

# ECAT FOUNDATION

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## REPORT



### **SURVEY 2022-L2** **Lupus Anticoagulant** **Labcode 1492**

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ECAT Foundation

Date of Issue : 18-July-2022  
Survey : 2022-L2  
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 **August 30th, 2022**. Complaints received after this date will not be taken into consideration.

**Exclusion of results**

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

**Use of units**

We observed several issue of improper use of units during this survey. This may result in the exclusion of results. It is the responsibility of the participant to use the correct units!

**Modified report**

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

**Lupus Anticoagulant**

See comments in the respective sections.

**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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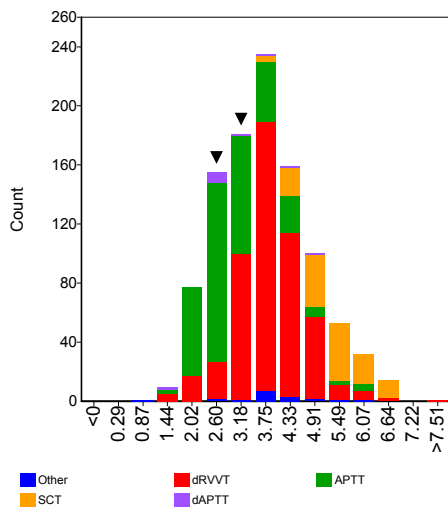
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Appendices are an integral part of the total report.



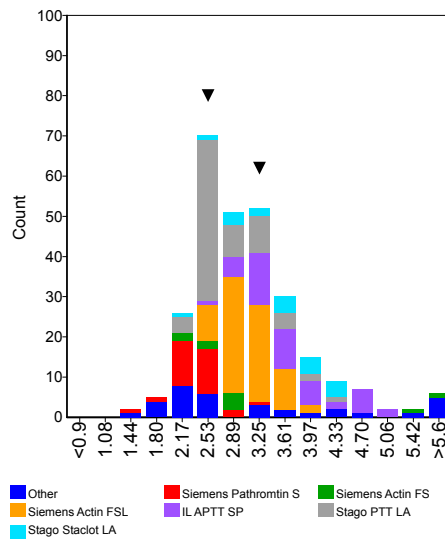
**Ratio Normal Plasma**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	345	2.94	24.9	1.51 - 5.88	1	2.40	-0.74	3.08	0.19		
Hyphen-Biomed Cephen LS	8	5.61		3.80 - 5.88							
IL APTT SP	45	3.65	17.8	2.40 - 4.98							
IL HemosIL SynthAsil	36	2.22	9.1	1.65 - 2.54							
IL MixCon	15	4.37	6.5	2.92 - 4.75							
Siemens Actin FS	10	2.80	22.6	2.06 - 5.61							
Siemens Actin FSL	74	3.06	11.9	2.50 - 4.03	1			3.08	0.04		
Siemens Pathromtin SL	27	2.40	7.1	1.56 - 3.21	1	2.40	-0.02				
Stago PTT Automate/STA APTT	17	2.23	10.2	1.79 - 3.08							
Stago PTT LA	68	2.72	13.4	2.01 - 4.17							
Stago Staclot LA	19	3.59	17.3	2.23 - 4.35							
Tcoag TriniClot Automated APTT	6	2.25		2.16 - 2.42							
<b>dAPTT</b>	13	2.87	39.6	1.30 - 4.76							
Stago PTT LA	7	2.53		1.30 - 4.57							
<b>dPT</b>	6	4.37		2.37 - 6.27							
<b>dRVVT</b>	513	3.83	18.7	1.59 - 7.77	1					3.27	-0.77
I.L. HemosIL dRVVT screen	186	4.34	13.6	2.41 - 6.21							
Precision Biologic LA check	6	2.22		1.95 - 2.38							
Siemens LA1 screen	212	3.70	11.7	1.59 - 5.31	1					3.27	-0.99
Stago DRVVT screen	83	3.17	10.3	1.76 - 5.58							
Technoclone LA Screen	7	3.49		2.89 - 3.73							
<b>PT</b>	8	4.04		3.02 - 4.81							
<b>SCT</b>	129	5.31	13.8	3.66 - 6.88							
IL SCT screen	128	5.30	13.7	3.66 - 6.88							

