ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2020-L3
Lupus Anticoagulant
Labcode 99906936

Date of Issue : 15-October-2020

Survey : 2020-L3

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 **November 27th, 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
Some participant did not perform a mix and confirm test, because the screen test was negative. However, for quality assesment it is also informative to have knowlegde about the performance in the lower range. Therefore, we advise to submit always the data of all three tests, screen, mix and confirm.

Antiphospholipid Antibodies
Please be aware of the proper use of units. We have frequently observed the use of different units by participants using the method "**IL Acustar / INOVA Quanta Flash**" while their results are all expressed in CU/mL. For now we have harmonised the units. 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

Director: Dr. P. Meijer
ECAT Office
P.O. Box 107
2250 AC Voorschoten, The Netherlands
phone +31 (0) 71 3030 910; fax + 31 (0) 71 3030 919
E-mail: info@ecat.nl
Website: www.ecat.nl
VAT number: NL802836872B01

Registration number with the Chamber of Commerce (KvK) Gouda : 41174102
General terms of delivery are applicable to all our services.

Lupus Anticoagulant

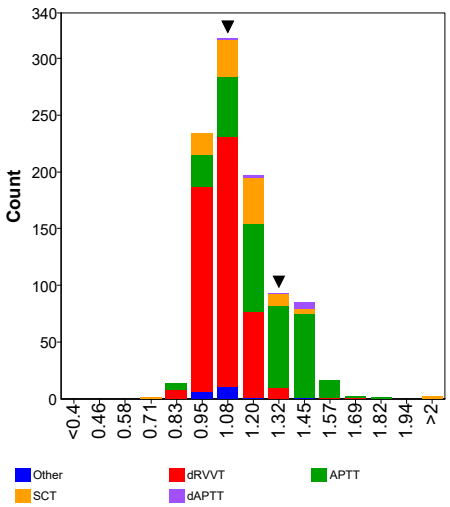
Screening

Sample No 20.151
Sample Details Plasma normal for Lupus Anticoagulant with an increased CRP level (10-15 mg/dL).
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 30-April-2022
Homogeneity 0.0 %
Homogeneity Parameter LA ratio
Number of Participants 621
Number of Responders 555
Response Rate 89 %
Comments

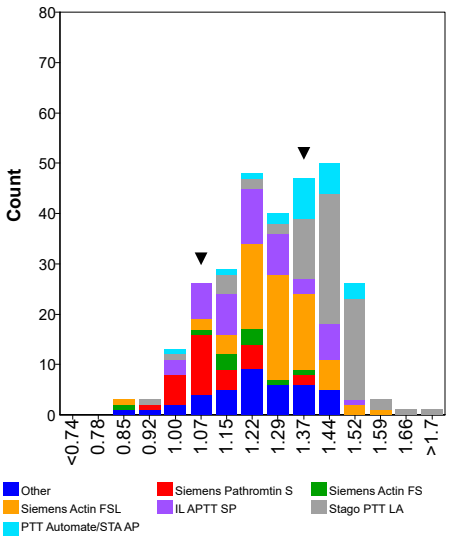
Assay	Normal	Borderline	Prolonged	No Classification	Your result		
					Screening 1	Screening 2	Screening 3
APTT	141	33	206	0	Normal	Normal	
dAPTT	1	1	11	0			
dPT	8	1	1	0			
dRVVT	477	30	39	10			Borderline
KCT	3	0	1	0			
Other	2	1	1	0			
PNP	0	0	1	0			
PT	0	0	5	0			
SCT	70	10	28	5			

Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	328	1.26	15.0	0.82 - 1.85	1.06	-1.04	1.36	0.53		
Hyphen-Biomed Cephen LS	5	1.17		1.14 - 1.26						
IL APTT SP	48	1.23	11.9	0.97 - 1.50						
IL HemosIL SynthAsil	24	0.97	7.9	0.82 - 1.08						
IL MixCon	14	1.08	6.1	0.94 - 1.16						
Siemens Actin FS	10	1.17	10.5	0.85 - 1.37						
Siemens Actin FSL	69	1.29	7.2	0.88 - 1.57			1.36	0.70		
Siemens Pathromtin SL	30	1.10	8.1	0.90 - 1.37	1.06	-0.47				
Stago PTT Automate/STA APTT	22	1.38	6.5	0.97 - 1.51						
Stago PTT LA	72	1.44	6.2	0.90 - 1.85						
Stagoe Staclot LA	6	1.41		1.23 - 1.48						
Tcoag TriniClot Automated APTT	6	1.29		1.24 - 1.43						
dAPTT	10	1.36	11.5	1.07 - 1.49						
Stago PTT LA	9	1.43		1.17 - 1.49						
dPT	9	1.03		0.92 - 1.24						
dRVVT	497	1.05	8.3	0.82 - 1.75					1.09	0.47
Hyphen Biomed Hemoclot LA-S	5	0.93		0.85 - 0.98						
I.L. HemosIL dRVVT screen	166	1.03	7.6	0.82 - 1.35						
I.L. LAC screen	15	1.12	6.8	0.98 - 1.27						
Precision Biologic LA check	10	0.98	8.0	0.90 - 1.09						
Siemens LA1 screen	183	1.05	7.3	0.83 - 1.51					1.09	0.51
Stago DRVVT screen	86	1.09	10.5	0.90 - 1.75						
Technoclone LA Screen	8	1.02		1.00 - 1.16						
PT	5	1.10		1.01 - 1.12						
SCT	109	1.13	11.1	0.74 - 2.22						
Haematex SACT Reagent	7	1.17		1.02 - 2.22						
IL SCT screen	102	1.12	11.0	0.74 - 1.45						

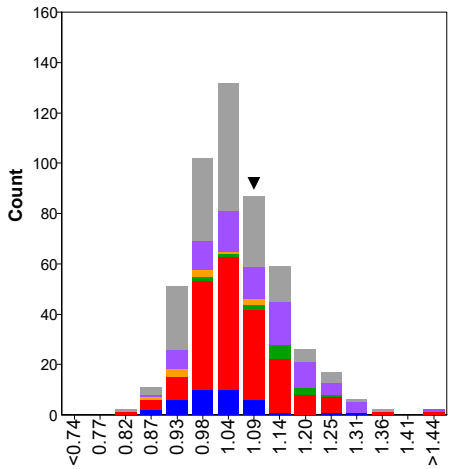
Assays



APTT



DRVVT



Comments

Several participants selected the wrong unit, ratio while the result was likely to be in seconds. A few other participants reported their result for the ECAT plasma in seconds while the result for their reference plasma was reported as a ratio . In all these cases the ratio between the ECAT plasma and the laboratories own reference plasma could not be correctly calculated. Therefore all these results were excluded from the statistical analysis.

A small majority of performed screening tests (66%) were classified as normal, while 27% of the performed screening test were classified as prolonged. A large proportion of the participants using dRVVT reagent (87%) classified the screening test as normal, while a large proportion of performed APTT-based assays classified the sample as prolonged (54%).

For the APTT based assay large differences were observed between classification . Ninty-two percent of the test using Stago (STA) APTT classified the screening test prolonged (n=24) and also 88% of the screening tests using Stago PTT LA (n=72). Also a relative high percentage of prolonged screening tests were observed with the Siemens Actin FSL reagent (65%, n=54) and the IL HemosIL APTT-SP (44%, n=24). Other APTT-based assays only showed occasionally a prolonged classification.

For the dRVVT assay the percentage prolonged screening is low . The maximum percentage prolonged classification is with the Stago dRVVT Screen (13%, n=12).

Lupus Anticoagulant

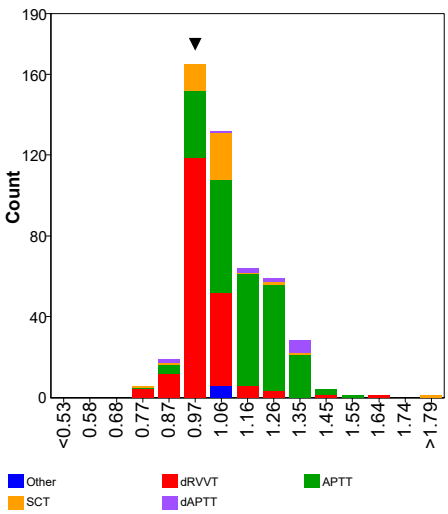
Mixing

Sample No 20.151
Sample Details Plasma normal for Lupus Anticoagulant with an increased CRP level (10-15 mg/dL).
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 30-April-2022
Homogeneity 0.0 %
Homogeneity Parameter LA ratio
Number of Participants 621
Number of Responders 346
Response Rate 56 %
Comments

