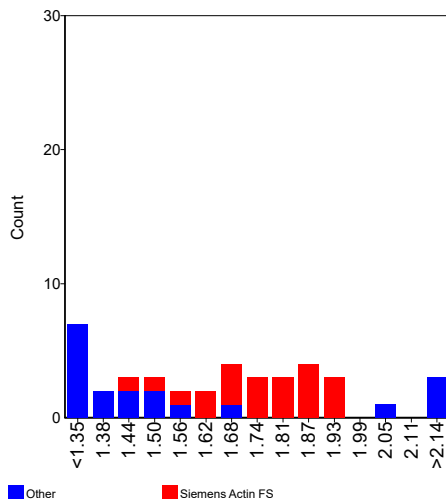
Lupus Anticoagulant **Confirmation**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	40	1.62	20.2	0.93 - 2.35							
Siemens Actin FS	21	1.75	7.5	1.46 - 1.90							
Siemens Pathromtin SL	6	1.12		0.93 - 1.46							
Stago Staclot LA	7	1.50		1.13 - 2.35							
dRVVT	110	1.49	15.9	1.06 - 3.26	1					1.44	-0.24
IL HemosIL dRVVT confirm	19	1.70	14.4	1.08 - 2.10							
IL HemosIL LAC confirm	5	1.67		1.18 - 1.98							
Siemens LA2 confirmation	67	1.44	13.0	1.06 - 2.03	1					1.44	-0.02
Stago DRVVT Confirm	10	1.40	11.8	1.07 - 1.55							
SCT	13	1.39	9.4	1.19 - 1.53							
IL HemosIL SCT confirm	13	1.39	9.4	1.19 - 1.53							

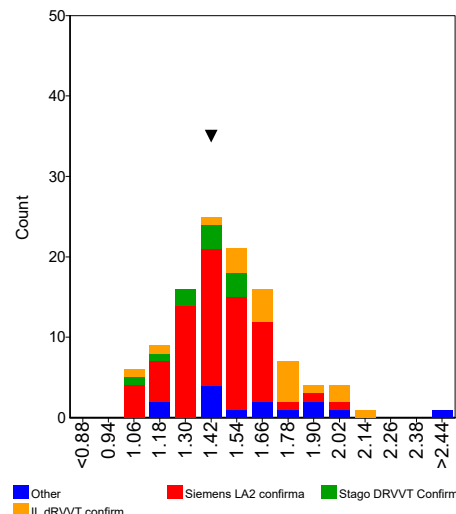
Assays



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 confirmation tests (> 91%) 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).

