ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2020-L1
Lupus Anticoagulant
Labcode 99906936

Date of Issue : 25-May-2020

Survey : 2020-L1

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 **July 8th, 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. 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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Lupus Anticoagulant

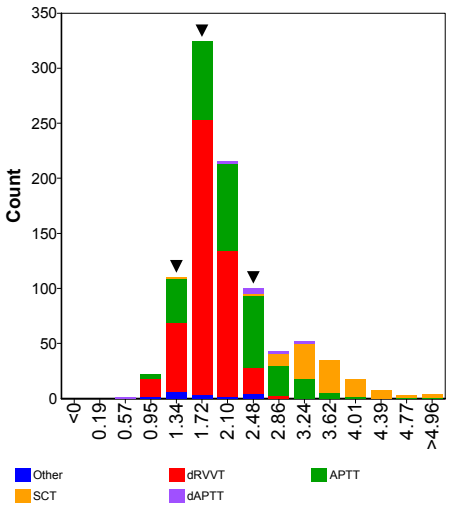
Screening

Sample No 20.62
Sample Details Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 24-October-2021
Homogeneity 0.0 %
Homogeneity Parameter LA ratio
Number of Participants 606
Number of Responders 544
Response Rate 90 %
Comments

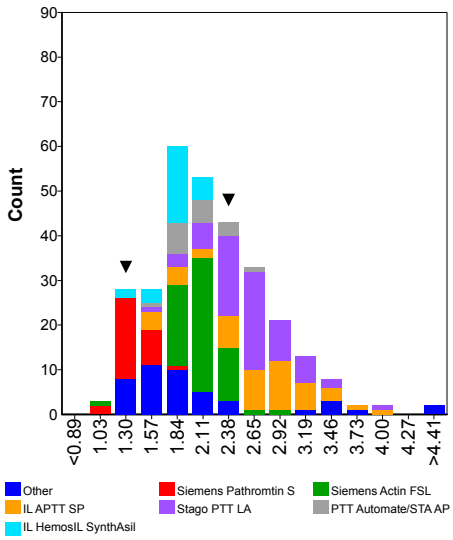
Assay	Normal	Borderline	Prolonged	No Classification	Your result		
					Screening 1	Screening 2	Screening 3
APTT	1	4	364	1	Prolonged	Prolonged	
dAPTT	1	0	18	0			
dPT	1	0	7	0			
dRVVT	14	11	505	14			Prolonged
KCT	0	0	4	0			
Other	1	0	2	0			
PNP	0	0	2	0			
PT	0	0	6	0			
SCT	7	0	102	7			

Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	314	2.13	27.4	1.00 - 5.09	1.33	-1.37	2.43	0.50		
IL APTT SP	48	2.65	22.1	1.56 - 3.90						
IL HemosIL SynthAsil	27	1.86	9.3	1.39 - 2.17						
IL MixCon	18	1.66	8.4	1.11 - 1.98						
Siemens Actin FS	8	1.35		1.22 - 2.13						
Siemens Actin FSL	63	2.10	10.3	1.00 - 2.85			2.43	1.51		
Siemens Pathromtin SL	29	1.40	7.7	1.13 - 1.86	1.33	-0.61				
Stago PTT Automate/STA APTT	17	2.04	14.8	1.70 - 2.59						
Stago PTT LA	68	2.59	14.5	1.69 - 4.03						
Stagoe Staclot LA	6	2.11		1.51 - 2.36						
Tcoag TriniClot Automated APTT	5	1.78		1.71 - 1.92						
Technoclone Lupus Anticoagulant Test	6	1.78		1.60 - 5.09						
dAPTT	12	2.49	21.0	0.65 - 3.17						
Stago PTT LA	9	2.61		0.65 - 3.17						
dPT	7	2.28		1.10 - 2.47						
dRVVT	486	1.78	15.3	0.94 - 2.83					1.69	-0.35
BioMedica Diagnostics DVV test	5	2.08		1.84 - 2.24						
I.L. HemosIL dRVVT screen	159	2.00	11.8	1.34 - 2.83						
I.L. LAC screen	11	1.96	8.5	1.67 - 2.25						
Precision Biologic LA check	12	1.14	8.3	1.03 - 1.49						
Siemens LA1 screen	182	1.74	10.2	0.94 - 2.38					1.69	-0.30
Stago DRVVT screen	87	1.62	8.5	1.25 - 2.34						
Technoclone LA Screen	5	1.58		1.50 - 1.70						
PT	6	1.40		1.30 - 1.65						
SCT	105	3.55	13.3	1.29 - 5.89						
Haematex SACT Reagent	7	3.65		3.21 - 5.89						
IL SCT screen	98	3.53	13.4	1.29 - 5.07						

