

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2023-L1 (A)
Lupus Anticoagulant
Labcode 1492

Date of Issue : 26-May-2023
Survey : 2023-L1 (A)
Report : Lupus Anticoagulant

Note:

In the Survey Manual 2023 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2023 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 in the paragraph on the statistical evaluation of the Survey Manual.

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

This is an amended survey report 2023-L1 (A) (version 2.0.0) and replaces the Mixing (confirm) module in the Lupus Anticoagulant Survey Report 2023-L1 dated 19 May 2023 (version 1.0.0). The report of 19 May 2023 is not valid anymore.

The reason for the amended report is the fact that in the Mixing (confirm) module, the Z-scores were not shown correctly in the tables for "Ratio Normal Plasma" and "Ratio MRI".

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 **July 11th, 2023**. 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.

Modified report

Because of the changes in the online result report form we have also modified the survey report. For the mixing test it is now possible to report a result separately for a screening and confirmation test. These results are displayed in the report as separate parameters.

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. 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.

ECAT Foundation

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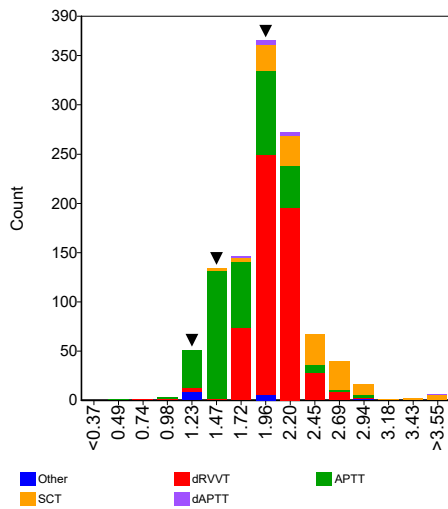
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Appendices are an integral part of the total report.

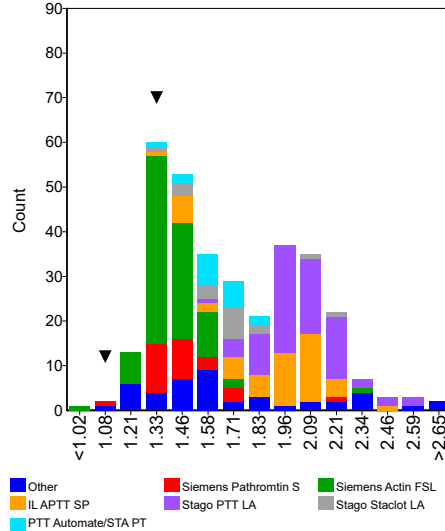
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	377	1.70	20.2	0.60 - 3.01	1	1.13	-1.65	1.35	-1.00		
Hyphen-Biomed Cephen LS	8	2.17		1.89 - 2.37							
IL APTT SP	51	1.91	13.0	1.33 - 2.47							
IL HemosIL SynthAsil	42	1.77	8.8	0.60 - 2.31							
IL MixCon	12	1.51	2.6	1.36 - 1.58							
Siemens Actin FS	7	1.22		1.07 - 1.97							
Siemens Actin FSL	89	1.40	7.2	0.94 - 2.39	1			1.35	-0.46		
Siemens Pathromtin SL	28	1.44	9.9	1.13 - 2.20	1	1.13	-2.18				
Stago CKPrest / APTT Kaolin	6	1.42		1.22 - 1.47							
Stago PTT Automate/STA PTT	18	1.63	7.3	1.28 - 1.83							
Stago PTT LA	75	2.03	8.7	1.60 - 2.61							
Stago Staclot LA	18	1.68	10.3	1.36 - 2.18							
Tcoag TriniClot APTT-HS	6	1.67		1.39 - 1.80							
Tcoag TriniClot Automated APTT	8	1.55		1.44 - 1.63							
dAPTT	11	2.05	12.2	1.72 - 4.55							
Stago PTT LA	9	2.02		1.76 - 2.28							
dPT	6	2.01		1.20 - 2.07							
dRVVT	560	2.04	9.5	0.64 - 2.92	1					1.93	-0.55
Hyphen Biomed Hemoclot LA-S	8	2.50		2.22 - 2.92							
I.L. HemosIL dRVVT screen	201	2.01	8.4	1.52 - 2.92							
Precision Biologic LA check	7	2.19		1.83 - 2.34							
Roche Lupus S	7	2.11		1.75 - 2.23							
Siemens LA1 screen	232	2.11	7.6	0.64 - 2.69	1					1.93	-1.11
Stago DRVVT screen	87	1.90	7.0	1.35 - 2.68							
Technoclone LA Screen	7	1.95		1.79 - 1.98							
PT	5	1.13		1.11 - 1.23							
SCT	142	2.39	16.3	1.36 - 7.26							
IL SCT screen	136	2.37	15.6	1.36 - 3.45							

