

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2020-L4
Lupus Anticoagulant
Labcode 99906936

Date of Issue : 18-January-2021
Survey : 2020-L4
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 **March 2nd, 2021**.
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 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 .

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Appendices are an integral part of the total report.

Lupus Anticoagulant

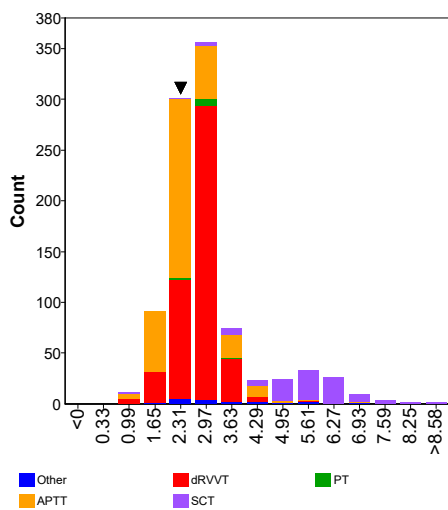
Screening

Sample No 20.189
Sample Details Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 01-July-2022
Homogeneity 2.9 % **Homogeneity Parameter** LA ratio
Number of Participants 621
Number of Responders 551 **Response Rate** 89 %
Comments

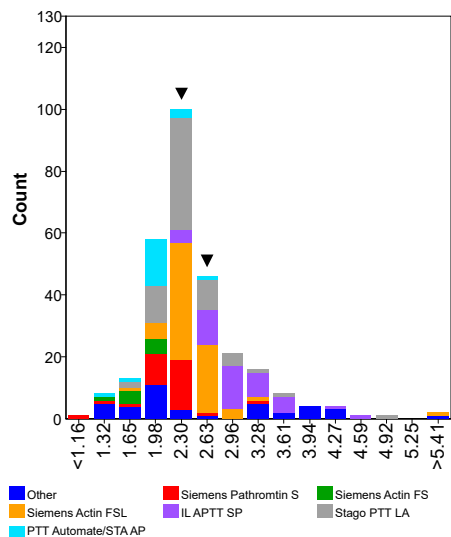
Assay	Normal	Borderline	Prolonged	No Classification	Your result		
					Screening 1	Screening 2	Screening 3
APTT	2	2	377	2	Prolonged	Prolonged	
dAPTT	0	0	15	0			
dPT	0	0	9	0			
dRVVT	2	9	537	9			Prolonged
KCT	0	0	3	0			
Other	1	0	3	1			
PNP	0	0	0	0			
PT	0	0	10	0			
SCT	9	0	109	9			

Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	330	2.38	21.6	1.00 - 7.06	2.20	-0.35	2.60	0.41		
IL APTT SP	44	2.99	14.4	2.19 - 4.71						
IL HemosIL SynthAsil	32	2.05	9.8	1.52 - 2.94						
IL MixCon	15	3.47	18.5	1.27 - 4.41						
Siemens Actin FS	10	1.81	12.0	1.17 - 2.13						
Siemens Actin FSL	71	2.40	10.1	1.75 - 5.73			2.60	0.80		
Siemens Pathromtin SL	31	2.19	9.6	1.00 - 3.22	2.20	0.07				
Stago PTT Automate/STA APTT	21	1.98	7.7	1.46 - 2.68						
Stago PTT LA	67	2.31	12.2	1.64 - 4.83						
Stagoe Staclot LA	7	3.38		1.78 - 4.14						
Tcoag TriniClot APTT-HS	5	2.03		1.85 - 2.32						
Tcoag TriniClot Automated APTT	7	1.89		1.83 - 2.20						
dAPTT	9	2.90		2.24 - 3.39						
Stago PTT LA	7	2.72		2.24 - 3.31						
dPT	8	4.77		2.06 - 6.80						
dRVVT	494	2.82	14.0	1.17 - 5.91					2.51	-0.77
Hyphen Biomed Hemoclot LA-S	7	1.37		1.25 - 1.66						
I.L. HemosIL dRVVT screen	166	3.01	12.0	1.81 - 5.91						
I.L. LAC screen	14	3.04	12.7	2.57 - 3.65						
Precision Biologic LA check	10	1.38	8.6	1.17 - 1.52						
Siemens LA1 screen	184	2.85	10.5	1.48 - 4.09					2.51	-1.14
Stago DRVVT screen	83	2.56	8.9	1.71 - 3.67						
Technoclone LA Screen	8	2.87		2.38 - 2.93						
PT	10	3.01	12.8	2.49 - 3.54						
IL HemosIL Recombiplastin (2nd gen.)	5	3.09		2.99 - 3.24						
SCT	107	5.61	17.6	1.05 - 9.04						
IL SCT screen	105	5.60	17.4	1.05 - 9.04						