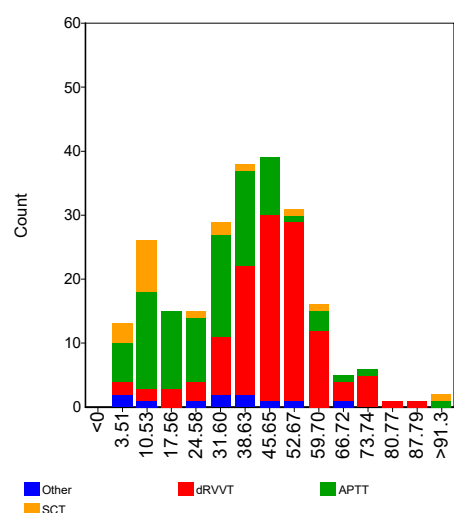
Lupus Anticoagulant

Interpretation

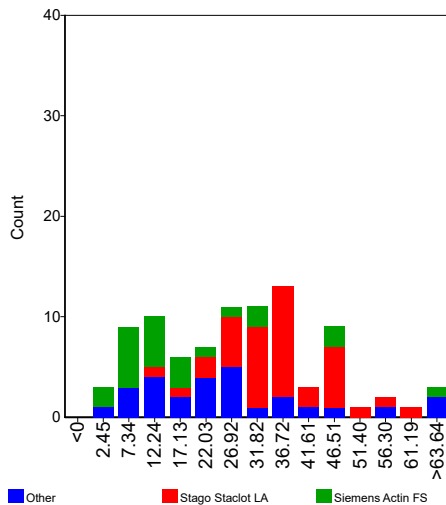
Delta Seconds

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	90	28.11	57.4	0.03 - 92.00							
IL Hemosil SynthAFax	6	17.45		2.50 - 27.60							
Siemens Actin FS	23	16.33	75.3	0.03 - 63.80							
Siemens Pathromtin SL	6	32.05		19.80 - 44.90							
Stago Staclot LA	39	35.94	25.7	12.00 - 59.20							
dRVVT	118	46.57	24.8	3.50 - 87.70							
IL Hemosil dRVVT confirm	30	43.34	23.1	17.90 - 60.60							
Siemens LA2 confirmation	68	48.88	21.0	3.50 - 79.70							
Stago DRVVT Confirm	11	41.74	33.9	10.00 - 60.10							
SCT	18	19.49	94.4	2.80 - 149.60							
IL Hemosil SCT confirm	16	15.16	87.8	2.80 - 49.50							

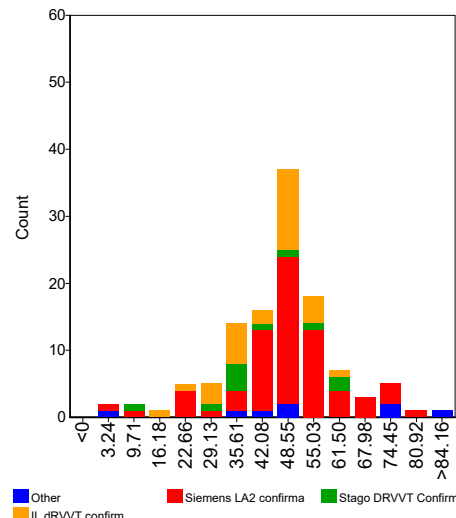
Assays



APTT



DRVVT



Comments

It is not clear whether all results submitted for Delta Seconds reflect in all cases 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 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.

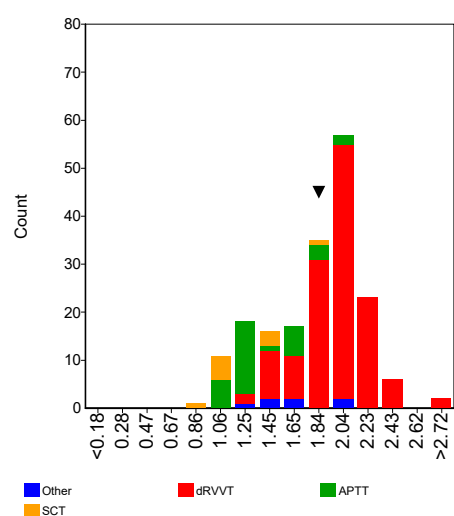
Lupus Anticoagulant

Interpretation

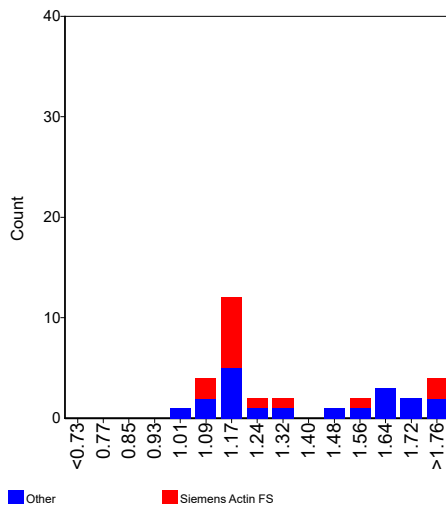
Ratio Screen/Confirmation - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	33	1.36	22.4	1.00 - 2.04							
Siemens Actin FS	14	1.24	13.8	1.05 - 2.03							
Stago Staclot LA	8	1.69		1.12 - 2.04							
dRVVT	136	1.97	11.3	1.33 - 3.32	1					1.88	-0.41
IL HemosIL dRVVT confirm	15	1.61	11.9	1.34 - 1.83							
Siemens LA2 confirmation	91	2.05	7.3	1.40 - 2.49	1					1.88	-1.11
Stago DRVVT Confirm	14	1.85	7.2	1.67 - 2.11							
SCT	10	1.21	28.4	0.83 - 1.75							
IL HemosIL SCT confirm	9	1.04		0.83 - 1.53							