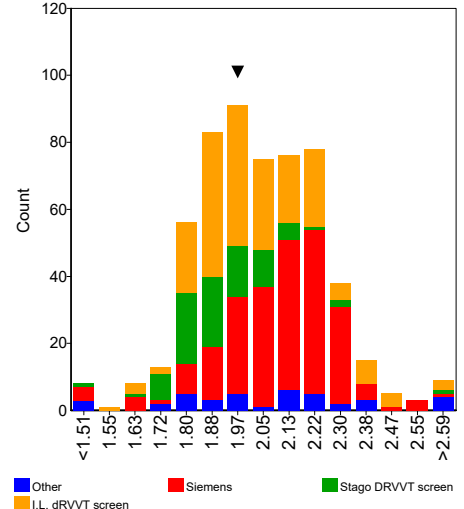
Assays



APTT



DRVVT

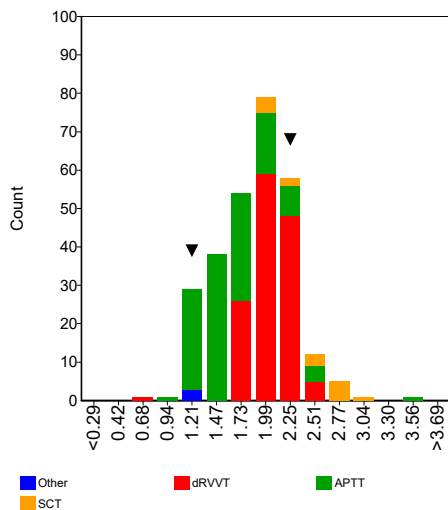


Lupus Anticoagulant

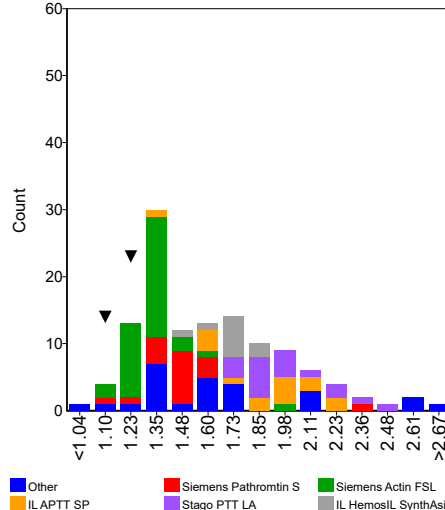
Screening

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	122	1.60	21.5	0.99 - 3.50	1	1.26	-1.00	1.10	-1.45		
IL APTT SP	15	1.90	13.6	1.38 - 2.20							
IL HemosIL SynthAsil	10	1.73	5.2	1.42 - 1.84							
Siemens Actin FSL	35	1.32	7.1	1.10 - 1.93	1			1.10	-2.34		
Siemens Pathromtin SL	18	1.47	7.0	1.12 - 2.39	1	1.26	-2.05				
Stago PTT Automate/STA PTT	6	1.66		1.58 - 1.70							
Stago PTT LA	18	1.96	9.7	1.74 - 2.47							
dRVVT	139	2.05	9.6	0.61 - 2.60	1					2.28	1.12
I.L. HemosIL dRVVT screen	27	1.99	9.6	1.67 - 2.44							
Siemens LA1 screen	85	2.10	7.9	0.61 - 2.43	1					2.28	1.07
Stago DRVVT screen	15	1.92	9.4	1.71 - 2.31							
SCT	15	2.45	16.8	1.86 - 2.94							
IL SCT screen	15	2.45	16.8	1.86 - 2.94							

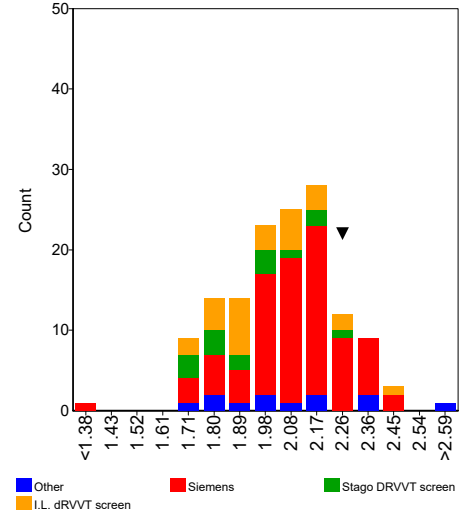
Assays



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. 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.

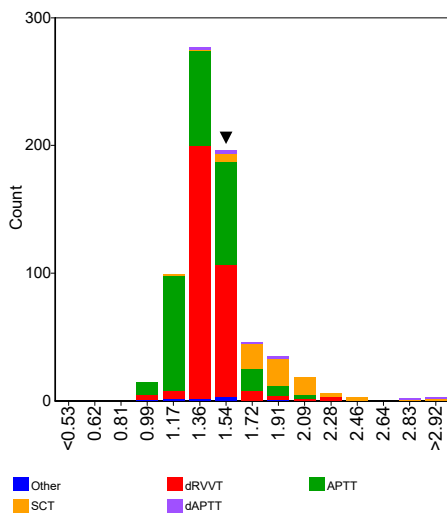
The vast majority of performed screening tests (> 98%) were classified as elevated.

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

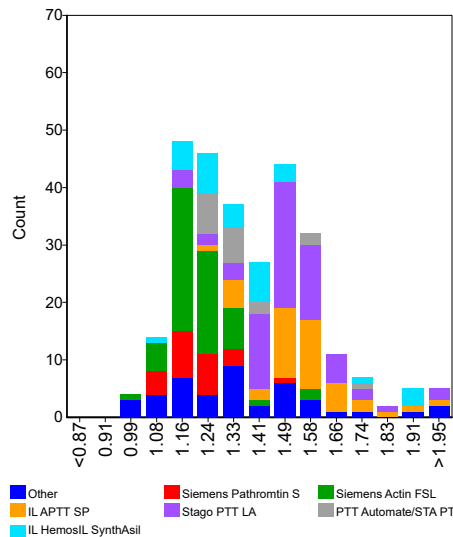
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	282	1.37	15.2	0.96 - 2.18							
Hyphen-Biomed Cephen LS	5	1.61		1.48 - 1.73							
IL APTT SP	42	1.55	8.6	1.25 - 2.18							
IL HemosIL SynthAsil	31	1.35	11.7	1.07 - 1.91							
IL MixCon	8	1.47		0.96 - 1.99							
Siemens Actin FS	5	1.13		1.03 - 1.21							
Siemens Actin FSL	59	1.21	6.2	1.00 - 1.62							
Siemens Pathromtin SL	23	1.19	7.2	1.09 - 1.51							
Stago PTT Automate/STA PTT	18	1.33	7.0	1.24 - 1.74							
Stago PTT LA	66	1.50	7.8	1.13 - 2.11							
Tocoag TriniClot APTT-HS	5	1.45		1.11 - 1.48							
Tocoag TriniClot Automated APTT	8	1.31		1.25 - 1.36							
dAPTT	10	1.72	23.1	1.44 - 3.46							
Stago PTT LA	7	1.46		1.44 - 1.83							
dRVVT	328	1.42	6.8	0.94 - 2.36	1					1.45	0.26
I.L. HemosIL dRVVT screen	85	1.45	7.1	1.03 - 1.94							
Siemens LA1 screen	168	1.43	6.0	0.94 - 2.23	1					1.45	0.28
Stago DRVVT screen	48	1.39	7.0	1.23 - 1.88							
Technoclone LA Screen	6	1.42		1.38 - 1.44							
SCT	72	1.90	13.0	1.21 - 3.23							
IL SCT screen	70	1.89	12.6	1.21 - 3.23							