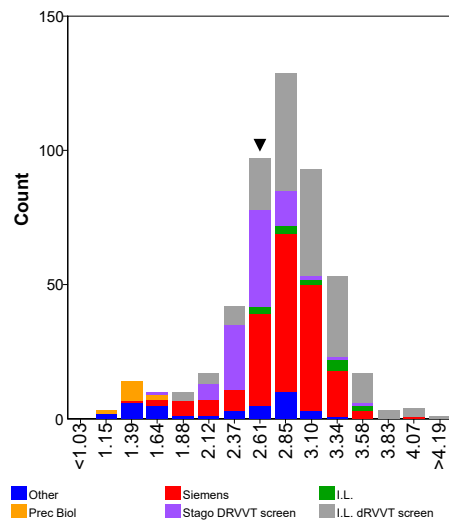
Assays



APTT



DRVVT



Comments

Several participants selected the wrong unit, e.g. ratio while the result was likely to be in seconds or vice versa. 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 or vice versa. One participant 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 screening tests (99%) were classified as (borderline) prolonged.

Lupus Anticoagulant

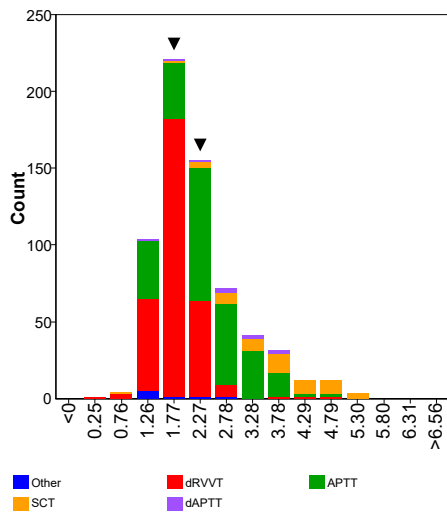
Mixing

Sample No 20.189
Sample Details Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 01-July-2022
Homogeneity 2.9 % **Homogeneity Parameter** LA ratio
Number of Participants 621
Number of Responders 411 **Response Rate** 66 %
Comments

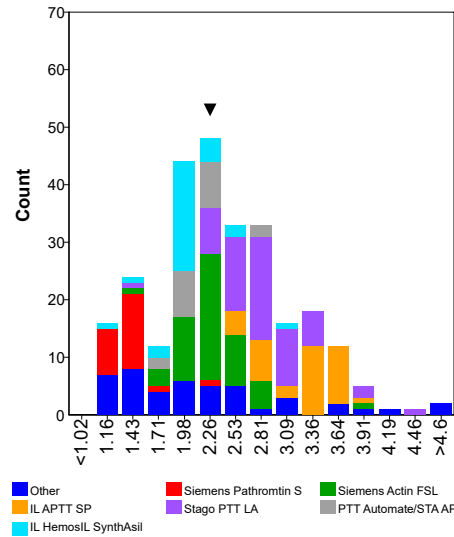
Assay	Normal	Borderline	Prolonged	No Classification	Your result		
					Mixing 1	Mixing 2	Mixing 3
APTT	11	4	280	3		Prolonged	
dAPTT	1	0	12	0			
dPT	1	0	3	0			
dRVVT	20	3	318	4			Prolonged
KCT	0	0	1	0			
Other	2	0	1	2			
PT	2	0	2	0			
SCT	1	0	57	1			

Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	265	2.39	31.7	1.04 - 4.74			2.31	-0.10		
IL APTT SP	36	3.27	13.5	2.49 - 3.91						
IL HemosIL SynthAsil	30	2.01	9.9	1.04 - 3.04						
IL MixCon	9	2.59		1.30 - 4.74						
Siemens Actin FS	7	1.17		1.13 - 1.72						
Siemens Actin FSL	52	2.29	12.4	1.55 - 3.83			2.31	0.05		
Siemens Pathromtin SL	23	1.34	8.0	1.09 - 2.34						
Stago PTT Automate/STA APTT	20	2.13	9.4	1.81 - 2.68						
Stago PTT LA	59	2.80	14.7	1.33 - 4.38						
Tcoag TriniClot Automated APTT	7	1.87		1.73 - 2.18						
dAPTT	10	2.91	32.6	1.15 - 4.04						
Stago PTT LA	7	3.28		1.98 - 4.04						
dRVVT	319	1.78	18.6	0.04 - 4.86					1.77	-0.03
I.L. HemosIL dRVVT confirm	7	1.75		1.09 - 2.74						
I.L. HemosIL dRVVT screen	61	2.09	12.2	1.45 - 4.86						
I.L. LAC screen	5	2.22		2.10 - 2.62						
Precision Biologic LA check	5	1.04		1.00 - 1.07						
Siemens LA1 screen	145	1.77	12.4	1.07 - 3.63					1.77	0.02
Siemens LA2 confirmation	14	1.16	7.9	1.07 - 1.80						
Stago DRVVT screen	56	1.67	13.2	0.04 - 2.84						
Technoclone LA Screen	5	1.58		1.51 - 1.68						
SCT	54	3.79	24.4	0.74 - 5.41						
IL SCT screen	51	3.76	22.8	1.69 - 5.31						

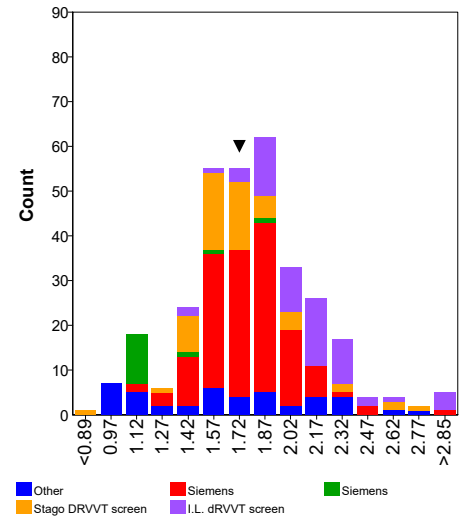
Assays



APTT



DRVVT



Comments

Several participants selected the wrong unit, e.g. ratio while the result was likely to be in seconds or vice versa. One participant reported the result for the ECAT plasma in seconds while the result for the reference plasma was reported as a ratio. A few other 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 (95%) were classified as (borderline) prolonged.