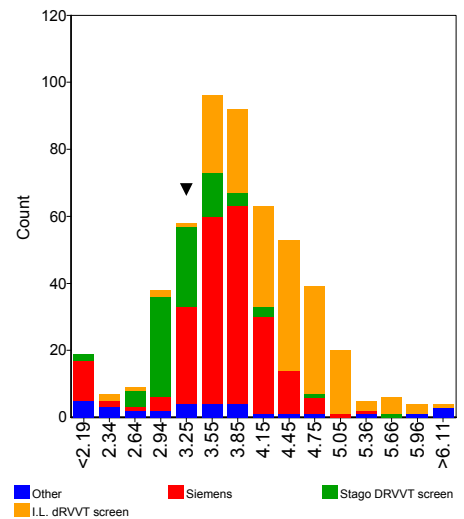
**Assays**



**APTT**



**DRVVT**

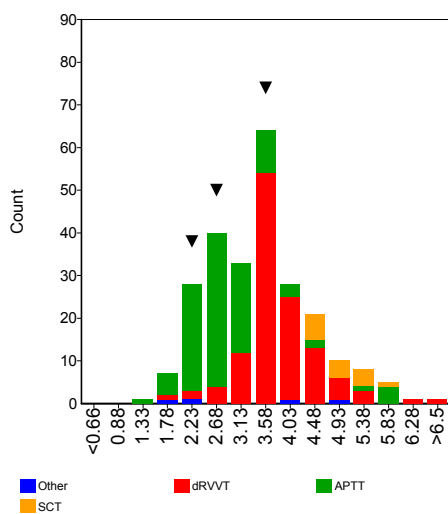


**Lupus Anticoagulant**

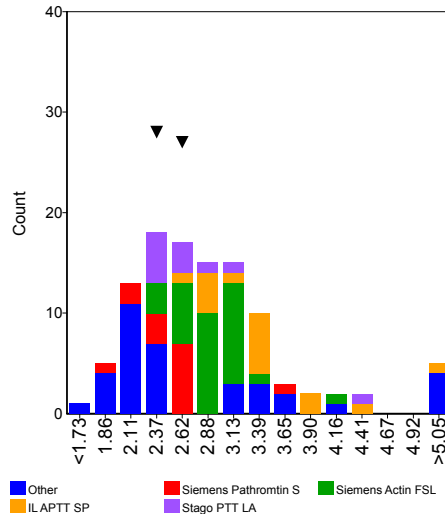
**Screening**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	108	2.80	21.7	1.54 - 5.79	1	2.50	-0.49	2.42	-0.63		
IL APTT SP	16	3.39	16.4	2.75 - 5.17							
IL HemosIL SynthAsil	8	2.26		1.90 - 3.34							
Siemens Actin FSL	31	2.88	9.5	2.42 - 4.14	1			2.42	-1.71		
Siemens Pathromtin SL	14	2.48	8.7	1.79 - 3.67	1	2.50	0.10				
Stago PTT Automate/STA APTT	5	2.18		2.02 - 2.37							
Stago PTT LA	11	2.62	10.7	2.29 - 4.30							
Stago Staclot LA	6	3.52		3.18 - 4.17							
<b>dRVVT</b>	120	3.77	13.3	1.58 - 8.14	1					3.61	-0.32
I.L. HemosIL dRVVT screen	23	4.26	12.3	3.49 - 5.27							
Siemens LA1 screen	71	3.66	7.7	1.58 - 5.10	1					3.61	-0.18
Stago DRVVT screen	13	3.52	13.0	2.85 - 4.05							
<b>SCT</b>	15	4.97	10.2	4.30 - 5.80							
IL SCT screen	15	4.97	10.2	4.30 - 5.80							

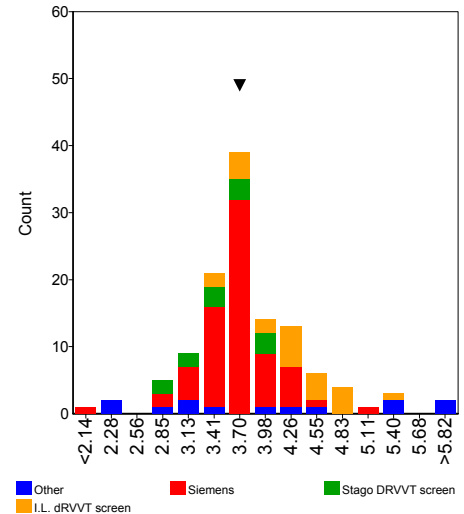
**Assays**



**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.

The vast majority of performed screening tests (> 99%) were classified as elevated.

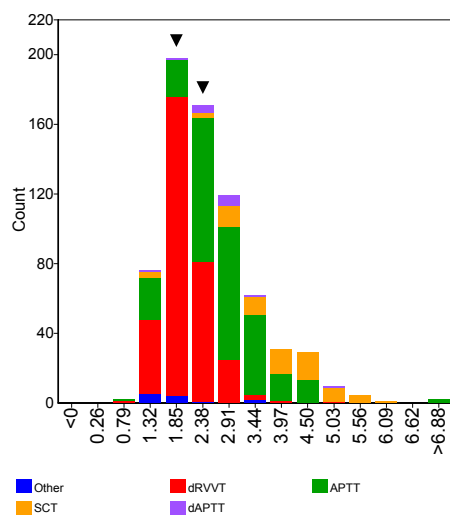
In general, comparable results were observed for the ratio ECAT plasma over Normal Plasma and ratio ECAT plasma over Mean Reference Interval (MRI).



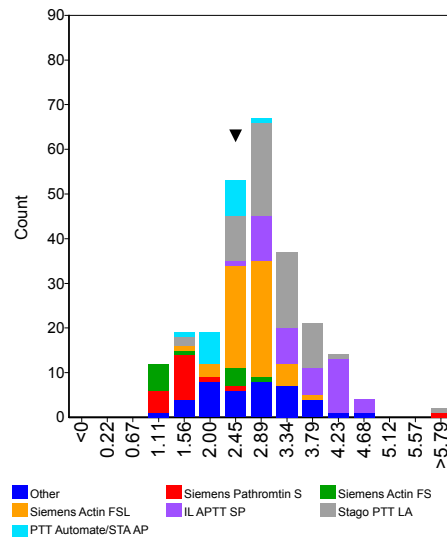
**Ratio Normal Plasma**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	282	2.76	26.5	1.05 - 8.60	1			2.55	-0.29		
Hyphen-Biomed Cephen LS	9	3.01		2.54 - 3.47							
IL APTT SP	40	3.66	19.4	2.54 - 4.72							
IL Hemosil SynthAFax	6	2.82		1.09 - 4.70							
IL Hemosil SynthAsil	29	2.32	7.3	2.02 - 2.59							
IL MixCon	7	3.10		1.42 - 3.82							
Siemens Actin FS	12	1.79	45.7	1.05 - 2.93							
Siemens Actin FSL	59	2.74	11.8	1.76 - 3.81	1		2.55	-0.58			
Siemens Pathromtin SL	18	1.51	14.0	1.30 - 2.62							
Stago PTT Automate/STA APTT	17	2.28	11.0	1.78 - 2.88							
Stago PTT LA	62	3.11	15.5	1.41 - 8.60							
Tooag TriniClot Automated APTT	6	2.30		2.08 - 2.52							
<b>dAPTT</b>	14	2.69	22.9	1.15 - 5.04							
Stago PTT LA	6	2.98		1.15 - 5.04							
<b>dRVVT</b>	326	1.98	20.8	1.03 - 5.06	1					1.65	-0.80
I.L. Hemosil dRVVT screen	83	2.39	15.7	1.37 - 3.73							
Siemens LA1 screen	151	1.92	12.4	1.03 - 3.60	1					1.65	-1.15
Siemens LA2 confirmation	16	1.19	3.3	1.10 - 1.72							
Stago DRVVT screen	49	1.80	14.0	1.45 - 5.06							
<b>SCT</b>	71	3.92	24.8	1.22 - 6.00							
IL SCT screen	66	3.96	23.4	1.32 - 6.00							