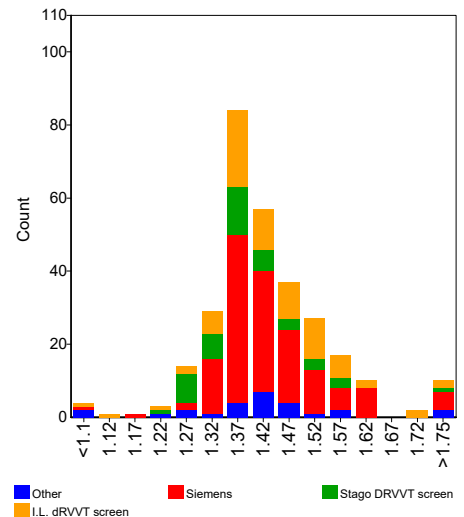
Assays



APTT



DRVVT

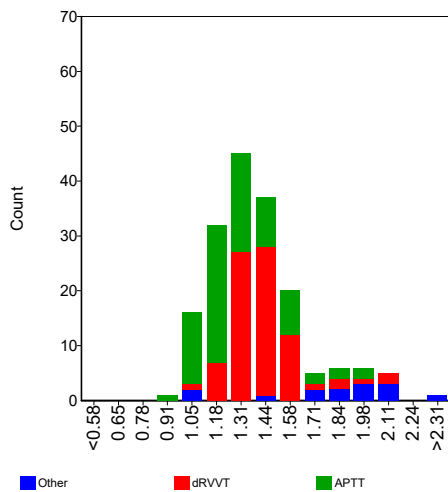


Lupus Anticoagulant

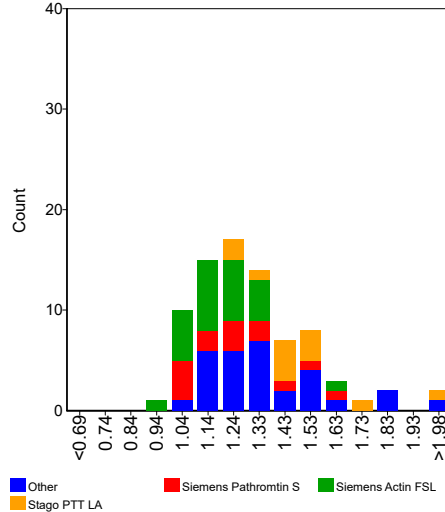
Mixing (screening)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	80	1.29	15.5	0.93 - 2.01							
IL APTT SP	8	1.56		1.25 - 1.79							
IL HemosIL SynthAsil	7	1.19		1.05 - 1.85							
Siemens Actin FSL	24	1.17	10.0	0.93 - 1.65							
Siemens Pathromtin SL	14	1.23	14.6	1.05 - 1.64							
Stago PTT Automate/STA PTT	6	1.30		1.22 - 1.36							
Stago PTT LA	12	1.46	11.9	1.22 - 1.99							
dRVVT	80	1.42	9.3	1.00 - 2.16							
I.L. HemosIL dRVVT screen	12	1.53	16.9	1.32 - 2.16							
Siemens LA1 screen	52	1.42	9.2	1.00 - 2.07							
Stago DRVVT screen	8	1.34		1.20 - 1.59							
SCT	7	1.99		1.78 - 2.11							
IL SCT screen	6	2.03		1.92 - 2.11							

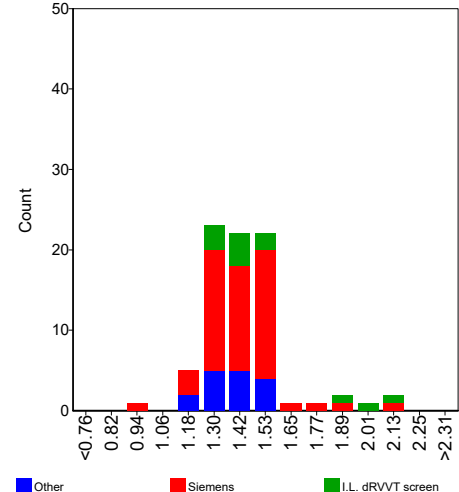
Assays



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. Two participants reported negative results 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.

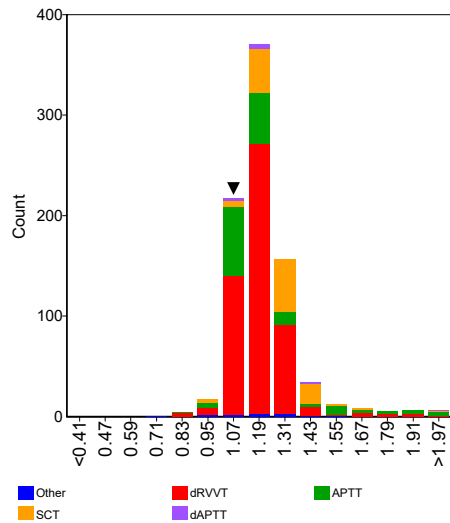
The vast majority of performed mixing (screen) tests (> 90%) were classified as elevated.

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

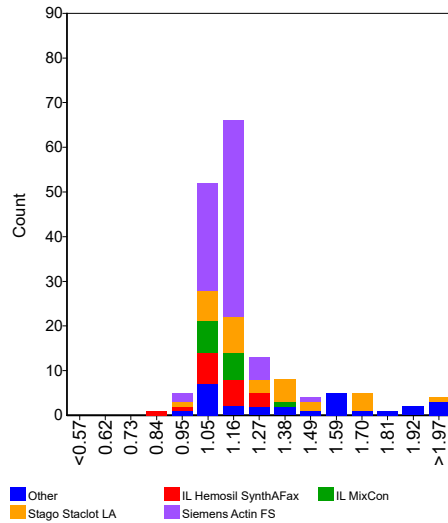
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	166	1.16	9.7	0.84 - 3.22							
IL Hemosil SynthAFax	18	1.13	8.6	0.84 - 1.29							
IL MixCon	14	1.11	3.8	1.03 - 1.35							
Siemens Actin FS	76	1.13	5.6	0.98 - 1.51							
Stago Staclot LA	31	1.27	18.4	1.00 - 2.10							
dAPTT	10	1.28	15.3	1.03 - 2.99							
dRVVT	559	1.18	7.1	0.84 - 2.00	1					1.11	-0.84
Hyphen Biomed Hemoclot LA-C	8	1.21		1.13 - 1.45							
IL Hemosil dRVVT confirm	200	1.21	7.3	0.86 - 1.89							
Precision Biologic LA sure	6	1.20		1.08 - 1.32							
Roche Lupus C	7	1.31		1.17 - 1.35							
Siemens LA2 confirmation	237	1.17	6.3	0.84 - 2.00	1					1.11	-0.84
Stago DRVVT Confirm	81	1.15	6.1	1.04 - 1.77							
Technoclone LA Confirm	9	1.11		1.02 - 1.23							
PNP	7	1.04		0.70 - 1.35							
SCT	139	1.28	8.8	0.92 - 2.23							
IL Hemosil SCT confirm	139	1.28	8.8	0.92 - 2.23							