Lupus Anticoagulant

Confirmation

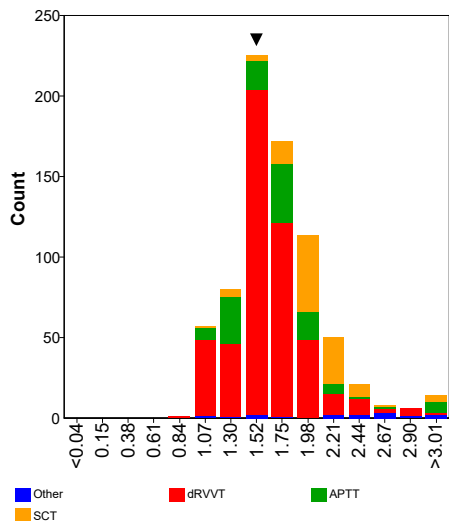
Sample No 20.189
Sample Details Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 01-July-2022
Homogeneity 2.9 % **Homogeneity Parameter** LA ratio
Number of Participants 621
Number of Responders 546 **Response Rate** 88 %
Comments

Assay	Positive	Borderline	Negative	No Classification	Your result		
					Confirm 1	Confirm 2	Confirm 3
APTT	175	2	6	6			
dAPTT	12	0	0	0			
dPT	6	0	1	1			
dRVVT	526	5	26	15			LA Positive
Other	4	0	0	0			
PNP	7	1	3	1			
PT	2	0	1	1			
SCT	110	0	7	7			

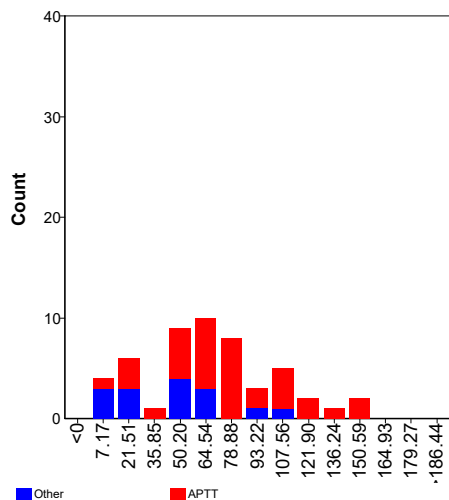
Ratio	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	124	1.66	21.3	0.98 - 4.50						
IL Hemosil SynthAFax	20	1.38	6.1	1.29 - 1.88						
IL MixCon	18	1.53	29.3	1.04 - 4.05						
Siemens Actin FS	57	1.67	16.3	0.98 - 2.04						
Stago Staclot LA	8	1.74		1.59 - 2.22						
Technoclone Lupus Anticoagulant Test	5	2.17		2.04 - 3.46						
dAPTT	5	2.37		1.61 - 3.09						
dPT	6	2.60		1.32 - 8.60						
dRVVT	497	1.60	16.7	0.92 - 5.63				1.46		-0.51
Helena Biosciences DRVVT confirm	6	2.15		1.84 - 2.80						
Hyphen Biomed Hemoclot LA-C	7	1.78		1.54 - 2.04						
IL HemosIL dRVVT confirm	155	1.79	10.2	1.07 - 2.90						
IL HemosIL LAC confirm	18	1.79	11.1	1.13 - 5.63						
Life Diagnostics LA confirm	5	1.45		1.08 - 1.87						
Precision Biologic LA sure	7	1.57		1.02 - 1.84						
Siemens LA2 confirmation	185	1.47	10.5	0.92 - 2.80				1.46		-0.07
Stago DRVVT Confirm	87	1.47	7.7	1.04 - 2.21						
Technoclone LA Confirm	9	1.48		1.09 - 1.62						
SCT	111	2.02	11.5	1.11 - 6.17						
IL HemosIL SCT confirm	109	2.01	11.1	1.11 - 5.05						

Delta Seconds	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	36	76.1	45.5	13.1 - 150.4						
Stago Staclot LA	31	82.5	35.1	31.9 - 150.4						
dAPTT	5	70.6		22.7 - 109.4						
PNP	6	10.6		-8.0 - 19.7						

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 vast majority of the performed confirmation tests (approx. 95%) were classified as borderline or positive.

