

# **ECAT FOUNDATION**

**External quality Control for Assays and Tests**

**With a focus on Thrombosis and Haemostasis**

## **REPORT**



**SURVEY 2020-L2**  
**Lupus Anticoagulant**  
**Labcode 99906936**

Date of Issue : 06-August-2020  
Survey : 2020-L2  
Report : Lupus Anticoagulant

**Note:**

In the Survey Manual 2020 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.

This Survey Manual 2020 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 **September 18th, 2020**. 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.

Lupus Anticoagulant

See comments in the respective sections.

Antiphospholipid Antibodies

Please be aware of the proper use of units. We have frequently observed the use of different units by participants using the same method, while their results are comparable. Therefore, we merged all different units per method except for CU/mL unit. For now we have corrected the units, when reported an incorrect unit for a certain method group. However it is the responsibility of the participant to use the correct units!

This report is authorized by:

Dr. P. Meijer  
Director

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

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Appendices are an integral part of the total report.

**Lupus Anticoagulant**

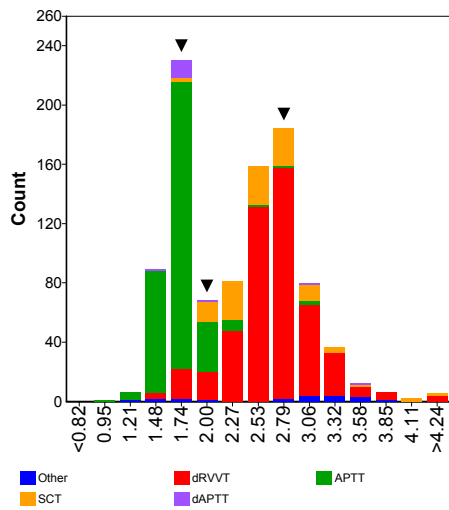
**Screening**

**Sample No** 20.98  
**Sample Details** Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)  
**Prior Use** Prior Use: None  
**Unit** Units: Ratio  
**Expiry Date** 31-January-2022  
**Homogeneity** 1.30 % **Homogeneity Parameter** LA ratio  
**Number of Participants** 618  
**Number of Responders** 550 **Response Rate** 89 %  
**Comments**

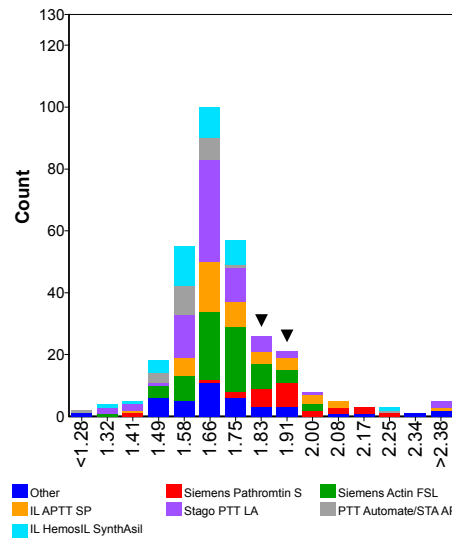
Assay	Normal	Borderline	Prolonged	No Classification	Your result		
					Screening 1	Screening 2	Screening 3
APTT	1	1	384	2	Prolonged	Prolonged	
dAPTT	0	0	20	0			
dPT	0	0	9	0			
dRVVT	2	3	534	9			Prolonged
KCT	0	0	4	0			
Other	0	0	3	0			
PNP	0	0	2	0			
PT	0	0	7	0			
SCT	4	0	113	4			

Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
<b>APTT</b>	329	1.69	8.4	0.83 - 3.14	1.82	0.93	1.93	1.69		
IL APTT SP	45	1.74	8.8	1.41 - 2.98						
IL HemosIL SynthAsil	38	1.62	6.1	1.35 - 2.26						
IL MixCon	16	1.59	4.7	1.14 - 2.76						
Siemens Actin FS	8	1.61		1.48 - 1.85						
Siemens Actin FSL	70	1.71	6.6	1.35 - 2.00			1.93	1.93		
Siemens Pathromtin SL	25	1.91	8.3	1.37 - 2.22	1.82	-0.53				
Stago PTT Automate/STA APTT	22	1.59	5.7	1.18 - 2.29						
Stago PTT LA	73	1.67	5.4	1.29 - 2.51						
Stagoe Staclot LA	5	1.78		1.48 - 1.91						
Tcoag TriniClot Automated APTT	6	1.68		1.62 - 1.78						
<b>dAPTT</b>	16	1.74	8.2	1.53 - 3.53						
Stago PTT LA	13	1.72	5.8	1.61 - 1.89						
<b>dPT</b>	8	3.15		1.53 - 3.76						
<b>dRVVT</b>	484	2.68	12.6	1.47 - 4.69					2.75	0.21
BioMedica Diagnostics DVV test	5	2.25		1.76 - 2.43						
I.L. HemosIL dRVVT screen	162	2.85	13.3	1.71 - 4.69						
I.L. LAC screen	13	2.90	15.4	2.35 - 3.80						
Precision Biologic LA check	10	2.16	6.4	1.75 - 2.36						
Siemens LA1 screen	183	2.70	8.4	1.47 - 3.40					2.75	0.23
Stago DRVVT screen	88	2.52	8.9	1.63 - 4.49						
Technoclone LA Screen	6	2.61		2.50 - 2.67						
<b>PT</b>	7	3.24		2.81 - 3.65						
<b>SCT</b>	112	2.57	15.5	1.68 - 6.65						
Haematex SACT Reagent	8	2.73		2.43 - 4.43						
IL SCT screen	104	2.55	15.6	1.68 - 6.65						

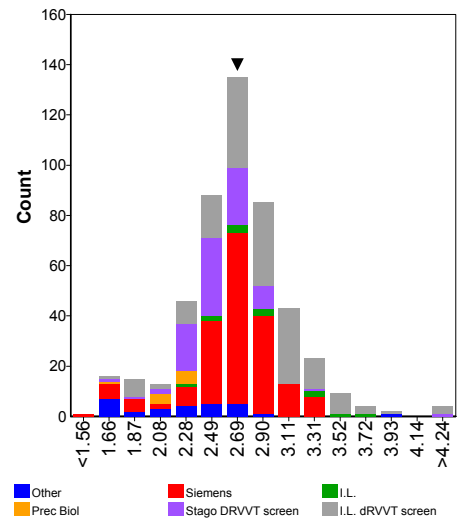
**Assays**



**APTT**



**DRVVT**



**Comments**

Several participants selected the wrong unit; ratio while the result was likely to be in seconds. Therefore all these results were excluded from the statistical analysis.

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

**Lupus Anticoagulant**

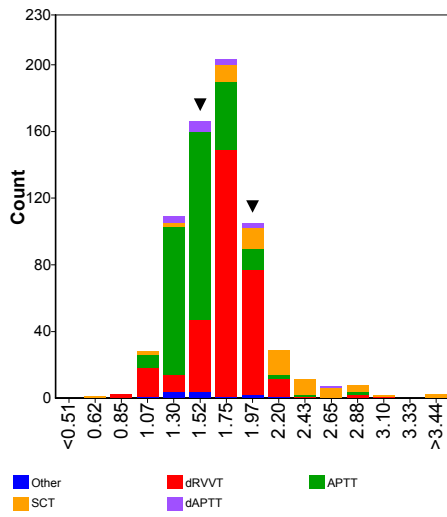
**Mixing**

**Sample No** 20.98  
**Sample Details** Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)  
**Prior Use** Prior Use: None  
**Unit** Units: Ratio  
**Expiry Date** 31-January-2022  
**Homogeneity** 1.30 % **Homogeneity Parameter** LA ratio  
**Number of Participants** 618  
**Number of Responders** 417 **Response Rate** 67 %  
**Comments**

