ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2022-L3
Lupus Anticoagulant
Labcode 1492

External quality Control for Assays and Tests
With a focus on Thrombosis and Haemostasis

Version: 1.0.0

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Date of Issue   :   10-November-2022

Survey   :   2022-L3

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 **December 23rd, 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 selecetd as 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 were 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.

ECAT Foundation

**External quality Control for Assays and Tests
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Lupus Anticoagulant

Screening

Sample No	22.164
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	Ratio
Expiry Date	30-April-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	576

Homogeneity Parameter LA Ratio

Response Rate 92 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	296	117	0	6
dAPTT	12	4	0	1
dPT	2	7	0	0
dRVVT	517	96	0	19
KCT	7	0	0	0
Other	2	1	0	0
PNP	0	0	0	1
PT	0	8	0	0
SCT	148	0	0	9

Assay	Your classification								
	Screening 1			Screening 2			Screening 3		
	TS1	TS2	TS3						
APTT	Elevated	Not elevated							
dAPTT									
dPT									
dRVVT			Elevated						
KCT									
Other									
PNP									
PT									
SCT									

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Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	368	1.37	16.5	0.61 - 2.11	1	1.22	-0.64	1.15	-0.98		
Hyphen-Biomed Cephen LS	8	1.55		0.61 - 1.63							
IL APTT SP	52	1.49	10.9	1.14 - 2.11							
IL HemosIL SynthAsil	39	1.44	8.8	1.19 - 1.68							
IL MixCon	14	1.36	5.8	1.24 - 1.47							
Siemens Actin FS	5	1.09		1.06 - 1.12							
Siemens Actin FSL	83	1.14	6.6	0.96 - 1.48	1			1.15	0.07		
Siemens Pathromtin SL	32	1.21	6.4	1.00 - 1.38	1	1.22	0.14				
Stago PTT Automate/STA APTT	17	1.34	7.8	1.20 - 1.50							
Stago PTT LA	73	1.56	8.5	1.22 - 1.90							
Stago Staclot LA	15	1.50	6.4	1.20 - 1.69							
Tcoag TriniClot APTT-HS	5	1.52		1.36 - 1.53							
Tcoag TriniClot Automated APTT	7	1.23		1.18 - 1.31							
dAPTT	13	1.50	16.5	1.05 - 2.13							
Stago PTT LA	7	1.63		1.37 - 1.65							
dPT	7	1.19		1.00 - 1.61							
dRVVT	557	1.33	9.5	0.93 - 3.87	1					1.14	-1.53
Hyphen Biomed Hemoclot LA-S	10	1.29	9.7	1.13 - 1.41							
I.L. HemosIL dRVVT screen	209	1.40	7.7	0.93 - 1.88							
Precision Biologic LA check	7	1.47		1.34 - 1.55							
Roche Lupus S	7	1.33		1.24 - 1.43							
Siemens LA1 screen	221	1.28	6.8	1.00 - 2.00	1					1.14	-1.66
Stago DRVVT screen	84	1.30	11.6	0.97 - 3.87							
Technoclone LA Screen	6	1.20		1.10 - 1.22							
PT	7	0.99		0.93 - 1.05							
SCT	149	2.33	12.6	0.37 - 4.67							
Haematex SACT Reagent	7	2.73		2.59 - 4.67							
IL SCT screen	141	2.30	12.0	0.37 - 3.23							

Assays

APTT

DRVVT

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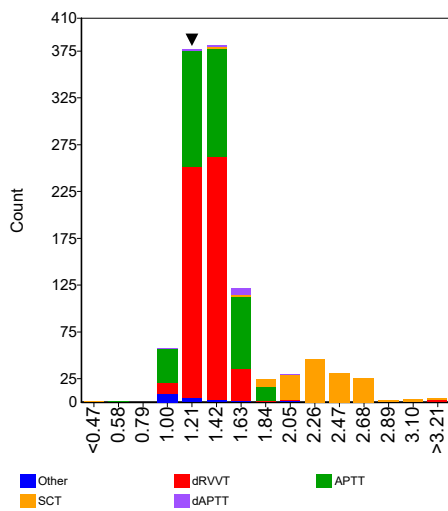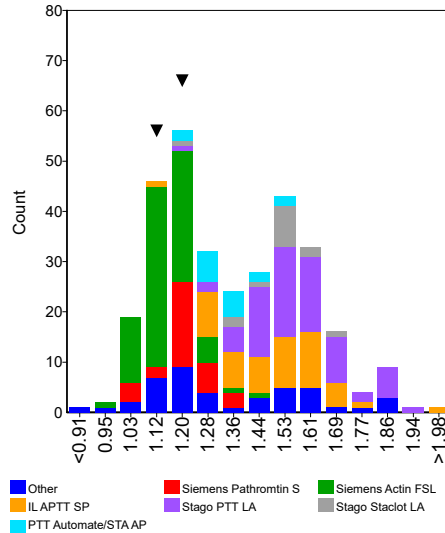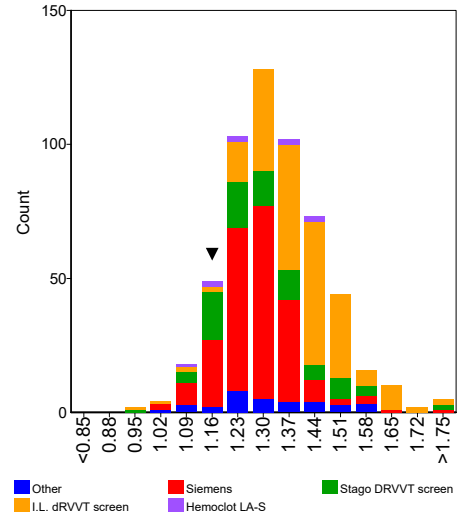
Lupus Anticoagulant

Screening

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	112	1.29	18.5	0.89 - 2.24	1	1.35	0.23	0.89	-1.68		
IL APTT SP	15	1.38	10.7	1.18 - 2.24							
IL HemosIL SynthAsil	7	1.47		1.31 - 1.87							
Siemens Actin FSL	35	1.07	7.1	0.89 - 1.38	1			0.89	-2.38		
Siemens Pathromtin SL	15	1.31	6.7	1.16 - 1.55	1	1.35	0.49				
Stago PTT Automate/STA APTT	5	1.33		1.30 - 1.37							
Stago PTT LA	16	1.56	10.0	1.33 - 1.79							
dRVVT	129	1.30	9.3	0.76 - 1.60	1					1.32	0.15
I.L. HemosIL dRVVT screen	23	1.36	8.4	1.12 - 1.55							
Roche Lupus S	13	1.40		1.14 - 1.46							
Siemens LA1 screen	74	1.27	7.3	0.76 - 1.60	1					1.32	0.48
Stago DRVVT screen	11	1.25	14.3	1.05 - 1.60							
SCT	15	2.39	8.9	1.86 - 2.76							
IL SCT screen	15	2.39	8.9	1.86 - 2.76							

