

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2025-L4 Lupus Anticoagulant Labcode 1492

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Date of Issue : 29-januari-2026

Survey : 2025-L4

Report : Lupus Anticoagulant

Note:

In the Survey Manual 2025 detailed information is given regarding the ECAT external quality assessment programme, including the statistical evaluation and explanation of the report.

This Survey Manual 2025 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 in the paragraph on the statistical evaluation of the Survey Manual.

General Information**Exclusion of results**

Results < [value] or > [value] are excluded from the statistical analysis. When other results (e.g., deviating results) are excluded from the statistical analysis, these results are placed between brackets.

Lupus Anticoagulant

When selecting the unit seconds; all results should be reported in seconds and not partly in ratios; e.g., the result for the ECAT sample, the result for normal plasma and the result for MRI.

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.

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.

Complaints

Any complaints regarding this survey report should be reported to the ECAT before **March 10th, 2026**. Complaints received after this date will not be taken into consideration.

This report is authorized by:

Dr. M.J. van Essen-Hollestelle
Programme Expert

Note: The current Survey Manual can be downloaded from the 'Participant Area' of the ECAT website. Login and select the option 'View Documents'.

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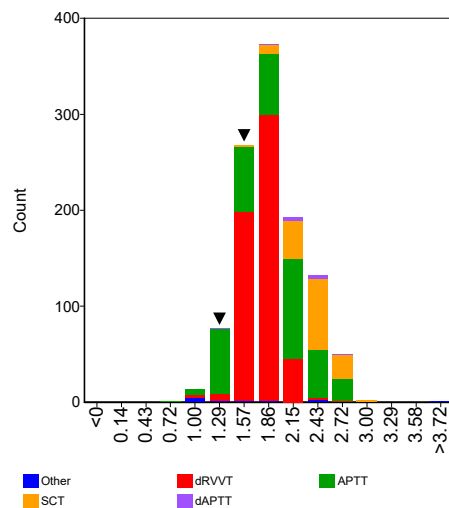
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Appendices are an integral part of the total report.

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

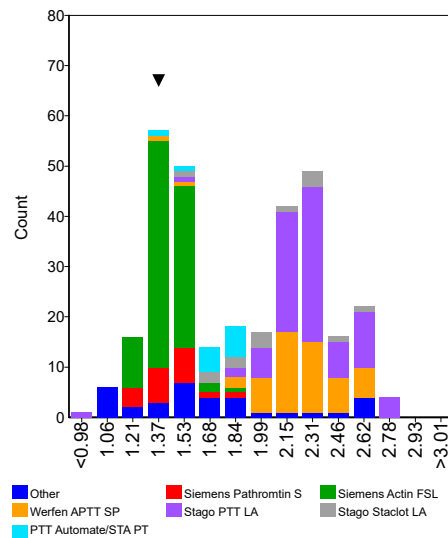
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	382	1.89	25.0	0.74 - 2.81	1	1.41	-1.02	1.40	-1.03		
Hyphen-Biomed Cephen LS	12	2.25	6.8	2.02 - 2.46							
Precision Biologic CRYOcheck Hex LA Star	6	2.56		2.33 - 2.63							
Siemens Actin FS	6	1.09		1.04 - 1.11							
Siemens Actin FSL	90	1.41	7.1	1.25 - 1.78	1			1.40	-0.06		
Siemens Pathromtin SL	20	1.43	10.6	1.22 - 1.83	1	1.41	-0.16				
Stago CKPrest / APTT Kaolin	5	1.49		1.26 - 1.54							
Stago PTT Automate/STA PTT	13	1.75	6.0	1.45 - 1.88							
Stago PTT LA	87	2.30	9.3	0.74 - 2.81							
Stago StacLOT LA	14	2.04	15.7	1.46 - 2.66							
Werfen APTT SP	54	2.24	9.8	1.36 - 2.68							
Werfen HemosIL SynthAsil	44	1.93	8.1	1.46 - 2.50							
Werfen MixCon	14	2.04	8.6	1.73 - 2.35							
dAPTT	11	2.26	12.1	1.28 - 2.63							
Stago PTT LA	8	2.35		2.21 - 2.63							
dRVVT	556	1.77	9.3	1.00 - 2.82	1					1.52	-1.55
Hyphen Biomed Hemoclot LA-S	8	2.00		1.87 - 2.23							
Precision Biologic LA check	7	2.00		1.76 - 2.20							
Roche Lupus S	8	1.72		1.69 - 1.81							
Siemens LA1 screen	226	1.71	8.9	1.00 - 2.82	1					1.52	-1.26
Stago DRVVT screen	74	1.70	9.9	1.43 - 2.10							
Technoclone LA Screen	5	1.80		1.69 - 1.88							
Werfen HemosIL dRVVT screen	220	1.85	7.0	1.26 - 2.44							
PT	6	1.09		1.08 - 1.16							
SCT	149	2.37	9.0	1.54 - 3.12							
Werfen SCT screen	147	2.37	9.1	1.54 - 3.12							

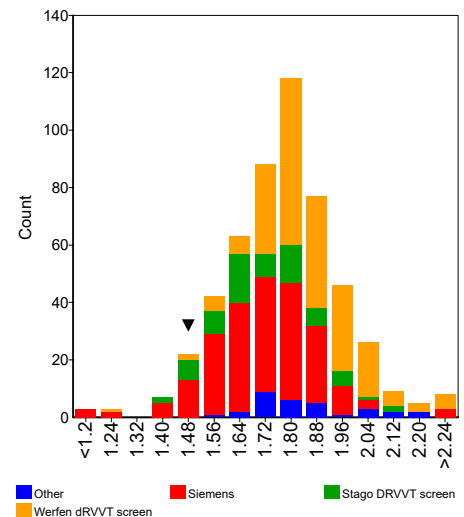
Assays



APTT

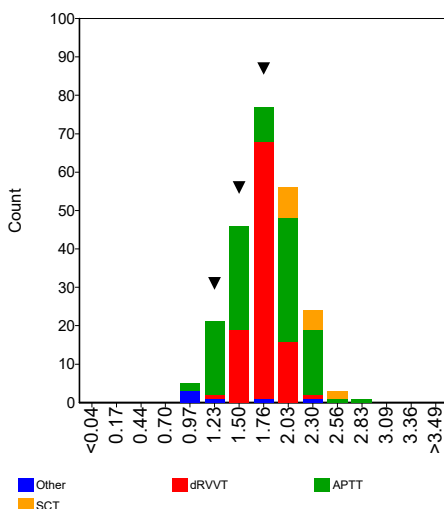
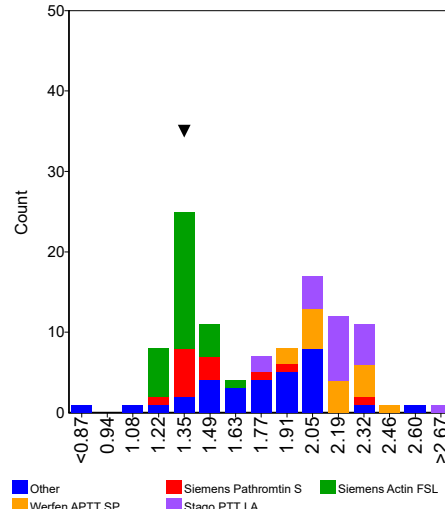
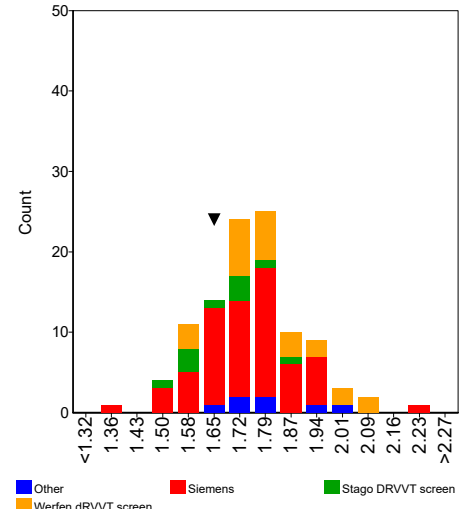