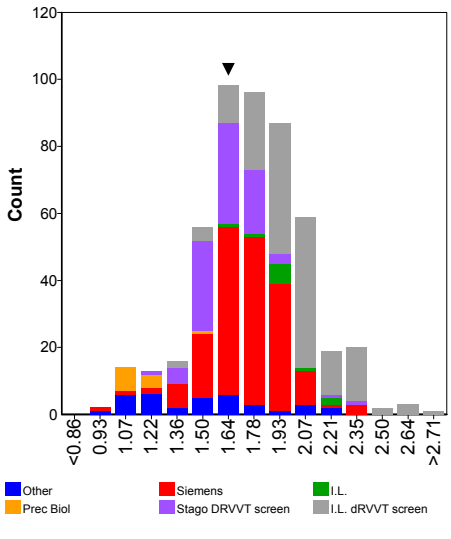
Assays



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 screening tests (approx. 98%) were classified as (borderline) prolonged. Interestingly, within the classification normal for the screening test more than 50% of the participants used the method Precision Biologic LA check. Furthermore, 57% of the participants using the method Precision Biological LA check classified the screening test as normal.

Lupus Anticoagulant

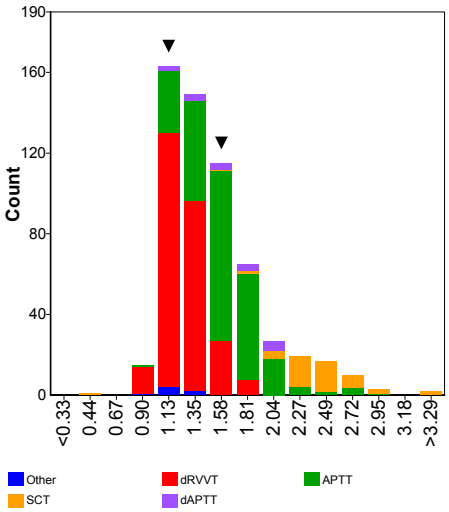
Mixing

Sample No 20.62
Sample Details Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 24-October-2021
Homogeneity 0.0 %
Homogeneity Parameter LA ratio
Number of Participants 606
Number of Responders 388
Response Rate 64 %
Comments

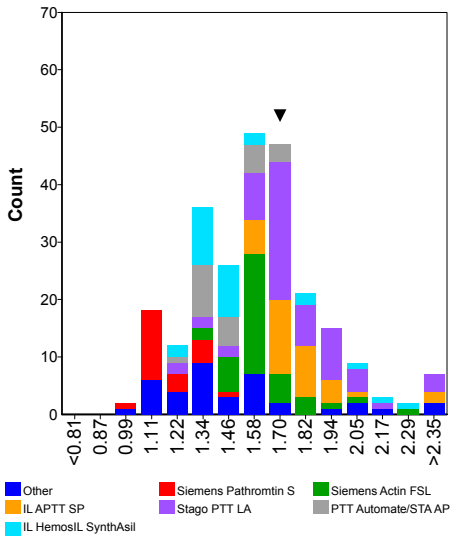
Assay	Normal	Borderline	Prolonged	No Classification	Your result		
					Mixing 1	Mixing 2	Mixing 3
APTT	16	12	247	3		Prolonged	
dAPTT	1	0	19	0			
dPT	1	0	2	0			
dRVVT	70	29	184	8			Borderline
KCT	1	0	2	0			
Other	0	0	3	0			
PT	0	0	2	0			
SCT	2	0	48	2			

Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	247	1.58	17.5	0.98 - 2.93			1.67	0.30		
IL APTT SP	35	1.76	7.8	1.59 - 2.93						
IL Hemosil SynthAFax	5	1.24		1.08 - 1.54						
IL HemosIL SynthAsil	28	1.47	11.6	1.21 - 2.27						
IL MixCon	7	1.60		1.06 - 1.75						
Siemens Actin FSL	40	1.59	6.3	1.36 - 2.24			1.67	0.74		
Siemens Pathromtin SL	21	1.16	10.2	1.04 - 1.40						
Stago PTT Automate/STA APTT	23	1.46	9.8	1.17 - 1.72						
Stago PTT LA	62	1.75	11.4	1.19 - 2.78						
Tcoag TriniClot Automated APTT	5	1.37		1.31 - 1.41						
dAPTT	16	1.66	21.6	1.09 - 2.10						
Stago PTT LA	9	2.00		1.52 - 2.10						
dRVVT	268	1.25	13.4	0.82 - 1.83					1.24	-0.07
I.L. HemosIL dRVVT screen	48	1.44	13.6	1.07 - 1.81						
Precision Biologic LA check	6	1.01		0.95 - 1.08						
Siemens LA1 screen	123	1.23	10.0	0.82 - 1.83					1.24	0.11
Siemens LA2 confirmation	13	1.10	8.0	0.99 - 1.40						
Stago DRVVT screen	54	1.23	10.0	1.03 - 1.71						
SCT	48	2.39	12.5	0.39 - 5.86						
Haematex SACT Reagent	5	2.26		0.39 - 5.86						
IL SCT screen	43	2.40	11.8	1.64 - 3.30						

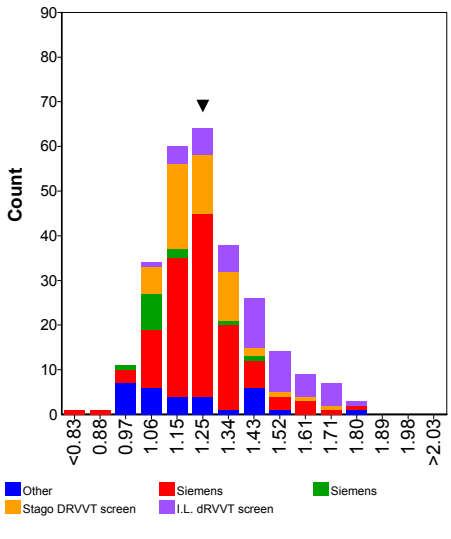
Assays



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. 86%) were classified as (borderline) prolonged. Interestingly, 100% of the participants using the method Precision Biological LA check classified the mixing test as normal. Also, 77% of the participants using the method Siemens LA2 confirm, 20% of Siemens LA1 Screen, 39% of Siemens Pathromtin SL and 29% of Stago dRVVT screen classified the mixing test as normal.

Lupus Anticoagulant

Confirmation

Sample No 20.62
Sample Details Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 24-October-2021
Homogeneity 0.0 %
Homogeneity Parameter LA ratio
Number of Participants 606
Number of Responders 538
Response Rate 89 %
Comments

Assay	Positive	Borderline	Negative	No Classification	Your result		
					Confirm 1	Confirm 2	Confirm 3
APTT	169	6	4	3			
dAPTT	15	0	0	0			
dPT	5	0	3	0			
dRVVT	480	23	36	8			LA Positive
Other	5	0	0	0			
PNP	11	1	1	0			
PT	1	0	1	1			
SCT	107	1	1	1			