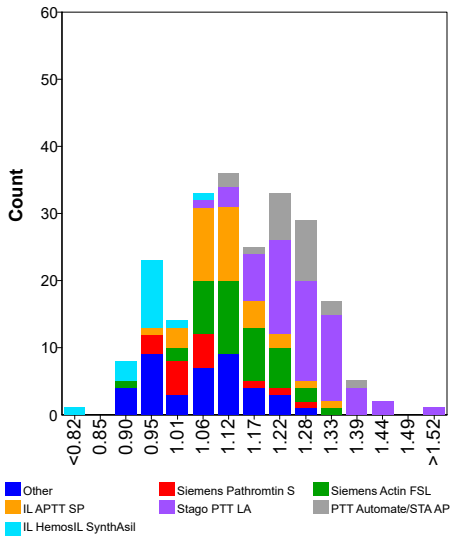
Assay	Normal	Borderline	Prolonged	No Classification	Your result		
					Mixing 1	Mixing 2	Mixing 3
APTT	147	28	82	2			
dAPTT	6	1	9	0			
dPT	0	0	3	0			
dRVVT	195	3	7	3			Normal
KCT	0	0	2	0			
Other	2	0	1	0			
PT	0	0	2	0			
SCT	37	2	4	1			

Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	227	1.14	12.1	0.76 - 1.56						
Hyphen-Biomed Cephen LS	6	1.07		1.05 - 1.28						
IL APTT SP	34	1.10	5.7	0.96 - 1.33						
IL HemosIL SynthAsil	16	0.95	4.1	0.76 - 1.04						
IL MixCon	8	0.96		0.88 - 1.20						
Siemens Actin FSL	39	1.13	6.9	0.92 - 1.34						
Siemens Pathromtin SL	16	1.05	7.2	0.96 - 1.27						
Stago PTT Automate/STA APTT	22	1.25	4.3	1.11 - 1.38						
Stago PTT LA	60	1.27	6.5	1.06 - 1.56						
Tcoag TriniClot Automated APTT	6	1.16		1.13 - 1.22						
dAPTT	13	1.22	13.8	0.90 - 1.37						
Stago PTT LA	10	1.29	7.1	1.12 - 1.37						
dRVVT	192	0.99	5.5	0.74 - 1.60					1.01	0.32
I.L. HemosIL dRVVT screen	39	0.98	5.1	0.84 - 1.08						
I.L. LAC screen	5	1.09		0.99 - 1.18						
Siemens LA1 screen	87	0.99	5.2	0.80 - 1.60					1.01	0.41
Siemens LA2 confirmation	5	1.01		0.99 - 1.07						
Stago DRVVT screen	35	1.01	5.5	0.86 - 1.28						
SCT	42	1.04	7.9	0.81 - 2.22						
IL SCT screen	37	1.03	7.4	0.81 - 1.34						

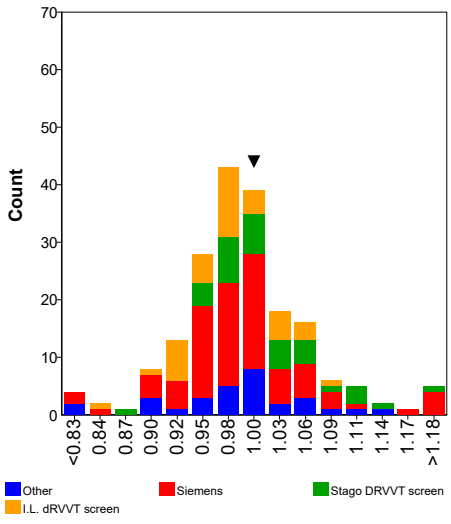
Assays



APTT



DRVVT



Comments

Several participants selected the wrong unit, ratio while the result was likely to be in seconds. A few other participants reported their result for the ECAT plasma in seconds while the result for their reference plasma was reported as a ratio . Two participants reported a negative result for their reference plasma .
In all these cases the ratio between the ECAT plasma and the laboratories own reference plasma could not be correctly calculated. Therefore all these results were excluded from the statistical analysis.