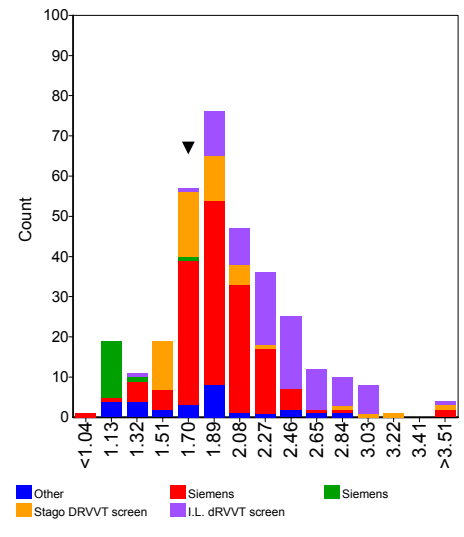
**Assays**



**APTT**



**DRVVT**



**Lupus Anticoagulant**

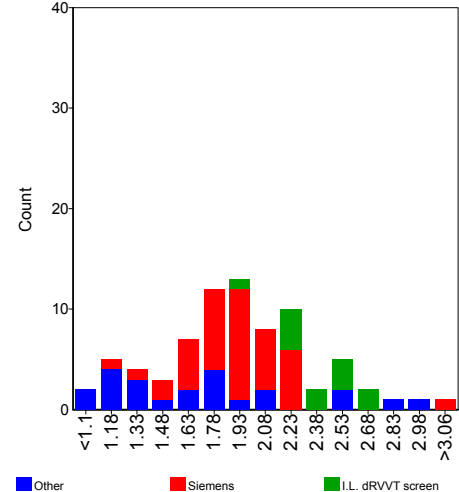
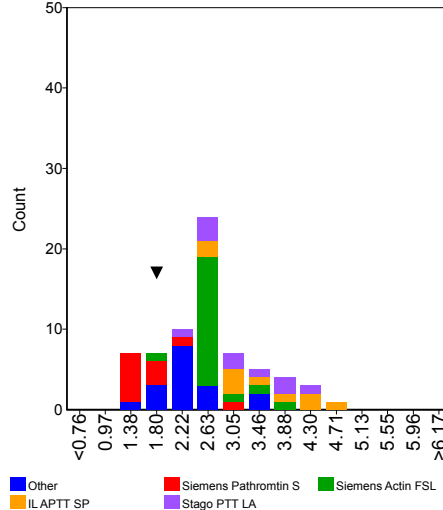
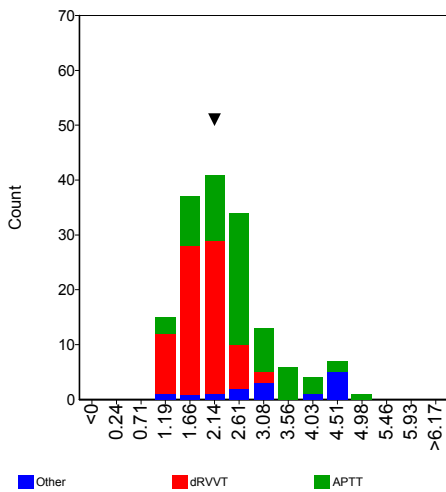
**Mixing**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	68	2.59	30.2	1.19 - 4.90	1			1.99	-0.77		
IL APTT SP	10	3.47	26.0	2.58 - 4.90							
Siemens Actin FSL	20	2.65	7.8	1.99 - 3.72	1			1.99	-3.20		
Siemens Pathromtin SL	11	1.61	15.7	1.37 - 2.93							
Stago PTT LA	10	3.22	22.5	2.36 - 4.30							
<b>dRVVT</b>	76	1.91	23.0	1.04 - 3.24							
I.L. HemosIL dRVVT screen	12	2.38	9.5	1.88 - 2.72							
Siemens LA1 screen	41	1.89	13.9	1.21 - 3.24							
Siemens LA2 confirmation	6	1.19		1.08 - 1.27							
Stago DRVVT screen	7	1.82		1.54 - 2.53							
<b>SCT</b>	7	4.43		3.24 - 4.69							
IL SCT screen	7	4.43		3.24 - 4.69							

**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.

The majority of performed mixing 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).