Assays

APTT

DRVVT
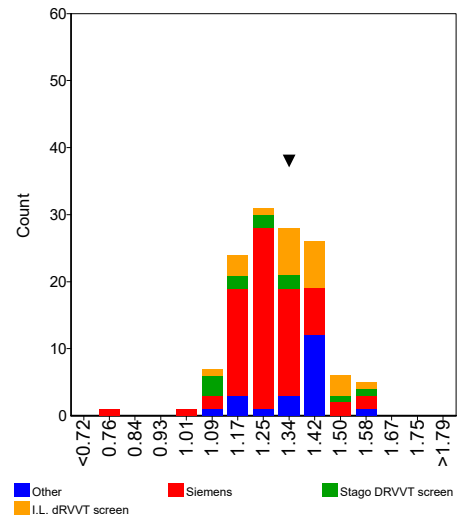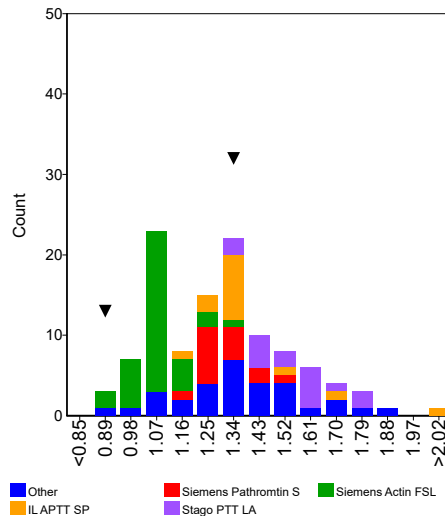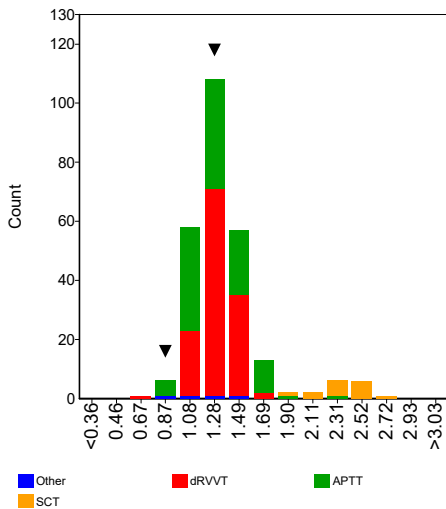
Comments

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 screening tests (> 80%) were classified as elevated. Interestingly within the assay group SCT 100% of the performed screening tests were classified as elevated for this weak positive Lupus Anticoagulant plasma . However, in the two assay groups APTT and dRVVT respectively 28% and 16% of the screening tests was classified as not elevated. Remarkably, 86% of the participants using the APTT reagent Siemens Actin FSL classified the sample as not elevated. This is in line with the lower ratio observed for Siemens Actin FSL compared to the other reagent groups . For the other most frequently used reagents (n≥10) less than 30% of the participants classifed the sample as non elevated.
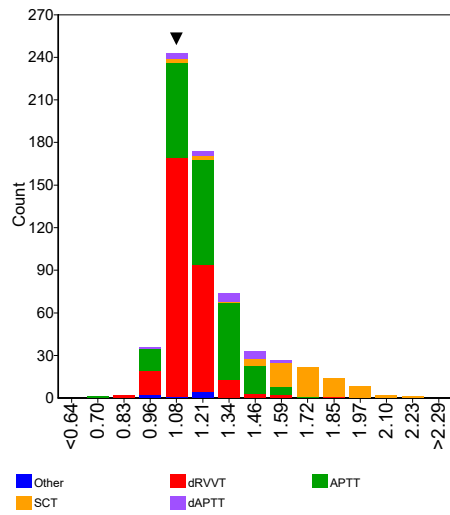
In general, comparable results were observed for the ratio ECAT plasma over Normal Plasma and ratio ECAT plasma over Mean Reference Interval (MRI).
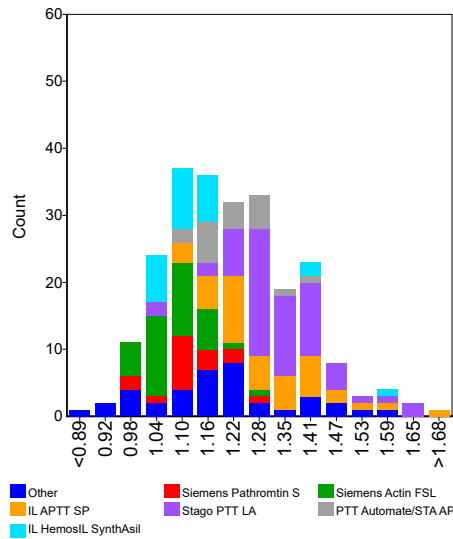
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Lupus Anticoagulant

Mixing

Sample No	22.164
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	Ratio
Expiry Date	30-April-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	391

Homogeneity Parameter   LA Ratio

Response Rate   63 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	139	118	0	11
dAPTT	17	5	0	1
dPT	1	1	0	0
dRVVT	111	190	0	13
KCT	3	1	0	0
Other	1	0	0	0
PNP	0	0	0	0
PT	0	2	0	0
SCT	73	4	0	2

Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Not elevated						
KCT									
Other									
PNP									
PT									
SCT									