The majority of performed mixing tests (73%) were classified as normal. A large proportion of the participants using dRVVT reagent (95%) classified the mixing test as normal. Twinty-one percent of the performed mixing tests were classified as prolonged. The APTT based mixing tests were classified for 32% (n=82) as prolonged, while the dRVVT tests were only classified for 3% (n=7) as prolonged. The classification of the APTT based reagents is comparable to observations seen for the screening tests.

Lupus Anticoagulant

Confirmation

Sample No 20.151
Sample Details Plasma normal for Lupus Anticoagulant with an increased CRP level (10-15 mg/dL).
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 30-April-2022
Homogeneity 0.0 %
Homogeneity Parameter LA ratio
Number of Participants 621
Number of Responders 482
Response Rate 78 %
Comments

Assay	Positive	Borderline	Negative	No Classification	Your result		
					Confirm 1	Confirm 2	Confirm 3
APTT	59	21	97	2			
dAPTT	9	1	3	0			
dPT	7	0	0	0			
dRVVT	16	23	391	8			LA Negative
Other	2	3	2	0			
PNP	3	2	7	0			
PT	1	0	0	1			
SCT	91	0	4	0			

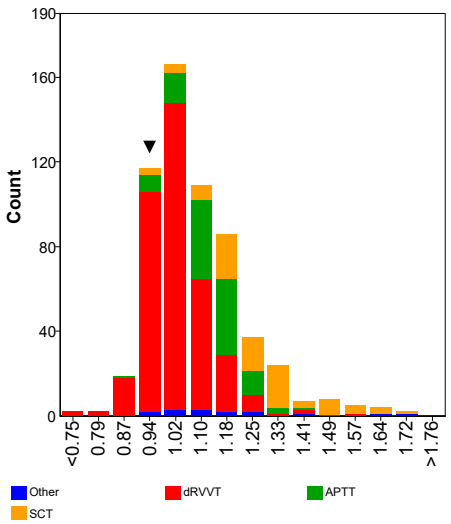
Ratio

	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	111	1.13	7.5	0.90 - 1.40						
IL Hemosil SynthAFax	16	1.13	4.8	1.03 - 1.20						
IL MixCon	17	1.09	8.3	0.91 - 1.26						
Siemens Actin FS	52	1.14	6.1	0.93 - 1.33						
Stago Staclot LA	9	1.12		0.92 - 1.40						
dAPTT	5	1.13		1.04 - 1.69						
dPT	6	1.00		0.97 - 1.17						
dRVVT	373	1.02	7.8	0.74 - 1.58					0.98	-0.45
IL HemosIL dRVVT confirm	126	1.06	7.4	0.88 - 1.51						
IL HemosIL LAC confirm	20	1.07	6.5	0.94 - 1.28						
Precision Biologic LA sure	6	0.96		0.91 - 1.03						
Siemens LA2 confirmation	128	0.98	7.1	0.80 - 1.30					0.98	-0.04
Stago DRVVT Confirm	63	1.00	5.6	0.90 - 1.58						
Technoclone LA Confirm	7	0.99		0.91 - 1.05						
SCT	89	1.27	12.5	0.91 - 1.72						
IL HemosIL SCT confirm	87	1.27	12.7	0.91 - 1.72						

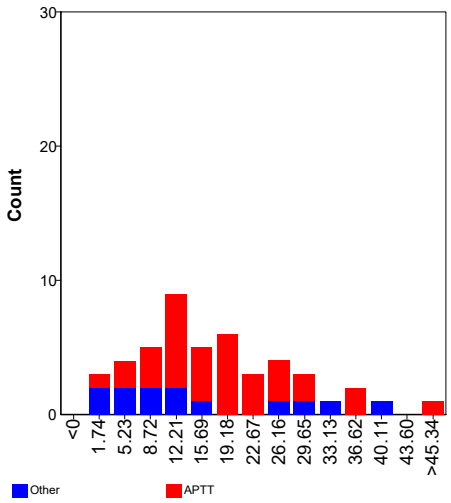
Delta Seconds

	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	34	17.9	49.7	1.2 - 70.3						
Stago Staclot LA	29	18.7	43.4	1.2 - 70.3						
dAPTT	5	16.7		11.6 - 40.5						
Stago Staclot LA	5	16.7		11.6 - 40.5						
PNP	7	0.0		-2.0 - 8.5						
Precision Biologic Platelet Lysate	5	-1.0		-2.0 - 3.6						

