

# ECAT FOUNDATION

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## REPORT



### **SURVEY 2023-L3** **Lupus Anticoagulant** **Labcode 1492**

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ECAT Foundation

Date of Issue : 13-October-2023  
Survey : 2023-L3  
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****Complaints**

Any complaints regarding this survey report should be reported to the ECAT before **December 12th, 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.

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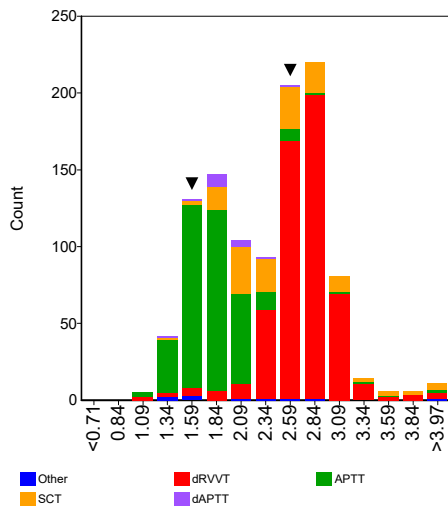
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Appendices are an integral part of the total report.



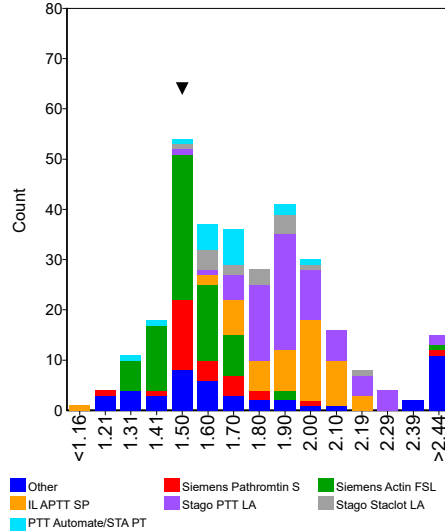
**Ratio Normal Plasma**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	359	1.77	15.4	1.06 - 4.55	1	1.54	-0.83	1.54	-0.84		
Hyphen-Biomed Cephen LS	6	2.57		2.37 - 2.80							
IL APTT SP	52	1.93	8.8	1.06 - 2.24							
IL HemosIL SynthAsil	40	1.91	8.2	1.63 - 2.30							
IL MixCon	14	1.74	7.0	1.59 - 2.06							
Siemens Actin FS	8	1.34		1.18 - 1.50							
Siemens Actin FSL	74	1.53	8.0	1.28 - 3.24	1			1.54	0.08		
Siemens Pathromtin SL	28	1.57	8.1	1.25 - 3.02	1	1.54	-0.22				
Stago CKPrest / APTT Kaolin	6	1.44		1.24 - 1.50							
Stago PTT Automate/STA PTT	18	1.66	8.7	1.32 - 2.04							
Stago PTT LA	71	1.93	8.4	1.55 - 2.52							
Stago Staclot LA	16	1.77	9.9	1.53 - 2.22							
Tcoag TriniClot APTT-HS	6	1.86		1.56 - 2.10							
Tcoag TriniClot Automated APTT	7	1.64		1.54 - 1.70							
Technoclone Lupus Anticoagulant Test	5	3.63		2.61 - 4.55							
<b>dAPTT</b>	16	1.96	10.5	1.45 - 2.60							
Stago PTT LA	12	1.98	6.7	1.84 - 2.29							
<b>dRVVT</b>	540	2.73	9.3	1.00 - 5.41	1					2.54	-0.73
Hyphen Biomed Hemoclot LA-S	8	4.06		3.46 - 5.41							
I.L. HemosIL dRVVT screen	199	2.71	7.6	1.30 - 3.42							
Precision Biologic LA check	7	2.66		2.19 - 2.98							
Roche Lupus S	7	3.20		2.88 - 3.64							
Siemens LA1 screen	222	2.81	7.8	1.00 - 3.85	1					2.54	-1.24
Stago DRVVT screen	83	2.52	7.3	1.24 - 3.03							
Technoclone LA Screen	6	2.50		2.28 - 2.77							
<b>SCT</b>	140	2.44	20.8	1.33 - 8.81							
Haematex SACT Reagent	5	4.74		3.79 - 8.81							
IL SCT screen	133	2.41	20.1	1.33 - 3.79							

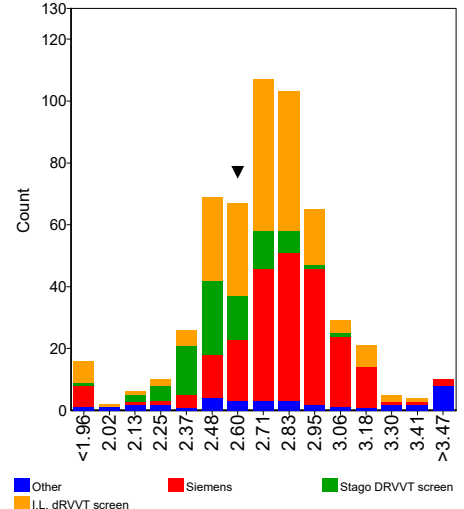
**Assays**



**APTT**



**DRVVT**

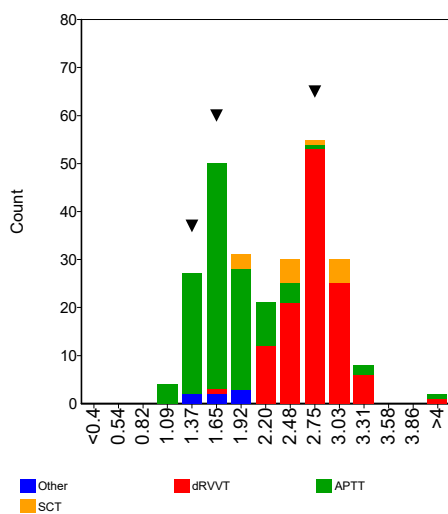


**Lupus Anticoagulant**

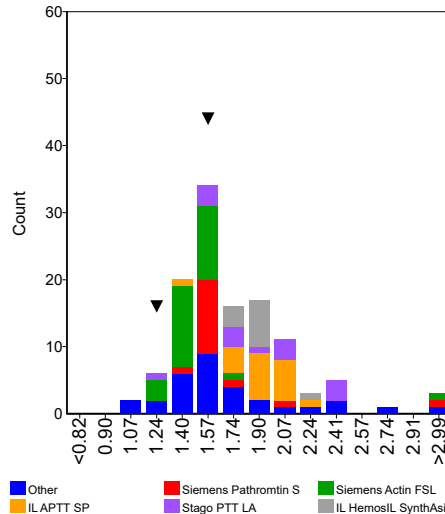
**Screening**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	118	1.70	17.8	1.02 - 5.58	1	1.55	-0.50	1.27	-1.42		
IL APTT SP	19	1.91	9.7	1.40 - 2.17							
IL HemosIL SynthAsil	11	1.88	5.1	1.77 - 2.24							
Siemens Actin FSL	28	1.49	8.1	1.16 - 3.20	1			1.27	-1.77		
Siemens Pathromtin SL	15	1.60	4.5	1.35 - 3.23	1	1.55	-0.62				
Stago PTT Automate/STA PTT	7	1.63		1.44 - 1.79							
Stago PTT LA	14	1.91	19.0	1.28 - 2.44							
Stago Staclot LA	6	1.71		1.40 - 2.28							
<b>dRVVT</b>	119	2.73	9.8	1.55 - 4.64	1					2.87	0.51
I.L. HemosIL dRVVT screen	23	2.73	12.5	2.12 - 4.64							
Siemens LA1 screen	76	2.76	7.9	1.55 - 3.43	1					2.87	0.47
Stago DRVVT screen	10	2.59	11.8	2.25 - 3.33							
<b>SCT</b>	14	2.54	18.4	1.79 - 2.98							
IL SCT screen	13	2.52	19.4	1.79 - 2.98							