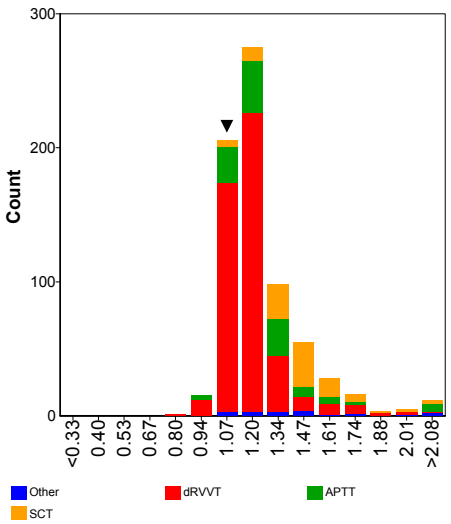
Ratio

	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	117	1.26	13.0	0.98 - 3.69						
IL Hemosil SynthAFax	20	1.16	6.4	1.06 - 1.38						
IL MixCon	19	1.23	22.4	1.00 - 1.70						
Siemens Actin FS	52	1.24	7.3	0.98 - 2.19						
Stago Staclot LA	8	1.44		1.24 - 3.69						
Technoclone Lupus Anticoagulant Test	6	1.39		1.13 - 2.60						
dAPTT	7	1.33		1.24 - 2.12						
dPT	7	1.52		1.10 - 2.19						
dRVVT	478	1.17	8.0	0.81 - 2.10					1.13	-0.37
Hyphen Biomed Hemoclot LA-C	5	1.16		1.04 - 1.44						
IL HemosIL dRVVT confirm	145	1.20	7.9	0.96 - 2.00						
IL HemosIL LAC confirm	22	1.20	10.3	1.01 - 2.10						
Life Diagnostics LA confirm	5	1.07		1.00 - 1.08						
Precision Biologic LA sure	7	1.10		0.81 - 1.25						
Siemens LA2 confirmation	187	1.15	7.6	0.92 - 1.80					1.13	-0.20
Stago DRVVT Confirm	80	1.15	6.2	1.01 - 1.81						
Technoclone LA Confirm	7	1.11		1.05 - 1.19						
SCT	100	1.45	12.3	1.06 - 2.69						
IL HemosIL SCT confirm	98	1.44	12.2	1.06 - 2.69						

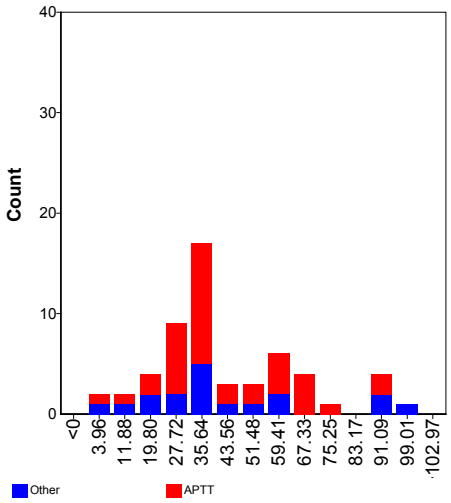
Delta Seconds

	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	38	41.9	46.9	5.6 - 91.8						
Stago Staclot LA	34	44.0	44.6	5.6 - 91.8						
dAPTT	6	56.2		16.2 - 97.5						
Stago Staclot LA	6	56.2		16.2 - 97.5						
PNP	6	28.8		4.0 - 43.0						

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 vast majority of the performed confirmation tests (approx. 95%) were classified as borderline or positive. Interestingly, 100% of the participants using the method Hyphen Biomed Hemaclot LA-C classified the confirm test as normal. Also, 90% of the participants using the method Precision Biological LA sure and 6% of the participants using the method Siemens LA2 confirm classified the confirm test as normal.

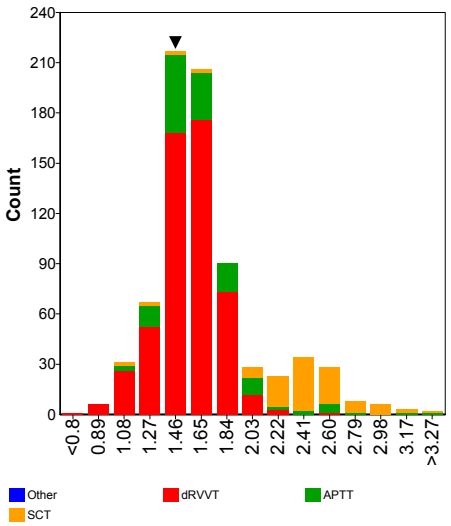
Lupus Anticoagulant

Ratio Screening/Confirmation

Sample No	20.62		
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)		
Prior Use	Prior Use: None		
Unit	Units: Ratio		
Expiry Date	24-October-2021		
Homogeneity	0.0 %	**Homogeneity Parameter**	LA ratio
Number of Participants	606		
Number of Responders	470	**Response Rate**	77.56%
Comments			

Ratio Screening/Confirmation	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	130	1.63	17.0	1.01 - 3.13						
dAPTT	8	1.67		1.42 - 2.31						
dPT	5	1.61		0.93 - 2.06						
dRVVT	518	1.56	13.1	0.78 - 2.53					1.53	-0.13
SCT	102	2.43	11.6	1.00 - 4.32						

Assays



Lupus Anticoagulant

Final Conclusion

Final Conclusion	Negative	Borderline	Positive	No Conclusion	Your Result
Total	21	14	429	6	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 comfirm. 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 Ratio = approx. 1.6). No other types of inhibitors were present.