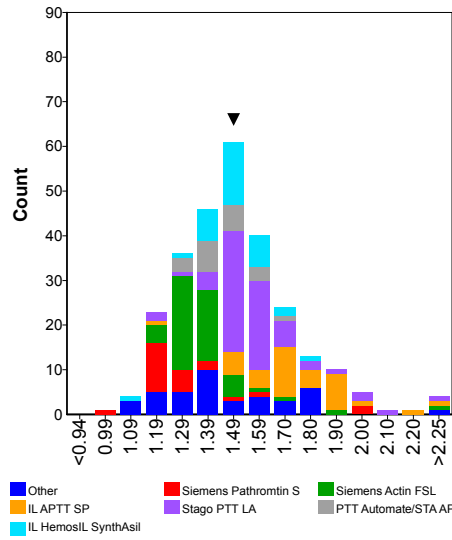
Assay	Normal	Borderline	Prolonged	No Classification	Your result		
					Mixing 1	Mixing 2	Mixing 3
APTT	14	10	274	3		Normal	
dAPTT	1	0	19	0			
dPT	0	0	4	0			
dRVVT	15	3	316	5			Prolonged
KCT	0	0	3	0			
Other	2	0	3	2			
PT	2	0	2	0			
SCT	2	1	61	1			

Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
<b>APTT</b>	269	1.49	13.2	1.00 - 2.83			1.46	-0.14		
IL APTT SP	36	1.72	10.3	1.20 - 2.83						
IL HemosIL SynthAsil	33	1.50	6.8	1.05 - 1.75						
IL MixCon	9	1.51		1.11 - 1.82						
Siemens Actin FS	7	1.22		1.08 - 1.67						
Siemens Actin FSL	50	1.35	6.1	1.21 - 2.80			1.46	1.35		
Siemens Pathromtin SL	23	1.29	8.9	1.00 - 2.01						
Stago PTT Automate/STA APTT	20	1.44	7.9	1.28 - 1.66						
Stago PTT LA	67	1.55	6.7	1.22 - 2.30						
Tcoag TriniClot Automated APTT	6	1.43		1.38 - 1.50						
<b>dAPTT</b>	17	1.65	19.0	1.28 - 2.61						
Stago PTT LA	12	1.68	16.6	1.33 - 2.02						
<b>dRVVT</b>	310	1.76	10.3	0.95 - 3.11					1.93	0.94
I.L. HemosIL dRVVT confirm	6	1.22		0.96 - 1.90						
I.L. HemosIL dRVVT screen	59	1.81	10.9	1.38 - 2.19						
I.L. LAC screen	7	1.88		1.69 - 2.16						
Precision Biologic LA check	5	1.92		1.78 - 2.20						
Siemens LA1 screen	141	1.79	8.7	0.95 - 3.11					1.93	0.92
Siemens LA2 confirmation	13	1.22	19.4	1.00 - 1.86						
Stago DRVVT screen	54	1.74	7.9	1.25 - 2.77						
Technoclone LA Screen	5	1.79		1.72 - 1.80						
<b>SCT</b>	64	2.18	19.2	0.63 - 4.43						
Haematex SACT Reagent	6	2.73		0.63 - 4.43						
IL SCT screen	55	2.17	15.0	1.26 - 3.70						

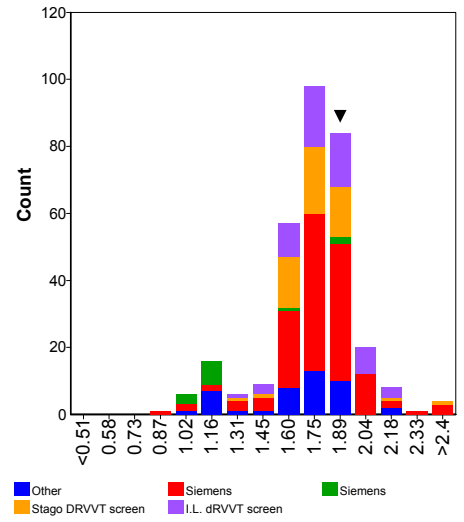
**Assays**



**APTT**



**DRVVT**



**Comments**

Several participants selected the wrong unit; ratio while the result was likely to be in seconds. Therefore all these results were excluded from the statistical analysis.

The majority of performed mixing tests (approx. 95%) were classified as (borderline) prolonged.