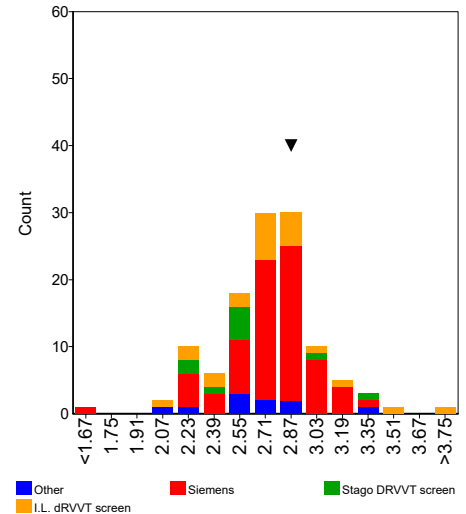
**Assays**



**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 from the statistical analysis.

Almost all performed screening tests (> 99.6%) were classified as elevated.

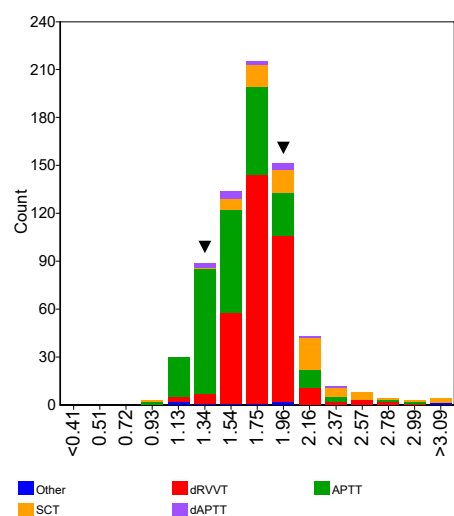
In general, comparable results were observed for the ratio ECAT plasma over Normal Plasma and ratio ECAT plasma over Mean Reference Interval (MRI).



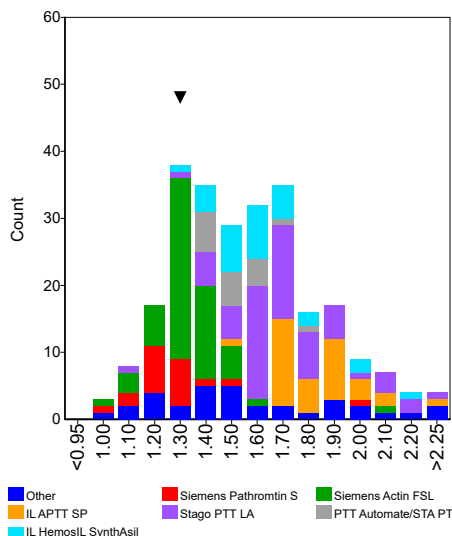
**Ratio Normal Plasma**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	267	1.55	18.3	0.96 - 3.06	1			1.31	-0.85		
IL APTT SP	37	1.80	8.0	1.50 - 2.77							
IL HemosIL SynthAsil	30	1.60	10.4	1.33 - 2.21							
IL MixCon	8	1.67		0.96 - 1.92							
Siemens Actin FSL	60	1.32	7.1	1.02 - 2.07	1		1.31	-0.13			
Siemens Pathromtin SL	21	1.26	8.1	1.04 - 1.96							
Stago PTT Automate/STA PTT	17	1.51	6.2	1.39 - 1.84							
Stago PTT LA	63	1.67	11.7	1.13 - 2.31							
Tocoag TriniClot APTT-HS	5	1.69		1.19 - 2.01							
Tocoag TriniClot Automated APTT	7	1.43		1.39 - 1.53							
<b>dAPTT</b>	16	1.71	15.6	1.36 - 2.31							
Stago PTT LA	10	1.71	10.8	1.55 - 2.07							
<b>dRVVT</b>	332	1.79	9.5	1.05 - 3.02	1					1.90	0.64
I.L. HemosIL dRVVT screen	90	1.80	8.7	1.42 - 3.02							
Siemens LA1 screen	170	1.80	9.7	1.05 - 2.86	1					1.90	0.55
Stago DRVVT screen	52	1.71	7.0	1.25 - 2.65							
<b>SCT</b>	73	2.05	17.0	1.02 - 4.47							
IL SCT screen	68	2.01	15.7	1.02 - 2.90							