DRVVT



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	108	1.76	25.0	0.85 - 2.79	1	1.38	-0.87	1.31	-1.03		
Siemens Actin FSL	28	1.36	6.2	1.19 - 1.59	1			1.31	-0.58		
Siemens Pathromtin SL	13	1.49	13.8	1.18 - 2.28	1	1.38	-0.54				
Stago PTT Automate/STA PTT	5	1.72		1.50 - 1.74							
Stago PTT LA	20	2.17	6.8	1.75 - 2.79							
Werfen APTT SP	16	2.17	7.7	1.90 - 2.42							
Werfen HemosIL SynthAsil	8	1.96		1.68 - 2.07							
dRVVT	104	1.75	7.4	1.36 - 2.21	1					1.65	-0.77
Siemens LA1 screen	62	1.74	7.1	1.36 - 2.21	1					1.65	-0.71
Stago DRVVT screen	10	1.68	7.1	1.54 - 1.89							
Werfen HemosIL dRVVT screen	25	1.81	8.5	1.59 - 2.12							
SCT	15	2.21	7.5	2.03 - 2.46							
Werfen SCT screen	15	2.21	7.5	2.03 - 2.46							

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. 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 screening tests performed (approx. 99%) were classified as prolonged.

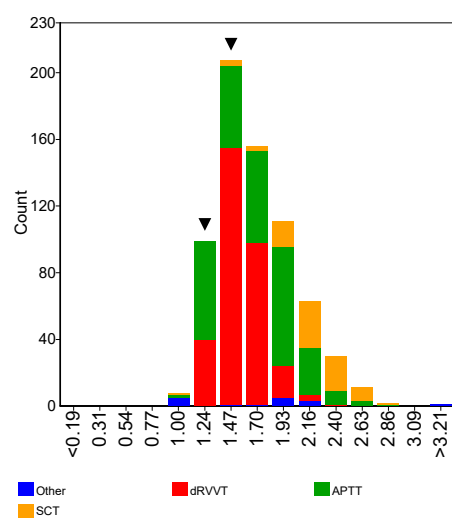
In general, comparable results were observed for the ratio ECAT plasma over Normal Plasma and ratio ECAT plasma over Mean Reference Interval (MRI).

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

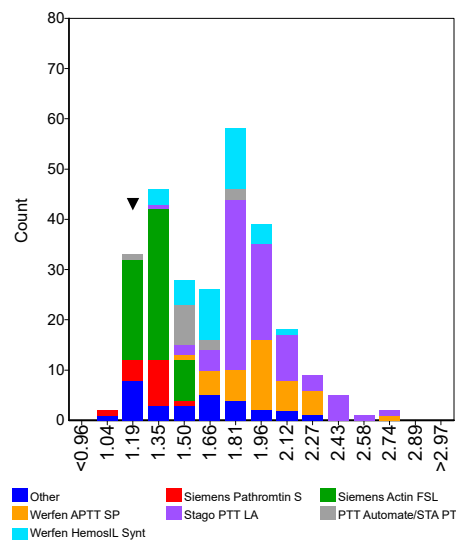
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	277	1.69	21.6	1.09 - 2.81	1			1.26	-1.16		
Hyphen-Biomed Cephen LS	10	2.11	13.5	1.81 - 2.58							
Siemens Actin FSL	58	1.32	8.0	1.17 - 1.54	1			1.26	-0.53		
Siemens Pathromtin SL	15	1.29	8.5	1.11 - 1.56							
Stago PTT Automate/STA PTT	13	1.56	7.4	1.24 - 1.78							
Stago PTT LA	79	1.93	9.8	1.40 - 2.68							
Werfen APTT SP	38	1.94	10.9	1.50 - 2.81							
Werfen HemosIL SynthAsil	35	1.72	10.3	1.35 - 2.13							
Werfen MixCon	8	1.76		1.13 - 2.23							
dAPTT	7	2.02		1.84 - 2.27							
Stago PTT LA	7	2.02		1.84 - 2.27							
dRVVT	315	1.53	11.0	1.13 - 2.44	1					1.38	-0.90
Roche Lupus S	5	1.40		1.25 - 1.56							
Siemens LA1 screen	149	1.46	8.7	1.14 - 2.20	1					1.38	-0.63
Stago DRVVT screen	44	1.47	8.0	1.30 - 2.06							
Werfen HemosIL dRVVT screen	106	1.67	7.7	1.13 - 2.44							
PT	5	1.02		1.01 - 1.04							
SCT	80	2.21	12.1	1.10 - 2.79							
Werfen SCT screen	77	2.21	11.6	1.36 - 2.79							