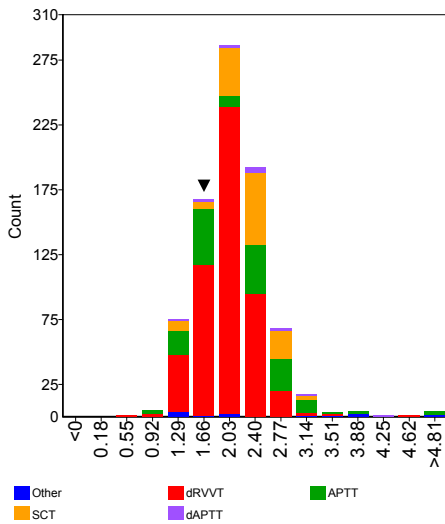




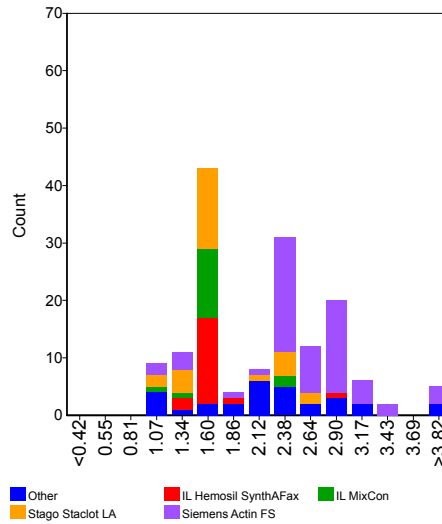
**Ratio Normal Plasma**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	151	2.14	33.7	1.00 - 5.61							
IL Hemosil SynthAFax	19	1.55	5.1	1.30 - 3.03							
IL MixCon	16	1.57	7.1	1.08 - 2.50							
Siemens Actin FS	60	2.64	14.8	1.13 - 5.61							
Stago Staclot LA	27	1.74	25.2	1.14 - 2.64							
Technoclone Lupus Anticoagulant Test	5	2.40		2.24 - 3.93							
<b>dAPTT</b>	13	2.31	32.3	1.15 - 4.23							
Siemens Actin FS	5	2.44		1.15 - 4.23							
<b>dPT</b>	5	3.44		1.22 - 4.00							
<b>dRVVT</b>	520	1.99	15.2	0.65 - 4.58	1					1.77	-0.76
Hyphen Biomed Hemoclot LA-C	5	2.16		1.10 - 3.37							
IL Hemosil dRVVT confirm	184	2.22	10.7	1.10 - 4.58							
IL Hemosil LAC confirm	14	2.16	9.7	1.13 - 2.43							
Roche Lupus C	5	2.58		2.30 - 2.62							
Siemens LA2 confirmation	214	1.89	9.8	1.14 - 2.58	1					1.77	-0.66
Stago DRVVT Confirm	77	1.81	6.7	1.12 - 2.29							
Technoclone LA Confirm	7	1.81		0.65 - 1.85							
<b>PNP</b>	5	1.82		1.13 - 1.95							
<b>SCT</b>	131	2.30	14.1	1.13 - 3.32							
IL Hemosil SCT confirm	130	2.29	14.0	1.13 - 3.32							

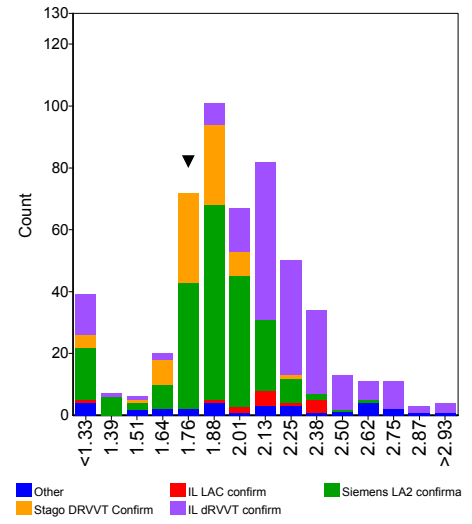
**Assays**



**APTT**



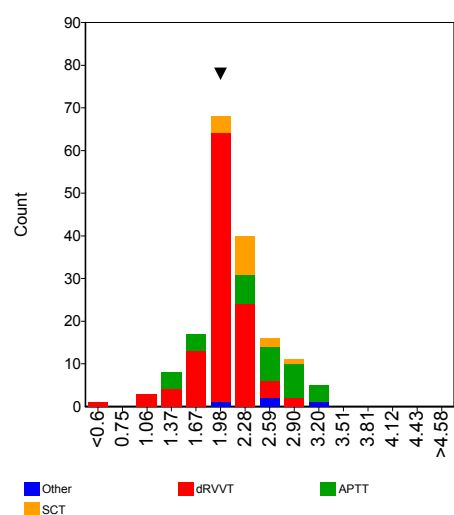
**DRVVT**



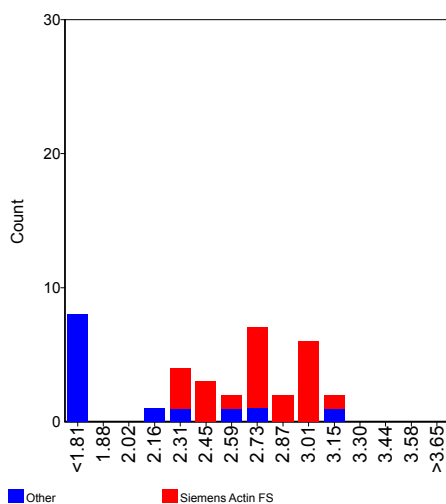
**Lupus Anticoagulant** **Confirmation**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	35	2.44	25.2	1.26 - 3.15							
Siemens Actin FS	22	2.73	11.2	2.28 - 3.15							
<b>dRVVT</b>	114	2.00	12.0	0.53 - 2.85	1					1.99	-0.05
IL HemosIL dRVVT confirm	20	2.17	9.4	1.15 - 2.75							
IL HemosIL LAC confirm	5	2.09		1.38 - 2.40							
Siemens LA2 confirmation	67	1.96	8.5	0.53 - 2.69	1					1.99	0.19
Stago DRVVT Confirm	12	1.90	5.9	1.42 - 2.17							
<b>SCT</b>	16	2.29	10.2	1.95 - 2.79							
IL HemosIL SCT confirm	16	2.29	10.2	1.95 - 2.79							

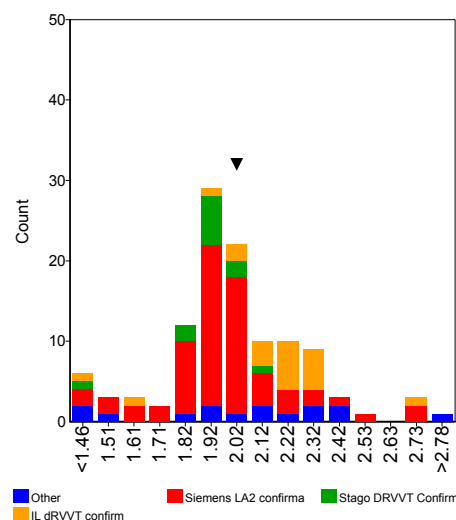
**Assays**



**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.

The majority of performed confirmation 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).