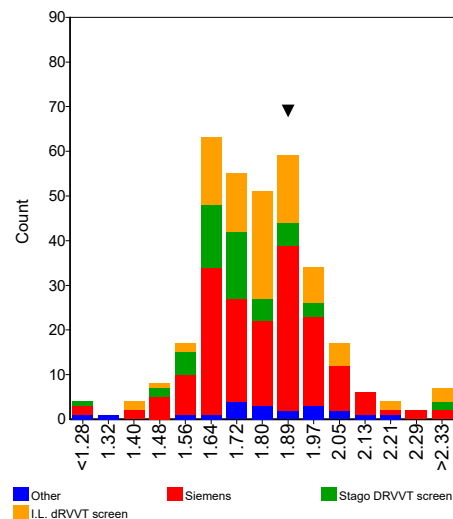
**Assays**



**APTT**



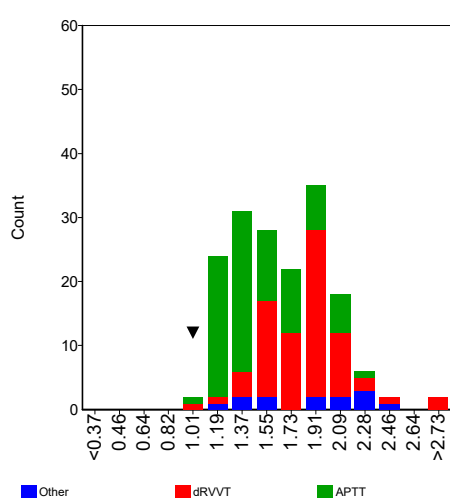
**DRVVT**



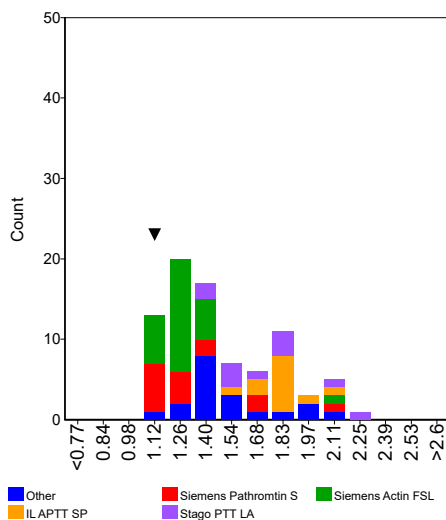
**Lupus Anticoagulant** **Mixing (screening)**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	83	1.48	20.2	1.07 - 2.23	1			1.07	-1.34		
IL APTT SP	12	1.82	7.7	1.53 - 2.04							
IL HemosIL SynthAsil	5	1.64		1.42 - 2.05							
Siemens Actin FSL	26	1.28	9.3	1.07 - 2.04	1			1.07	-1.72		
Siemens Pathromtin SL	15	1.30	13.7	1.13 - 2.10							
Stago PTT Automate/STA PTT	5	1.42		1.37 - 1.52							
Stago PTT LA	11	1.70	17.8	1.33 - 2.23							
<b>dAPTT</b>	6	1.56		1.28 - 2.27							
<b>dRVVT</b>	74	1.83	13.7	0.97 - 3.23							
I.L. HemosIL dRVVT screen	14	1.89	14.4	1.59 - 3.23							
Siemens LA1 screen	50	1.81	14.0	0.97 - 2.73							
Stago DRVVT screen	5	1.80		1.63 - 2.06							
<b>SCT</b>	6	2.19		1.95 - 2.42							
IL SCT screen	6	2.19		1.95 - 2.42							

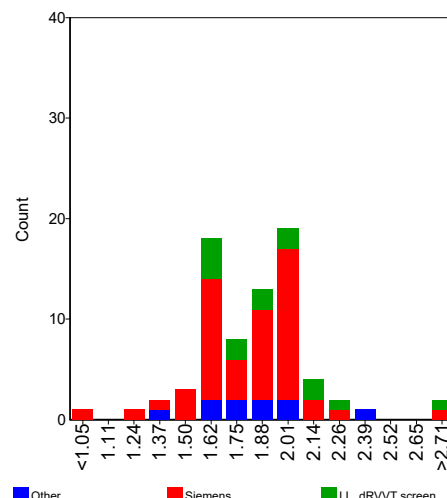
**Assays**



**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 from the statistical analysis.

Almost all performed mixing screen tests (> 97.2%) 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).

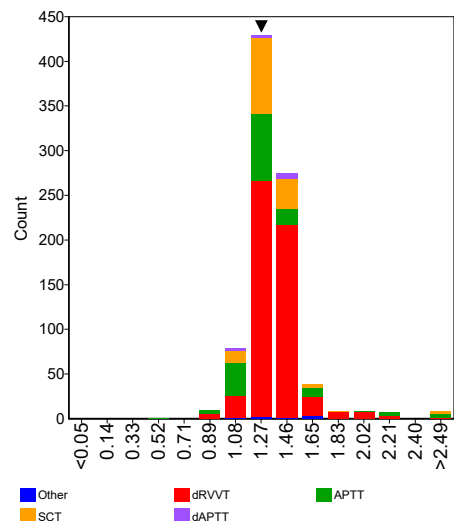




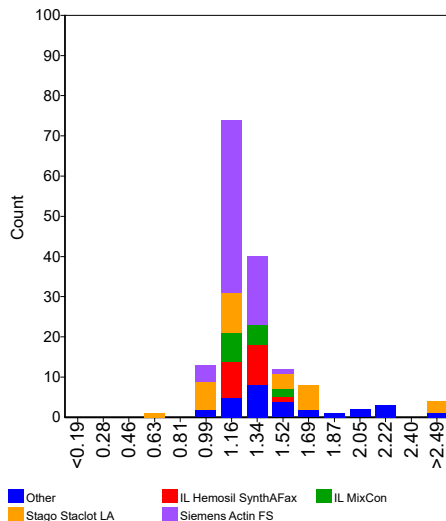
**Ratio Normal Plasma**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	158	1.26	13.2	0.56 - 5.12							
IL Hemosil SynthAFax	20	1.25	6.7	1.11 - 1.54							
IL MixCon	14	1.24	10.2	1.08 - 1.50							
Siemens Actin FS	65	1.21	6.6	0.98 - 1.43							
Stago Staclot LA	31	1.34	28.7	0.56 - 5.12							
Technoclone Lupus Anticoagulant Test	5	2.24		1.42 - 3.64							
<b>dAPTT</b>	12	1.33	12.3	1.13 - 1.51							
Siemens Actin FS	6	1.23		1.13 - 1.51							
<b>dRVVT</b>	547	1.36	8.0	0.86 - 2.83	1					1.24	-1.05
Hyphen Biomed Hemoclot LA-C	8	1.46		1.41 - 1.76							
IL Hemosil dRVVT confirm	212	1.41	7.8	0.96 - 2.83							
Precision Biologic LA sure	6	1.39		1.28 - 1.77							
Roche Lupus C	7	1.53		1.31 - 1.87							
Siemens LA2 confirmation	220	1.33	6.5	0.87 - 2.13	1					1.24	-1.03
Stago DRVVT Confirm	81	1.29	5.3	0.86 - 1.94							
Technoclone LA Confirm	7	1.26		1.11 - 1.35							
<b>PNP</b>	5	1.32		1.05 - 1.56							
<b>SCT</b>	139	1.33	9.4	1.02 - 2.76							
IL Hemosil SCT confirm	138	1.33	9.2	1.02 - 2.73							