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Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	239	1.22	12.2	0.76 - 1.72							
Hyphen-Biomed Cephen LS	6	1.20		0.76 - 1.57							
IL APTT SP	39	1.29	10.0	1.09 - 1.72							
IL HemosIL SynthAsil	26	1.12	5.8	1.02 - 1.59							
IL MixCon	7	1.26		0.96 - 1.44							
Siemens Actin FSL	36	1.09	6.1	0.99 - 1.26							
Siemens Pathromtin SL	17	1.12	6.4	0.98 - 1.27							
Stago PTT Automate/STA APTT	19	1.23	6.9	1.12 - 1.40							
Stago PTT LA	61	1.33	7.2	1.04 - 1.64							
Tcoag TriniClot Automated APTT	6	1.14		1.13 - 1.19							
dAPTT	21	1.31	13.6	1.01 - 1.63							
Stago PTT LA	8	1.42		1.28 - 1.63							
dRVVT	297	1.12	6.6	0.82 - -104.30	1					1.06	-0.85
I.L. HemosIL dRVVT screen	84	1.17	6.6	0.82 - 1.47							
Siemens LA1 screen	130	1.10	4.5	0.90 - 1.80	1					1.06	-0.87
Siemens LA2 confirmation	11	1.05	9.6	0.91 - 1.38							
Stago DRVVT screen	47	1.13	7.5	0.94 - -104.30							
SCT	74	1.71	11.5	1.05 - 2.23							
Haematex SACT Reagent	5	1.91		1.75 - 2.07							
IL SCT screen	65	1.70	10.9	1.12 - 2.23							

Assays

APTT

DRVVT

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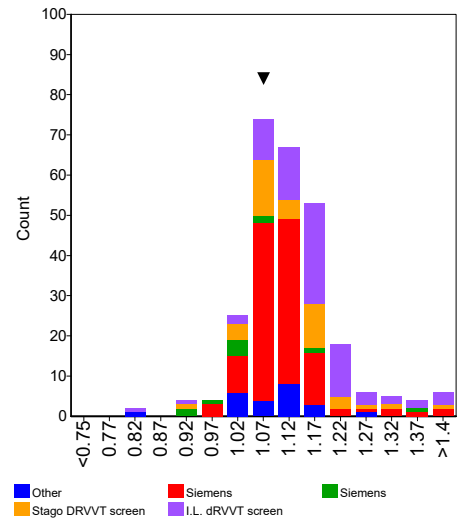
Lupus Anticoagulant

Mixing

| Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	59	1.20	12.7	0.97 - 1.82							
IL APTT SP	9	1.23		1.04 - 1.82							
Siemens Actin FSL	14	1.07	9.2	0.97 - 1.30							
Siemens Pathromtin SL	9	1.26		1.05 - 1.36							
Stago PTT Automate/STA APTT	6	1.17		1.13 - 1.20							
Stago PTT LA	10	1.38	11.1	1.17 - 1.58							
dAPTT	7	1.28		1.16 - 1.35							
dRVVT	62	1.12	8.3	0.88 - 8.00							
I.L. HemosIL dRVVT screen	7	1.15		1.04 - 1.23							
Siemens LA1 screen	42	1.11	7.5	0.95 - 8.00							
Stago DRVVT screen	7	1.10		0.88 - 1.56							
SCT	7	1.78		1.41 - 1.99							
IL SCT screen	6	1.76		1.41 - 1.99							

Assays
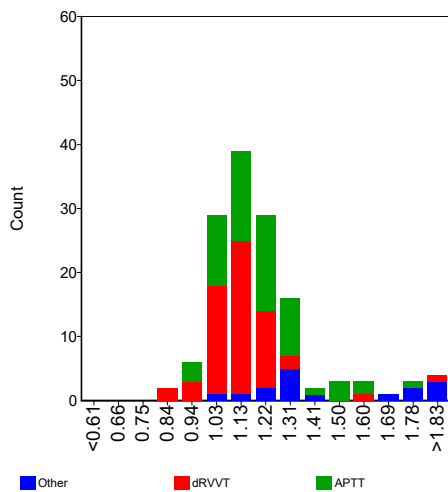
APTT
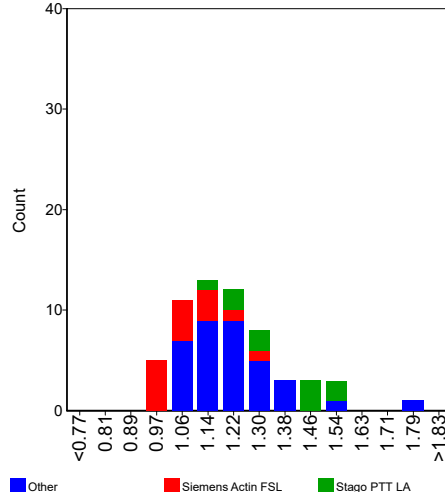
DRVVT
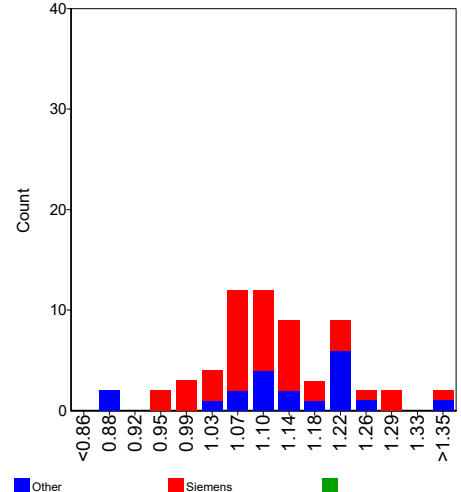
Comments

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.

Approximately, half of performed mixing tests (52%) were classified as elevated, which was expected because the sample was weak positive for Lupus Anticoagulant. Especially participants using reagents derived from the assay groups APTT and dRVVT showed a large percent of not elevated classifications, respectivily 46% and 63%. This is expected, since a weak positive patient sample was used in this survey and therefore a larger number of not eleveted classifications will be observed compared to the screening test results.

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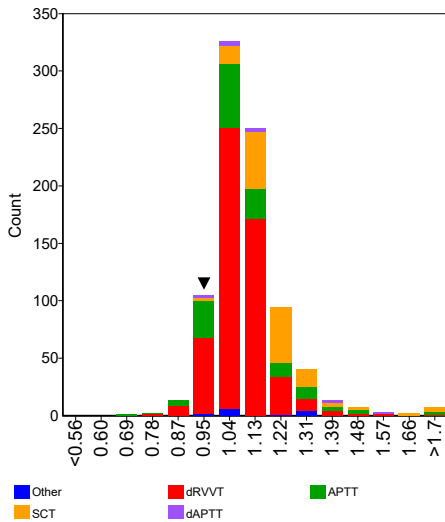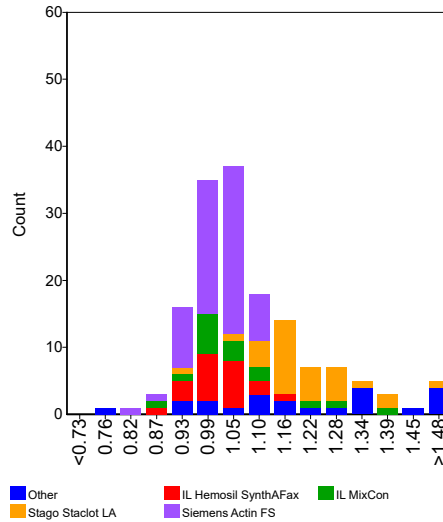
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Lupus Anticoagulant | Confirmation