**Lupus Anticoagulant**

**Interpretation**

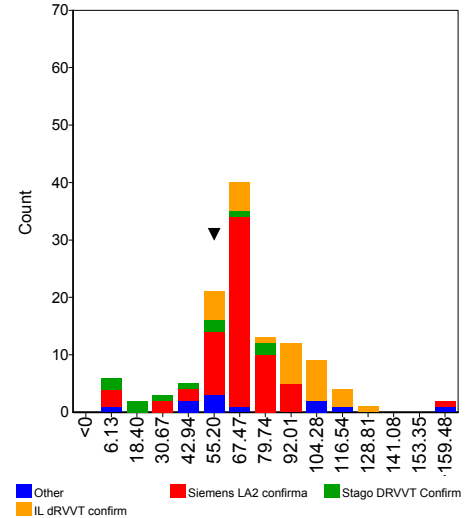
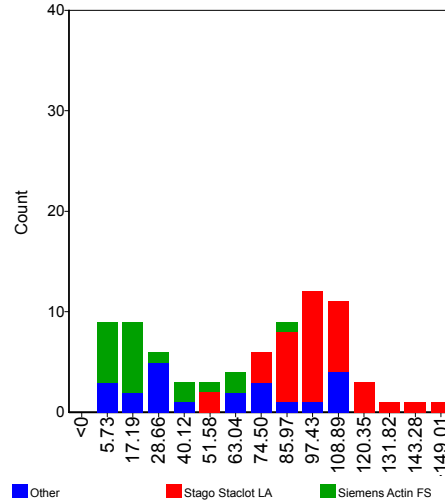
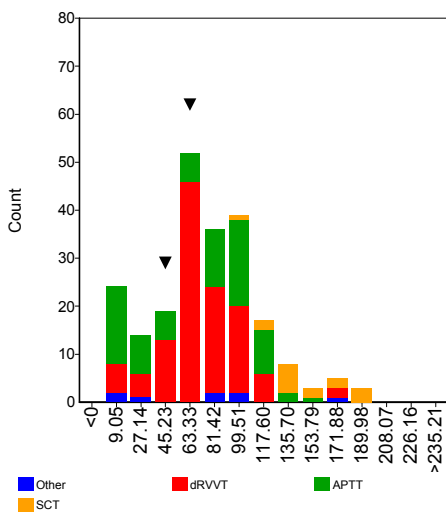
**Delta Seconds**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	78	67.10	68.1	1.00 - 152.00							
IL Hemosil SynthAFax	5	79.68		74.11 - 104.80							
Siemens Actin FS	20	22.94	82.0	6.30 - 83.60							
Stago Staclot LA	36	98.17	17.3	45.90 - 152.00							
<b>dRVVT</b>	118	70.73	30.6	1.30 - 172.00	1					59.00	-0.54
IL Hemosil dRVVT confirm	29	87.79	27.2	49.30 - 123.40							
Siemens LA2 confirmation	67	67.68	17.5	1.30 - 167.00	1					59.00	-0.73
Stago DRVVT Confirm	11	42.15	70.9	1.97 - 82.70							
<b>SCT</b>	16	148.29	18.9	105.20 - 194.10							
IL Hemosil SCT confirm	15	145.21	17.1	105.20 - 187.60							

**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 difference in clotting time between the screen and confirmation test (or difference between reagent 1 and reagent 2).**

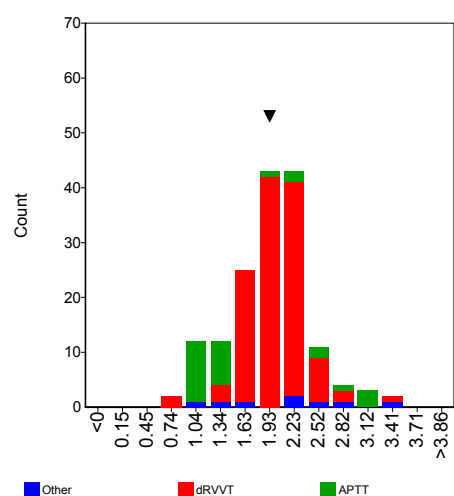
**Lupus Anticoagulant**

**Interpretation**

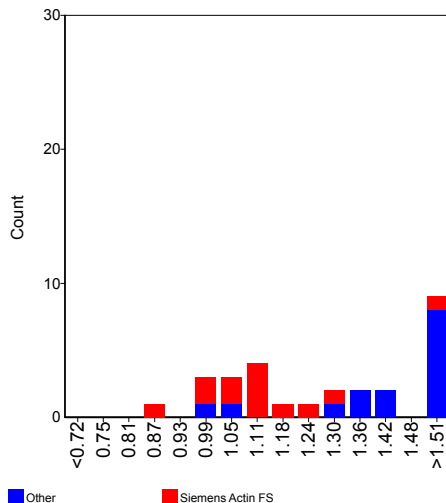
**Ratio Screen/Confirmation - Standard**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	28	1.59	47.8	0.90 - 3.10							
Siemens Actin FS	13	1.11	11.9	0.90 - 1.98							
Stago Staclot LA	6	2.43		1.39 - 3.10							
<b>dRVVT</b>	121	2.00	13.4	0.85 - 3.50	1					1.93	-0.26
IL HemosIL dRVVT confirm	10	2.03	16.1	1.60 - 2.64							
Siemens LA2 confirmation	87	2.05	10.9	1.44 - 2.73	1					1.93	-0.55
Stago DRVVT Confirm	15	1.75	10.4	1.27 - 1.95							
<b>SCT</b>	5	2.63		2.18 - 3.37							

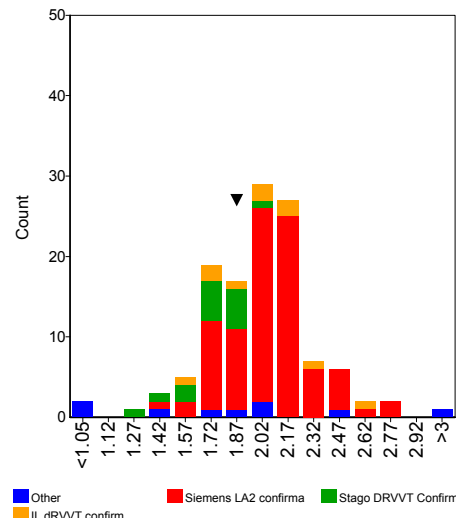
**Assays**



**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. 1.9).

A few participants (333, 705, 1447) reported a value for the ratio screen/confirm which actually was not likely to be a ratio screen over confirm. Therefore these results were excluded from the statistical analysis.