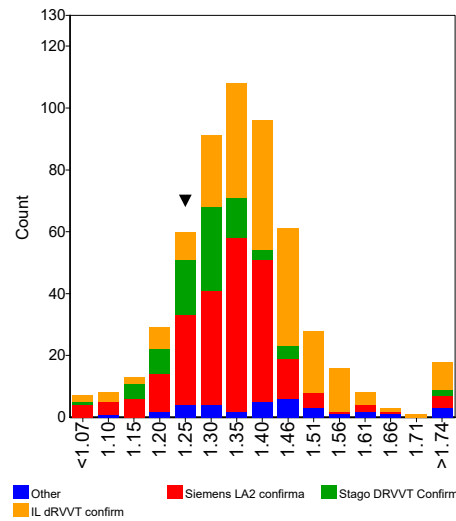
**Assays**



**APTT**



**DRVVT**

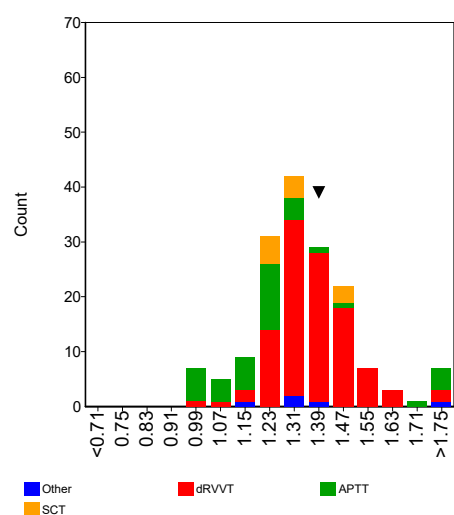


**Lupus Anticoagulant**

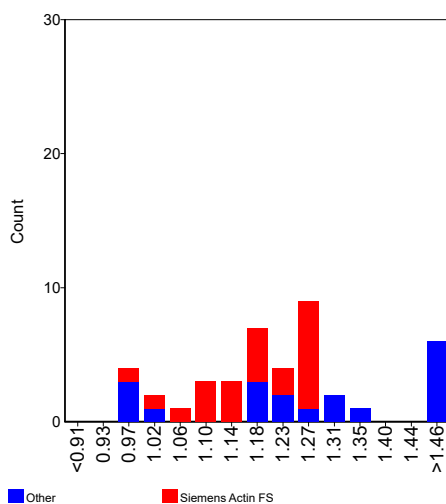
**Confirmation**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	42	1.22	13.1	0.96 - 7.22							
Siemens Actin FS	23	1.19	7.7	0.96 - 1.29							
Stago Staclot LA	8	1.24		0.97 - 7.22							
<b>dRVVT</b>	112	1.37	7.8	0.96 - 2.14	1					1.42	0.52
IL HemosIL dRVVT confirm	24	1.40	8.2	1.20 - 1.64							
Siemens LA2 confirmation	72	1.37	7.4	0.96 - 1.88	1					1.42	0.55
Stago DRVVT Confirm	9	1.29		1.12 - 1.43							
<b>SCT</b>	13	1.30	8.8	1.19 - 1.48							
IL HemosIL SCT confirm	13	1.30	8.8	1.19 - 1.48							

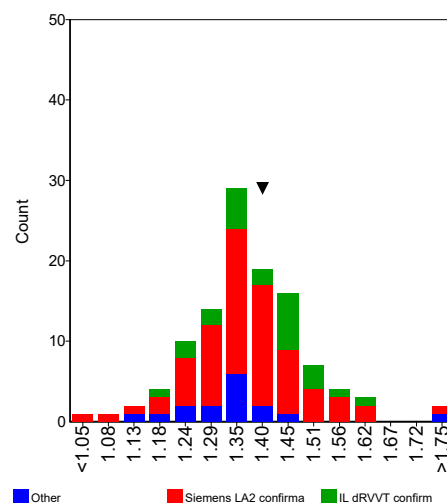
**Assays**



**APTT**



**DRVVT**



**Comments**

Several 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. Therefore all these results were excluded from the statistical analysis.

The majority of performed confirmation tests (86%) 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**

**Mixing (confirm)**

<b>Sample No</b>	23.170		
<b>Sample Details</b>	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 2.2)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	Ratio		
<b>Expiry Date</b>	31-May-2025		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	629		
<b>Number of Responders</b>	200	<b>Response Rate</b>	32 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	24	30	0	4
dAPTT	3	1	0	2
dPT	0	0	0	0
dRVVT	82	100	0	13
SCT	10	22	0	3

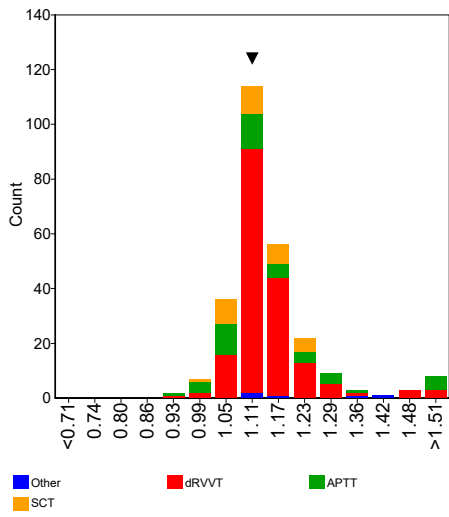
Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Not elevated						
SCT									

**Ratio Normal Plasma**

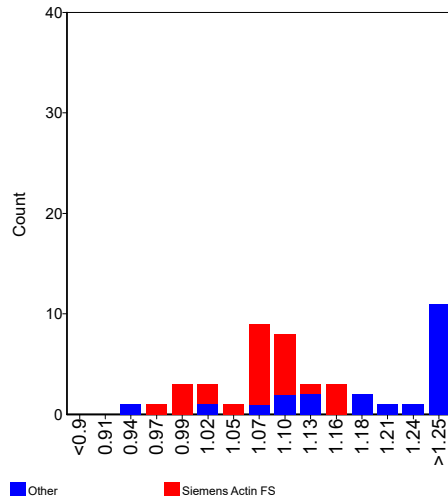
n assigned CV (%) Range Test System Panel 1 Z-score Panel 2 Z-score Panel 3 Z-score

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	48	1.14	10.7	0.93 - 1.71							
IL Hemosil SynthAFax	5	1.24		1.18 - 1.33							
Siemens Actin FS	25	1.08	5.3	0.97 - 1.16							
Siemens Pathromtin SL	6	1.13		1.03 - 1.26							
<b>dAPTT</b>	5	1.20		1.13 - 1.40							
<b>dRVVT</b>	176	1.13	4.8	0.94 - 1.90	1					1.10	-0.63
IL Hemosil dRVVT confirm	45	1.16	5.4	1.05 - 1.37							
Siemens LA2 confirmation	109	1.13	4.1	0.94 - 1.90	1					1.10	-0.60
Stago DRVVT Confirm	17	1.12	5.8	1.05 - 1.31							
<b>SCT</b>	32	1.12	6.4	1.00 - 1.26							
IL Hemosil SCT confirm	32	1.12	6.4	1.00 - 1.26							