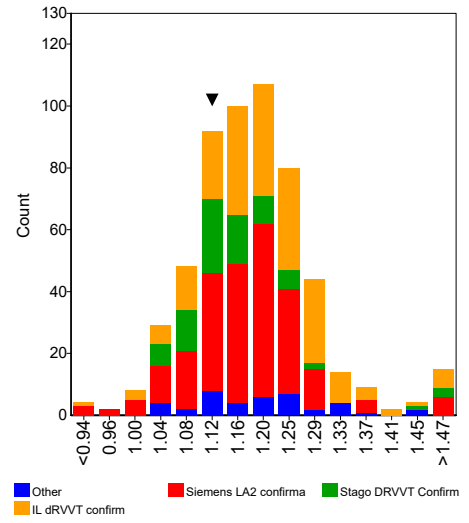
Assays



APTT



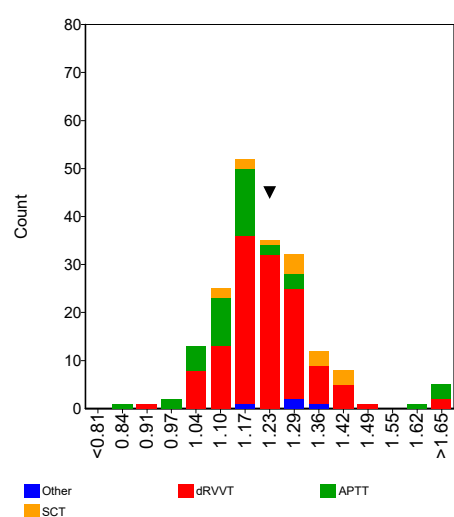
DRVVT



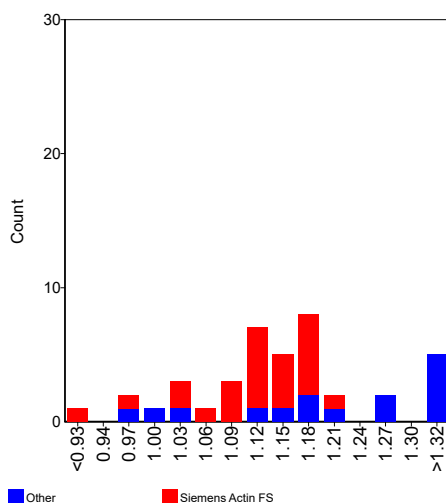
Lupus Anticoagulant **Confirmation**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	41	1.15	9.0	0.86 - 1.72							
Siemens Actin FS	26	1.12	5.8	0.86 - 1.21							
Stago Staclot LA	6	1.44		1.01 - 1.71							
dRVVT	128	1.22	7.8	0.93 - 1.93	1					1.25	0.34
IL HemosIL dRVVT confirm	25	1.26	8.0	1.02 - 1.76							
Siemens LA2 confirmation	78	1.21	7.8	0.93 - 1.44	1					1.25	0.44
Stago DRVVT Confirm	14	1.17	7.3	1.01 - 1.27							
SCT	15	1.29	9.5	1.10 - 1.44							
IL HemosIL SCT confirm	15	1.29	9.5	1.10 - 1.44							

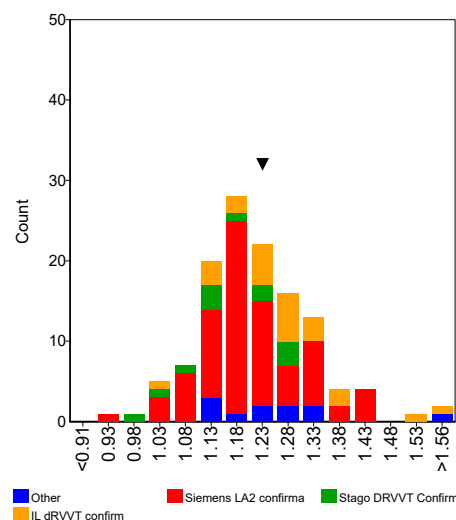
Assays



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. 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 performed confirmation tests (> 61%) 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 can vary between (slightly) elevated and (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

Mixing (confirm)

Sample No	23.63		
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.7)		
Prior Use	Prior Use: None		
Unit	Ratio		
Expiry Date	30-September-2024		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	619		
Number of Responders	169	Response Rate	27 %

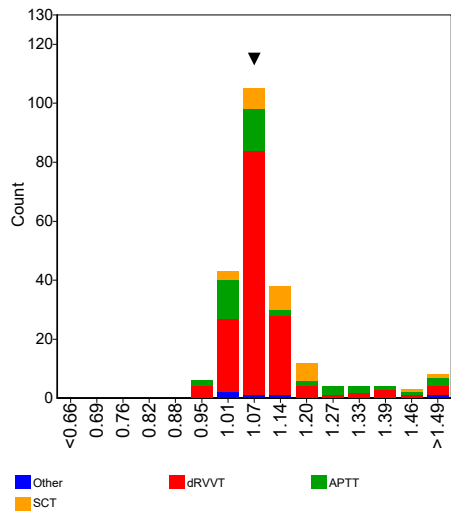
Assay	Elevated	Not elevated	Borderline	No Classification
APTT	20	27	0	3
dAPTT	2	1	0	0
dPT	0	1	0	0
dRVVT	49	107	0	9
Other	0	0	0	0
PT	0	1	0	0
SCT	7	18	0	2

Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Not elevated						
Other									
PT									
SCT									

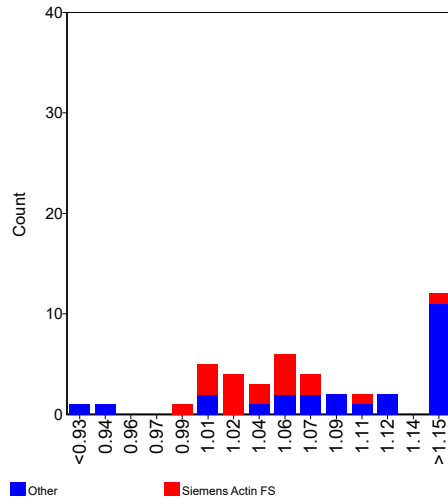
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	43	1.11	11.5	0.92 - 1.55							
Siemens Actin FS	18	1.04	3.4	0.99 - 1.18							
dRVVT	153	1.08	4.5	0.94 - 1.90	1					1.06	-0.49
IL HemosIL dRVVT confirm	34	1.08	4.8	0.95 - 1.31							
Siemens LA2 confirmation	96	1.09	4.0	0.94 - 1.90	1					1.06	-0.58
Stago DRVVT Confirm	15	1.07	4.3	1.02 - 1.19							
SCT	26	1.13	7.4	1.01 - 1.67							
IL HemosIL SCT confirm	26	1.13	7.4	1.01 - 1.67							