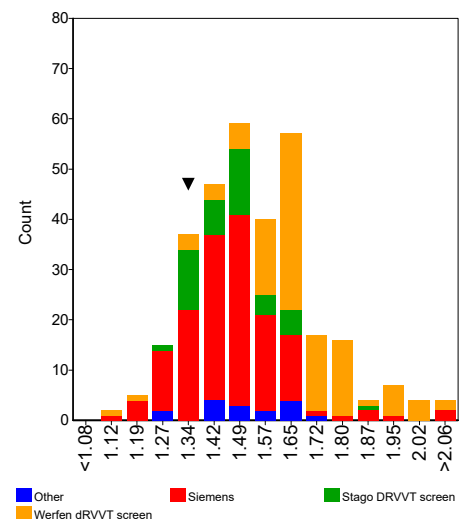
Assays



APTT

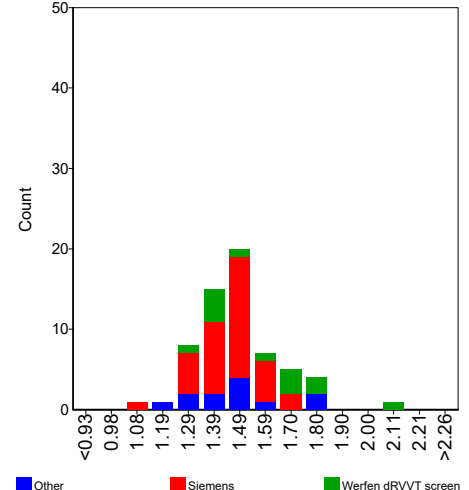
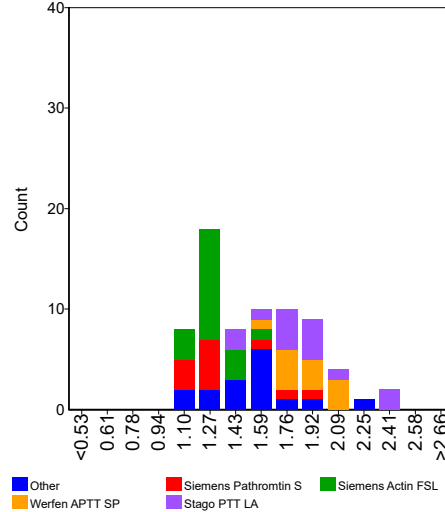
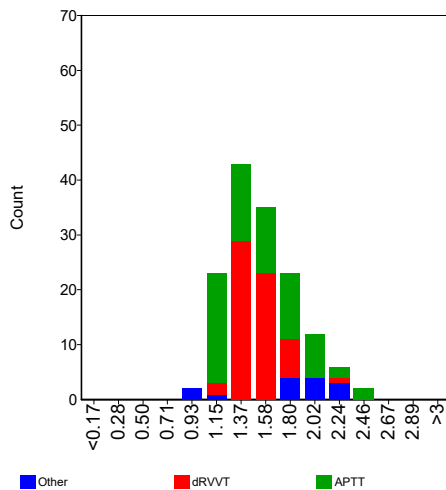


DRVVT



Lupus Anticoagulant
Mixing (screening)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	70	1.55	23.4	1.06 - 2.40							
Siemens Actin FSL	18	1.26	8.6	1.06 - 1.52							
Siemens Pathromtin SL	11	1.34	20.1	1.08 - 1.95							
Stago PTT LA	14	1.82	15.3	1.43 - 2.40							
Werfen APTT SP	11	1.91	9.7	1.62 - 2.13							
Werfen HemosIL SynthAsil	5	1.67		1.64 - 1.93							
dRVVT	62	1.48	9.9	1.13 - 2.14							
Siemens LA1 screen	37	1.46	8.0	1.13 - 1.73							
Stago DRVVT screen	6	1.49		1.31 - 1.59							
Werfen HemosIL dRVVT screen	13	1.59	13.8	1.29 - 2.14							
SCT	8	1.98		1.73 - 2.33							
Werfen SCT screen	8	1.98		1.73 - 2.33							

Assays
APTT
DRVVT

Comments

Several participants selected the wrong unit, e.g., ratio while the result was likely to be in seconds. 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. 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.

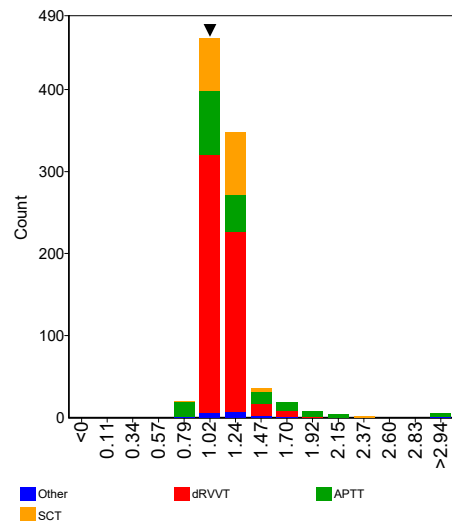
The majority of performed mixing tests (> 97%) were classified as elevated.

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

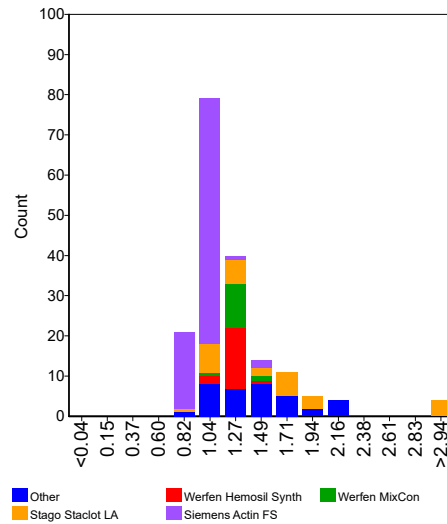
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	178	1.16	19.7	0.84 - 4.26							
Hyphen Biomed Cephen	6	1.22		1.10 - 1.26							
Precision Biologic CRYOcheck Hex LA Cor	7	1.45		1.27 - 1.77							
Siemens Actin FS	83	1.01	9.7	0.84 - 1.49							
Stago PTT LA	7	1.58		1.05 - 2.25							
Stago Staclot LA	29	1.49	32.3	0.93 - 4.26							
Werfen Hemosil SynthAFax	18	1.23	5.7	1.08 - 1.47							
Werfen MixCon	13	1.19	2.9	1.15 - 1.57							
dAPTT	7	1.23		1.01 - 3.62							
dPT	5	1.38		1.12 - 1.59							
dRVVT	561	1.13	6.6	0.70 - 1.94	1					1.06	-1.01
Hyphen Biomed Hemoclot LA-C	8	1.18		1.10 - 1.23							
Precision Biologic LA sure	6	1.07		0.97 - 1.28							
Roche Lupus C	8	1.17		1.09 - 1.21							
Siemens LA2 confirmation	226	1.11	5.4	0.70 - 1.82	1					1.06	-0.93
Stago DRVVT Confirm	72	1.10	4.6	0.94 - 1.52							
Technoclone LA Confirm	5	1.11		1.01 - 1.19							
Werfen Hemosil dRVVT confirm	228	1.16	7.2	0.91 - 1.94							
PNP	6	1.12		0.89 - 1.34							
SCT	148	1.15	8.8	0.79 - 2.41							
Werfen Hemosil SCT confirm	148	1.15	8.8	0.79 - 2.41							