Sample No	22.164
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	Ratio
Expiry Date	30-April-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	559

Homogeneity Parameter LA Ratio

Response Rate 90 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	61	119	0	11
dAPTT	9	6	0	1
dPT	1	5	0	2
dRVVT	135	430	0	50
Other	3	1	0	0
PNP	4	3	0	3
PT	0	1	0	0
SCT	67	60	0	25

Assay	Your classification								
	Confirmation 1			Confirmation 2			Confirmation 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Not elevated						
Other									
PNP									
PT									
SCT									

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Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	153	1.07	10.9	0.73 - 5.00							
IL Hemosil SynthAFax	21	1.01	5.8	0.86 - 1.15							
IL MixCon	16	1.05	10.0	0.90 - 1.40							
Siemens Actin FS	63	1.02	5.3	0.81 - 1.13							
Stago Staclot LA	31	1.20	7.7	0.95 - 5.00							
Technoclone Lupus Anticoagulant Test	5	1.48		1.31 - 1.98							
dAPTT	12	1.13	16.8	0.97 - 1.53							
Siemens Actin FS	6	1.04		0.98 - 1.10							
dPT	6	1.05		0.97 - 1.30							
dRVVT	544	1.07	6.6	0.78 - 2.37	1					0.99	-1.12
Hyphen Biomed Hemoclot LA-C	10	0.99	9.0	0.89 - 1.08							
IL HemosIL dRVVT confirm	195	1.10	6.4	0.83 - 1.53							
IL HemosIL LAC confirm	24	1.10	7.8	0.95 - 1.35							
Precision Biologic LA sure	6	0.99		0.96 - 1.06							
Roche Lupus C	7	1.10		1.02 - 1.14							
Siemens LA2 confirmation	214	1.05	5.7	0.85 - 1.47	1					0.99	-1.03
Stago DRVVT Confirm	72	1.05	5.1	0.85 - 2.37							
Technoclone LA Confirm	7	1.01		0.97 - 1.04							
PNP	6	1.24		1.05 - 1.31							
SCT	142	1.18	7.8	0.94 - 2.20							
IL HemosIL SCT confirm	141	1.18	7.7	0.94 - 2.20							

Assays

APTT

DRVVT

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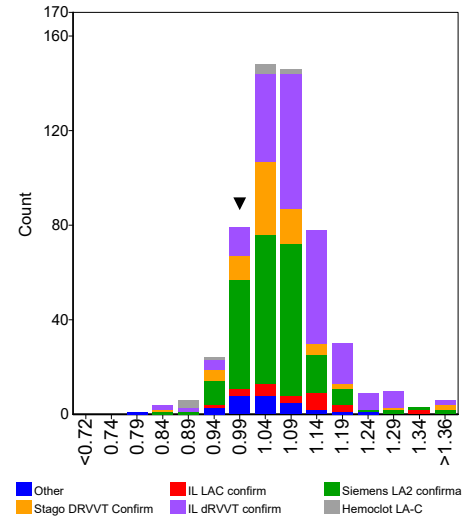
Lupus Anticoagulant   Confirmation

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	34	1.04	6.8	0.82 - 1.45							
Siemens Actin FS	23	1.01	4.1	0.82 - 1.13							
dRVVT	125	1.07	6.7	0.76 - 1.42	1					1.08	0.28
IL HemosIL dRVVT confirm	18	1.09	9.4	0.76 - 1.38							
IL HemosIL LAC confirm	7	1.13		0.83 - 1.21							
Roche Lupus C	13	1.07		0.99 - 1.15							
Siemens LA2 confirmation	68	1.06	7.1	0.82 - 1.42	1					1.08	0.31
Stago DRVVT Confirm	11	1.05	5.4	0.77 - 1.14							
SCT	15	1.18	6.3	1.04 - 1.30							
IL HemosIL SCT confirm	15	1.18	6.3	1.04 - 1.30							

Assays
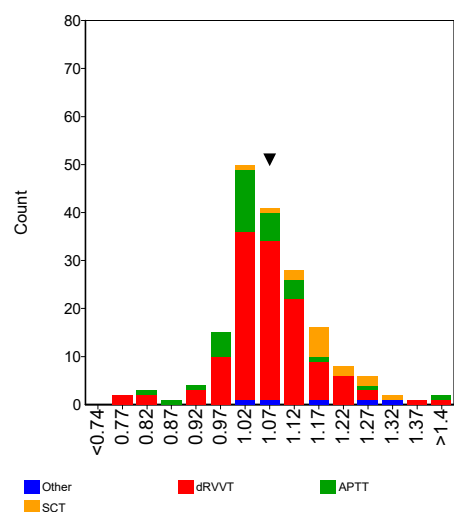
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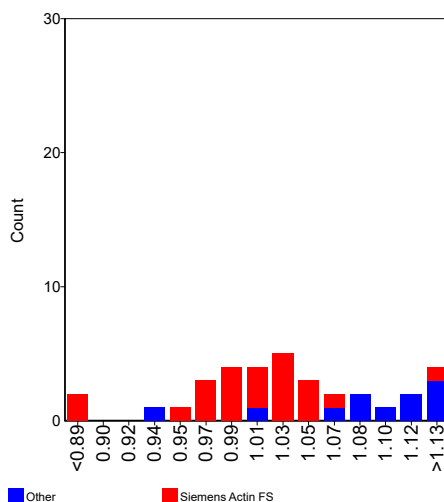
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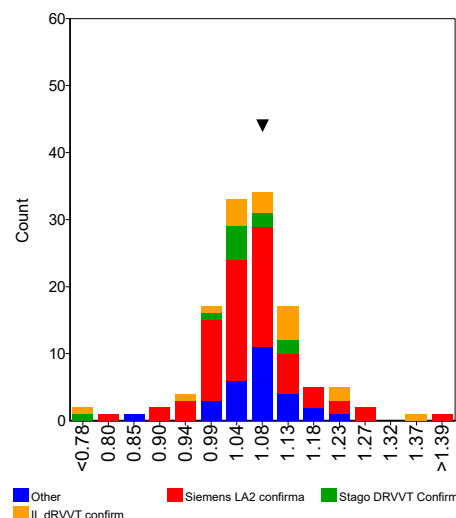
Comments

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. Several participants reported also a confirmtion result in Delta Seconds. However the difference in clotting time between the screen and confirmation test (or reagent 1 and reagent 2) should be reported in the Interpretation section. All these results were excluded from the statistical analysis.