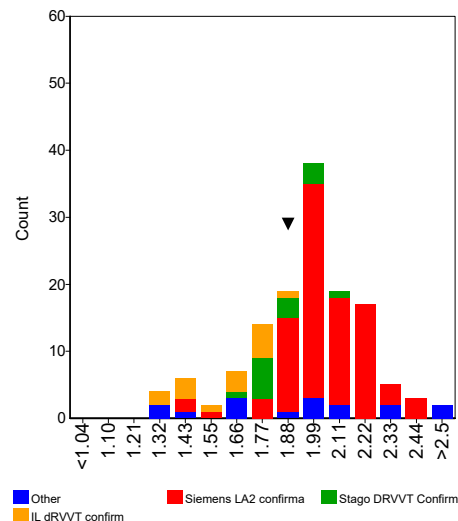
Assays



APTT



DRVVT



Comments

Some participants did not indicate which type of ratio screen/confirmation they reported (standard ratio or normalised ratio). A few participants reported a ratio, which was likely to be the result in seconds. These results have been excluded in the statistical evaluation. Don't forget to select the type of ratio in the next survey.

The average ratio screen / confirmation is slightly lower compared to the expected LA ratio (approx. 2.0).

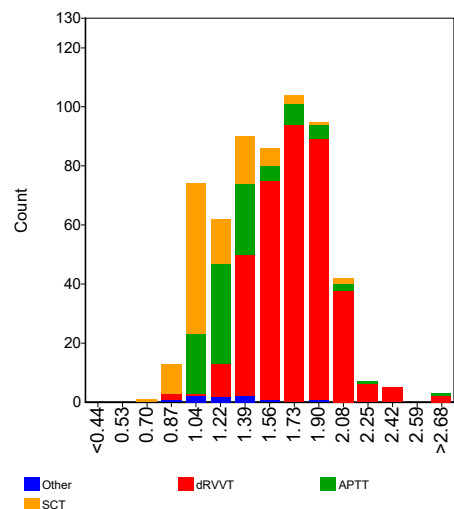
Lupus Anticoagulant

Interpretation

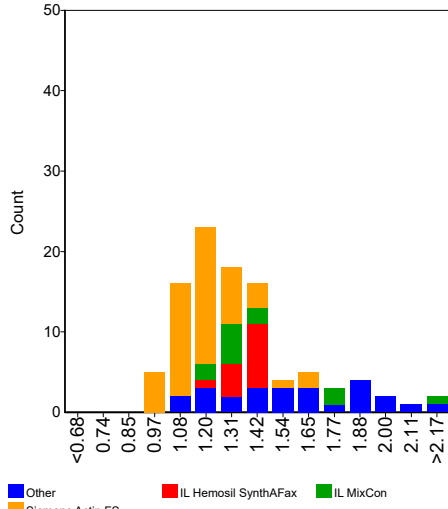
Ratio Screen/Confirmation - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	99	1.32	17.9	0.99 - 4.40							
IL Hemosil SynthAFax	13	1.37	5.4	1.25 - 1.47							
IL MixCon	12	1.43	17.4	1.14 - 2.26							
Siemens Actin FS	49	1.18	10.6	0.99 - 1.70							
Siemens Pathromtin SL	6	1.91		1.71 - 2.12							
Stago Staclot LA	5	1.61		1.20 - 1.87							
dRVVT	369	1.73	14.8	0.83 - 2.91							
Hyphen Biomed Hemoclot LA-C	6	1.71		1.34 - 2.77							
IL HemosIL dRVVT confirm	150	1.57	13.2	0.83 - 2.36							
IL HemosIL LAC confirm	9	1.70		1.28 - 1.98							
Siemens LA2 confirmation	120	1.91	9.0	0.90 - 2.91							
Stago DRVVT Confirm	59	1.72	7.7	1.46 - 2.02							
Technoclone LA Confirm	5	1.91		1.84 - 2.50							
SCT	105	1.15	18.3	0.77 - 2.09							
IL HemosIL SCT confirm	104	1.14	18.0	0.77 - 2.09							