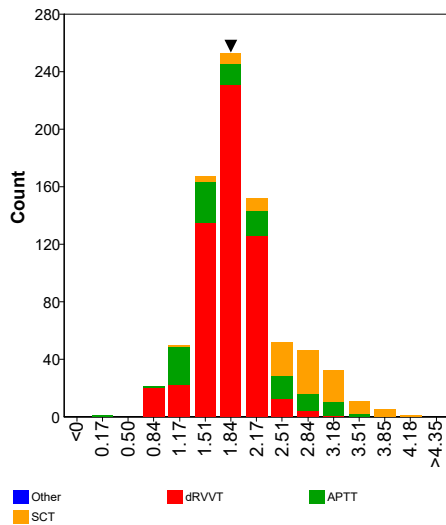
Lupus Anticoagulant

Ratio Screening/Confirmation

Sample No 20.189
Sample Details Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Units: Ratio
Expiry Date 01-July-2022
Homogeneity 2.9 % **Homogeneity Parameter** LA ratio
Number of Participants 621
Number of Responders 491 **Response Rate** 79.07%
Comments

Ratio Screening/Confirmation	n	assigned value	CV (%)	range	panel 1	z-score	panel 2	z-score	panel 3	z-score
APTT	128	1.93	37.3	0.28 - 3.65						
dAPTT	6	1.86		1.31 - 2.76						
dRVVT	552	1.81	16.4	0.67 - 3.10					1.90	0.32
SCT	111	2.78	18.8	1.22 - 4.31						

Assays



Lupus Anticoagulant**Final Conclusion**

Final Conclusion	Negative	Borderline	Positive	No Conclusion	Your Result
Total	6	3	466	16	Positive

Comments

The sample used in this survey was plasma from a patient diagnosed with Lupus Anticoagulant (LA Ratio = approx. 1.60). No information about the use of medication by this patient is available. In total 475 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 98% classified the sample as positive. Less than one 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.

Multiple participants indicated that the presence of another inhibitor (INR>3.0) and therefore interpretation of the sample was with reservation due to the possible VKA therapy. One participant measured anti-Xa level and concluded that no DOAC was present in the sample. Furthermore some participants reported that an increased CRP level should be ruled out.

Lupus Anticoagulant

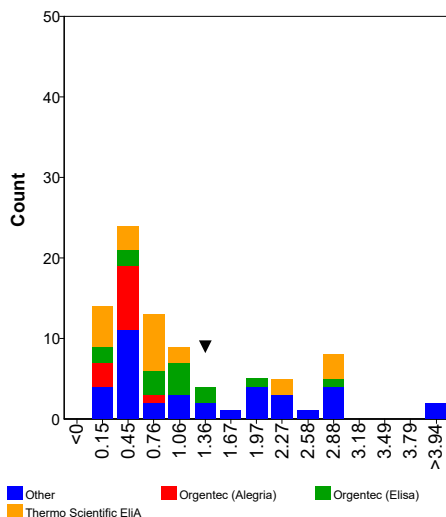
β2-Glycoprotein I Antibodies IgM

Sample No 20.189
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 01-July-2022
Homogeneity 2.9 % **Homogeneity Parameter** LA ratio
Number of Participants 621
Number of Responders 182 **Response Rate** 29 %
Comments

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

IgM	n	assigned value	CV (%)	Your result	z-score	
U, U/mL, µg/mL	86	1.0	87.2	0.0 - 6.0	1.3	0.32
Aeskulisa Diagnostic GmbH	7	0.9		0.0 - 1.0		
Biorad Bioplex	6	0.6		0.5 - 0.6		
Euroimmun	7	2.8		1.3 - 4.0		
Orgentec (Alegria)	12	0.4	25.8	0.3 - 0.8		
Orgentec (Elisa)	15	0.9	65.4	0.0 - 3.0	1.3	0.59
Thermo Scientific EliA	22	1.0	101.5	0.0 - 2.9		
CU/mL	24	0.9	39.4	0.1 - 20.0		
I.L. Acustar / INOVA Quanta Flash	24	0.9	39.4	0.1 - 20.0		

U, U/mL, µg/mL



Comments
None.