As expected, the majority of performed confirmation tests (69%) were classified as not elevated. For a weak positive Lupus Anticoagulant plasma, it is expected that the test result (almost) fully normalised in the confirmation test.

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

The results from participant **1325** were not included in the evaluation, because the results were submitted with the wrong test; Confirm instead of Screen.

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Lupus Anticoagulant	Interpretation

Delta Seconds

|	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	80	14.47	60.5	0.30 - 98.70							
IL Hemosil SynthAFax	7	13.50		4.00 - 27.70							
Siemens Actin FS	18	21.54	115.3	0.30 - 98.70							
Stago Staclot LA	35	12.39	38.7	4.50 - 21.20							
dAPTT	7	18.00		4.20 - 34.50							
dRVVT	124	12.70	39.4	0.00 - 84.80							
IL HemosIL dRVVT confirm	35	16.52	22.5	0.00 - 23.30							
IL HemosIL LAC confirm	6	8.95		0.90 - 20.10							
Roche Lupus C	12	13.10	0.0	6.80 - 13.10							
Siemens LA2 confirmation	57	11.30	26.7	4.20 - 84.80							
Stago DRVVT Confirm	7	9.30		0.08 - 17.90							
SCT	19	59.84	20.6	33.15 - 105.70							
IL HemosIL SCT confirm	18	58.43	17.8	33.15 - 100.70							

Assays
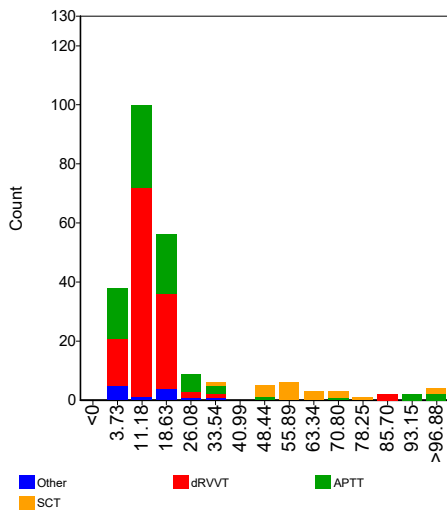
APTT
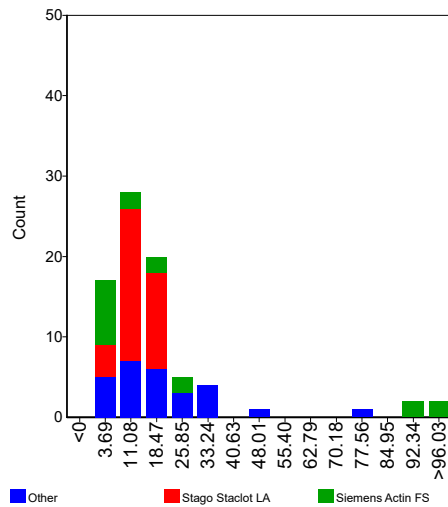
DRVVT
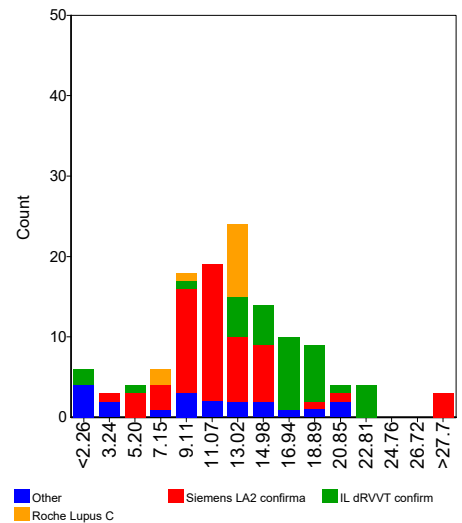
Comments

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).

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

External quality Control for Assays and Tests
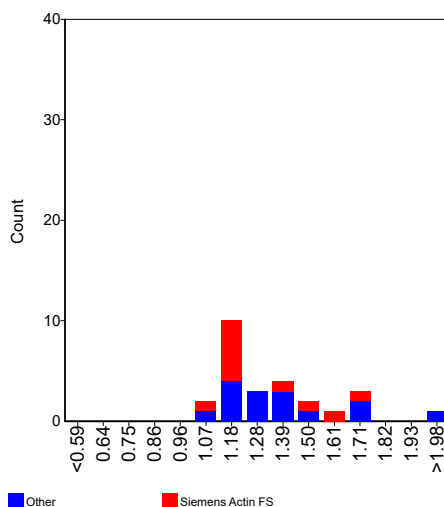*With a focus on Thrombosis and Haemostasis*

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
APTT	26	1.32	17.3	1.10 - 3.30							
Siemens Actin FS	11	1.29	18.0	1.10 - 1.70							
Stago Staclot LA	5	1.27		1.19 - 1.39							
dPT	5	1.28		1.18 - 1.43							
dRVVT	133	1.32	7.6	1.00 - 1.60	1					1.29	-0.25
IL HemosIL dRVVT confirm	17	1.36	13.9	1.07 - 1.60							
Siemens LA2 confirmation	88	1.32	6.0	1.13 - 1.59	1					1.29	-0.35
Stago DRVVT Confirm	15	1.27	12.9	1.00 - 1.52							
SCT	11	2.10	23.0	1.55 - 2.90							
IL HemosIL SCT confirm	9	1.86		1.55 - 2.90							