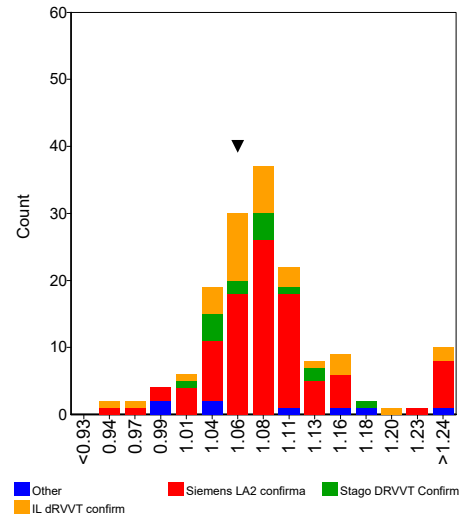
Assays



APTT



DRVVT

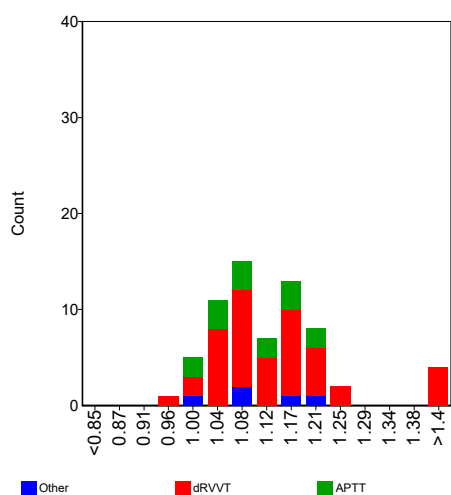


Lupus Anticoagulant

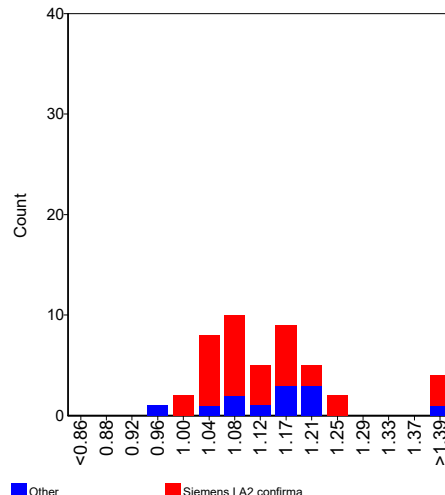
Mixing (confirm)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	15	1.11	7.7	1.00 - 1.23							
Siemens Actin FS	9	1.08		1.01 - 1.18							
dRVVT	46	1.13	8.0	0.95 - 2.00							
IL HemosIL dRVVT confirm	8	1.14		0.95 - 1.50							
Siemens LA2 confirmation	34	1.12	7.9	1.01 - 2.00							

Assays



DRVVT



Comments

One participant 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. 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.

A part of performed mixing (confirm) tests (> 33%) 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 mixing confirm 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

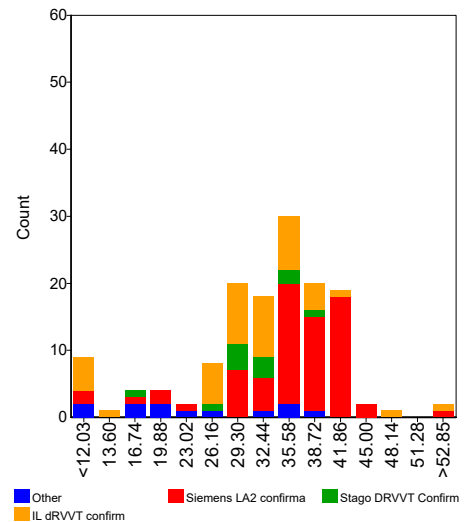
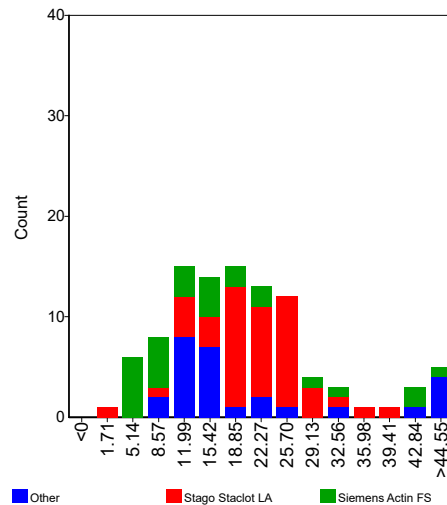
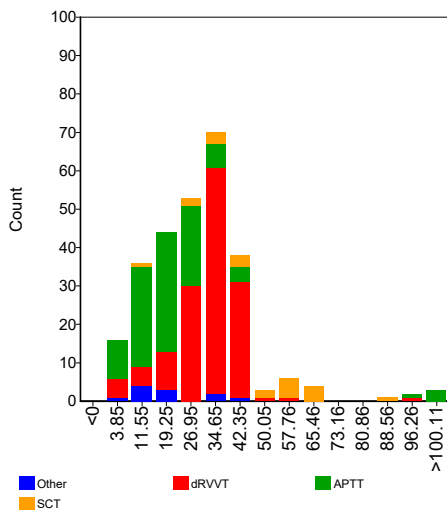
Delta Seconds

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	102	19.16	47.5	0.00 - 154.30							
IL Hemosil SynthAFax	8	15.20		10.59 - 21.60							
Siemens Actin FS	27	15.10	65.0	6.00 - 45.60							
Stago Staclot LA	47	21.24	26.5	0.00 - 37.90							
dRVVT	142	33.31	22.1	1.00 - 99.20							
IL Hemosil dRVVT confirm	45	31.23	20.5	1.00 - 58.30							
Siemens LA2 confirmation	71	36.77	14.6	5.50 - 99.20							
Stago DRVVT Confirm	12	30.93	11.3	17.60 - 38.00							
PNP	6	11.45		0.20 - 31.10							
SCT	21	49.94	33.5	8.20 - 88.60							
IL Hemosil SCT confirm	21	49.94	33.5	8.20 - 88.60							

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).

