ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2024-L4
Lupus Anticoagulant
Labcode 1492

Date of Issue : 23-January-2025

Survey : 2024-L4

Report : Lupus Anticoagulant

Note:
In the Survey Manual 2024 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.
This Survey Manual 2024 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

IMPORTANT: No z-score analysis
Because of the strong lupus anticoagulant positivity of this patient sample, it was advised in an additional e-mail to the participants to dilute the patient sample in normal pooled plasma. However, the dilution factor used by the participants for reporting the results for all parameters varies greatly and it is not clear for all participants which dilution factor they used for the reported results. Therefore, the results could not be split in different approaches and the statistical analysis should be interpret with caution and as a consequence no z-score analysis was performed in this report.

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.

Complaints
Any complaints regarding this survey report should be reported to the ECAT before **March 6th 2025**. 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: A printed version of the actual Survey Manual is provided to all participants once a year . This manual can also be downloaded from the member section of the ECAT website.

ECAT Foundation

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Lupus Anticoagulant

Screening

Sample No 24.238

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. >2.0)

Prior Use Prior Use: None

Unit Ratio

Expiry Date 31-July-2026

Homogeneity 0.2 %

Homogeneity Parameter LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 0.7%** 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 626

Number of Responders 521

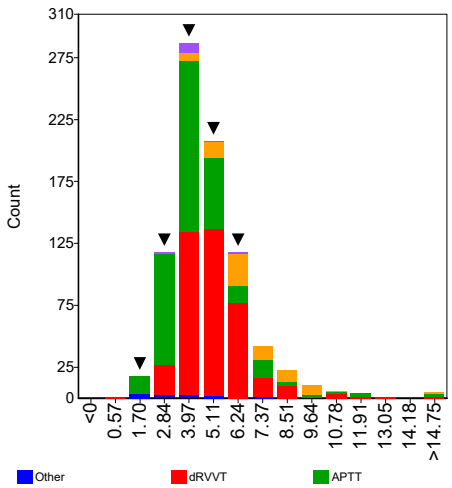
Response Rate 83 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	402	0	0	15
dAPTT	13	0	0	0
dPT	6	0	0	1
dRVVT	510	2	0	37
KCT	6	0	0	0
Other	1	0	0	0
PNP	3	0	0	0
PT	5	0	0	0
SCT	100	1	0	18

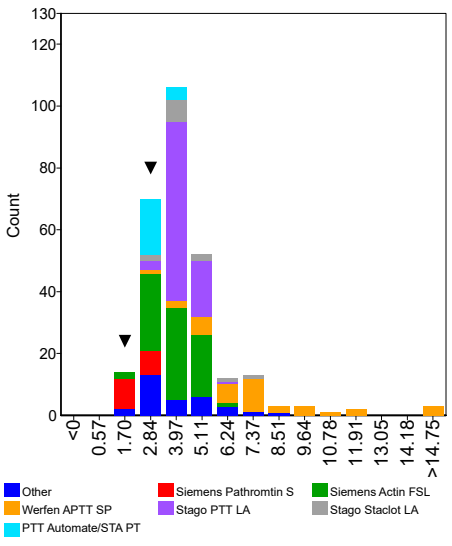
Assay	Your classification								
	Screening 1			Screening 2			Screening 3		
	TS1	TS2	TS3	TS1	TS2	TS3			
APTT	Elevated	Elevated		Elevated	Elevated				
dAPTT									
dPT									
dRVVT			Elevated			Elevated			
KCT									
Other									
PNP									
PT									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	340	4.00	29.5	1.55 - 17.06	1	2.51		4.54			
APTT	340	4.00	29.5	1.55 - 17.06	2	1.99		2.61			
Hyphen-Biomed Cephen LS	7	4.12		3.61 - 8.02							
Siemens Actin FSL	78	3.88	29.6	2.23 - 5.82	1			4.54			
Siemens Actin FSL	78	3.88	29.6	2.23 - 5.82	2			2.61			
Siemens Pathromtin SL	18	2.32	26.2	1.55 - 3.11	1	2.51					
Siemens Pathromtin SL	18	2.32	26.2	1.55 - 3.11	2	1.99					
Stago PTT Automate/STA PTT	22	3.02	10.5	2.60 - 4.11							
Stago PTT LA	80	4.14	12.5	3.25 - 6.51							
Stago Staclot LA	13	4.25	29.2	2.36 - 7.58							
Tcoag TriniClot Automated APTT	7	3.01		2.58 - 3.15							
Werfen APTT SP	37	7.31	33.9	3.23 - 17.06							
Werfen HemosIL SynthAsil	44	3.54	10.0	3.00 - 4.38							
Werfen MixCon	15	4.72	34.1	2.60 - 11.80							
dAPTT	11	4.30	12.6	3.31 - 5.71							
Stago PTT LA	9	4.48		3.63 - 5.71							
dRVVT	401	4.98	23.8	1.04 - 18.58	1					6.11	
dRVVT	401	4.98	23.8	1.04 - 18.58	2					4.06	
Hyphen Biomed Hemoclot LA-S	5	5.60		4.55 - 10.46							
Siemens LA1 screen	177	5.06	22.1	1.04 - 18.58	1					6.11	
Siemens LA1 screen	177	5.06	22.1	1.04 - 18.58	2					4.06	
Stago DRVVT screen	82	4.70	21.5	2.37 - 6.61							
Technoclone LA Screen	5	4.97		3.03 - 6.62							
Werfen HemosIL dRVVT screen	121	5.13	30.2	2.53 - 12.81							
PT	5	1.88		1.21 - 2.28							
SCT	76	6.66	25.6	3.81 - 27.07							
Werfen SCT screen	75	6.61	25.1	3.81 - 10.51							