Assays
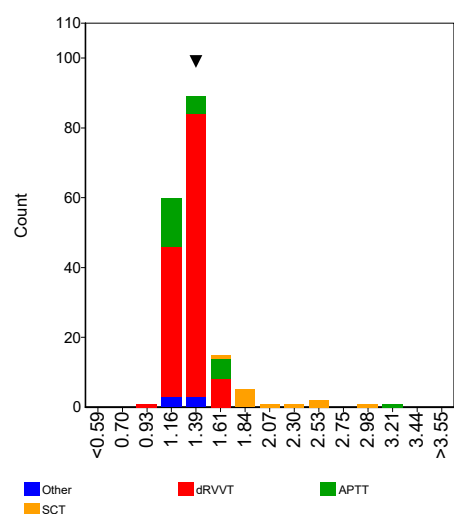
APTT

DRVVT
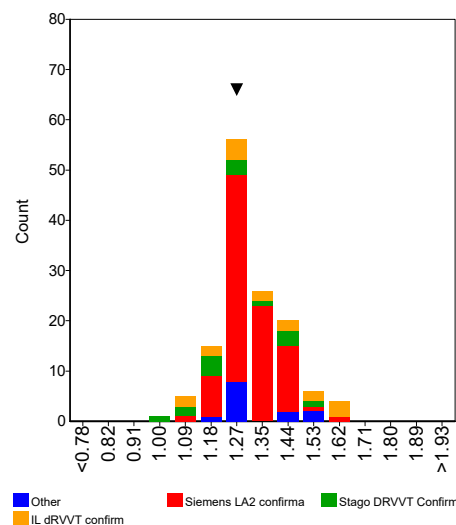
Comments

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. 1.4).

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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
APTT	85	1.27	13.7	1.02 - 1.97							
IL Hemosil SynthAFax	18	1.30	8.1	1.04 - 1.97							
IL MixCon	10	1.35	4.7	1.09 - 1.44							
Siemens Actin FS	39	1.20	13.9	1.02 - 1.94							
Stago Staclot LA	6	1.25		1.09 - 1.53							
dAPTT	5	1.39		1.07 - 1.63							
dRVVT	383	1.25	8.9	0.78 - 3.39							
Hyphen Biomed Hemoclot LA-C	8	1.33		1.11 - 1.37							
IL HemosIL dRVVT confirm	165	1.27	8.4	0.78 - 1.72							
IL HemosIL LAC confirm	16	1.27	5.1	1.04 - 1.37							
Roche Lupus C	12	1.30	0.0	1.18 - 1.30							
Siemens LA2 confirmation	121	1.21	8.3	0.98 - 1.42							
Stago DRVVT Confirm	52	1.25	11.9	1.06 - 3.39							
SCT	118	1.96	10.6	1.15 - 2.56							
IL HemosIL SCT confirm	118	1.96	10.6	1.15 - 2.56							

Assays
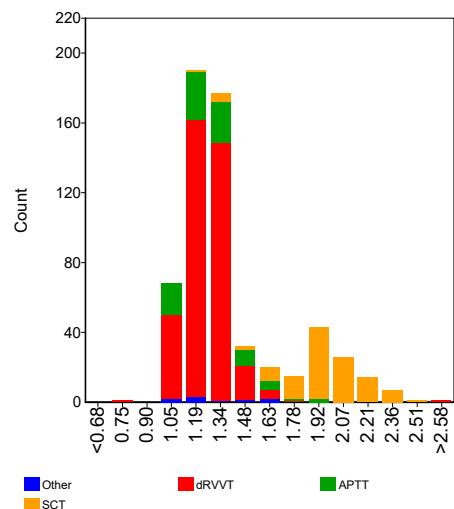
APTT
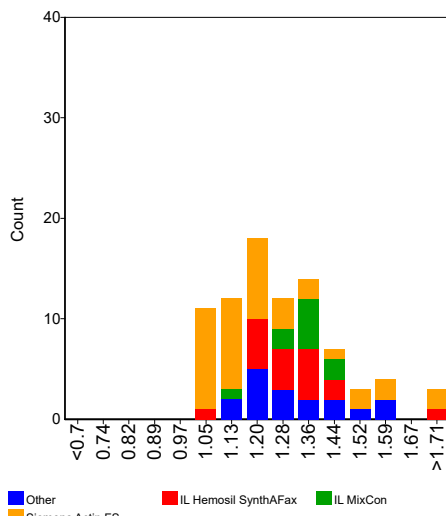
DRVVT
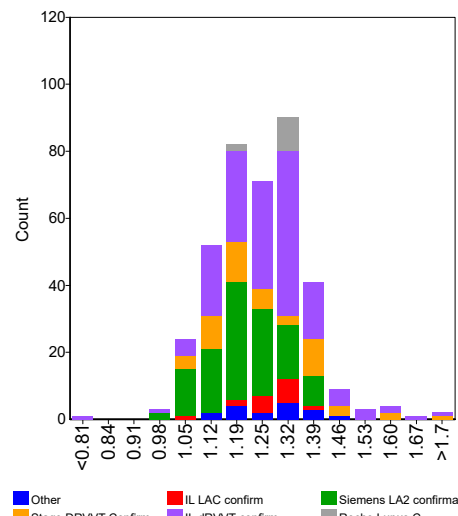
Comments

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. 1.4).

**External quality Control for Assays and Tests
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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
APTT	16	20.72	54.6	6.67 - 36.90							
Siemens Actin FS	8	15.10		6.67 - 36.90							
dRVVT	51	24.88	22.9	6.32 - 56.82							
IL HemosIL dRVVT confirm	6	30.84		24.00 - 36.95							
Siemens LA2 confirmation	35	24.60	18.3	6.32 - 56.82							
SCT	8	55.99		45.50 - 65.50							
IL HemosIL SCT confirm	7	56.37		53.10 - 65.50							

Assays
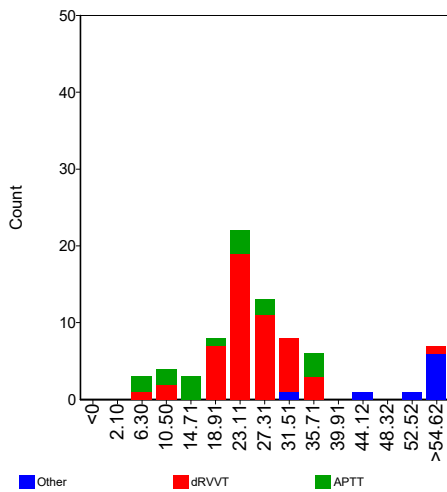
DRVVT
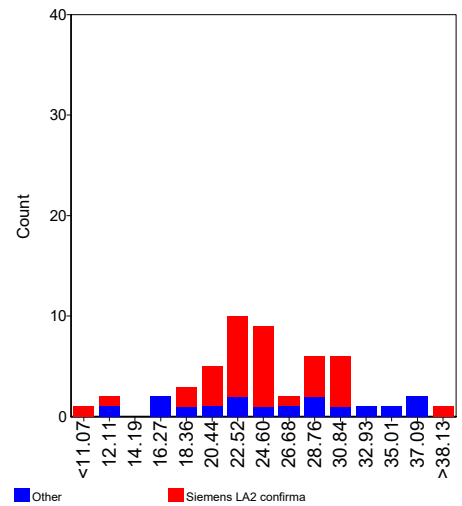
Comments

For most methods the percentage correction is lower in the sample 22.164 used in this survey compared to sample 22.108 in survey 2022-L2, which was a more positive Lupus Anticoagulant plasma.