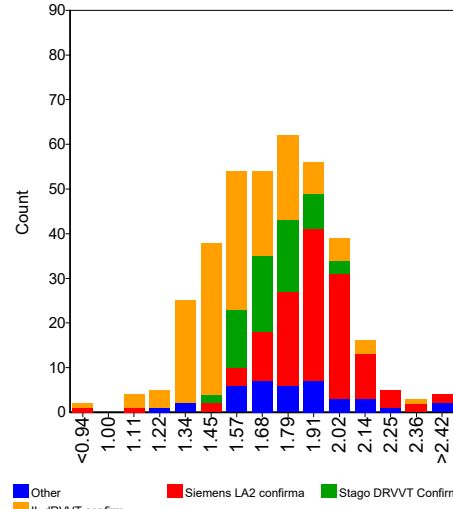
Assays



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 statistical evaluation. Don't forget to select the type of ratio in the next survey.

The average ratio screen / confirmation is slightly lower compared to the expected LA ratio (approx. 2.0).

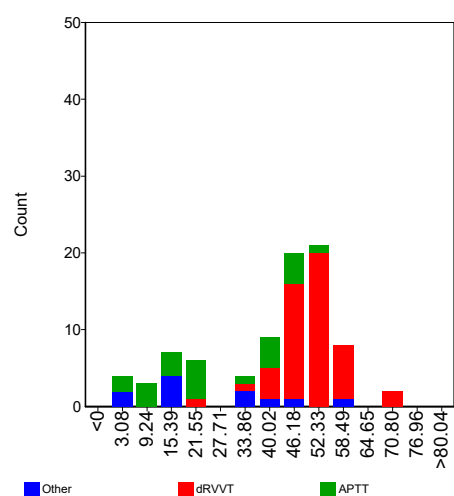
Lupus Anticoagulant

Interpretation

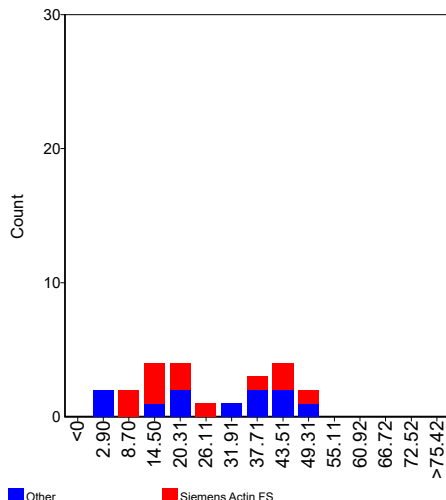
Percentage Correction - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	23	26.17	68.6	0.00 - 50.78							
Siemens Actin FS	12	24.88	67.7	8.00 - 50.78							
Stago Staclot LA	6	38.15		12.00 - 47.20							
dRVVT	50	50.38	10.5	22.70 - 70.00							
Siemens LA2 confirmation	36	51.59	8.8	22.70 - 70.00							
Stago DRVVT Confirm	6	44.03		38.40 - 52.80							
SCT	7	17.91		3.70 - 42.70							
IL HemosIL SCT confirm	6	16.04		3.70 - 35.30							

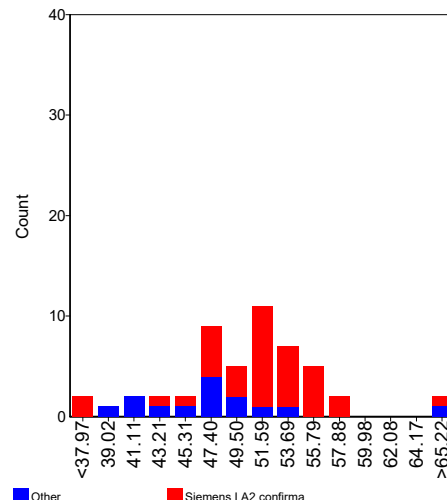
Assays



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 statistical evaluation. Don't forget to select the type of correction in the next survey.