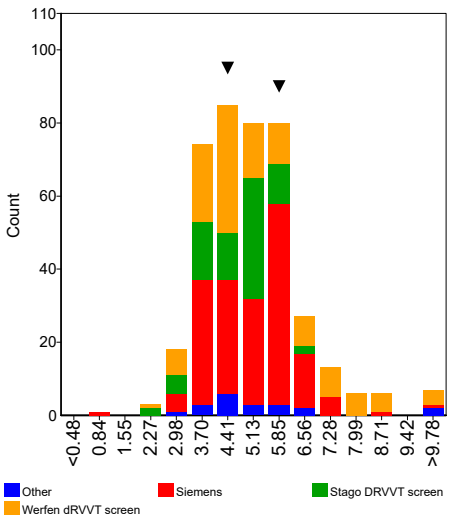
Assays



APTT



DRVVT

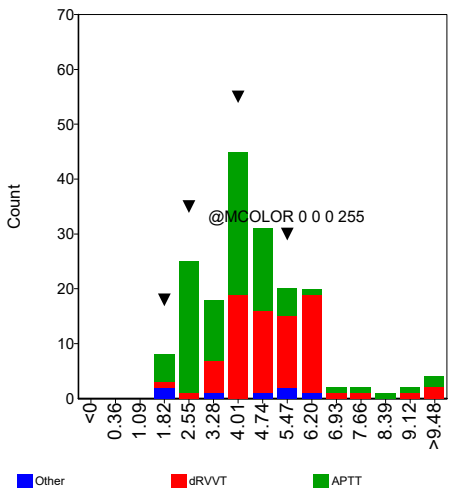


Lupus Anticoagulant

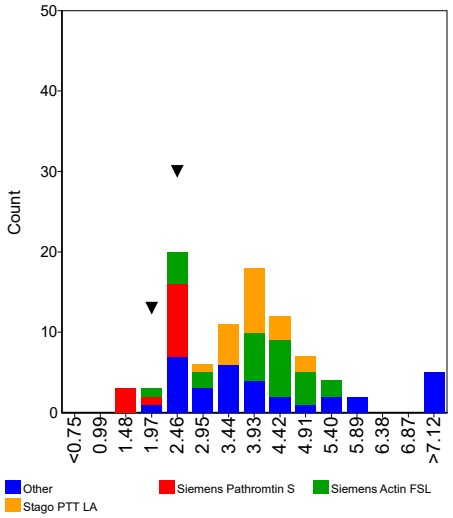
Screening

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	93	3.72	33.2	1.54 - 16.95	1	2.35		4.27			
APTT	93	3.72	33.2	1.54 - 16.95	2	1.87		2.46			
Siemens Actin FSL	26	3.94	26.9	2.22 - 5.41	1			4.27			
Siemens Actin FSL	26	3.94	26.9	2.22 - 5.41	2			2.46			
Siemens Pathromtin SL	13	2.20	20.0	1.54 - 2.70	1	2.35					
Siemens Pathromtin SL	13	2.20	20.0	1.54 - 2.70	2	1.87					
Stago PTT Automate/STA PTT	7	2.70		2.62 - 3.58							
Stago PTT LA	19	3.93	12.8	3.10 - 5.02							
Werfen APTT SP	6	8.83		5.42 - 16.95							
Werfen HemosIL SynthAsil	7	3.68		3.48 - 4.38							
dRVVT	78	4.99	23.5	1.88 - 10.37	1					5.80	
dRVVT	78	4.99	23.5	1.88 - 10.37	2					3.86	
Siemens LA1 screen	53	5.09	22.5	3.43 - 10.37	1					5.80	
Siemens LA1 screen	53	5.09	22.5	3.43 - 10.37	2					3.86	
Stago DRVVT screen	13	4.54	32.2	1.88 - 6.07							
Werfen HemosIL dRVVT screen	7	4.74		3.89 - 6.68							