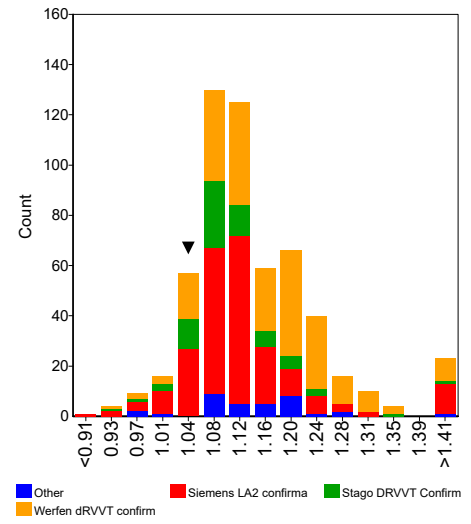
Assays



APTT



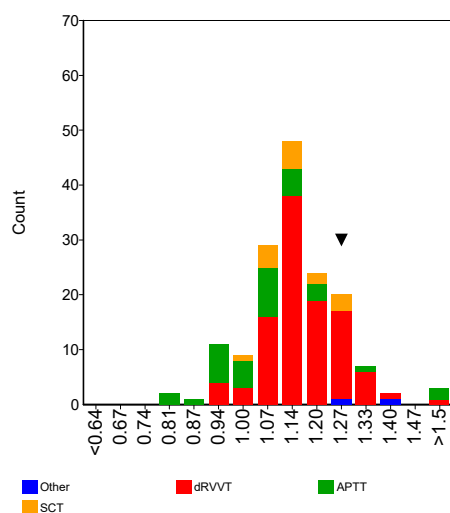
DRVVT



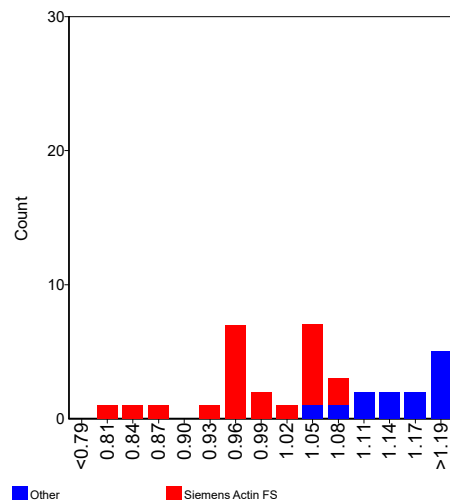
Confirmation

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	35	1.05	11.1	0.81 - 2.11							
Siemens Actin FS	22	0.99	6.8	0.81 - 1.07							
Stago Staclot LA	5	1.17		1.08 - 1.85							
dRVVT	104	1.17	7.5	0.91 - 1.56	1					1.27	1.25
Siemens LA2 confirmation	63	1.16	8.9	0.91 - 1.37	1					1.27	1.09
Stago DRVVT Confirm	10	1.13	2.5	0.95 - 1.20							
Werfen HemosIL dRVVT confirm	25	1.19	6.9	1.07 - 1.56							
SCT	15	1.14	8.1	1.02 - 1.29							
Werfen HemosIL SCT confirm	15	1.14	8.1	1.02 - 1.29							

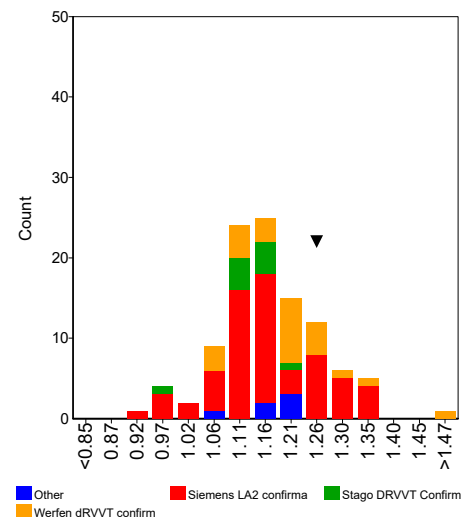
Assays



APTT



DRVVT



Comments

Several participants selected the wrong unit, e.g., ratio while the result was likely to be in seconds, or vice versa. Several participants reported their result for the ECAT plasma in seconds, while the result for their reference plasma was reported as a ratio. 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 in the statistical analysis.

Approximately half of the performed confirmation tests were classified as not elevated and the other half as elevated. In general, no relation could be observed with the type of method used.

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

Lupus Anticoagulant
Mixing (confirm)

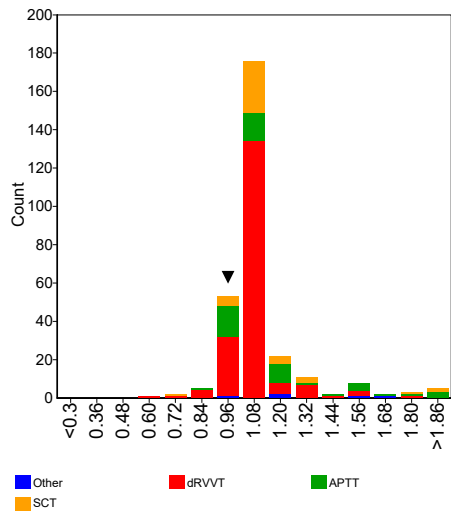
Sample No	25.244		
Sample Details	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.7)		
Prior Use	Prior Use: None		
Unit	Ratio		
Expiry Date	30-september-2028		
Homogeneity	1.1 %	Homogeneity Parameter	LA ratio
For any method used for the measurement of this parameter with a CV ≤ 3.7% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.			
Number of Participants	641		
Number of Responders	208	Response Rate	32 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	26	34	0	3
dAPTT	9	0	0	0
dPT	1	0	0	0
dRVVT	52	144	0	8
PNP	1	0	0	0
SCT	13	32	0	1

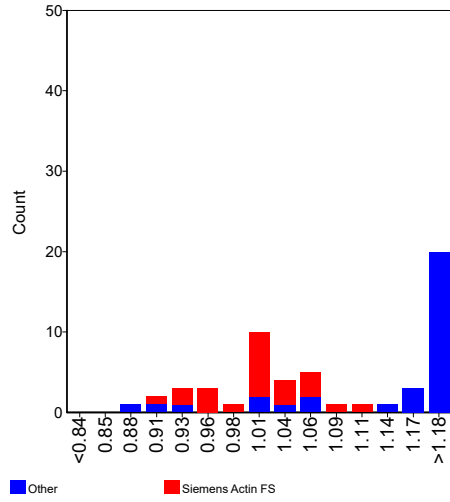
Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Not elevated						
PNP									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	55	1.16	20.4	0.89 - 2.02							
Siemens Actin FS	23	1.01	5.5	0.92 - 1.12							
Werfen Hemosil SynthAFax	6	1.21		1.19 - 1.54							
Werfen MixCon	8	1.20		1.01 - 1.82							
dRVVT	191	1.06	4.8	0.63 - 1.79	1					0.99	-1.34
Siemens LA2 confirmation	98	1.05	4.2	0.85 - 1.53	1					0.99	-1.43
Stago DRVVT Confirm	21	1.04	5.4	0.67 - 1.79							
Werfen Hemosil dRVVT confirm	65	1.07	4.9	0.63 - 1.59							
SCT	45	1.09	8.2	0.68 - 2.14							
Werfen Hemosil SCT confirm	44	1.09	7.6	0.68 - 2.14							