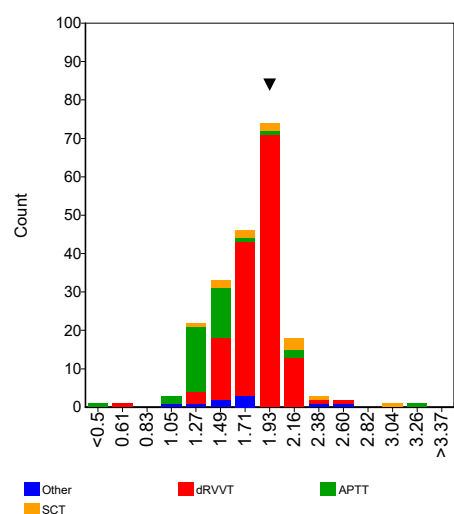
Lupus Anticoagulant

Interpretation

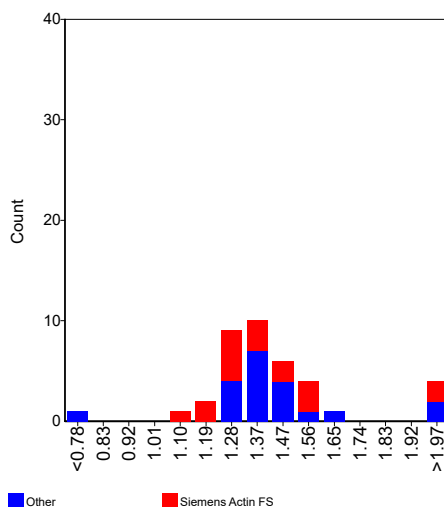
Ratio Screen/Confirmation - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	38	1.39	12.2	0.40 - 3.15							
Siemens Actin FS	18	1.37	14.4	1.09 - 3.15							
Stago Staclot LA	8	1.41		1.35 - 1.68							
dAPTT	5	1.61		1.30 - 2.55							
dRVVT	146	1.84	10.1	0.70 - 2.55	1					1.94	0.53
IL HemosIL dRVVT confirm	22	1.70	9.9	1.47 - 2.18							
Siemens LA2 confirmation	96	1.92	6.8	1.30 - 2.55	1					1.94	0.18
Stago DRVVT Confirm	15	1.74	8.4	1.53 - 1.93							
SCT	12	1.93	24.7	1.36 - 3.10							
IL HemosIL SCT confirm	12	1.93	24.7	1.36 - 3.10							

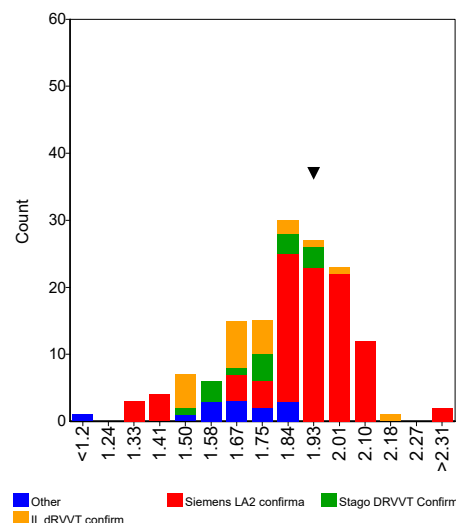
Assays



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).

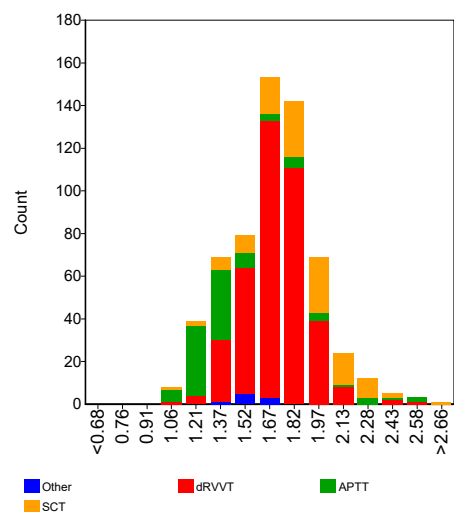
Lupus Anticoagulant

Interpretation

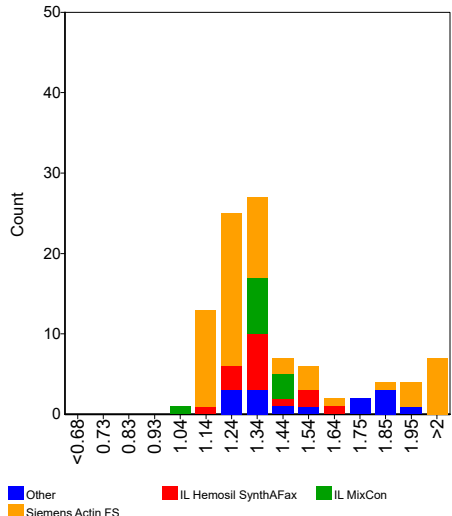
Ratio Screen/Confirmation - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	98	1.37	15.3	1.00 - 2.60							
IL Hemosil SynthAFax	15	1.36	9.5	1.11 - 1.61							
IL MixCon	11	1.37	3.1	1.00 - 1.46							
Siemens Actin FS	58	1.34	16.5	1.09 - 2.60							
dRVVT	384	1.71	9.8	1.04 - 2.53							
Hyphen Biomed Hemoclot LA-C	8	2.05		1.36 - 2.53							
IL Hemosil dRVVT confirm	162	1.65	9.1	1.04 - 2.13							
Siemens LA2 confirmation	135	1.79	7.6	1.25 - 2.17							
Stago DRVVT Confirm	63	1.67	6.0	1.29 - 2.04							
Technoclone LA Confirm	5	1.65		1.39 - 1.75							
SCT	113	1.87	14.2	1.07 - 2.70							
IL Hemosil SCT confirm	113	1.87	14.2	1.07 - 2.70							

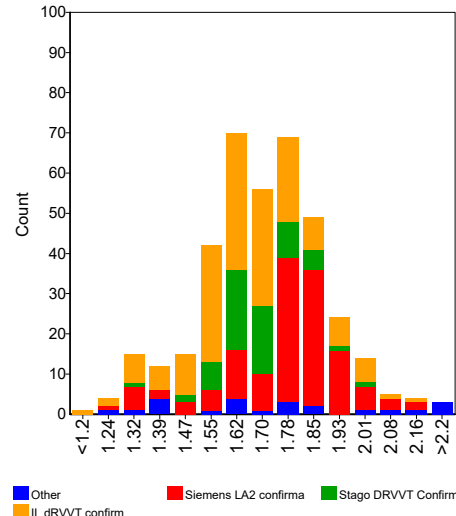
Assays



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).