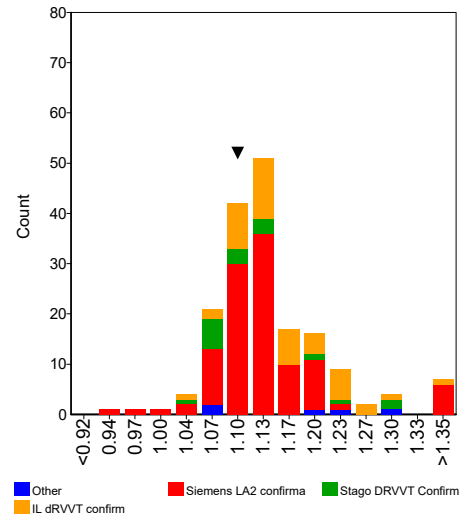
**Assays**



**APTT**



**DRVVT**

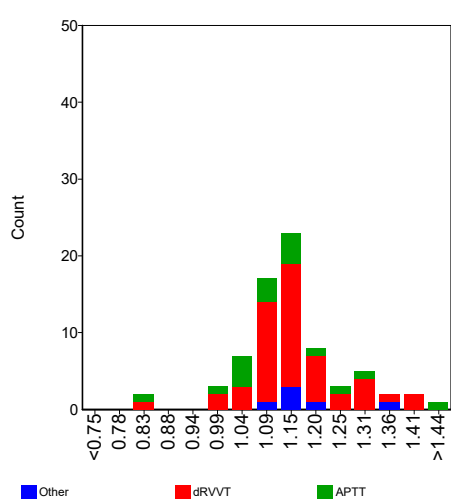


**Lupus Anticoagulant**

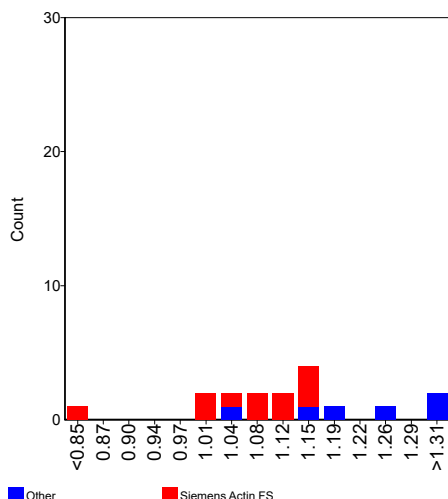
**Mixing (confirm)**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	17	1.12	9.7	0.81 - 1.71							
Siemens Actin FS	11	1.08	7.1	0.81 - 1.16							
<b>dRVVT</b>	50	1.15	6.9	0.82 - 1.41							
IL HemosIL dRVVT confirm	13	1.16	6.9	1.06 - 1.41							
Siemens LA2 confirmation	36	1.14	7.6	0.82 - 1.38							

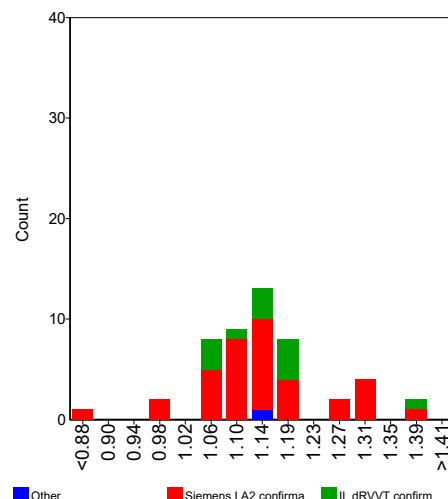
**Assays**



**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. All these results were excluded from the statistical analysis.

A part of performed mixing confirm tests (56%) were classified as not elevated, while other participants still observed elevated test results (44%). For all different assay types about the same distributions between elevated and not elevated test results were observed.

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**

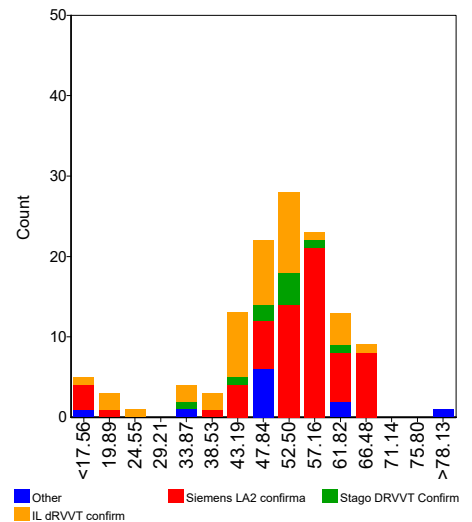
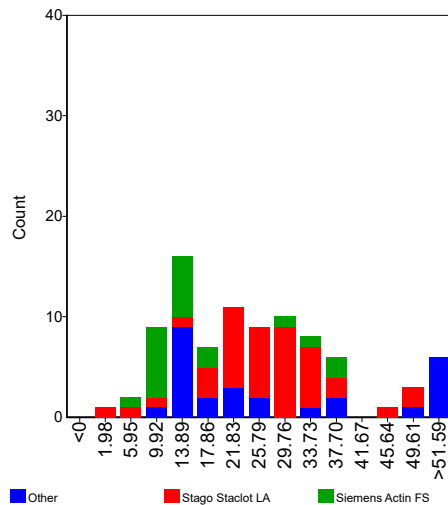
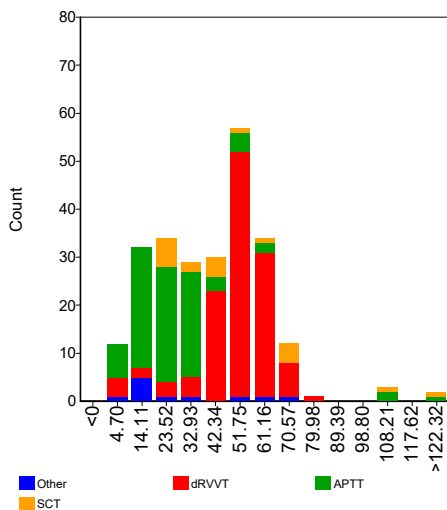
**Delta Seconds**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	90	24.03	51.4	3.00 - 222.50							
IL Hemosil SynthAFax	9	14.63		13.10 - 38.90							
Siemens Actin FS	20	15.30	49.5	7.50 - 36.80							
Stago Staclot LA	42	27.28	29.7	3.00 - 51.30							
<b>dAPTT</b>	7	24.40		9.50 - 70.00							
<b>dRVVT</b>	125	51.85	18.0	2.04 - 78.70							
IL HemosIL dRVVT confirm	40	47.32	21.0	2.50 - 68.30							
Siemens LA2 confirmation	64	55.19	13.9	5.90 - 68.50							
Stago DRVVT Confirm	10	50.76	13.4	31.60 - 63.40							
<b>SCT</b>	20	47.40	52.7	20.30 - 143.40							
IL HemosIL SCT confirm	19	45.15	50.7	20.30 - 106.30							

**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), which are both derived from the same assay type!**

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

- 127 : 1.22
- 914 : 1.47
- 9205 : 1.0

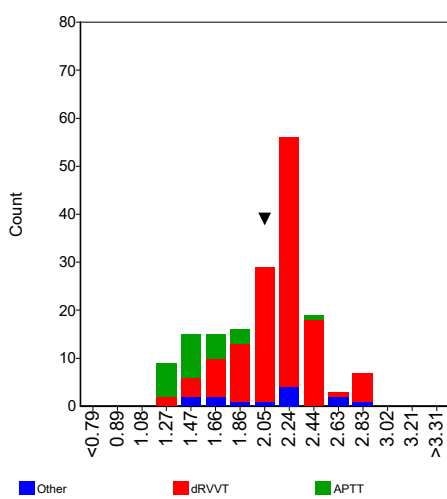
**Lupus Anticoagulant**

**Interpretation**

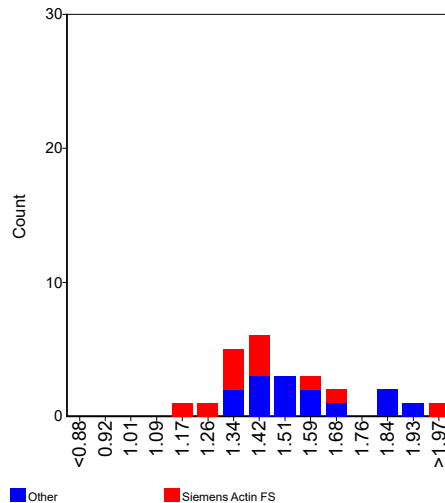
**Ratio Screen/Confirmation - Standard**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	25	1.51	14.2	1.20 - 2.45							
Siemens Actin FS	11	1.43	12.7	1.20 - 2.45							
Stago Staclot LA	6	1.57		1.44 - 1.88							
<b>dRVVT</b>	131	2.17	10.0	1.25 - 2.78	1					2.14	-0.12
IL HemosIL dRVVT confirm	18	1.96	18.3	1.46 - 2.77							
Siemens LA2 confirmation	92	2.23	7.5	1.25 - 2.78	1					2.14	-0.53
Stago DRVVT Confirm	9	2.14		1.94 - 2.29							
<b>SCT</b>	8	2.22		1.58 - 2.80							
IL HemosIL SCT confirm	7	2.25		1.58 - 2.80							