**Lupus Anticoagulant**

**Interpretation**

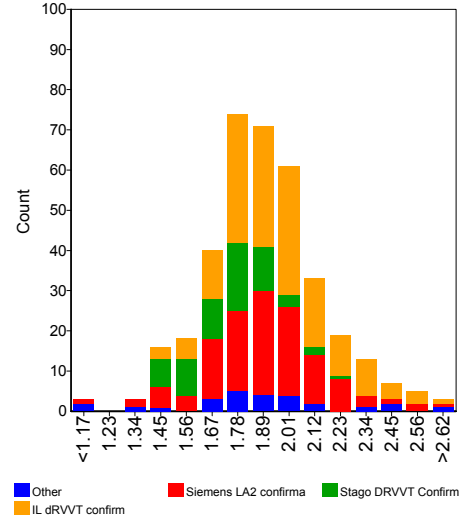
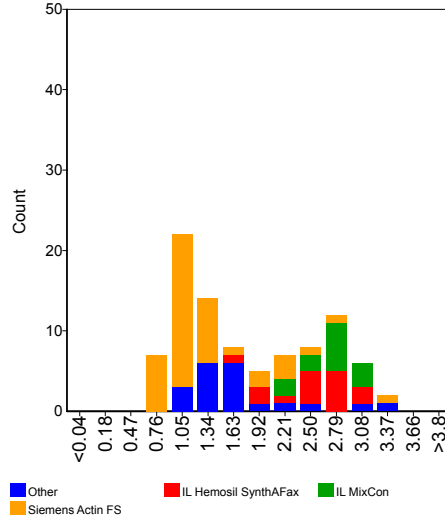
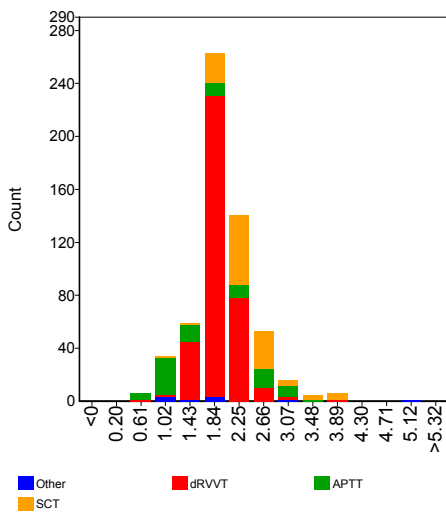
**Ratio Screen/Confirmation - Normalised**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	91	1.79	48.2	0.66 - 3.46							
IL Hemosil SynthAFax	15	2.53	16.8	1.59 - 3.17							
IL MixCon	13	2.73	10.4	2.08 - 3.13							
Siemens Actin FS	43	1.22	32.2	0.66 - 3.26							
<b>dRVVT</b>	366	1.90	12.3	0.71 - 3.84							
IL Hemosil dRVVT confirm	158	1.95	11.5	1.47 - 3.10							
IL Hemosil LAC confirm	8	1.87		1.68 - 2.08							
Siemens LA2 confirmation	122	1.90	12.0	1.10 - 3.84							
Stago DRVVT Confirm	60	1.75	11.1	1.45 - 2.20							
<b>SCT</b>	117	2.33	15.2	1.15 - 3.98							
IL Hemosil SCT confirm	117	2.33	15.2	1.15 - 3.98							

**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. 1.9).

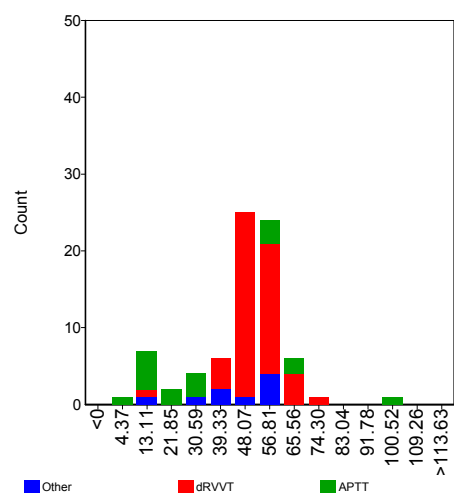
**Lupus Anticoagulant**

**Interpretation**

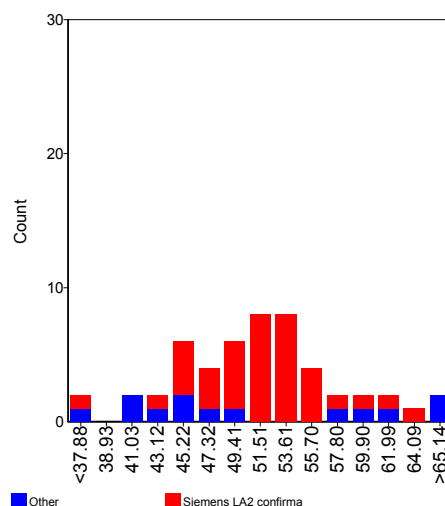
**Percentage Correction - Standard**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	17	33.59	79.4	1.21 - 101.00							
Siemens Actin FS	7	11.00		1.21 - 21.90							
Stago Staclot LA	6	58.85		27.90 - 101.00							
<b>dRVVT</b>	51	51.32	12.4	10.00 - 72.00							
Siemens LA2 confirmation	38	51.51	8.8	35.40 - 63.20							
Stago DRVVT Confirm	8	44.20		10.00 - 66.80							
<b>SCT</b>	5	53.80		51.30 - 59.85							