**Lupus Anticoagulant**

**Confirmation**

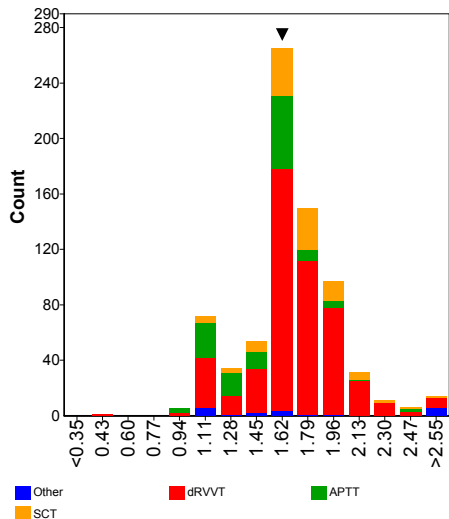
**Sample No** 20.98  
**Sample Details** Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)  
**Prior Use** Prior Use: None  
**Unit** Units: Ratio  
**Expiry Date** 31-January-2022  
**Homogeneity** 1.30 % **Homogeneity Parameter** LA ratio  
**Number of Participants** 618  
**Number of Responders** 548 **Response Rate** 89 %  
**Comments**

Assay	Positive	Borderline	Negative	No Classification	Your result		
					Confirm 1	Confirm 2	Confirm 3
APTT	124	9	46	11			
dAPTT	16	0	2	0			
dPT	3	1	2	1			
dRVVT	518	14	20	25			LA Positive
Other	8	0	0	0			
PNP	1	1	6	2			
PT	1	0	1	1			
SCT	95	7	8	4			

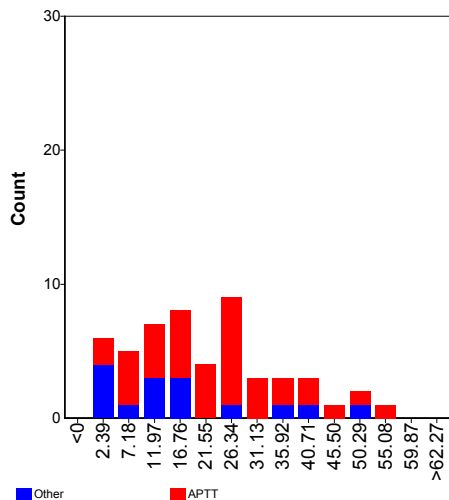
Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
<b>APTT</b>	126	1.47	19.2	0.88 - 2.46						
IL Hemosil SynthAFax	21	1.21	8.7	1.07 - 1.97						
IL MixCon	17	1.20	16.6	0.88 - 1.97						
Siemens Actin FS	56	1.59	6.7	1.06 - 1.85						
Stago Staclot LA	7	1.25		1.13 - 2.11						
Technoclone Lupus Anticoagulant Test	5	1.92		1.49 - 2.46						
<b>dAPTT</b>	8	1.55		1.17 - 1.93						
<b>dPT</b>	6	3.00		1.15 - 3.42						
<b>dRVVT</b>	490	1.71	13.1	0.50 - 3.00					1.66	-0.24
IL Hemosil dRVVT confirm	157	1.87	10.1	1.07 - 2.84						
IL Hemosil LAC confirm	19	1.82	9.4	1.23 - 2.07						
Precision Biologic LA sure	9	2.00		0.50 - 2.25						
Siemens LA2 confirmation	187	1.62	9.4	1.01 - 1.97					1.66	0.25
Stago DRVVT Confirm	87	1.62	5.9	1.09 - 2.29						
Technoclone LA Confirm	8	1.60		1.13 - 1.82						
<b>SCT</b>	103	1.73	12.2	1.06 - 3.40						
IL Hemosil SCT confirm	102	1.73	12.0	1.06 - 2.40						

Delta Seconds	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
<b>APTT</b>	37	22.9	56.8	2.0 - 57.4						
Stago Staclot LA	34	23.3	50.2	2.0 - 57.4						
<b>dAPTT</b>	6	21.0		12.8 - 51.0						
Stago Staclot LA	6	21.0		12.8 - 51.0						
<b>PNP</b>	7	4.1		0.0 - 16.0						

**Ratio**



**Delta Seconds**



**Comments**

Several participants selected the wrong unit; ratio while the result was likely to be in seconds. Therefore all these results were excluded from the statistical analysis.