In total 464 participants reported a final conclusion. Of the participants who gave a final conclusion, approximately 92% classified the sample as positive. Three 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 the presence of indirect anticoagulant or DOAC should be excluded. Furthermore some participants reported that an increased CRP level should be ruled out.

Lupus Anticoagulant

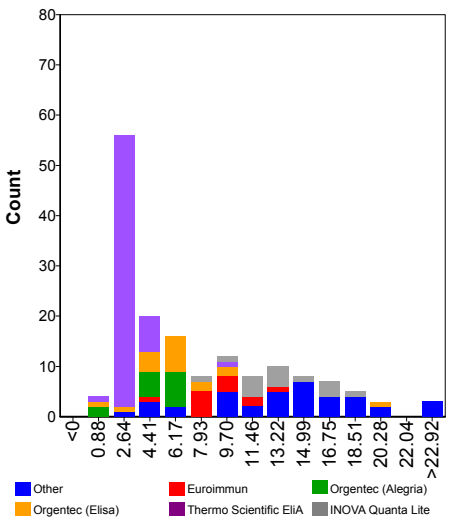
AntiCardiolipin Antibodies IgG

Sample No	20.62
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use	Prior Use: None
Unit	GPL, U/mL, µg/mL, CU/mL
Expiry Date	24-October-2021
Homogeneity	0.0 %
Homogeneity Parameter	LA ratio
Number of Participants	606
Number of Responders	221
Response Rate	36 %
Comments	

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	159	28	27	5	0	2

IgG	n	assigned value	CV (%)	range	Your result	z-score
U/mL, µg/mL, GPL/MPL	160	7.2	77.9	0.3 - 42.0		
Aeskulisa Diagnotic GmbH	8	10.5		4.2 - 16.5		
Biorad Bioplex	7	14.7		10.1 - 15.9		
Euroimmun	12	9.1	22.1	3.6 - 14.0		
INOVA Quanta Lite	15	13.4	23.5	8.2 - 19.0		
Orgentec (Alegria)	14	5.0	20.7	0.3 - 6.4		
Orgentec (Elisa)	18	6.3	37.0	0.9 - 20.9		
Reaads	5	18.0		17.0 - 24.8		
Thermo Scientific EliA	63	2.9	21.1	1.6 - 9.0		
CU/mL	59	20.2	13.4	1.0 - 26.4		
I.L. Acustar / INOVA Quanta Flash	58	20.2	13.6	1.0 - 26.4		

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!

Lupus Anticoagulant

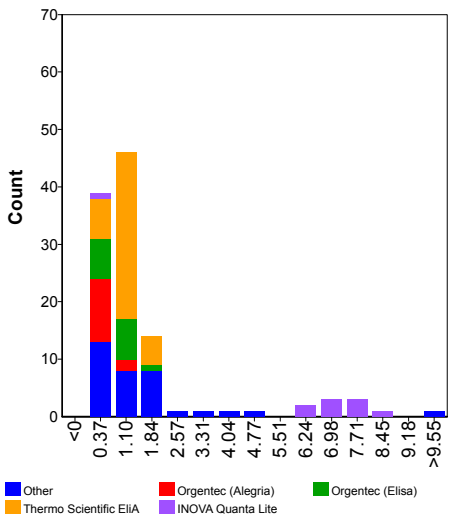
AntiCardiolipin Antibodies IgM

Sample No	20.62
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	24-October-2021
Homogeneity	0.0 %
Homogeneity Parameter	LA ratio
Number of Participants	606
Number of Responders	200
Response Rate	33 %
Comments	

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	200	0	0	0	0	0

IgM	n	assigned value	CV (%)	range	Your result	z-score
U/mL, µg/mL, GPL/MPL	113	1.1	73.1	0.0 - 13.5		
Aeskulisa Diagnotic GmbH	8	1.0		0.4 - 3.4		
Biorad Bioplex	5	0.3		0.2 - 0.3		
INOVA Quanta Lite	10	7.0	12.3	0.0 - 8.1		
Orgentec (Alegria)	13	0.5	35.4	0.2 - 1.0		
Orgentec (Elisa)	15	0.8	58.4	0.2 - 1.9		
Reaads	5	2.0		1.0 - 2.3		
Thermo Scientific EliA	41	1.0	32.6	0.0 - 2.1		
CU/mL	43	1.1	15.9	0.0 - 17.7		
I.L. Acustar / INOVA Quanta Flash	43	1.1	15.9	0.0 - 17.7		