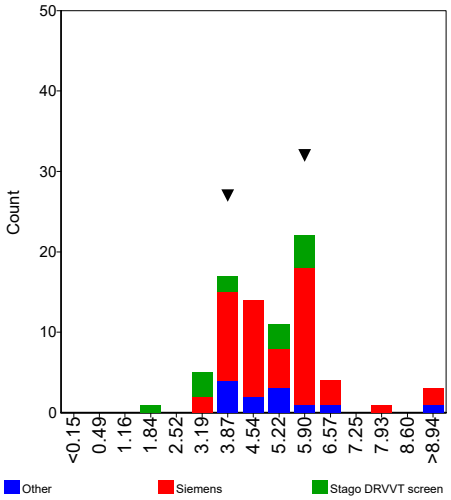
Assays



APTT



DRVVT



Comments

Several participants selected the wrong unit; 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 mean of the reference interval (MRI) was reported as a ratio or reported a deviating value for their Normal Plasma. All these results were excluded in the statistical analysis.

The submitted results were a mix of measurements derived from undiluted ECAT plasma and ECAT plasma diluted with normal pooled plasma. This resulted in most cases in a wide range of ratio's.

Almost all performed screening tests **(99.7%)** were classified as elevated. Some participants concluded "not elevated" because of a failed coagulation test. This failed coagulation test could be caused by the presence of high LA inhibitors titers. 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 (screening)

Sample No 24.238
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. >2.0)
Prior Use Prior Use: None
Unit Ratio
Expiry Date 31-July-2026
Homogeneity 0.2 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 0.7%** 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.

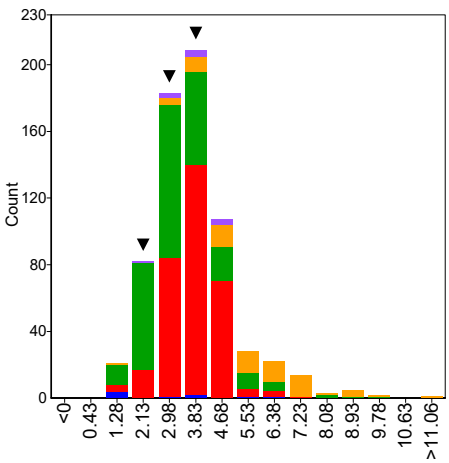
Number of Participants 626
Number of Responders 413 **Response Rate** 66 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	292	2	0	5
dAPTT	15	0	0	0
dPT	3	0	0	1
dRVVT	355	0	0	11
KCT	2	0	0	0
Other	0	0	0	0
PNP	2	0	0	0
PT	2	2	0	0
SCT	81	1	0	5