The majority of the performed confirmation tests (approx. 90%) were classified as borderline or positive. Approx. 54% of the participants using Siemens Actin FS APTT reagent classified the confirm test as normal. For all other reagents none or < 10% of the participants classified the confirm test as normal.



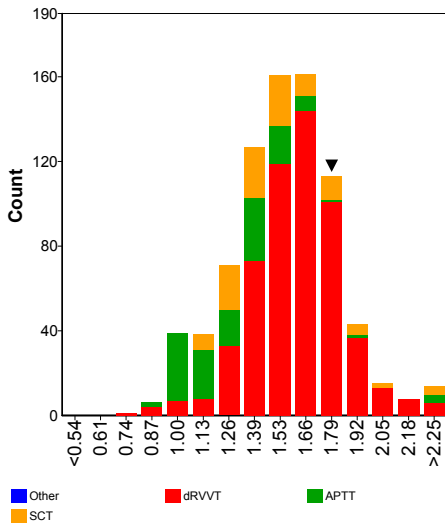
**Lupus Anticoagulant**

**Ratio Screening/Confirmation**

**Sample No** 20.98  
**Sample Details** Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)  
**Prior Use** Prior Use: None  
**Unit** Units: Ratio  
**Expiry Date** 31-January-2022  
**Homogeneity** 1.30 % **Homogeneity Parameter** LA ratio  
**Number of Participants** 618 **Response Rate** 78.64%  
**Number of Responders** 486  
**Comments**

Ratio Screening/Confirmation	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	135	1.27	19.3	0.90 - 3.86						
dAPTT	9	1.29		1.02 - 1.80						
dRVVT	555	1.62	13.0	0.80 - 2.73					1.84	1.07
Other	5	1.32		0.95 - 1.80						
SCT	108	1.49	16.3	1.07 - 3.80						

**Assays**



**Lupus Anticoagulant**

**Final Conclusion**

Final Conclusion	Negative	Borderline	Positive	No Conclusion	Your Result
<b>Total</b>	8	11	440	27	Positive

Comments

Ratio Screen/Confirm

Several participants 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.

Final conclusion

The sample used in this survey was plasma from a patient diagnosed with Lupus Anticoagulant (LA dRVVT Ratio = approx. 1.6 ). No other types of inhibitors were present.

The patient was treated with a Vitamin K Antagonist, resulting in an INR between 3 and 3.5.

No information is available about the use of any other medication.

In total 459 participants reported a final conclusion. Twenty-seven participants did not give a final conclusion. Of the participants who gave a final conclusion, approximately 96% classified the sample as positive. Two percent classified the sample as borderline. Thus, the vast majority of the participants correctly classified this sample as positive.

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

Some participants indicated that, because of an INR > 2, normally this samples would not have been tested for Lupus Anticoagulant or that no final conclusion could be drawn because of the elevated INR value. The lupus anticoagulant test should be repeated on a sample with an INR < 1.5.

Some also indicated that the presence of DOACs should be excluded.

Furthermore, some participants reported that an increased CRP level should be ruled out.

**Lupus Anticoagulant**

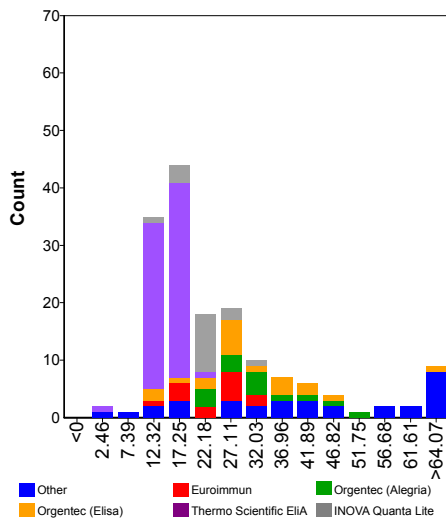
**AntiCardiolipin Antibodies IgG**

<b>Sample No</b>	20.98		
<b>Sample Details</b>	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	GPL, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	31-January-2022		
<b>Homogeneity</b>	1.30 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	618		
<b>Number of Responders</b>	236	<b>Response Rate</b>	38 %
<b>Comments</b>			