MPL, U/mL, µg/mL



Comments

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Lupus Anticoagulant

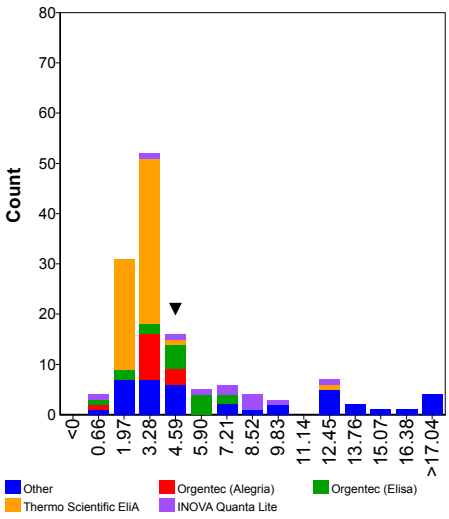
ß2-Glycoprotein I Antibodies IgG

Sample No	20.62
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	24-October-2021
Homogeneity	0.0 %
Homogeneity Parameter	LA ratio
Number of Participants	606
Number of Responders	199
Response Rate	33 %
Comments	

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	130	10	12	29	17	1

IgG	n	assigned value	CV (%)	range	Your result	z-score
U, U/mL, µg/mL	136	3.9	52.7	0.0 - 30.0	4.5	0.29
Aeskulisa Diagnotic GmbH	8	4.3		0.6 - 9.5		
Biorad Bioplex	6	12.2		10.1 - 14.4		
Euroimmun	9	3.6		1.9 - 4.0		
INOVA Quanta Lite	11	7.0	47.9	0.0 - 12.7		
Orgentec (Alegria)	13	3.3	19.5	1.3 - 5.0		
Orgentec (Elisa)	16	4.4	41.4	0.1 - 7.0	4.5	0.05
Thermo Scientific EliA	57	2.8	20.0	1.5 - 12.8		
CU/mL	56	85.5	20.8	1.1 - 129.8		
I.L. Acustar / INOVA Quanta Flash	56	85.5	20.8	1.1 - 129.8		

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

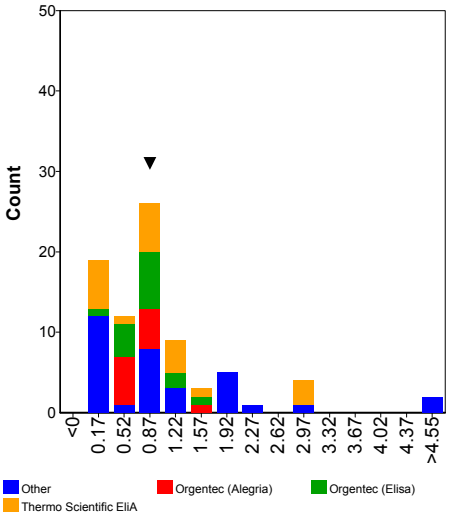
ß2-Glycoprotein I Antibodies IgM

Sample No	20.62
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	24-October-2021
Homogeneity	0.0 %
Homogeneity Parameter	LA ratio
Number of Participants	606
Number of Responders	171
Response Rate	28 %
Comments	

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	169	0	0	2	0	0

IgM	n	assigned value	CV (%)		Your result	z-score
U, U/mL, µg/mL	83	0.9	74.3	0.0 - 7.6	0.8	-0.15
Aeskulisa Diagnotic GmbH	8	1.0		0.2 - 7.6		
INOVA Quanta Lite	7	1.3		0.0 - 2.0		
Orgentec (Alegria)	12	0.7	21.4	0.5 - 1.5		
Orgentec (Elisa)	15	0.8	46.8	0.0 - 1.6	0.8	0.01
Thermo Scientific EliA	23	1.2	93.8	0.0 - 2.9		
CU/mL	27	0.8	69.0	0.0 - 118.6		
I.L. Acustar / INOVA Quanta Flash	27	0.8	69.0	0.0 - 118.6		

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!