**Assays**



**DRVVT**



**Comments**

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

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

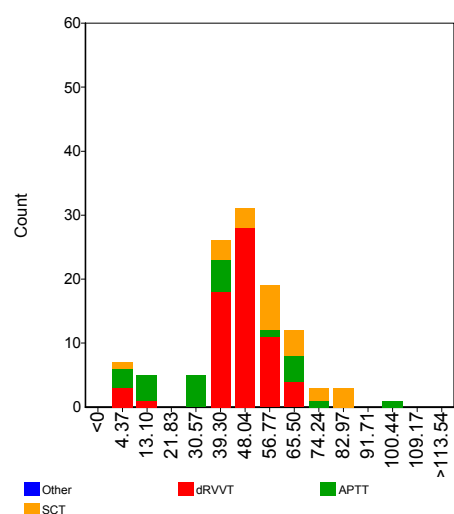
**Lupus Anticoagulant**

**Interpretation**

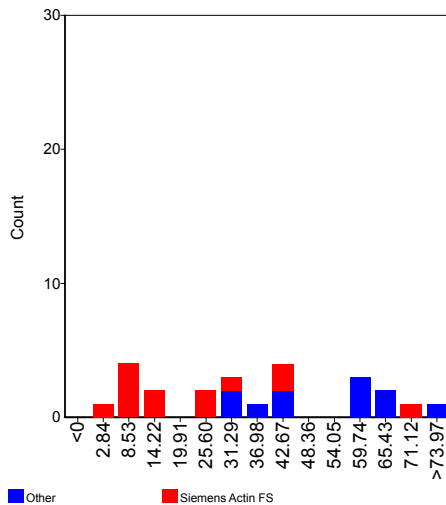
**Percentage Correction - Normalised**

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
<b>APTT</b>	24	36.49	70.4	0.60 - 100.00							
Siemens Actin FS	13	21.73	80.1	0.60 - 72.30							
<b>dRVVT</b>	65	46.92	17.0	0.46 - 69.13							
IL HemosIL dRVVT confirm	23	49.52	23.6	0.46 - 69.13							
Siemens LA2 confirmation	23	48.33	12.4	1.83 - 57.90							
Stago DRVVT Confirm	11	39.14	11.8	1.90 - 45.10							
<b>SCT</b>	23	57.77	26.2	2.27 - 80.32							
IL HemosIL SCT confirm	23	57.77	26.2	2.27 - 80.32							

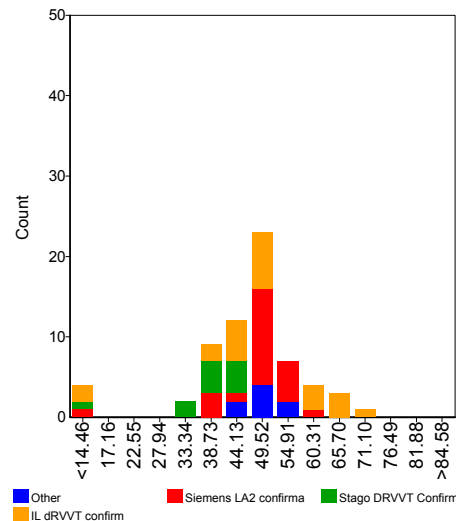
**Assays**



**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.**

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

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

- 6223 (panel1, instr.1): 0.001                      6223 (panel2, instr.1): 0.0038
- 6223 (panel1, instr.2): 0.0001                6223 (panel2, instr.2): 0.0001
- 6223 (panel1, instr.3): 0.0001



**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	15	1	5	1		LA detected	
					2			
					3			
Screen and mixing test	2	77	2	12	1			
					2			
					3			
Screen and confirm test	1	367	11	27	1			
					2			
					3			
Screen, mixing and confirm test	14	261	9	14	1			LA detected
					2			
					3			
Screen, confirm, mixing test	5	136	8	9	1			
					2			
					3			
Mixing - confirmation	0	40	0	4	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			
467		5	27	LA detected		

**Comments**

The sample used in this survey was plasma from a patient diagnosed with Lupus Anticoagulant (LA Ratio = approx. 1.9). This patient was under oral anticoagulation treatment (VKA) (INR > 3.0).

In total 499 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 94% indicated Lupus Anticoagulant was detected. About 1% classified the sample as equivocal. Thus, the vast majority of the participants correctly classified this sample as a Lupus Anticoagulant positive.

Some participants indicated that they were not able to detect Lupus Anticoagulant because of a potential interference of another inhibitor or because of a high INR result.

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 6 or 12 weeks.

**Lupus Anticoagulant**

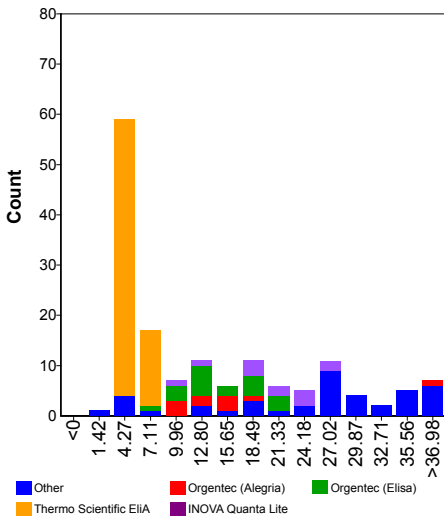
**AntiCardiolipin Antibodies IgG**

<b>Sample No</b>	22.108		
<b>Sample Details</b>	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.9)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	GPL, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	29-February-2024		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	615		
<b>Number of Responders</b>	221	<b>Response Rate</b>	36 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	82	12	92	31	6	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/mL, µg/mL, GPL/MPL</b>	152	12.9	81.2	0.0 - 57.5						
Aeskulisa Diagnostic GmbH	6	24.9		13.1 - 44.0						
Biorad Bioplex	8	29.9		22.2 - 37.4						
Euroimmun	9	27.0		14.0 - 52.7						
INOVA Quanta Lite	12	20.4	27.1	11.0 - 27.2						
Orgentec (Alegria)	10	14.3	24.9	9.9 - 57.5						
Orgentec (Elisa)	19	14.7	33.6	7.4 - 22.6						
Thermo Scientific ELIA	70	5.1	13.2	3.2 - 6.4						
<b>CU/mL</b>	70	32.2	11.7	22.2 - 41.3						
I.L. Acustar / INOVA Quanta Flash	69	32.3	11.8	22.2 - 41.3						

**GPL, U/mL, µg/mL**



**Comments**

A heterogeneous pattern in the classification has been observed.