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	19	25	63	55	72	2

IgG	n	assigned value	CV (%)	range	Your result	z-score
<b>U/mL, µg/mL, GPL/MPL</b>	160	22.7	48.7	3.0 - 271.0		
Aeskulisa Diagnostik GmbH	6	51.2		18.9 - 59.2		
Euroimmun	13	23.0	32.4	11.0 - 32.0		
INOVA Quanta Lite	17	22.6	15.7	12.6 - 33.5		
Orgentec (Alegria)	14	31.1	28.5	21.0 - 53.0		
Orgentec (Elisa)	19	30.3	37.2	13.5 - 66.0		
Thermo Scientific EliA	65	14.7	15.1	3.0 - 21.0		
<b>CU/mL</b>	61	125.1	10.5	20.4 - 172.3		
I.L. Acustar / INOVA Quanta Flash	61	125.1	10.5	20.4 - 172.3		

**GPL, U/mL, µg/mL**



**Comments**

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

One participant (**labcode 1353**) reported a result as ratio. This result was excluded in the statistical evaluation.

**Lupus Anticoagulant**

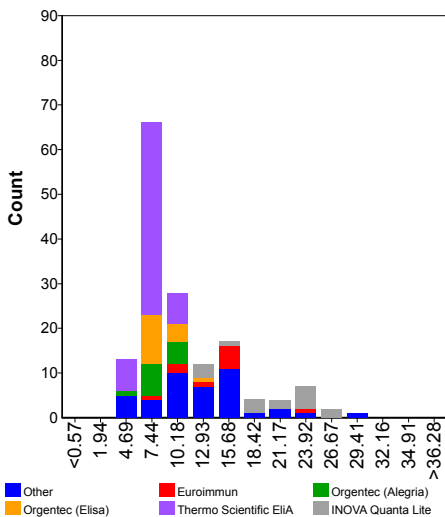
**AntiCardiolipin Antibodies IgM**

**Sample No** 20.98  
**Sample Details** Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)  
**Prior Use** Prior Use: None  
**Unit** MPL, U/mL, µg/mL, CU/mL  
**Expiry Date** 31-January-2022  
**Homogeneity** 1.30 % **Homogeneity Parameter** LA ratio  
**Number of Participants** 618  
**Number of Responders** 215 **Response Rate** 35 %  
**Comments**

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	148	23	38	2	2	2

IgM	n	assigned value	CV (%)	range	Your result	z-score
<b>U/mL, µg/mL, GPL/MPL</b>	154	10.1	43.5	3.7 - 29.5		
Aeskulisa Diagnostic GmbH	6	7.1		5.2 - 9.6		
Biorad Bioplex	9	15.2		11.2 - 18.0		
Bio-rad EIA	7	13.9		9.0 - 20.4		
Euroimmun	10	14.1	32.0	8.4 - 23.0		
INOVA Quanta Lite	16	20.4	25.9	12.5 - 28.0		
Orgentec (Alegria)	13	8.3	13.9	5.9 - 10.2		
Orgentec (Elisa)	16	8.6	17.9	7.0 - 13.0		
Thermo Scientific EliA	57	7.3	14.5	3.7 - 9.3		
<b>CU/mL</b>	57	15.4	12.9	8.9 - 21.8		
I.L. Acustar / INOVA Quanta Flash	57	15.4	12.9	8.9 - 21.8		

**MPL, U/mL, µg/mL**



**Comments**

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

One participant (**labcode 1353**) reported a result as ratio. This result was excluded in the statistical evaluation.