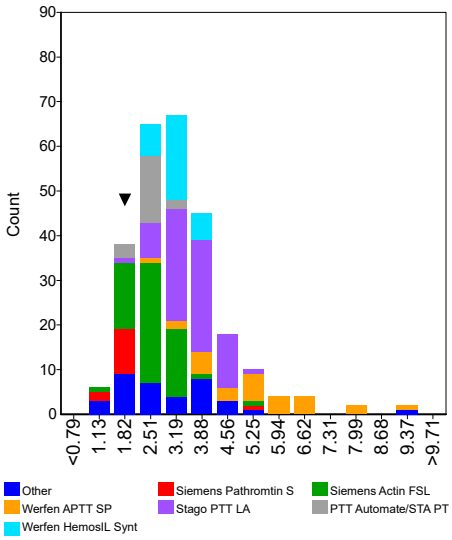
Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3		TS2	TS3			
APTT					Elevated				
dAPTT									
dPT									
dRVVT			Elevated			Elevated			
KCT									
Other									
PNP									
PT									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	264	3.12	33.1	1.00 - 9.37	2			1.90			
Hyphen-Biomed Cephen LS	7	4.12		2.81 - 4.59							
Siemens Actin FSL	60	2.52	22.6	1.01 - 5.47	2			1.90			
Siemens Pathromtin SL	13	1.81	17.2	1.36 - 5.10							
Stago PTT Automate/STA PTT	20	2.40	9.1	2.10 - 3.26							
Stago PTT LA	72	3.58	18.7	1.74 - 4.94							
Tcoag TriniClot Automated APTT	7	2.69		1.97 - 3.20							
Werfen APTT SP	28	5.25	28.3	2.60 - 9.37							
Werfen HemosIL SynthAsil	32	3.21	13.5	2.23 - 3.97							
Werfen MixCon	8	3.92		1.00 - 9.19							
dAPTT	11	3.72	24.3	2.08 - 5.02							
Stago PTT LA	8	3.69		2.87 - 4.64							
dRVVT	321	3.74	19.9	1.22 - 6.91	1					4.06	
dRVVT	321	3.74	19.9	1.22 - 6.91	2					3.02	
Roche Lupus S	7	3.82		2.32 - 6.20							
Siemens LA1 screen	150	3.75	19.8	1.22 - 5.23	1					4.06	
Siemens LA1 screen	150	3.75	19.8	1.22 - 5.23	2					3.02	
Stago DRVVT screen	50	3.45	13.5	2.39 - 6.01							
Werfen HemosIL dRVVT screen	99	3.89	19.4	1.62 - 6.91							
SCT	72	5.71	31.3	1.11 - 27.07							
Werfen SCT screen	71	5.66	30.7	1.11 - 9.38							

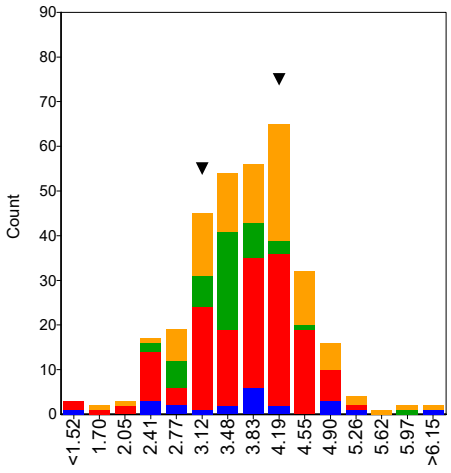
Assays



APTT



DRVVT

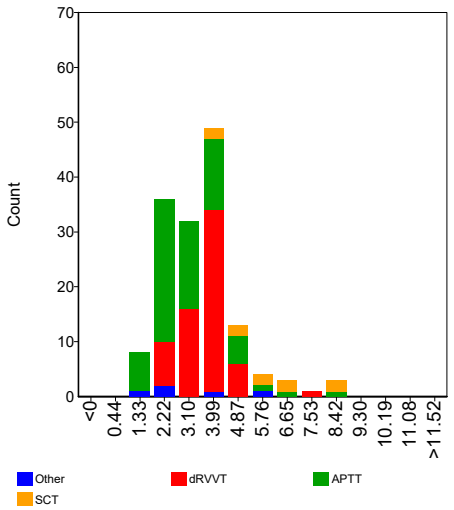


Lupus Anticoagulant

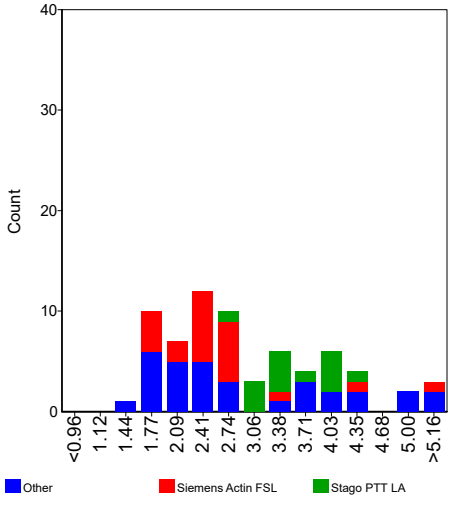
Mixing (screening)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	70	2.95	35.9	1.46 - 7.99							
Siemens Actin FSL	22	2.50	20.5	1.78 - 5.54							
Siemens Pathromtin SL	8	1.73		1.46 - 2.01							
Stago PTT Automate/STA PTT	6	2.28		2.13 - 2.75							
Stago PTT LA	14	3.53	15.3	2.78 - 4.19							
Werfen APTT SP	7	4.50		2.60 - 7.99							
dRVVT	64	3.70	22.4	2.01 - 7.24							
Siemens LA1 screen	37	3.74	23.1	2.26 - 5.23							
Stago DRVVT screen	7	3.77		2.44 - 4.21							
Werfen HemosIL dRVVT screen	15	3.81	19.1	2.90 - 7.24							
SCT	10	6.00	30.6	3.90 - 8.30							
Werfen SCT screen	10	6.00	30.6	3.90 - 8.30							