Ratio



Delta Seconds



Comments
Several participants selected the wrong unit, e.g. ratio while the result was likely to be in seconds or vice versa.
Several participants reported their result for the ECAT plasma in seconds while the result for their reference plasma was reported as a ratio.
In all these cases the ratio between the ECAT plasma and the laboratories own reference plasma could not be correctly calculated. Therefore all these results were excluded from the statistical analysis.

The majority of the performed confirmation tests (approx. 69%) were classified as negative. A large proportion of the participants using dRVVT reagent (91%) classified the confirm test as negative. Only 4% (n=16) of the dRVVT based assays were classified as positive, while 33% (n=59) of the APTT based assay were classified as positive. A high proportion of positive confirming tests (81%, n=42) was observed for the APTT based test; Stago Staclot LA method in contrast to other assays. In addition, 96% (n=91) of the SCT tests showed a positive result for the confirming test.

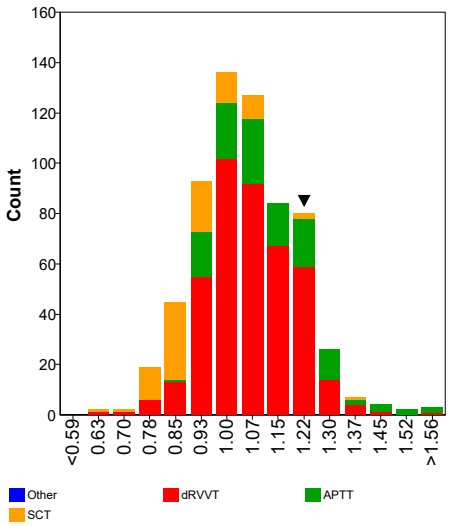
Lupus Anticoagulant

Ratio Screening/Confirmation

Sample No	20.151
Sample Details	Plasma normal for Lupus Anticoagulant with an increased CRP level (10-15 mg/dL).
Prior Use	Prior Use: None
Unit	Units: Ratio
Expiry Date	30-April-2022
Homogeneity	0.0 %
Homogeneity Parameter	LA ratio
Number of Participants	621
Number of Responders	465
Response Rate	74.88%
Comments	

Ratio Screening/Confirmation	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	124	1.12	13.4	0.87 - 1.60						
dAPTT	7	1.21		0.95 - 1.70						
dRVVT	416	1.07	11.2	0.60 - 1.89					1.24	1.41
SCT	90	0.90	11.3	0.98 - 1.37						

Assays



Lupus Anticoagulant

Final Conclusion

Final Conclusion	Negative	Borderline	Positive	No Conclusion	Your Result
Total	360	32	64	9	Negative

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 without Lupus Anticoagulant (LA Ratio = approx. 1), but with an increased CRP level (10-15 mg/dL). It is known that CRP could result in a falsely positive LA test, depending on the reagent used.

In total 456 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 79% classified the sample as Negative. Fourteen percent classified the sample as positive. Thus, the majority of the participants correctly classified this sample as negative.

Some participants indicated that the presence of an increased CRP level, which could result in a false positive result. Therefore, they indicated to repeat in real clinical practice this lupus anticoagulant test in a new sample after 12 weeks, when the infection is resolved.

In survey 2014-3 a similar plasma is used. In this previous survey 73% classified the sample as negative and 14% as positive. It can be concluded that no improvement is observed in the awareness of the interference of CRP. Still the same percentage of participants gave a positive final conclusion,