**Lupus Anticoagulant**

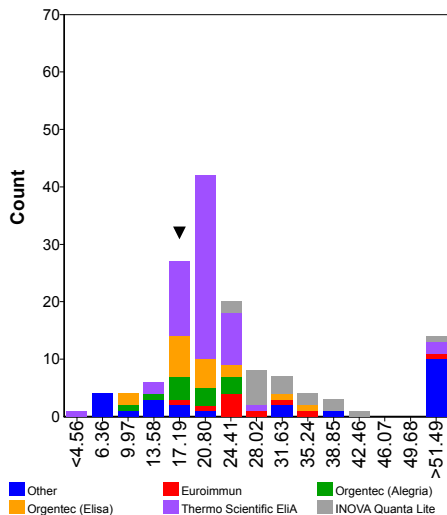
**β2-Glycoprotein I Antibodies IgG**

<b>Sample No</b>	20.98		
<b>Sample Details</b>	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)		
<b>Prior Use</b>	Prior Use: None		
<b>Unit</b>	U, U/mL, µg/mL, CU/mL		
<b>Expiry Date</b>	31-January-2022		
<b>Homogeneity</b>	1.30 %	<b>Homogeneity Parameter</b>	LA ratio
<b>Number of Participants</b>	618		
<b>Number of Responders</b>	210	<b>Response Rate</b>	34 %
<b>Comments</b>			

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
<b>Total</b>	7	4	39	64	94	2

IgG	n	assigned value	CV (%)	range	Your result	z-score
<b>U, U/mL, µg/mL</b>	141	22.5	34.3	1.5 - 619.6	15.5	-0.90
Aeskulisa Diagnostic GmbH	6	7.9		5.9 - 20.0		
Euroimmun	10	26.7	25.9	18.6 - 94.4		
INOVA Quanta Lite	17	31.9	20.4	23.5 - 53.0		
Orgentec (Alegria)	12	19.2	22.7	11.6 - 24.4		
Orgentec (Elisa)	18	19.0	25.4	9.0 - 36.0	15.5	-0.73
Thermo Scientific EliA	60	20.0	14.3	1.5 - 121.0		
<b>CU/mL</b>	59	517.3	14.6	10.8 - 712.9		
I.L. Acustar / INOVA Quanta Flash	58	519.3	14.3	355.9 - 712.9		

**U, U/mL, µg/mL**



**Comments**

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

**Lupus Anticoagulant**

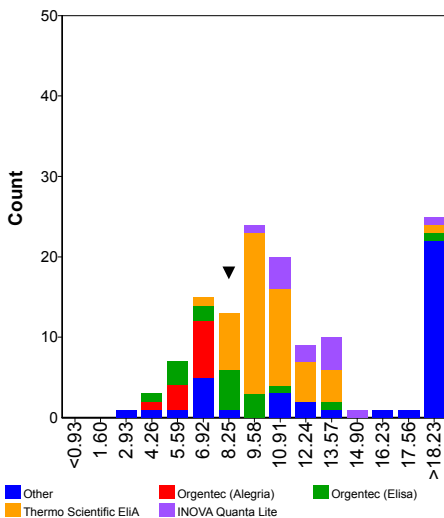
**β2-Glycoprotein I Antibodies IgM**

**Sample No** 20.98  
**Sample Details** Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)  
**Prior Use** Prior Use: None  
**Unit** U, U/mL, µg/mL, CU/mL  
**Expiry Date** 31-January-2022  
**Homogeneity** 1.30 % **Homogeneity Parameter** LA ratio  
**Number of Participants** 618  
**Number of Responders** 184 **Response Rate** 30 %  
**Comments**

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	82	37	42	18	4	1

IgM	n	assigned value	CV (%)	Your result	z-score	
<b>U, U/mL, µg/mL</b>	130	11.4	43.2	3.2 - 92.0	8.3	-0.63
Aeskulisa Diagnostic GmbH	6	6.1		3.2 - 11.0		
Biorad Bioplex	7	27.6		23.7 - 35.8		
Euroimmun	9	75.3		11.0 - 92.0		
INOVA Quanta Lite	13	12.4	15.6	10.0 - 18.6		
Orgentec (Alegria)	11	6.4	14.9	4.8 - 7.3		
Orgentec (Elisa)	17	8.2	29.6	4.5 - 30.0	8.3	0.04
Thermo Scientific EliA	50	10.3	14.5	7.0 - 19.4		
<b>CU/mL</b>	52	11.6	13.2	8.7 - 16.0		
I.L. Acustar / INOVA Quanta Flash	52	11.6	13.2	8.7 - 16.0		

**U, U/mL, µg/mL**



**Comments**

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