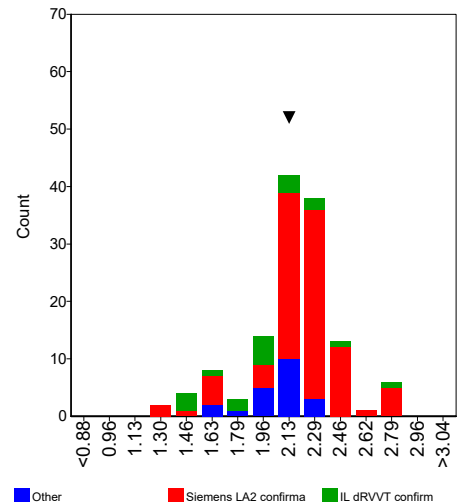
**Assays**



**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.**

The average ratio screen / confirmation is in general in line with the expected LA ratio (approx. 2.2). For the assay type "APTT" the LA ratio is slightly lower compared to the other assay types.



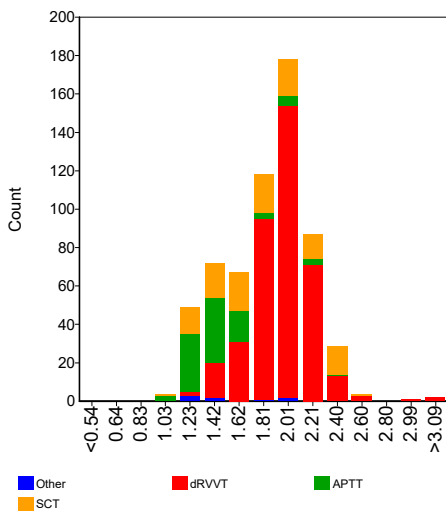
**Lupus Anticoagulant**

**Interpretation**

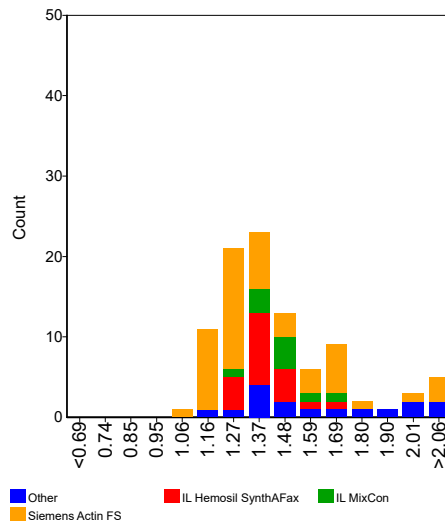
**Ratio Screen/Confirmation - Normalised**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	95	1.42	15.2	1.10 - 2.34							
IL Hemosil SynthAFax	19	1.40	7.7	1.24 - 1.72							
IL MixCon	10	1.47	8.6	1.26 - 1.68							
Siemens Actin FS	50	1.38	16.6	1.10 - 2.34							
<b>dRVVT</b>	387	1.97	10.3	1.30 - 3.68							
Hyphen Biomed Hemoclot LA-C	8	2.64		2.27 - 3.68							
IL Hemosil dRVVT confirm	179	1.92	8.8	1.30 - 2.39							
Siemens LA2 confirmation	123	2.08	8.8	1.39 - 2.46							
Stago DRVVT Confirm	66	1.92	6.5	1.31 - 2.46							
<b>SCT</b>	121	1.81	23.4	1.02 - 2.60							
IL Hemosil SCT confirm	121	1.81	23.4	1.02 - 2.60							

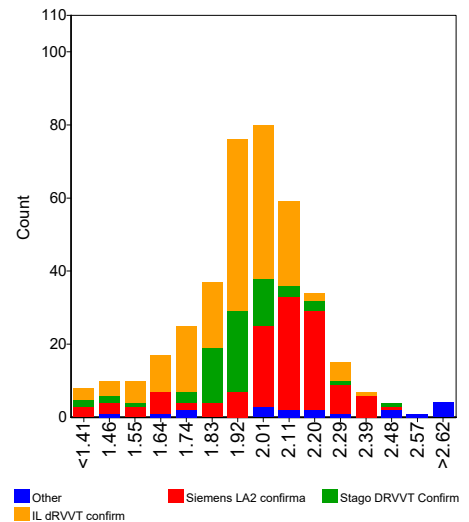
**Assays**



**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.**

The average ratio screen / confirmation is in general in line with the expected LA ratio (approx. 2.2). For the assay type "APTT" the LA ratio is slightly lower compared to the other assay types, as also was observed for the parameter: "Ratio Screen/Confirmation - Standard".

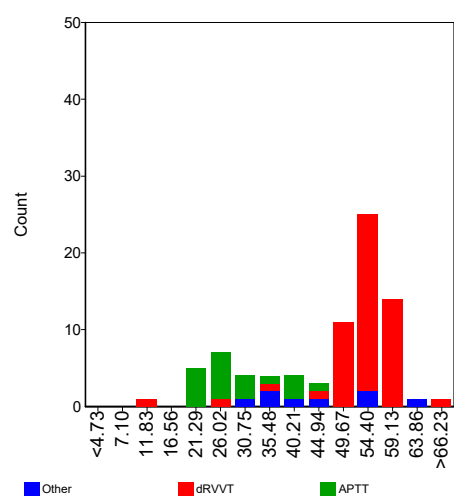
**Lupus Anticoagulant**

**Interpretation**

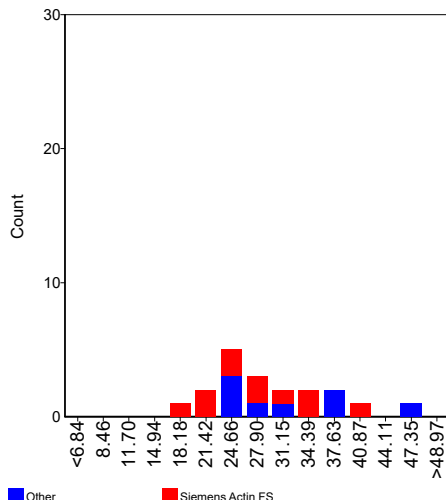
**Percentage Correction - Standard**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	19	29.33	26.3	19.40 - 46.70							
Siemens Actin FS	11	27.91	25.2	19.40 - 40.00							
<b>dRVVT</b>	53	54.30	6.8	10.00 - 111.60							
IL HemosIL dRVVT confirm	7	50.90		27.00 - 58.00							
Siemens LA2 confirmation	37	55.20	6.1	10.00 - 111.60							
Stago DRVVT Confirm	6	51.95		50.82 - 54.30							
<b>SCT</b>	7	46.36		33.30 - 63.10							
IL HemosIL SCT confirm	6	49.28		33.30 - 63.10							