Lupus Anticoagulant

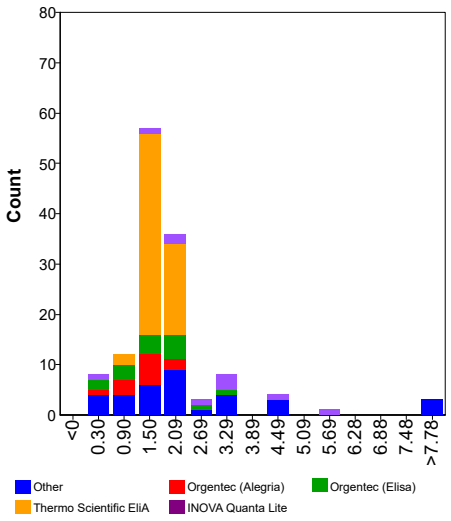
AntiCardiolipin Antibodies IgG

Sample No	20.151
Sample Details	Plasma normal for Lupus Anticoagulant with an increased CRP level (10-15 mg/dL).
Prior Use	Prior Use: None
Unit	GPL, U/mL, µg/mL, CU/mL
Expiry Date	30-April-2022
Homogeneity	0.0 %
Homogeneity Parameter	LA ratio
Number of Participants	621
Number of Responders	230
Response Rate	37 %
Comments	

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	230	0	0	0	0	0

IgG	n	assigned value	CV (%)	range	Your result	z-score
U/mL, µg/mL, GPL/MPL	132	1.7	35.0	0.0 - 19.0		
Aeskulisa Diagnotic GmbH	8	1.7		0.7 - 3.0		
Euroimmun	6	2.0		0.0 - 3.0		
INOVA Quanta Lite	10	2.9	57.4	0.0 - 5.4		
Orgentec (Alegria)	12	1.3	35.4	0.5 - 2.0		
Orgentec (Elisa)	16	1.5	60.5	0.2 - 3.0		
Thermo Scientific EliA	60	1.6	16.9	0.7 - 2.3		
CU/mL	54	3.3	21.1	1.8 - 19.8		
I.L. Acustar / INOVA Quanta Flash	54	3.3	21.1	1.8 - 19.8		

GPL, U/mL, µg/mL



Comments
None.

Lupus Anticoagulant

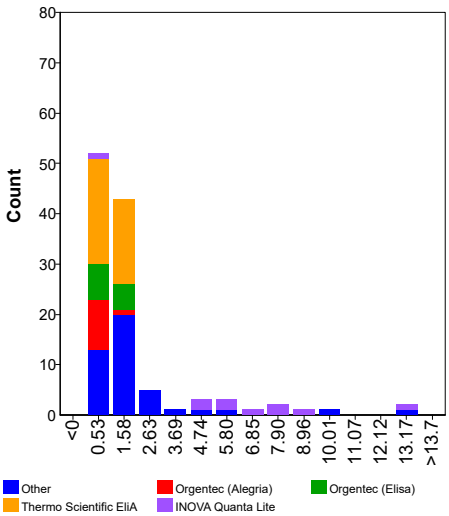
AntiCardiolipin Antibodies IgM

Sample No	20.151
Sample Details	Plasma normal for Lupus Anticoagulant with an increased CRP level (10-15 mg/dL).
Prior Use	Prior Use: None
Unit	MPL, U/mL, µg/mL, CU/mL
Expiry Date	30-April-2022
Homogeneity	0.0 %
Homogeneity Parameter	LA ratio
Number of Participants	621
Number of Responders	208
Response Rate	33 %
Comments	

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	209	0	0	0	0	1

IgM	n	assigned value	CV (%)	range	Your result	z-score
U/mL, µg/mL, GPL/MPL	114	1.3	68.7	0.0 - 13.5		
Aeskulisa Diagnotic GmbH	8	1.0		0.0 - 2.9		
Biorad Bioplex	8	1.8		1.5 - 2.0		
Bio-rad EIA	5	1.8		1.5 - 10.0		
INOVA Quanta Lite	10	6.7	35.0	0.0 - 13.2		
Orgentec (Alegria)	11	0.5	54.5	0.2 - 1.5		
Orgentec (Elisa)	12	1.0	48.1	0.4 - 1.9		
Reaads	5	2.2		2.0 - 6.3		
Thermo Scientific EliA	38	1.0	31.9	0.0 - 1.6		
CU/mL	57	1.6	19.1	1.0 - 2.6		
I.L. Acustar / INOVA Quanta Flash	57	1.6	19.1	1.0 - 2.6		

MPL, U/mL, µg/mL



Comments
None.