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

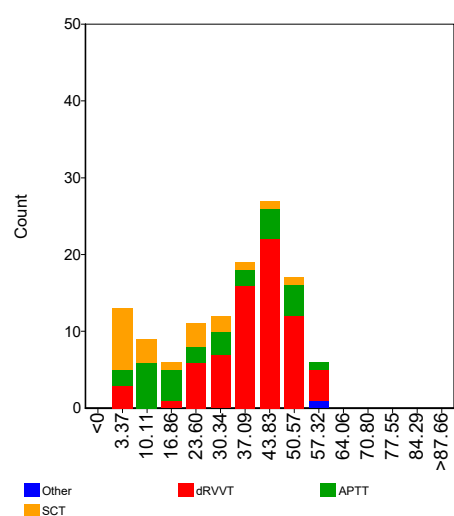
Lupus Anticoagulant

Interpretation

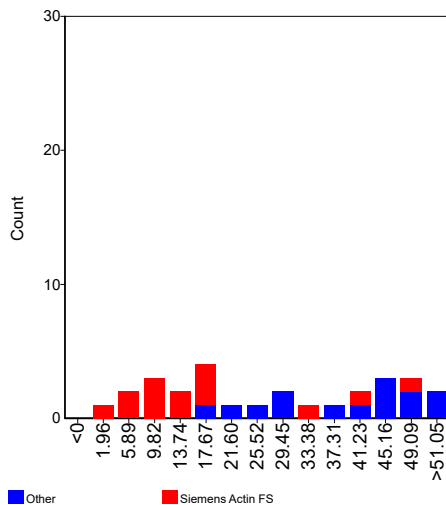
Percentage Correction - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	28	28.14	68.0	1.66 - 55.00							
Siemens Actin FS	14	15.82	74.3	1.66 - 49.70							
Siemens Pathromtin SL	6	47.59		41.50 - 52.82							
dRVVT	71	40.58	25.9	0.30 - 59.70							
IL HemosIL dRVVT confirm	28	36.95	36.5	0.30 - 59.70							
Siemens LA2 confirmation	24	47.25	7.7	3.00 - 53.84							
Stago DRVVT Confirm	12	37.08	18.8	1.67 - 46.00							
SCT	21	14.14	115.6	-0.03 - 53.30							
IL HemosIL SCT confirm	20	12.75	118.4	-0.03 - 53.30							

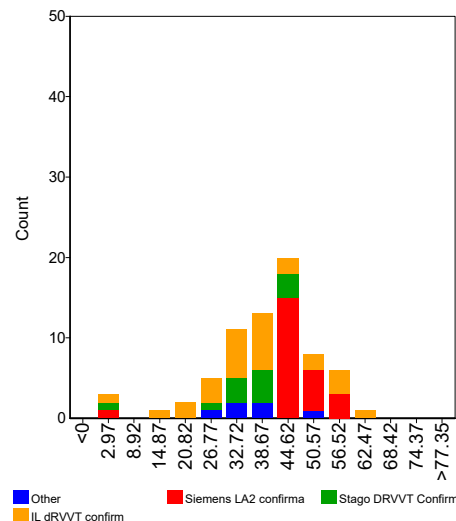
Assays



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 statistical evaluation. Don't forget to select the type of correction in the next survey.

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	0	12	0	10	1			
					2			
					3			
Screen and mixing test	2	71	1	13	1			
					2			
					3			
Screen and confirm test	17	334	59	14	1			
					2			
					3			
Screen, mixing and confirm test	20	241	18	8	1			LA detected
					2			
					3			
Screen, confirm, mixing test	3	155	14	9	1			
					2			
					3			
Mixing - confirmation		29	2	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			
493	2	8	17	LA detected		

Comments

The sample used in this survey was plasma from a patient diagnosed with Lupus Anticoagulant (LA Ratio = approx. 2.0).

In total 503 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 98% indicated Lupus Anticoagulant was detected. About 1.6 % classified the sample as equivocal. Thus, the vast majority of the participants correctly classified this sample as a Lupus Anticoagulant positive.

A few participants indicated that a coagulation factor deficiency can not be excluded. Also some participants reported an INR of approximately 2.