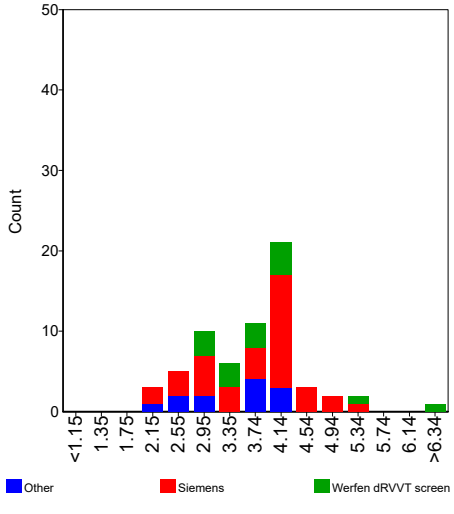
Assays



APTT



DRVVT



Comments

One participant selected the wrong unit; 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 mean of the reference interval (MRI) was reported as a ratio or reported a deviating value for their Normal Plasma. All these results were excluded in the statistical analysis.

The submitted results were a mix of measurements derived from ECAT plasma diluted with normal pooled plasma with various dilution factors. This resulted in most cases in a wide range of ratio's.

Almost all performed mixing screening tests (99.3%) 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).

Lupus Anticoagulant

Confirmation

Sample No 24.238

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. >2.0)

Prior Use Prior Use: None

Unit Ratio

Expiry Date 31-July-2026

Homogeneity 0.2 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 0.7%** 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 626

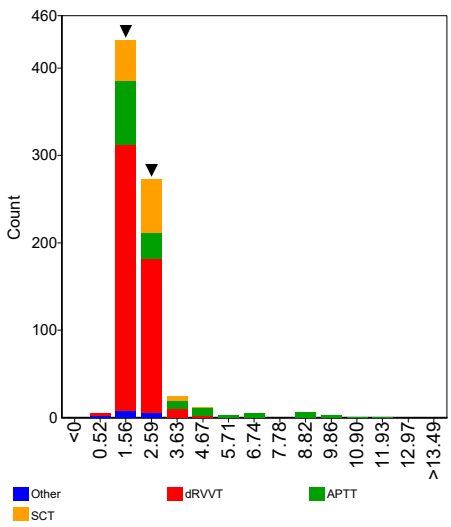
Number of Responders 518 **Response Rate** 83 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	168	5	0	27
dAPTT	9	0	0	1
dPT	5	0	0	2
dRVVT	502	13	0	45
Other	1	0	0	0
PNP	9	0	0	0
SCT	102	5	0	16

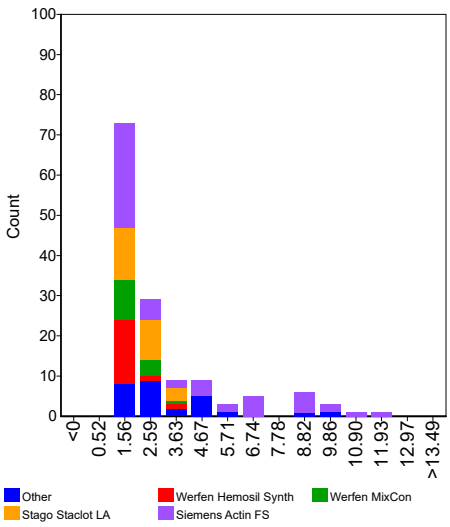
Assay	Your classification								
	Confirmation 1			Confirmation 2			Confirmation 3		
			TS3			TS3			
APTT									
dAPTT									
dPT									
dRVVT			Elevated			Elevated			
Other									
PNP									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	141	2.47	51.7	1.05 - 11.75							
Siemens Actin FS	53	3.80	85.1	1.09 - 11.75							
Stago Staclot LA	26	2.12	30.1	1.35 - 3.29							
Stago/Roche PTT LA	6	3.01		1.80 - 4.59							
Werfen Hemosil SynthAFax	18	1.88	12.1	1.59 - 3.24							
Werfen MixCon	15	2.00	32.8	1.05 - 3.96							
dAPTT	6	1.97		1.28 - 2.36							
dRVVT	496	1.88	24.3	0.90 - 4.88	1					2.20	
dRVVT	496	1.88	24.3	0.90 - 4.88	2					1.42	
Hyphen Biomed Hemoclot LA-C	8	3.49		1.54 - 4.29							
Roche Lupus C	7	2.16		1.24 - 2.47							
Siemens LA2 confirmation	205	1.96	23.1	1.00 - 3.10	1					2.20	
Siemens LA2 confirmation	205	1.96	23.1	1.00 - 3.10	2					1.42	
Stago DRVVT Confirm	78	1.94	21.1	1.16 - 2.93							
Technoclone LA Confirm	5	1.99		1.45 - 2.24							
Werfen HemosIL dRVVT confirm	183	1.73	23.6	0.90 - 4.88							
PNP	6	1.72		0.79 - 2.40							
SCT	113	2.12	28.2	1.18 - 4.74							
Werfen HemosIL SCT confirm	113	2.12	28.2	1.18 - 4.74							