Lupus Anticoagulant

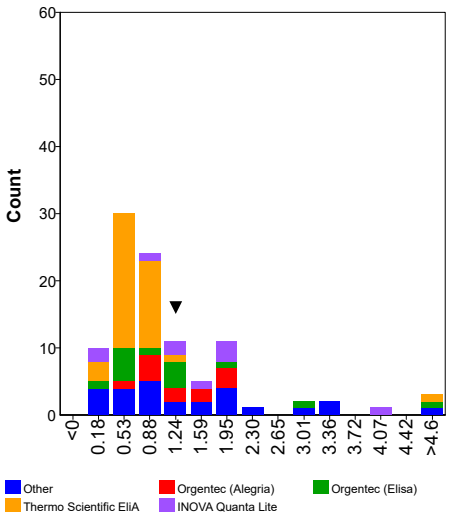
ß2-Glycoprotein I Antibodies IgG

Sample No	20.151
Sample Details	Plasma normal for Lupus Anticoagulant with an increased CRP level (10-15 mg/dL).
Prior Use	Prior Use: None
Unit	U, U/mL, µg/mL, CU/mL
Expiry Date	30-April-2022
Homogeneity	0.0 %
Homogeneity Parameter	LA ratio
Number of Participants	621
Number of Responders	207
Response Rate	33 %
Comments	

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	207	1	0	0	0	0

IgG	n	assigned value	CV (%)	range	Your result	z-score
U, U/mL, µg/mL	100	1.0	68.4	0.0 - 10.9	1.3	0.32
Aeskulisa Diagnotic GmbH	6	0.8		0.0 - 1.5		
INOVA Quanta Lite	10	1.4	74.1	0.0 - 4.1		
Orgentec (Alegria)	12	1.3	43.5	0.7 - 2.1		
Orgentec (Elisa)	14	1.1	70.3	0.1 - 4.6	1.3	0.18
Thermo Scientific EliA	38	0.7	32.9	0.0 - 10.9		
CU/mL	26	6.4	0.0	0.6 - 9.4		
I.L. Acustar / INOVA Quanta Flash	26	6.4	0.0	0.6 - 9.4		

U, U/mL, µg/mL



Comments
None.

Lupus Anticoagulant

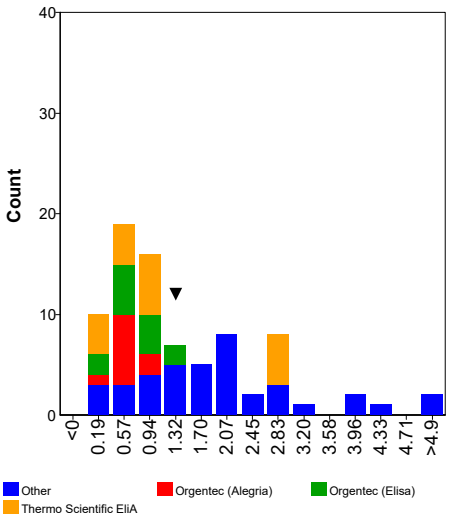
ß2-Glycoprotein I Antibodies IgM

Sample No	20.151
Sample Details	Plasma normal for Lupus Anticoagulant with an increased CRP level (10-15 mg/dL).
Prior Use	Prior Use: None
Unit	U, U/mL, µg/mL, CU/mL
Expiry Date	30-April-2022
Homogeneity	0.0 %
Homogeneity Parameter	LA ratio
Number of Participants	621
Number of Responders	180
Response Rate	29 %
Comments	

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	180	1	0	0	0	0

IgM	n	assigned value	CV (%)		Your result	z-score
U, U/mL, µg/mL	81	1.3	82.2	0.0 - 8.9	1.2	-0.11
Aeskulisa Diagnotic GmbH	6	0.9		0.1 - 1.2		
Biorad Bioplex	6	1.9		1.5 - 2.0		
Euroimmun	5	3.2		2.2 - 4.4		
INOVA Quanta Lite	8	1.9		0.0 - 2.5		
Orgentec (Alegria)	10	0.5	43.7	0.2 - 0.9		
Orgentec (Elisa)	13	0.8	48.0	0.2 - 1.3	1.2	1.18
Thermo Scientific EliA	19	1.2	102.8	0.0 - 2.9		
CU/mL	24	1.1	0.0	0.5 - 2.1		
I.L. Acustar / INOVA Quanta Flash	24	1.1	0.0	0.5 - 2.1		

U, U/mL, µg/mL



Comments
None.