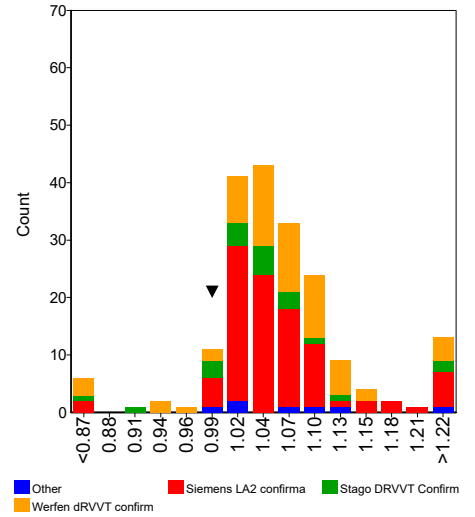
Assays



APTT



DRVVT

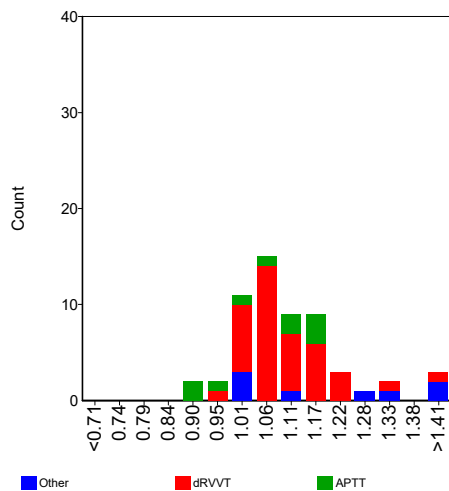


Lupus Anticoagulant

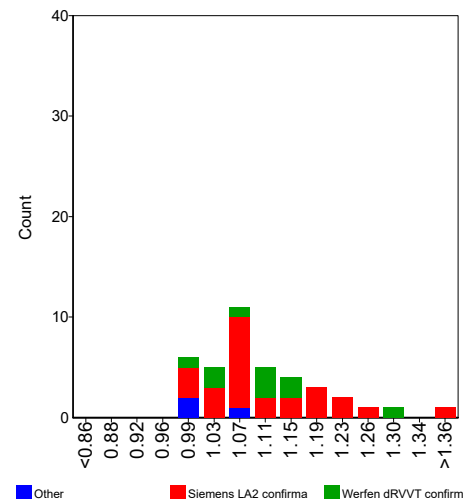
Mixing (confirm)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	10	1.06	11.0	0.90 - 1.17							
Siemens Actin FS	5	0.96		0.90 - 1.07							
dRVVT	39	1.10	7.3	0.98 - 1.46							
Siemens LA2 confirmation	26	1.11	7.5	1.00 - 1.46							
Werfen HemosIL dRVVT confirm	10	1.10	6.3	1.00 - 1.31							
SCT	6	1.06		0.98 - 1.31							
Werfen HemosIL SCT confirm	6	1.06		0.98 - 1.31							

Assays



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. All these results were excluded from the statistical analysis.

The majority of performed mixing confirmation tests (67%) were classified as not elevated.

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

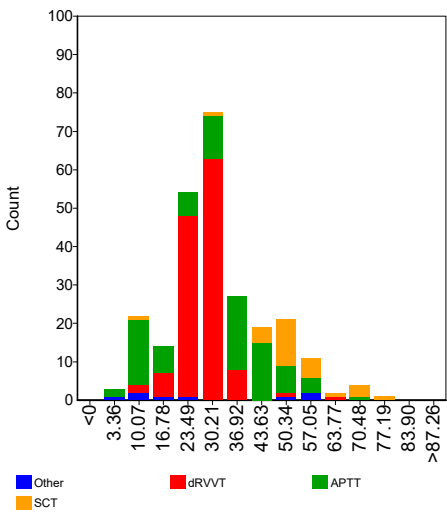
Lupus Anticoagulant

Interpretation

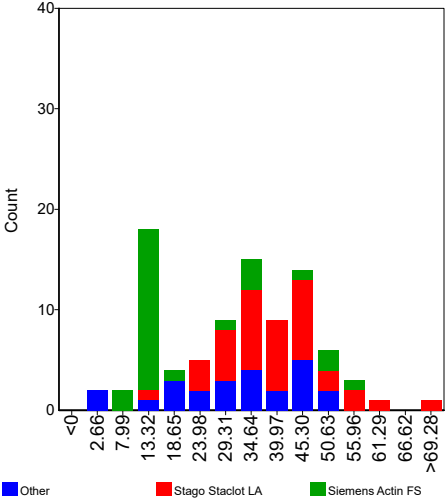
Delta Seconds

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	89	31.39	51.5	2.10 - 73.00							
Precision Biologic CRYOcheck Hex LA Cor	9	45.10		32.70 - 49.00							
Siemens Actin FS	27	19.04	64.8	8.50 - 57.30							
Stago Staclot LA	38	38.80	26.2	15.50 - 73.00							
dRVVT	128	27.47	14.9	11.40 - 64.40							
Siemens LA2 confirmation	65	26.24	11.7	11.80 - 64.40							
Stago DRVVT Confirm	9	24.40		22.50 - 27.10							
Werfen HemosIL dRVVT confirm	48	30.02	12.0	11.40 - 36.20							
SCT	28	52.81	14.2	6.90 - 74.40							
Werfen HemosIL SCT confirm	27	53.23	13.2	31.30 - 74.40							

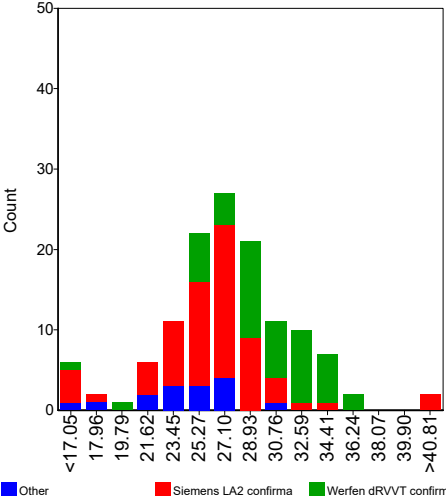
Assays



APTT



DRVVT



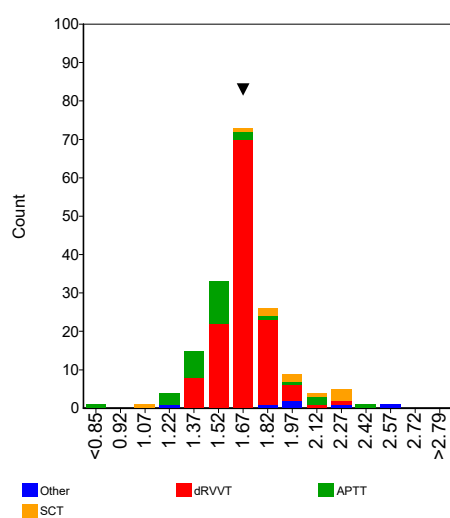
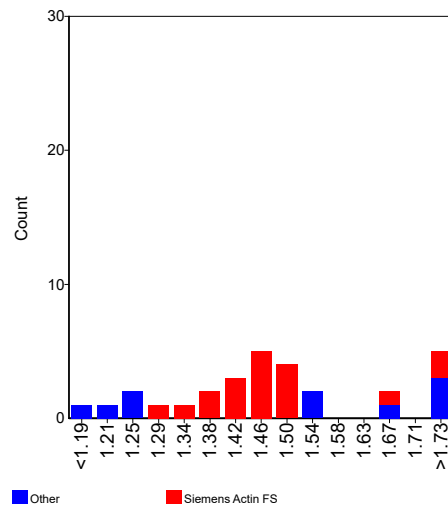
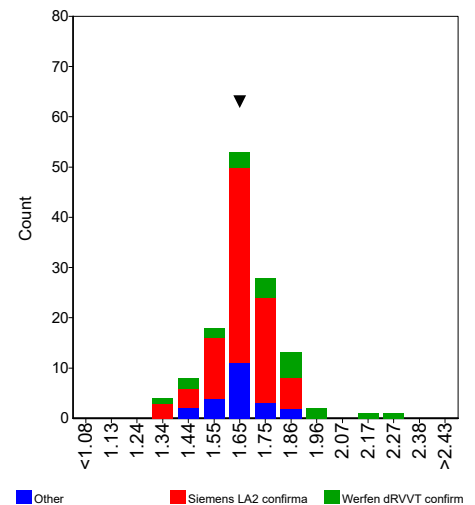
Comments

It is not clear whether all results submitted for Delta Seconds reflect in all cases 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).