Lupus Anticoagulant

AntiCardiolipin Antibodies IgG

Sample No 22.63
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 2.0)
Prior Use Prior Use: None
Unit GPL, U/mL, µg/mL, CU/mL
Expiry Date 31-October-2023
Homogeneity 0.0 %

Homogeneity Parameter LA ratio

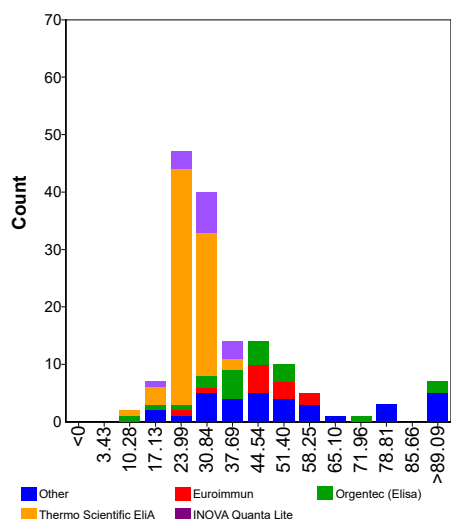
For any method used for the measurement of this parameter with a **CV ≤ 0.0%** the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.

Number of Participants 607
Number of Responders 232 **Response Rate** 38 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	8	15	51	64	94	4

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	33.4	35.9	8.2 - 280.0						
Aeskulisa Diagnostic GmbH	7	79.0		40.0 - 131.4						
Euroimmun	12	46.2	18.5	26.0 - 58.2						
INOVA Quanta Lite	14	30.8	16.5	18.4 - 41.0						
Orgentec (Alegria)	9	44.2		38.2 - 58.4						
Orgentec (Elisa)	20	41.4	38.4	8.2 - 91.6						
Thermo Scientific EliA	72	26.5	15.5	12.7 - 35.0						
CU/mL	74	174.8	11.4	34.8 - 936.5						
I.L. Acustar / INOVA Quanta Flash	73	174.7	11.5	34.8 - 936.5						

GPL, U/mL, µg/mL



Comments

A positive classification has been observed for the majority of participants.

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

Lupus Anticoagulant

AntiCardiolipin Antibodies IgM

Sample No 22.63
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 2.0)
Prior Use Prior Use: None
Unit MPL, U/mL, µg/mL, CU/mL
Expiry Date 31-October-2023
Homogeneity 0.0 %

Homogeneity Parameter LA ratio

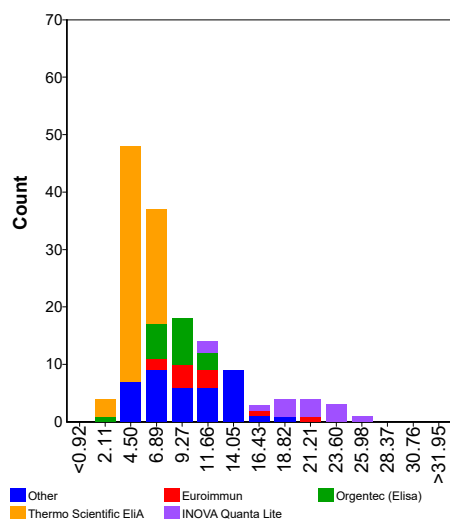
For any method used for the measurement of this parameter with a **CV ≤ 0.0%** the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.

Number of Participants 607
Number of Responders 214 **Response Rate** 35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	172	17	24	0	2	3

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	7.9	48.1	1.0 - 25.0						
Aeskulisa Diagnostic GmbH	7	9.3		5.0 - 17.0						
Biorad Bioplex	8	13.4		11.9 - 14.9						
Euroimmun	11	10.4	30.4	5.9 - 21.0						
INOVA Quanta Lite	13	19.7	20.9	11.4 - 25.0						
Orgentec (Alegria)	9	7.7		6.0 - 8.8						
Orgentec (Elisa)	18	8.8	21.1	1.0 - 11.7						
Thermo Scientific EliA	64	5.2	16.9	2.6 - 7.7						
CU/mL	68	13.1	10.0	10.4 - 15.7						
I.L. Acustar / INOVA Quanta Flash	67	13.1	10.0	10.4 - 15.7						

MPL, U/mL, µg/mL



Comments

A negative classification has been observed for the majority of participants.