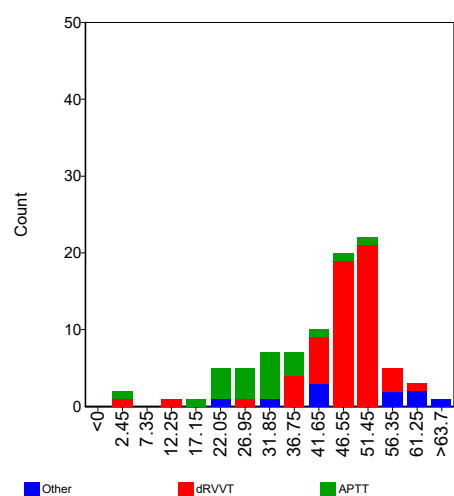
Lupus Anticoagulant

Interpretation

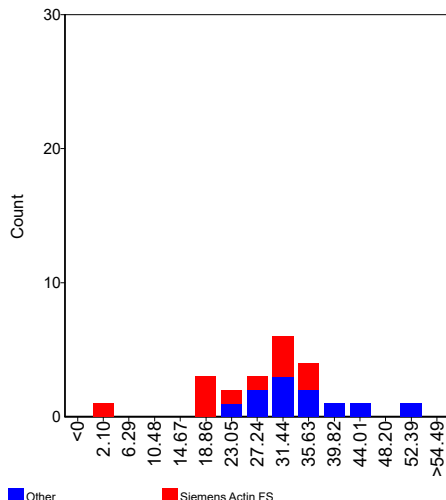
Percentage Correction - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	22	30.01	29.3	1.25 - 53.00							
Siemens Actin FS	11	26.28	35.8	1.25 - 36.50							
dRVVT	57	47.34	10.4	2.00 - 62.40							
IL HemosIL dRVVT confirm	9	46.42		27.00 - 54.60							
Siemens LA2 confirmation	37	48.92	7.2	2.00 - 62.40							
Stago DRVVT Confirm	7	44.40		37.00 - 47.25							
SCT	8	56.45		40.18 - 65.10							
IL HemosIL SCT confirm	8	56.45		40.18 - 65.10							

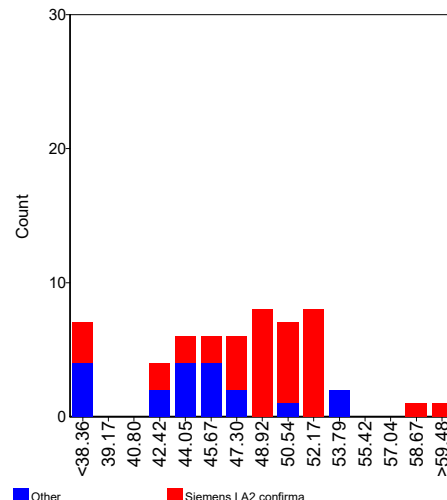
Assays



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.**

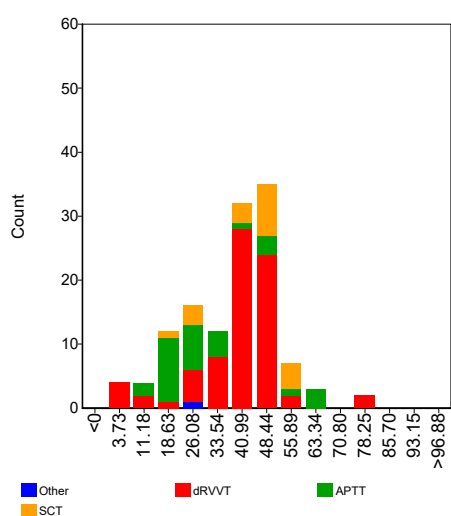
Lupus Anticoagulant

Interpretation

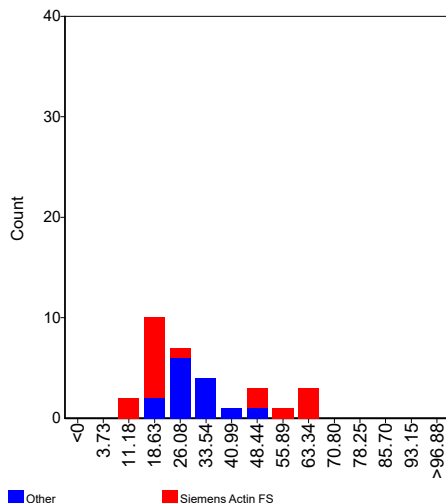
Percentage Correction - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	31	30.13	51.2	8.80 - 61.70							
Siemens Actin FS	17	31.06	70.7	8.80 - 61.70							
Stago Staclot LA	5	28.70		25.00 - 48.00							
dRVVT	76	41.11	20.4	1.73 - 80.10							
IL HemosIL dRVVT confirm	29	37.07	26.3	2.68 - 52.50							
Siemens LA2 confirmation	34	45.63	11.1	1.73 - 80.10							
Stago DRVVT Confirm	9	41.00		36.95 - 50.00							
SCT	19	44.76	26.5	20.30 - 59.00							
IL HemosIL SCT confirm	19	44.76	26.5	20.30 - 59.00							

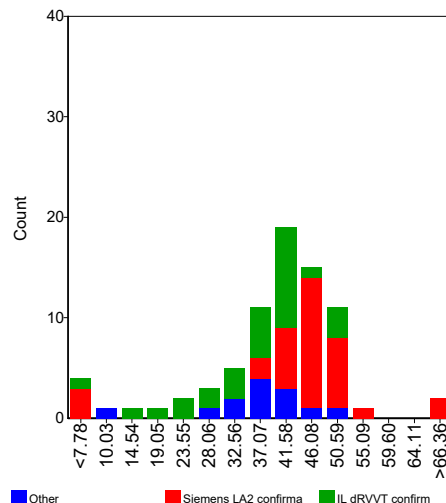
Assays



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.**

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	19	3	11	1			
					2			
					3			
Screen and mixing test	2	68	7	7	1			
					2			
					3			
Screen and confirm test	4	454	9	2	1			
					2			
					3			
Screen, mixing and confirm test	3	289	13	4	1			LA detected
					2			
					3			
Screen, confirm, mixing test	8	158	6	3	1			
					2			
					3			
Mixing - confirmation	0	35	2	2	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			
502	8	8	2	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 518 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 97% 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.

Lupus Anticoagulant

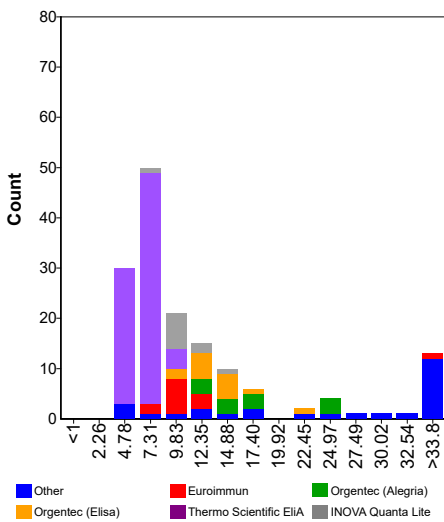
AntiCardiolipin Antibodies IgG

Sample No	23.63		
Sample Details	Plasma weak 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-September-2024		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	619		
Number of Responders	232	Response Rate	37 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	107	9	47	43	27	2

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	154	10.0	50.3	4.0 - 149.2						
Aeskulisa Diagnostic GmbH	6	24.0		10.2 - 43.8						
Biorad Bioplex	7	138.0		130.9 - 149.2						
Euroimmun	13	10.3	24.4	7.0 - 38.2						
Orgentec (Alegria)	12	17.4	31.4	11.7 - 24.8						
Orgentec (Elisa)	14	13.4	20.7	9.6 - 22.0						
Other	5	11.8		5.9 - 144.0						
Thermo Scientific EliA	77	6.5	15.4	4.0 - 9.6						
Werfen INOVA Quanta Lite	11	10.6	15.0	7.1 - 14.6						
CU/mL	76	61.3	11.7	43.9 - 253.8						
I.L. Acustar / INOVA Quanta Flash	75	61.2	11.6	43.9 - 253.8						

GPL, U/mL, µg/mL



Comments

A heterogeneous pattern in the classification has been observed.