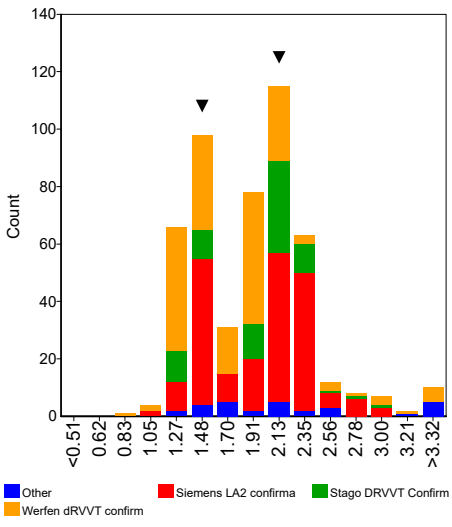
Assays



APTT



DRVVT

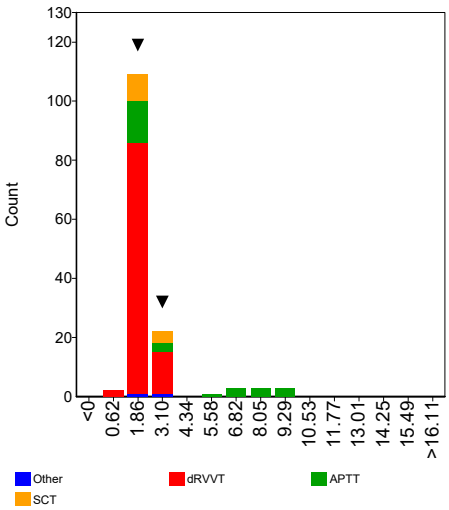


Lupus Anticoagulant

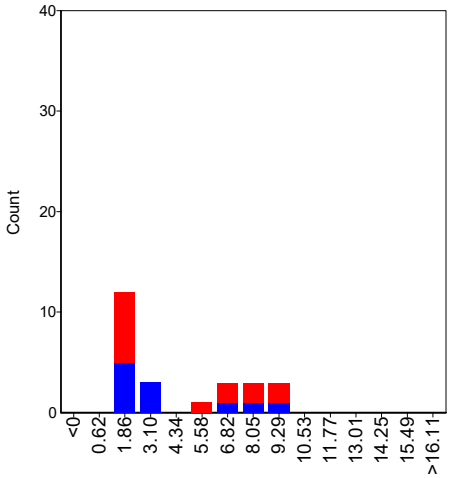
Confirmation

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	27	3.99	88.0	1.30 - 9.36							
Siemens Actin FS	14	4.55	84.6	1.30 - 9.36							
Stago Staclot LA	6	1.68		1.36 - 2.71							
dRVVT	101	2.02	22.2	1.16 - 3.60	1					2.54	
dRVVT	101	2.02	22.2	1.16 - 3.60	2					1.63	
Siemens LA2 confirmation	60	2.07	22.3	1.20 - 3.12	1					2.54	
Siemens LA2 confirmation	60	2.07	22.3	1.20 - 3.12	2					1.63	
Stago DRVVT Confirm	13	1.83	23.1	1.16 - 2.22							
Werfen HemosIL dRVVT confirm	22	1.90	20.1	1.28 - 3.60							
SCT	13	2.35	16.5	1.31 - 3.07							
Werfen HemosIL SCT confirm	13	2.35	16.5	1.31 - 3.07							