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	29	1.49	13.7	0.58 - 2.36							
Siemens Actin FS	19	1.46	6.1	1.30 - 2.36							
dRVVT	128	1.67	6.8	1.31 - 2.27	1					1.61	-0.52
Siemens LA2 confirmation	85	1.66	5.6	1.32 - 1.91	1					1.61	-0.54
Stago DRVVT Confirm	9	1.62		1.40 - 1.70							
Technoclone LA Confirm	5	1.70		1.59 - 1.83							
Werfen HemosIL dRVVT confirm	21	1.76	12.8	1.31 - 2.27							
SCT	10	1.96	14.2	1.06 - 2.28							
Werfen HemosIL SCT confirm	9	1.98		1.72 - 2.28							

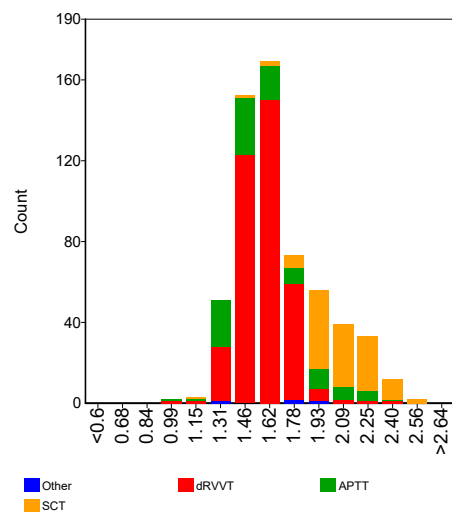
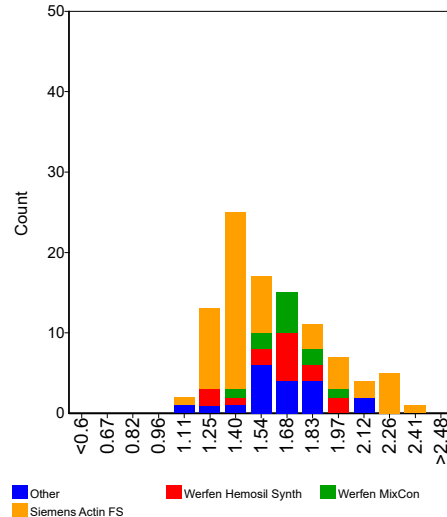
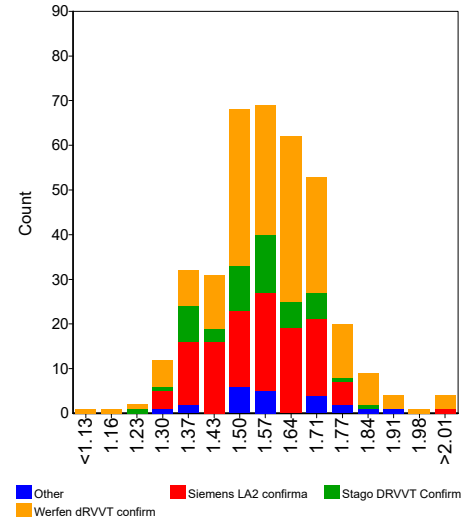
Assays

APTT

DRVVT

Comments

Some participants did not indicate which type of ratio screen/confirmation they reported (standard ratio or normalised ratio). A few participants reported a ratio, which was likely to be the result in seconds or delta seconds. These results have been excluded from the statistical analysis. **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. 1.7).

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	100	1.59	18.2	1.05 - 2.42							
Siemens Actin FS	55	1.54	20.3	1.05 - 2.42							
Stago Staclot LA	5	1.57		1.48 - 2.10							
Werfen Hemosil SynthAFax	15	1.63	14.5	1.26 - 1.99							
Werfen MixCon	11	1.69	11.1	1.42 - 2.03							
dRVVT	369	1.57	8.7	1.03 - 2.44							
Hyphen Biomed Hemoclot LA-C	8	1.71		1.57 - 1.93							
Roche Lupus C	5	1.48		1.40 - 1.55							
Siemens LA2 confirmation	115	1.55	8.6	1.27 - 2.44							
Stago DRVVT Confirm	50	1.54	8.7	1.25 - 1.83							
Werfen Hemosil dRVVT confirm	182	1.60	8.5	1.03 - 2.26							
SCT	119	2.08	9.0	1.20 - 2.61							
Werfen Hemosil SCT confirm	119	2.08	9.0	1.20 - 2.61							

Assays

APTT

DRVVT

Comments

Some participants did not indicate which type of ratio screen/confirmation they reported (standard ratio or normalised ratio). A few participants reported a ratio, which was likely to be the result in seconds or delta seconds. These results have been excluded from the statistical analysis. **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. 1.7).

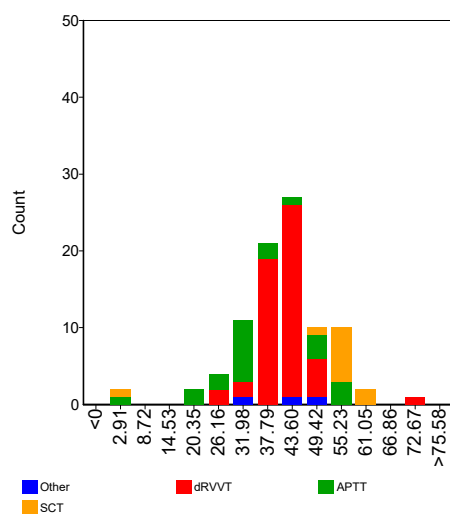
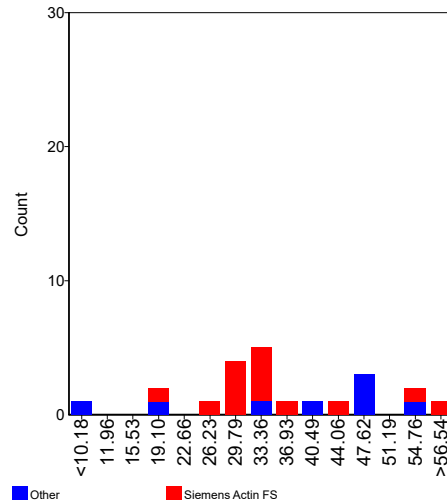
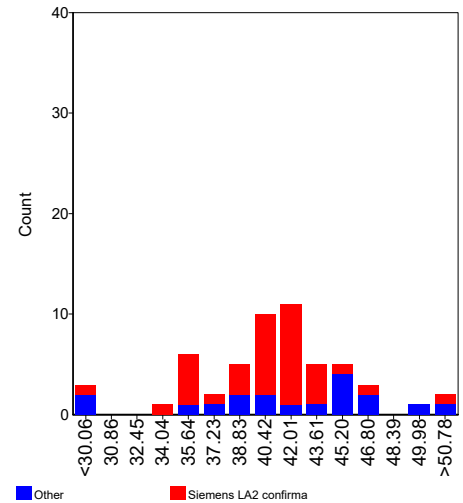
The following participant reported deviating results which were excluded from the statistical analysis:

3618 (panel 1): 0.04%

3618 (panel 2): 0.03%

Lupus Anticoagulant
Interpretation
Percentage Correction - Standard

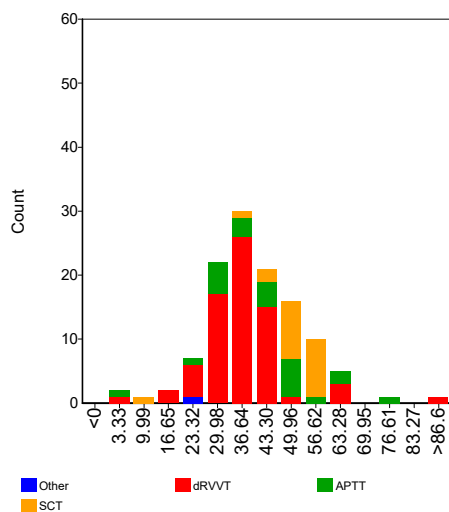
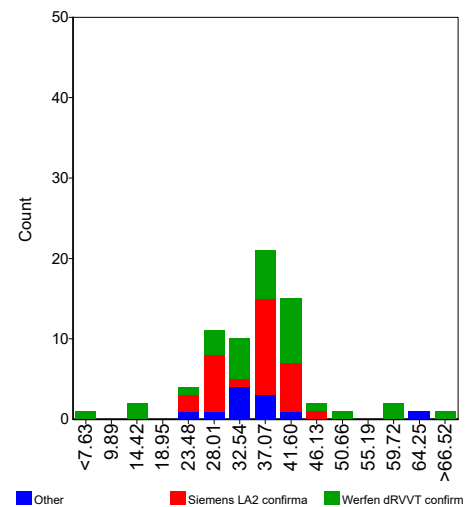
	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	22	36.04	36.6	3.16 - 57.60							
Siemens Actin FS	14	33.36	23.2	19.78 - 57.60							
dRVVT	54	40.99	10.7	28.91 - 72.00							
Siemens LA2 confirmation	36	40.42	8.5	28.91 - 72.00							
Stago DRVVT Confirm	5	38.40		28.92 - 45.75							
Werfen HemosIL dRVVT confirm	9	45.70		36.20 - 51.40							
SCT	11	54.52	8.9	5.60 - 60.83							
Werfen HemosIL SCT confirm	10	55.41	7.0	48.00 - 60.83							

Assays

APTT

DRVVT

Comments

Some participants did not indicate which type of correction they have reported (standard correction or normalised correction). These results have been excluded from the statistical analysis. **Don't forget to select the type of correction in the next survey.**

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	24	42.33	34.9	1.30 - 77.00							
Siemens Actin FS	9	47.30		27.80 - 56.80							
dRVVT	71	35.84	20.7	1.62 - 89.00							
Siemens LA2 confirmation	29	35.23	18.5	23.00 - 44.00							
Stago DRVVT Confirm	8	36.50		25.20 - 62.90							
Werfen HemosIL dRVVT confirm	31	37.08	26.5	1.62 - 89.00							
SCT	22	51.14	11.1	11.00 - 58.90							
Werfen HemosIL SCT confirm	22	51.14	11.1	11.00 - 58.90							

Assays

DRVVT

Comments

Some participants did not indicate which type of correction they have reported (standard correction or normalised correction). These results have been excluded from the statistical analysis. **Don't forget to select the type of correction in the next survey.**

Lupus Anticoagulant
Final Conclusion

Testing Strategies	Classification				Your Classification			
	Equivocal	LA detected	LA not detected	No conclusion	Test System	Panel 1	Panel 2	Panel 3
Screen test only	0	18	0	8	1			
					2			
					3			
Screen and mixing test	2	82	1	13	1			
					2			
					3			
Screen and confirm test	4	462		4	1			
					2			
					3			
Screen, mixing and confirm test	2	285	3	2	1			LA detected
					2			
					3			
Screen, confirm, mixing test	3	166	1		1			
					2			
					3			
Mixing - confirmation	0	36	0	0	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			
504	3	1	1	LA detected		

Comments

The sample used in this survey consisted of citrated plasma obtained from a patient with a confirmed lupus anticoagulant (LA), with an LA ratio of approximately 1.7. At the time of blood collection, the patient was receiving daily subcutaneous enoxaparin at a dose of 100 mg.

In total, 508 participants provided a final classification. Of these, approximately 99% classified the sample as positive. Less than 1% (0.2%) classified the sample as equivocal. Consequently, the vast majority of participants correctly identified the sample as positive. A small minority (0.6%) classified the sample as negative. This misclassification does not appear to be related to the applied test strategy but is more likely attributable to differences in reagent sensitivity and local result interpretation, such as the use of laboratory-specific cut-off values.

Participants indicated that this sample is weakly positive for lupus anticoagulant however, in daily clinical practice, such a finding should be confirmed in a new sample obtained after 12 weeks.

Lupus Anticoagulant

Sample No 25.244
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.7)
Prior Use Prior Use: None
Unit GPL, U/mL, µg/mL, CU/mL
Expiry Date 30-september-2028
Homogeneity 1.1 %

AntiCardiolipin Antibodies IgG

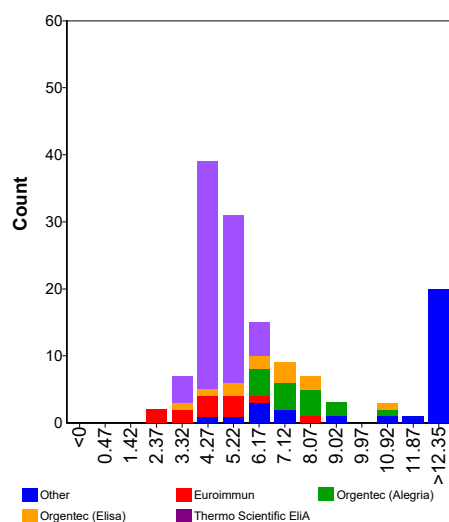
Homogeneity Parameter LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 3.7%** the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.

Number of Participants 641
Number of Responders 234 **Response Rate** 37 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	124	7	42	46	15	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	137	6.0	38.2	2.6 - 106.3						
Aeskulisa Diagnostic GmbH	6	14.2		6.0 - 21.3						
Biorad Bioplex	8	100.5		88.0 - 106.3						
Euroimmun	12	4.4	33.4	2.6 - 8.0						
IDS	5	12.5		6.5 - 16.4						
Orgentec (Alegria)	15	7.4	15.8	5.7 - 11.3						
Orgentec (Elisa)	12	6.3	32.0	3.0 - 11.1						
Thermo Scientific EliA	68	4.7	12.5	2.9 - 6.2						
CU/mL	90	49.9	9.4	36.2 - 61.3						
Werfen Acustar / INOVA Quanta Flash	89	49.9	9.5	36.2 - 61.3						

GPL, U/mL, µg/mL


Comments

A heterogeneous pattern in classification has been observed by the majority of participants . In particular two methods; Werfen Acustar/INOVA Quanta Flash and Biorad Bioplex were associated with a positive classification , correlating with their reported antibody titer.