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

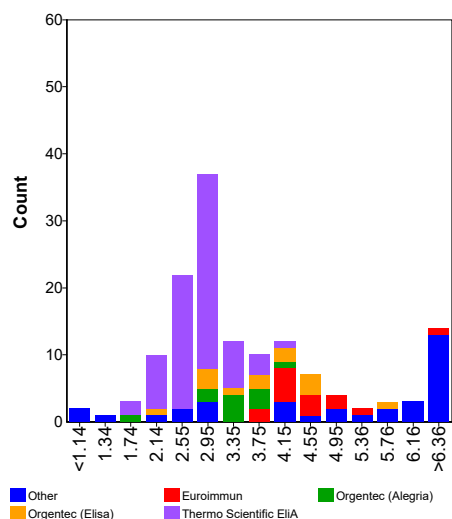
AntiCardiolipin Antibodies IgM

Sample No	23.63		
Sample Details	Plasma weak 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-September-2024		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	619		
Number of Responders	218	Response Rate	35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	217	1	0	0	0	2

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	142	3.5	34.2	0.9 - 13.3						
Aeskulisa Diagnostic GmbH	5	2.5		1.0 - 4.0						
Biorad Bioplex	8	5.9		4.9 - 7.2						
Euroimmun	14	4.5	13.6	4.0 - 6.9						
Orgentec (Alegria)	11	3.4	14.0	1.9 - 4.1						
Orgentec (Elisa)	13	3.8	23.2	2.3 - 5.6						
Thermo Scientific ELIA	70	2.8	14.4	1.8 - 4.1						
Werfen INOVA Quanta Lite	9	10.1		7.1 - 13.3						
CU/mL	70	5.7	10.7	4.0 - 7.4						
I.L. Acustar / INOVA Quanta Flash	70	5.7	10.7	4.0 - 7.4						

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.

The following participant reported a deviating result which was excluded in the statistical evaluation:

618 : 51 U/mL

Lupus Anticoagulant

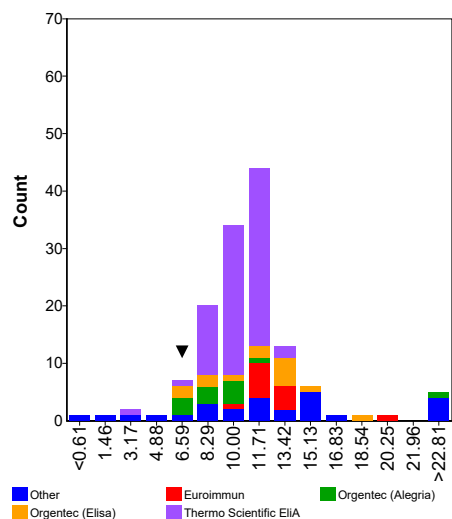
β2-Glycoprotein I Antibodies IgG

Sample No	23.63		
Sample Details	Plasma weak 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-September-2024		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	619		
Number of Responders	219	Response Rate	35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	38	24	63	30	63	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	137	10.7	21.2	0.2 - 160.0	6.7	-1.75				
Aeskulisa Diagnostic GmbH	7	6.4		2.0 - 52.0						
Euroimmun	12	12.2	9.3	9.9 - 20.0						
Orgentec (Alegria)	12	9.0	21.4	6.3 - 25.0						
Orgentec (Elisa)	14	11.7	31.6	6.6 - 18.0	6.7	-1.35				
Thermo Scientific ELIA	73	10.3	12.5	3.9 - 13.0						
Werfen INOVA Quanta Lite	9	14.6		10.9 - 16.5						
CU/mL	76	247.8	15.9	53.0 - 368.1						
I.L. Acustar / INOVA Quanta Flash	75	246.8	15.5	53.0 - 368.1						

U, U/mL, µg/mL



Comments

A heterogeneous pattern in the classification has been observed.

Lupus Anticoagulant

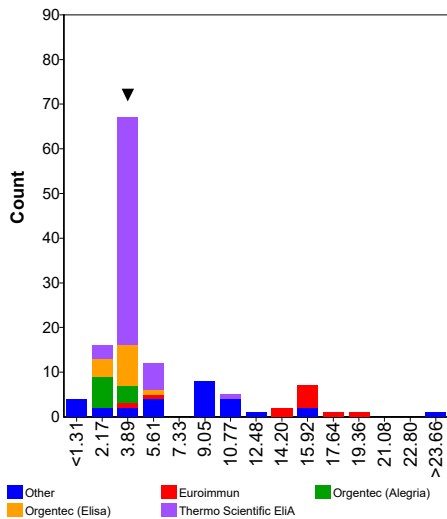
β2-Glycoprotein I Antibodies IgM

Sample No	23.63		
Sample Details	Plasma weak 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-September-2024		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	619		
Number of Responders	199	Response Rate	32 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	197	2	0	0	1	2

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	125	4.5	43.9	0.0 - 51.0	3.1	-0.71				
Aeskulisa Diagnostic GmbH	7	2.2		1.0 - 51.0						
Biorad Bioplex	8	9.5		8.3 - 12.2						
Euroimmun	11	14.9	19.7	4.0 - 19.0						
Orgentec (Alegria)	11	2.9	10.5	2.5 - 3.4						
Orgentec (Elisa)	14	3.4	20.3	2.3 - 5.0	3.1	-0.38				
Thermo Scientific ELIA	61	3.9	14.9	2.7 - 11.0						
Werfen INOVA Quanta Lite	5	5.0		0.0 - 9.4						
CU/mL	67	3.8	15.3	2.6 - 5.2						
I.L. Acustar / INOVA Quanta Flash	67	3.8	15.3	2.6 - 5.2						

U, U/mL, µg/mL



Comments

Most of the participants reported a negative classification.