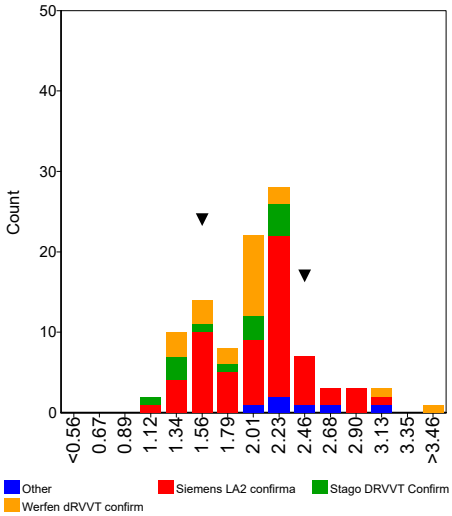
Assays



APTT



DRVVT



Comments

One participant selected the wrong unit, e.g. ratio while the result was likely to be in seconds. Several 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. One participant reported also a confirmation 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. Other participants (**labcode 143**, panel 1 and **labcode 351**, panel 2) reported deviating results. All these results were excluded from the statistical analysis.

The submitted results were a mix of measurements derived from undiluted ECAT plasma and ECAT plasma diluted with normal pooled plasma. This resulted in most cases in a wide range of ratio's.

Almost all performed confirmation tests (97.2%) 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).

Lupus Anticoagulant

Mixing (confirm)

Sample No 24.238

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. >2.0)

Prior Use Prior Use: None

Unit Ratio

Expiry Date 31-July-2026

Homogeneity 0.2 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 0.7%** 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 626

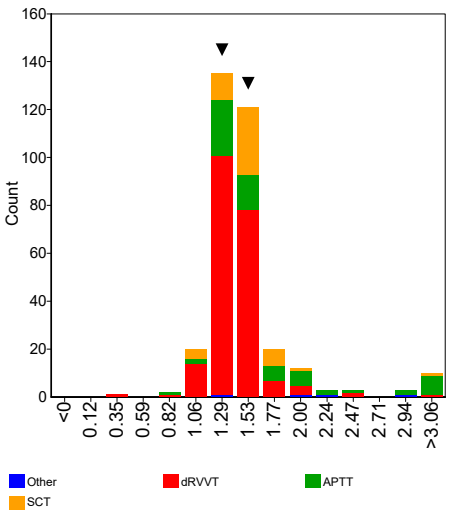
Number of Responders 229 **Response Rate** 37 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	63	6	0	4
dAPTT	7	0	0	1
dPT	1	0	0	0
dRVVT	187	25	0	16
PNP	2	0	0	0
SCT	45	5	0	7

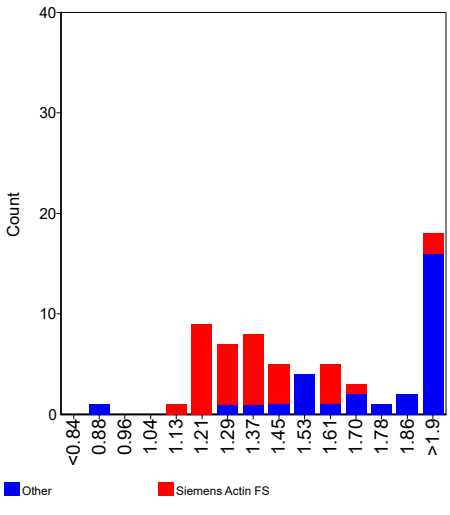
Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3			TS3			
APTT									
dAPTT									
dPT									
dRVVT			Elevated			Not elevated			
PNP									
SCT									

Ratio Normal Plasma	**n**	**assigned value**	**CV (%)**	**Range**	**Test System**	**Panel 1**	**Z-score**	**Panel 2**	**Z-score**	**Panel 3**	**Z-score**
APTT	66	1.65	28.6	0.90 - 6.47							
Siemens Actin FS	34	1.37	12.9	1.14 - 4.83							
Werfen Hemosil SynthAFax	6	1.89		1.52 - 2.33							
Werfen MixCon	7	2.08		1.52 - 5.70							
dRVVT	208	1.38	10.4	0.42 - 4.16	1					1.42	
dRVVT	208	1.38	10.4	0.42 - 4.16	2					1.22	
Siemens LA2 confirmation	104	1.41	10.3	0.97 - 4.16	1					1.42	
Siemens LA2 confirmation	104	1.41	10.3	0.97 - 4.16	2					1.22	
Stago DRVVT Confirm	22	1.38	10.1	1.17 - 2.05							
Werfen HemosIL dRVVT confirm	71	1.34	10.0	0.42 - 2.03							
SCT	52	1.47	12.5	1.10 - 4.46							
Werfen HemosIL SCT confirm	52	1.47	12.5	1.10 - 4.46							