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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
APTT	25	25.75	68.9	3.96 - 51.50							
Siemens Actin FS	14	25.77	84.6	3.96 - 51.50							
dRVVT	67	19.64	43.6	0.26 - 100.00							
IL HemosIL dRVVT confirm	23	21.33	36.2	4.81 - 100.00							
IL HemosIL LAC confirm	6	18.00		1.22 - 30.20							
Siemens LA2 confirmation	24	19.47	35.6	0.26 - 36.70							
Stago DRVVT Confirm	12	17.63	67.8	1.38 - 50.00							
SCT	22	46.37	23.7	25.00 - 61.02							
IL HemosIL SCT confirm	22	46.37	23.7	25.00 - 61.02							

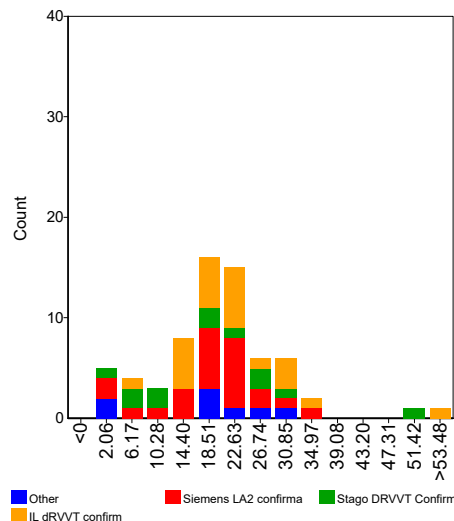## Assays
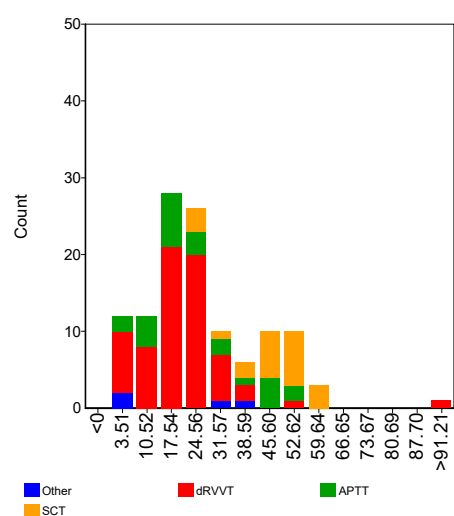
APTT
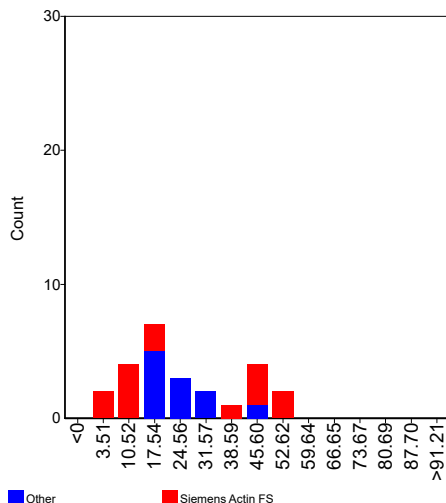
DRVVT

Comments

For most methods the percentage correction is lower in the sample 22.164 used in this survey compared to sample
22.108 in survey 2022-L2, which was a more positive Lupus Anticoagulant plasma.

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With a focus on Thrombosis and Haemostasis

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Lupus Anticoagulant | Final Conclusion

	Classification				Your Classification			
Testing Strategies	**Equivocal**	**LA detected**	**LA not detected**	**No conclusion**	**Test System**	**Panel 1**	**Panel 2**	**Panel 3**
Screen test only	2	9	27	10	1			
					2			
					3			
Screen and mixing test	12	26	35	12	1			
					2			
					3			
Screen and confirm test	33	342	121	7	1			
					2			
					3			
Screen, mixing and confirm test	19	145	81	3	1			LA detected
					2			
					3			
Screen, confirm, mixing test	14	94	59	2	1			
					2			
					3			
Mixing - confirmation	4	17	5	3	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			
358	110	46	11	LA detected		

Comments
The sample used in this survey was plasma from a patient diagnosed with Lupus Anticoagulant (LA Ratio = approx. 1.4).
No other types of inhibitors were present.

In total 514 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 70%
classified the sample as positive. Nine percent classified the sample as equivocal. Thus, the vast majority of the
participants correctly classified this sample as positive. A minority (21%) of the participants classified this sample as
negative, this does not seems to be affected by the test strategy but is probably caused by the sensitivy of the reagent
and the local interpretation of the result (e.g. local cut-off value used).

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 direct oral anticoagulants and/or an increased CRP level should be
excluded.

External quality Control for Assays and Tests
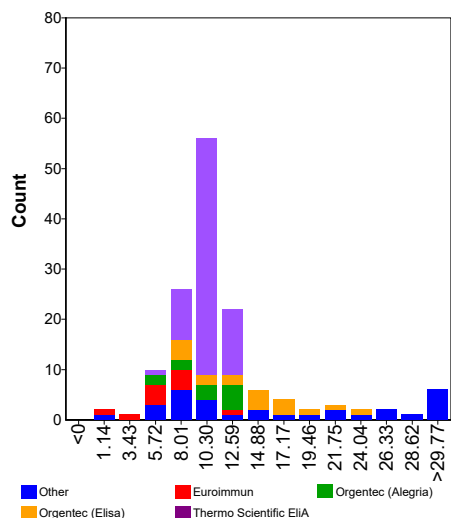*With a focus on Thrombosis and Haemostasis*

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Lupus Anticoagulant

AntiCardiolipin Antibodies IgG

Sample No	22.164
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	GPL, U/mL, µg/mL, CU/mL
Expiry Date	30-April-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	231

Homogeneity Parameter LA Ratio

Response Rate 37 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	78	22	63	44	26	2

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U/mL, µg/mL, GPL/MPL	143	10.8	28.3	0.0 - 278.0						
Aeskulisa Diagnotic GmbH	7	22.0		13.0 - 30.7						
Euroimmun	11	6.1	42.5	0.8 - 12.9						
INOVA Quanta Lite	8	9.0		0.0 - 18.0						
Orgentec (Alegria)	12	10.0	28.5	5.4 - 13.5						
Orgentec (Elisa)	18	14.0	37.3	7.3 - 24.8						
Thermo Scientific EliA	71	10.4	11.5	6.6 - 13.0						
CU/mL	77	72.7	10.2	6.9 - 103.8						
I.L. Acustar / INOVA Quanta Flash	76	72.6	10.2	6.9 - 103.8						

GPL, U/mL, µg/mL

Comments

A heterogeneous pattern in the classification has been observed.