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

Lupus Anticoagulant

β2-Glycoprotein I Antibodies IgG

Sample No 22.63
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 2.0)
Prior Use Prior Use: None
Unit U, U/mL, µg/mL, CU/mL
Expiry Date 31-October-2023
Homogeneity 0.0 % **Homogeneity Parameter** LA ratio

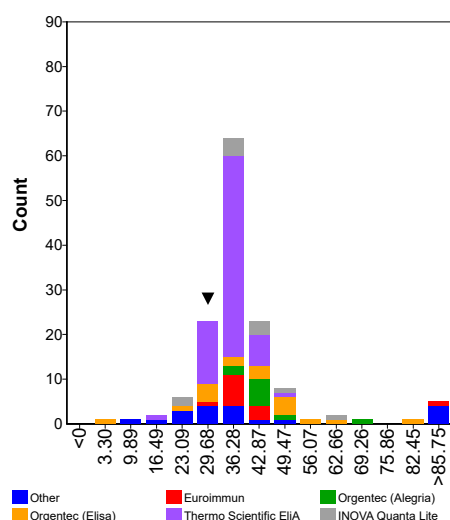
For any method used for the measurement of this parameter with a **CV ≤ 0.0%** the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.

Number of Participants 607
Number of Responders 215 **Response Rate** 35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	1	2	22	65	124	4

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	138	36.6	18.7	6.5 - 199.2	26.8	-1.43				
Aeskulisa Diagnostic GmbH	8	27.0		13.4 - 51.9						
Euroimmun	12	37.9	15.0	30.0 - 199.2						
INOVA Quanta Lite	11	38.1	26.9	23.0 - 60.0						
Orgentec (Alegria)	10	41.6	14.2	33.3 - 69.4						
Orgentec (Elisa)	18	41.9	34.9	6.5 - 80.4	26.8	-1.03				
Thermo Scientific EliA	68	35.1	11.3	19.7 - 47.0						
CU/mL	72	821.4	16.8	29.7 - 1119.0						
I.L. Acustar / INOVA Quanta Flash	71	824.3	16.5	29.7 - 1119.0						

U, U/mL, µg/mL



Comments

A positive classification has been observed for the majority of participants.

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

Lupus Anticoagulant

β2-Glycoprotein I Antibodies IgM

Sample No 22.63
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 2.0)
Prior Use Prior Use: None
Unit U, U/mL, µg/mL, CU/mL
Expiry Date 31-October-2023
Homogeneity 0.0 %

Homogeneity Parameter LA ratio

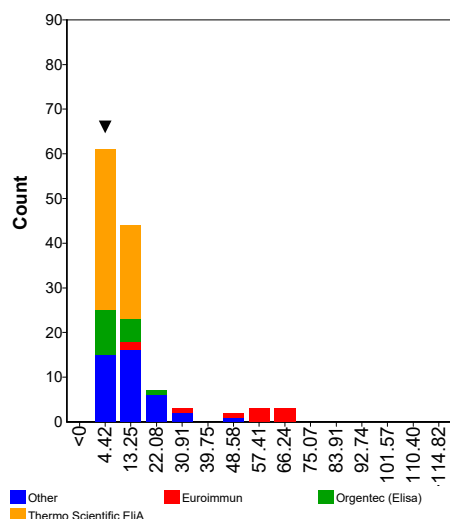
For any method used for the measurement of this parameter with a **CV ≤ 0.0%** the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.

Number of Participants 607
Number of Responders 189 **Response Rate** 31 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	105	38	39	8	2	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	123	9.4	33.0	1.0 - 68.0	7.7	-0.54				
Aeskulisa Diagnostic GmbH	8	5.8		1.0 - 11.0						
Biorad Bioplex	6	24.9		23.3 - 27.4						
Euroimmun	10	47.9	46.6	10.0 - 68.0						
INOVA Quanta Lite	8	11.6		10.0 - 13.0						
Orgentec (Alegria)	9	7.6		6.4 - 10.7						
Orgentec (Elisa)	16	8.5	32.9	4.5 - 19.7	7.7	-0.28				
Thermo Scientific EliA	57	8.4	16.5	4.8 - 13.0						
CU/mL	65	9.8	13.7	6.7 - 13.6						
I.L. Acustar / INOVA Quanta Flash	64	9.8	13.5	6.7 - 13.6						

U, U/mL, µg/mL



Comments

A negative classification has been observed for the majority of participants.

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