**Lupus Anticoagulant**

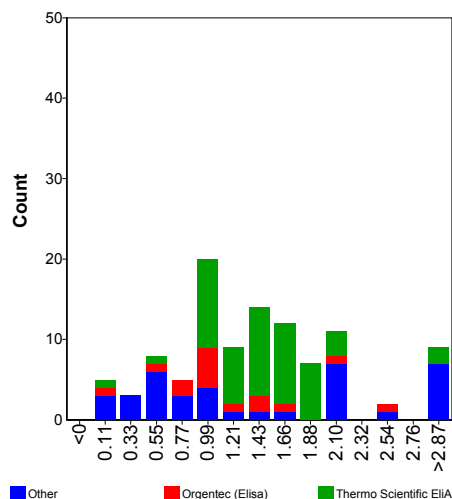
**AntiCardiolipin Antibodies IgM**

<b>Sample No</b>	22.108		
<b>Sample Details</b>	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.9)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	MPL, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	29-February-2024		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	615		
<b>Number of Responders</b>	206	<b>Response Rate</b>	33 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	207	1	1	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>	105	1.4	49.4	0.0 - 12.6						
Aeskulisa Diagnostik GmbH	5	1.0		0.3 - 2.0						
INOVA Quanta Lite	8	8.9		0.0 - 12.6						
Orgentec (Alegria)	8	0.6		0.4 - 0.7						
Orgentec (Elisa)	15	1.1	50.7	0.1 - 2.6						
Thermo Scientific ELIA	53	1.5	27.4	0.1 - 3.1						
<b>CU/mL</b>	63	1.4	19.3	0.8 - 2.0						
I.L. Acustar / INOVA Quanta Flash	63	1.4	19.3	0.8 - 2.0						

**MPL, U/mL, µg/mL**



**Comments**

Most of the participants reported a negative classification.

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

**9907251** : 7.6

**Lupus Anticoagulant**

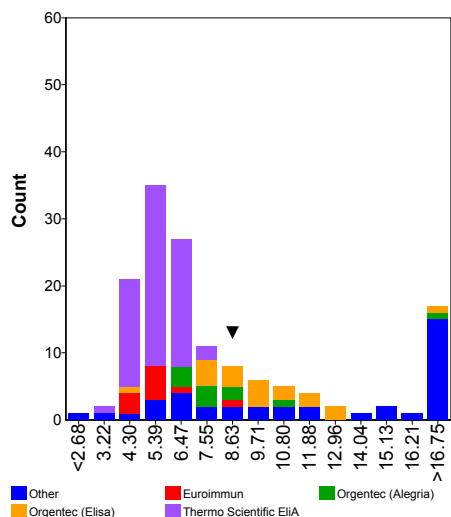
**β2-Glycoprotein I Antibodies IgG**

<b>Sample No</b>	22.108		
<b>Sample Details</b>	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.9)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	U, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	29-February-2024		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	615		
<b>Number of Responders</b>	208	<b>Response Rate</b>	34 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	99	13	28	21	49	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>	143	7.4	43.3	0.0 - 169.0	8.5	0.35				
Aeskulisa Diagnostic GmbH	7	8.0		5.4 - 16.3						
Biorad Bioplex	8	31.8		22.2 - 36.7						
Euroimmun	10	5.0	6.6	4.6 - 8.1						
INOVA Quanta Lite	9	11.9		0.0 - 18.5						
Orgentec (Alegria)	10	8.0	19.1	6.6 - 41.4						
Orgentec (Elisa)	19	9.8	23.9	4.5 - 24.9	8.5	-0.54				
Thermo Scientific EliA	65	5.4	16.9	3.6 - 7.7						
<b>CU/mL</b>	66	160.7	15.4	112.0 - 271.3						
I.L. Acustar / INOVA Quanta Flash	65	160.4	15.5	112.0 - 271.3						

**U, U/mL, µg/mL**



**Comments**

A heterogeneous pattern in the classification has been observed.

**Lupus Anticoagulant**

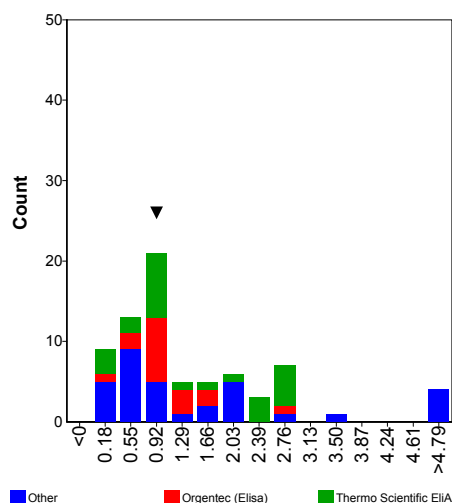
**β2-Glycoprotein I Antibodies IgM**

<b>Sample No</b>	22.108		
<b>Sample Details</b>	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.9)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	U, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	29-February-2024		
<b>Homogeneity</b>	0.0 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	615		
<b>Number of Responders</b>	186	<b>Response Rate</b>	30 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	187	1	0	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, U/mL, µg/mL</b>	74	1.3	76.1	0.0 - 8.2	0.9	-0.40				
Aeskulisa Diagnostic GmbH	6	0.8		0.1 - 1.0						
Euroimmun	6	2.1		0.9 - 5.0						
Orgentec (Alegria)	8	0.4		0.3 - 0.6						
Orgentec (Elisa)	17	1.0	36.1	0.3 - 2.9	0.9	-0.39				
Thermo Scientific ELIA	24	1.5	73.7	0.0 - 2.9						
<b>CU/mL</b>	29	1.1	0.0	0.2 - 1.1						
I.L. Acustar / INOVA Quanta Flash	29	1.1	0.0	0.2 - 1.1						

**U, U/mL, µg/mL**



**Comments**

Most of the participants reported a negative classification.

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

**9907251** : 6.5