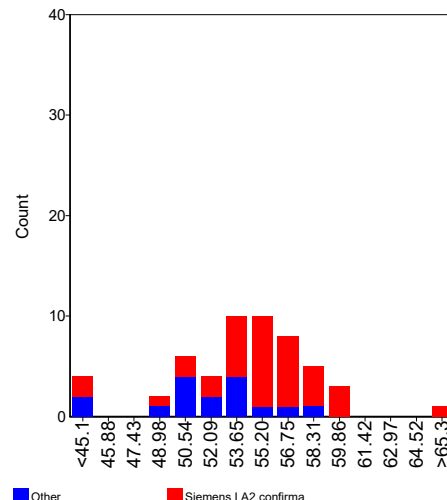
**Assays**



**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.**

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

- 1624 (panel 1): 0
- 1624 (panel 2): 0

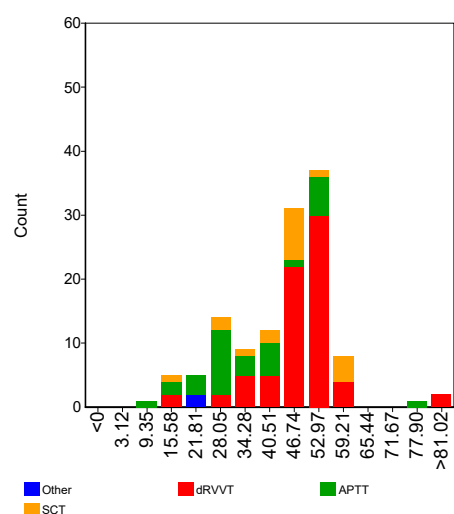
**Lupus Anticoagulant**

**Interpretation**

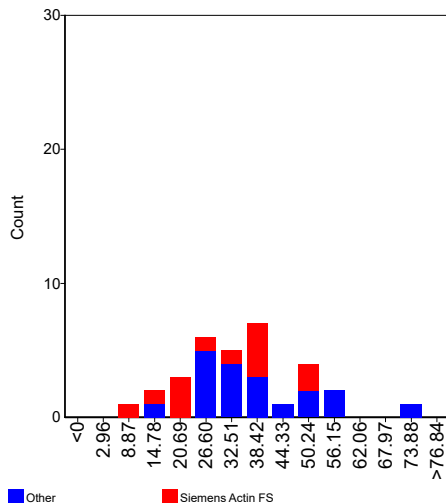
**Percentage Correction - Normalised**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	32	34.46	41.8	8.70 - 75.00							
IL Hemosil SynthAFax	5	30.61		26.30 - 75.00							
Siemens Actin FS	13	30.27	51.3	8.70 - 52.00							
Stago Staclot LA	5	30.70		26.00 - 45.90							
<b>dRVVT</b>	72	49.26	12.9	17.39 - 93.00							
IL Hemosil dRVVT confirm	30	47.53	11.3	17.39 - 90.00							
Siemens LA2 confirmation	28	52.09	8.8	17.40 - 58.40							
Stago DRVVT Confirm	12	48.61	17.9	31.00 - 93.00							
<b>SCT</b>	19	45.28	23.3	13.10 - 59.75							
IL Hemosil SCT confirm	19	45.28	23.3	13.10 - 59.75							

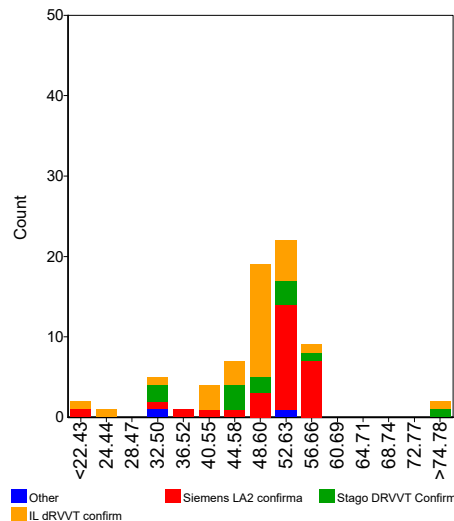
**Assays**



**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.**

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

**6238 :** 661

**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	8	1			
					2			
					3			
Screen and mixing test	1	71	2		1			
					2			
					3			
Screen and confirm test	4	451	3	3	1			
					2			
					3			
Screen, mixing and confirm test		281	7	0	1			LA detected
					2			
					3			
Screen, confirm, mixing test	5	167	3	1	1			
					2			
					3			
Mixing - confirmation	0	26	0	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			
495	1	5	5	LA detected		

**Comments**

The sample used in this survey was plasma from a patient diagnosed with Lupus Anticoagulant (LA Ratio = approx. 2.2). In total 501 participants gave a final conclusion. Of the participants who gave a final conclusion, almost all indicated Lupus Anticoagulant was detected except one participant. About 1% classified the sample as equivocal. The majority of the participants correctly classified this sample as a Lupus Anticoagulant positive.

Some participants indicated that they had difficulties to interpret the results from the mixing studies, since the conformation test didn't fully normalise on mixing. It was suggested that these results need to be interpret in combination with cardiolipin and beta-2 glycoprotein I antibodies titres.

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**

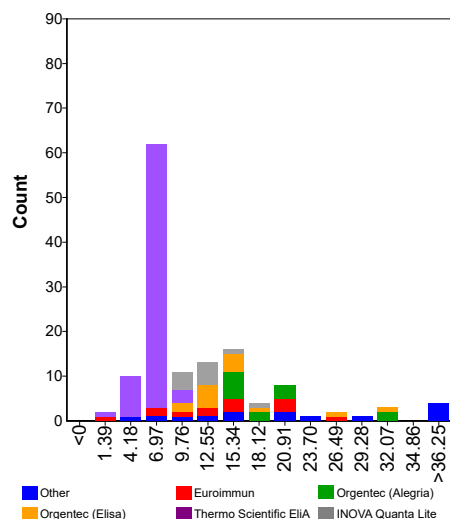
**AntiCardiolipin Antibodies IgG**

<b>Sample No</b>	23.170		
<b>Sample Details</b>	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 2.2)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	GPL, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	31-May-2025		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	629		
<b>Number of Responders</b>	221	<b>Response Rate</b>	35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	93	5	42	50	37	0

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
<b>U/mL, µg/mL, GPL/MPL</b>	137	10.5	53.3	1.2 - 160.0						
Euroimmun	13	14.3	51.0	1.2 - 27.0						
Orgentec (Alegria)	13	18.7	21.6	14.8 - 32.6						
Orgentec (Elisa)	14	14.4	22.2	9.9 - 32.7						
Thermo Scientific Elia	72	6.8	14.8	1.4 - 9.9						
Werfen INOVA Quanta Lite	11	12.5	19.8	9.0 - 18.9						
<b>CU/mL</b>	82	70.9	10.3	56.8 - 85.6						
I.L. Acustar / INOVA Quanta Flash	81	70.9	10.4	56.8 - 85.6						

**GPL, U/mL, µg/mL**



**Comments**

A heterogeneous pattern in the classification has been observed. A negative classification was reported by 41% of the participants, while on the other hand 57% of the participants classified the sample as (low till high) positive.