The following participants reported deviating results which were excluded from the statistical analysis:

1353: 0.31 U/mL

9907155: 0 U/mL

Lupus Anticoagulant

Sample No 25.244
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.7)
Prior Use Prior Use: None
Unit MPL, U/mL, µg/mL, CU/mL
Expiry Date 30-september-2028
Homogeneity 1.1 %

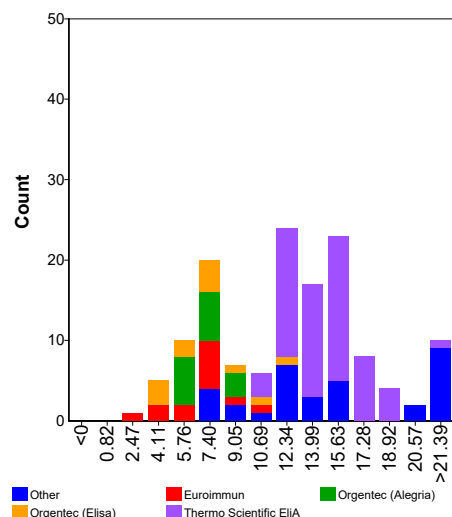
AntiCardiolipin Antibodies IgM

Homogeneity Parameter LA ratio
 For any method used for the measurement of this parameter with a **CV ≤ 3.7%** the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.

Number of Participants 641
Number of Responders 225 **Response Rate** 35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	143	23	52	9	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	137	12.6	40.5	3.3 - 38.2						
Aeskulisa Diagnostic GmbH	6	14.3		11.0 - 20.0						
Biorad Bioplex	7	13.1		12.6 - 16.0						
Euroimmun	13	6.5	29.5	3.3 - 9.9						
IDS	5	8.0		7.6 - 8.3						
Orgentec (Alegria)	15	7.1	20.0	5.3 - 9.5						
Orgentec (Elisa)	12	7.4	38.0	4.0 - 12.2						
Thermo Scientific ELIA	64	14.8	14.9	11.0 - 30.0						
Werfen INOVA Quanta Lite	7	33.0		25.0 - 38.2						
CU/mL	89	11.2	10.1	8.0 - 13.9						
Werfen Acustar / INOVA Quanta Flash	88	11.2	10.1	8.0 - 13.9						

MPL, U/mL, µg/mL


Comments

Most of the participants reported a negative classification.

Thirty-seven percent of the participant reported the plasma sample as borderline/positive. This was not associated with specific titers or methods.

The following participants reported deviating results which were excluded from the statistical analysis:

1353: 0.78 U/mL

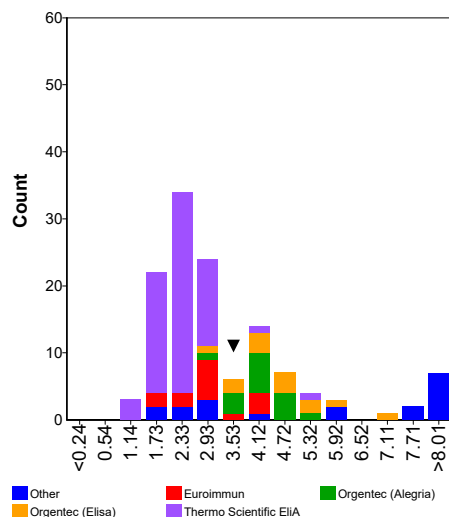
3167: 0.45 U/mL

Lupus Anticoagulant
β2-Glycoprotein I Antibodies IgG

Sample No	25.244		
Sample Details	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.7)		
Prior Use	Prior Use: None		
Unit	U, U/mL, µg/mL, CU/mL		
Expiry Date	30-september-2028		
Homogeneity	1.1 %	Homogeneity Parameter	LA ratio
	For any method used for the measurement of this parameter with a CV ≤ 3.7% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.		
Number of Participants	641		
Number of Responders	229	Response Rate	36 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	123	3	11	13	81	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, U/mL, µg/mL	127	3.1	41.5	1.0 - 153.7	3.3	0.16				
Aeskulisa Diagnostic GmbH	6	2.9		2.0 - 5.8						
Euroimmun	14	3.0	30.7	1.5 - 4.2						
Orgentec (Alegria)	15	4.1	13.3	2.8 - 5.3						
Orgentec (Elisa)	13	4.6	24.2	3.0 - 7.3	3.3	-1.19				
Thermo Scientific EliA	66	2.3	20.0	1.0 - 5.3						
CU/mL	89	247.9	10.5	167.7 - 316.2						
Werfen Acustar / INOVA Quanta Flash	88	247.8	10.6	167.7 - 316.2						

U, U/mL, µg/mL


Comments

A heterogeneous pattern in classification has been observed by the majority of participants . In particular two methods; Werfen Acustar/INOVA Quanta Flash and Biorad Bioplex were associated with a positive classification , correlating with their reported antibody titer.

All participants using the method Biorad Bioplex reported a result higher than the upper limit of their method (>160).

The following participants reported deviating results which were excluded from the statistical analysis:

174: 2.1 CU/mL

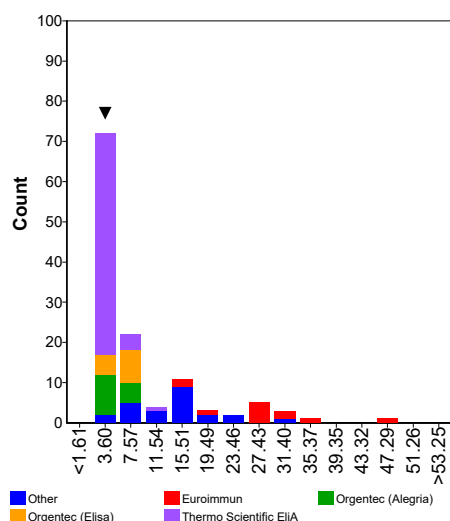
9907155: 0 U/mL

Lupus Anticoagulant
β2-Glycoprotein I Antibodies IgM

Sample No	25.244		
Sample Details	Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.7)		
Prior Use	Prior Use: None		
Unit	U, U/mL, µg/mL, CU/mL		
Expiry Date	30-september-2028		
Homogeneity	1.1 %	Homogeneity Parameter	LA ratio
	For any method used for the measurement of this parameter with a CV ≤ 3.7% the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.		
Number of Participants	641		
Number of Responders	214	Response Rate	33 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	188	9	14	5	1	0

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	124	6.4	54.2	2.0 - 46.0	4.7	-0.48				
Aeskulisa Diagnostic GmbH	6	20.9		10.3 - 30.0						
Biorad Bioplex	7	15.1		13.9 - 16.0						
Euroimmun	12	27.4	31.4	15.0 - 46.0						
Orgentec (Alegria)	15	4.9	21.0	3.8 - 7.2						
Orgentec (Elisa)	13	5.7	20.3	4.0 - 7.0	4.7	-0.83				
Thermo Scientific EliA	60	4.3	19.8	2.0 - 9.6						
CU/mL	87	10.5	12.8	8.0 - 19.2						
Werfen Acustar / INOVA Quanta Flash	86	10.5	12.9	8.0 - 19.2						

U, U/mL, µg/mL

Comments

Most of the participants reported a negative classification.

The following participants reported deviating results which were excluded from the statistical analysis:

3167: 2.75 U/mL

9907155: 0 U/mL