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Lupus Anticoagulant | ## AntiCardiolipin Antibodies IgM

Sample No	22.164
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	MPL, U/mL, µg/mL, CU/mL
Expiry Date	30-April-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	218

Homogeneity Parameter LA Ratio

Response Rate 35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	221	0	0	0	0	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
U/mL, µg/mL, GPL/MPL	128	1.9	42.6	0.0 - 12.3						
Aeskulisa Diagnotic GmbH	7	1.0		0.4 - 1.9						
Biorad Bioplex	7	1.9		1.5 - 2.1						
Euroimmun	6	0.6		0.0 - 2.5						
INOVA Quanta Lite	8	8.3		0.0 - 12.3						
Orgentec (Alegria)	11	0.8	20.2	0.6 - 1.0						
Orgentec (Elisa)	15	1.3	34.9	0.8 - 3.1						
Thermo Scientific EliA	62	2.1	19.8	0.3 - 3.8						
CU/mL	71	2.3	13.7	1.8 - 5.9						
I.L. Acustar / INOVA Quanta Flash	71	2.3	13.7	1.8 - 5.9						

MPL, U/mL, µg/mL

Comments

Most of the participants reported a negative classification.

External quality Control for Assays and Tests
With a focus on Thrombosis and Haemostasis

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Lupus Anticoagulant

ß2-Glycoprotein I Antibodies IgG

Sample No	22.164
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	U, U/mL, µg/mL, CU/mL
Expiry Date	30-April-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	218

Homogeneity Parameter	LA Ratio
Response Rate	35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	47	39	48	17	68	3

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U, U/mL, µg/mL	136	10.4	27.6	2.5 - 160.0	7.0	-1.19				
Aeskulisa Diagnotic GmbH	7	6.0		3.3 - 12.0						
Euroimmun	10	13.6	12.2	11.8 - 82.4						
INOVA Quanta Lite	9	12.2		9.8 - 20.0						
Orgentec (Alegria)	11	5.9	23.6	4.2 - 16.4						
Orgentec (Elisa)	18	10.1	38.1	4.3 - 17.7	7.0	-0.81				
Thermo Scientific EliA	69	10.3	12.6	7.3 - 13.0						
CU/mL	74	376.7	13.5	227.3 - 547.0						
I.L. Acustar / INOVA Quanta Flash	73	376.2	13.5	227.3 - 547.0						

U, U/mL, µg/mL
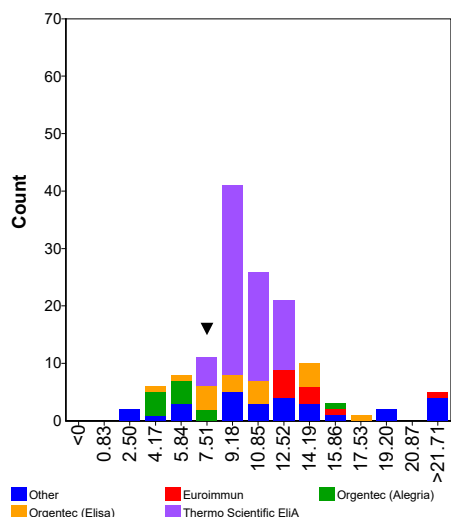
Comments
A heterogeneous pattern in the classification has been observed .

The following participant reported a deviating result which was excluded in the statistical evaluation:
9028 : 11.39 CU/mL

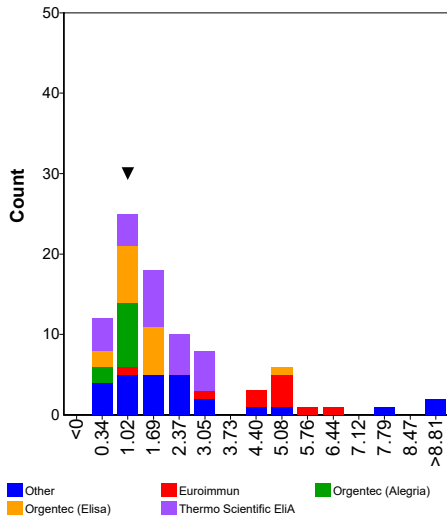**External quality Control for Assays and Tests**
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Lupus Anticoagulant

ß2-Glycoprotein I Antibodies IgM

Sample No	22.164
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	U, U/mL, µg/mL, CU/mL
Expiry Date	30-April-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	196

Homogeneity Parameter LA Ratio

Response Rate 31 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	198	0	0	0	0	2

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U, U/mL, µg/mL	87	1.8	74.3	0.0 - 9.4	0.7	-0.84				
Aeskulisa Diagnotic GmbH	6	1.0		0.3 - 1.0						
Biorad Bioplex	6	2.2		1.7 - 2.6						
Euroimmun	10	4.7	29.3	1.0 - 6.7						
INOVA Quanta Lite	5	1.7		0.0 - 9.4						
Orgentec (Alegria)	10	0.8	0.0	0.5 - 0.9						
Orgentec (Elisa)	16	1.2	54.4	0.0 - 4.9	0.7	-0.77				
Thermo Scientific EliA	25	1.8	56.8	0.0 - 2.9						
CU/mL	66	1.5	15.2	1.0 - 2.3						
I.L. Acustar / INOVA Quanta Flash	66	1.5	15.2	1.0 - 2.3						

U, U/mL, µg/mL

Legend: Other, Euroimmun, Orgentec (Alegria), Orgentec (Elisa), Thermo Scientific EliA

Comments

Most of the participants reported a negative classification.