**Lupus Anticoagulant**

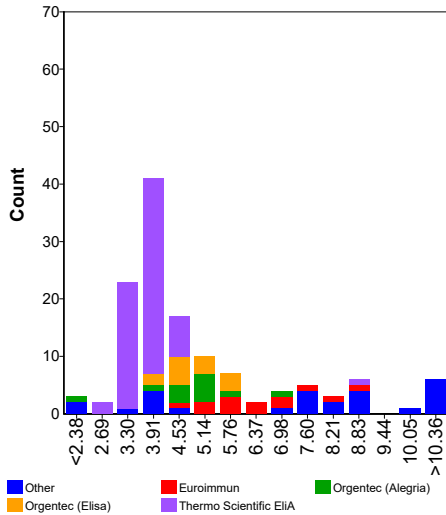
**AntiCardiolipin Antibodies IgM**

<b>Sample No</b>	23.170		
<b>Sample Details</b>	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 2.2)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	MPL, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	31-May-2025		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	629		
<b>Number of Responders</b>	209	<b>Response Rate</b>	33 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	212	1	2	0	0	0

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
<b>U/mL, µg/mL, GPL/MPL</b>	130	4.7	33.1	2.0 - 13.8						
Biorad Bioplex	6	8.2		7.6 - 9.0						
Euroimmun	13	6.4	20.9	4.4 - 9.0						
Orgentec (Alegria)	12	4.9	13.2	2.2 - 7.2						
Orgentec (Elisa)	13	4.9	15.5	3.7 - 5.9						
Thermo Scientific ELIA	66	3.8	12.2	2.7 - 8.8						
Werfen INOVA Quanta Lite	8	11.6		3.7 - 13.8						
<b>CU/mL</b>	77	8.2	9.6	6.0 - 10.2						
I.L. Acustar / INOVA Quanta Flash	77	8.2	9.6	6.0 - 10.2						

**MPL, U/mL, µg/mL**



**Comments**

Most of the participants reported a negative classification.

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

- 1353 :** 0.51
- 9907155 :** 0
- 9907322 :** 24

**Lupus Anticoagulant**

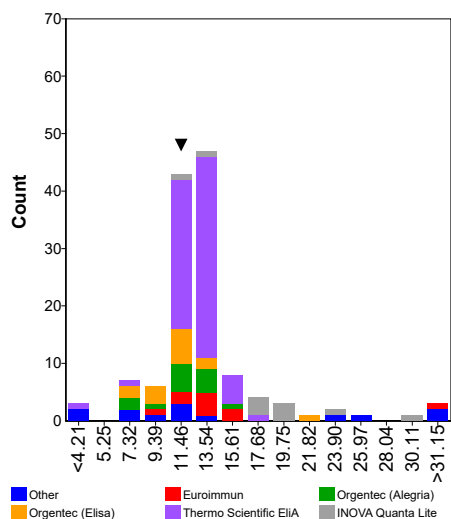
**β2-Glycoprotein I Antibodies IgG**

<b>Sample No</b>	23.170		
<b>Sample Details</b>	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 2.2)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	U, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	31-May-2025		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	629		
<b>Number of Responders</b>	212	<b>Response Rate</b>	34 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	24	12	71	30	79	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
<b>U, U/mL, µg/mL</b>	129	12.7	16.3	1.3 - 160.0	12.1	-0.27				
Aeskulisa Diagnostic GmbH	6	9.1		1.3 - 25.1						
Euroimmun	10	13.2	17.3	9.0 - 58.1						
Orgentec (Alegria)	13	11.5	21.1	7.3 - 14.6						
Orgentec (Elisa)	14	10.9	20.0	7.7 - 21.9	12.1	0.53				
Thermo Scientific ELIA	69	12.7	9.3	3.4 - 17.0						
Werfen INOVA Quanta Lite	10	18.7	22.2	11.9 - 29.5						
<b>CU/mL</b>	82	282.8	14.7	183.6 - 370.3						
I.L. Acustar / INOVA Quanta Flash	81	283.1	14.7	183.6 - 370.3						

**U, U/mL, µg/mL**



**Comments**

A majority of participant (83%) classified this sample as positive (low till high). A negative classification was reported by 11% of the participants.

**Lupus Anticoagulant**

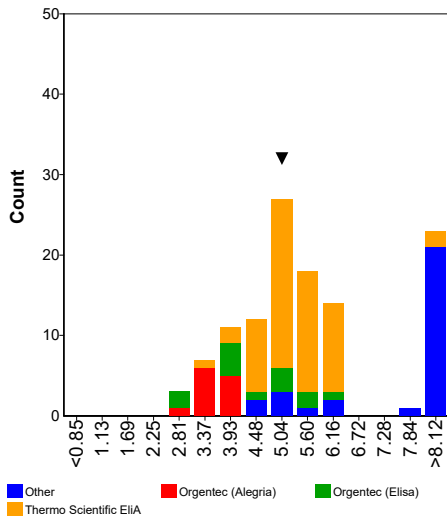
**β2-Glycoprotein I Antibodies IgM**

<b>Sample No</b>	23.170		
<b>Sample Details</b>	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 2.2)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	U, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	31-May-2025		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	629		
<b>Number of Responders</b>	193	<b>Response Rate</b>	31 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	180	9	7	2	1	0

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
<b>U, U/mL, µg/mL</b>	116	5.6	31.2	2.7 - 37.0	5.1	-0.30				
Aeskulisa Diagnostic GmbH	6	11.0		6.2 - 17.9						
Biorad Bioplex	5	14.6		13.5 - 16.0						
Euroimmun	9	24.5		5.3 - 37.0						
Orgentec (Alegria)	12	3.7	8.7	2.8 - 4.1						
Orgentec (Elisa)	13	4.5	27.0	2.7 - 6.0	5.1	0.51				
Thermo Scientific Elia	61	5.3	13.1	3.4 - 9.8						
<b>CU/mL</b>	74	5.5	10.7	4.1 - 7.2						
I.L. Acustar / INOVA Quanta Flash	74	5.5	10.7	4.1 - 7.2						

**U, U/mL, µg/mL**



**Comments**

Most of the participants reported a negative classification.

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

**280** : 1.6  
**9907155** : 0