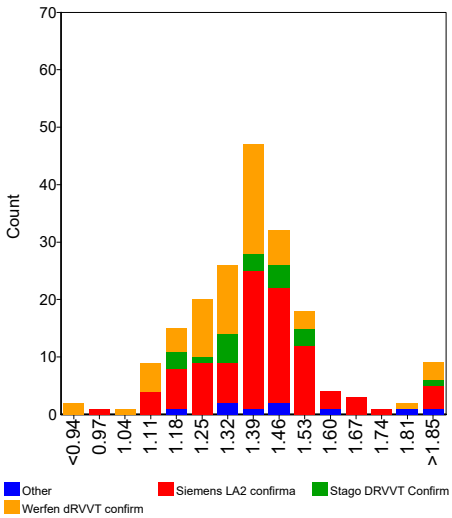
Assays



APTT



DRVVT

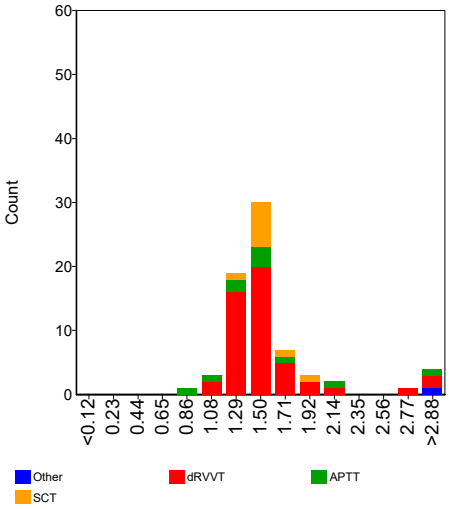


Lupus Anticoagulant

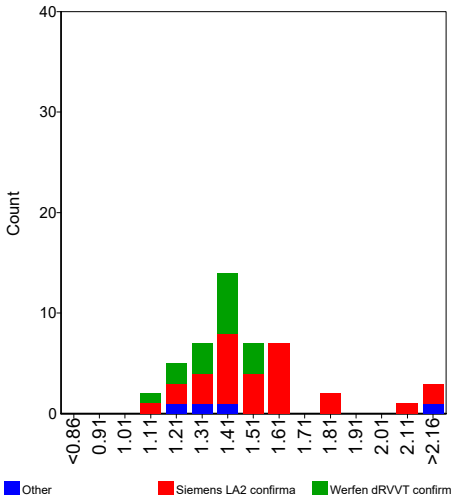
Mixing (confirm)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	10	1.50	30.7	0.82 - 2.97							
Siemens Actin FS	6	1.41		1.10 - 2.97							
dRVVT	49	1.45	13.5	1.14 - 15.30							
Siemens LA2 confirmation	29	1.51	14.3	1.16 - 15.30							
Werfen HemosIL dRVVT confirm	16	1.37	9.7	1.14 - 1.96							
SCT	10	1.51	7.4	1.39 - 2.00							
Werfen HemosIL SCT confirm	10	1.51	7.4	1.39 - 2.00							

Assays



DRVVT



Comments

Several participants reported the result for the ECAT plasma in seconds while the result for the reference plasma (derived from the Normal Plasma or mean of the reference interval (MRI)) was reported as a ratio.

The submitted results were a mix of measurements derived from ECAT plasma diluted with normal pooled plasma with various dilution factors. This resulted in most cases in a wide range of ratio's.

As expected, the majority of performed mixing confirmation tests (89.4%) were classified as elevated. For a strong positive Lupus Anticoagulant plasma, it is expected that the test result still is not normalised in the mixing confirm test.

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

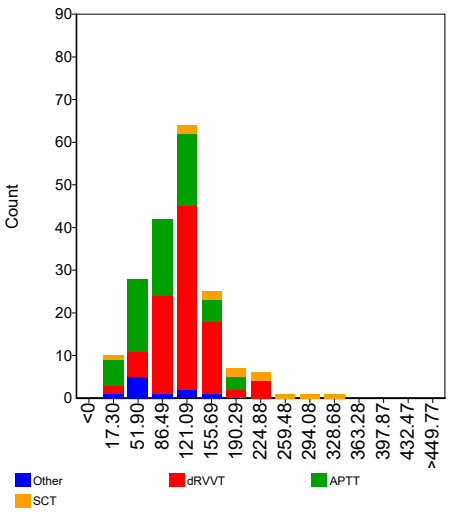
Lupus Anticoagulant

Interpretation

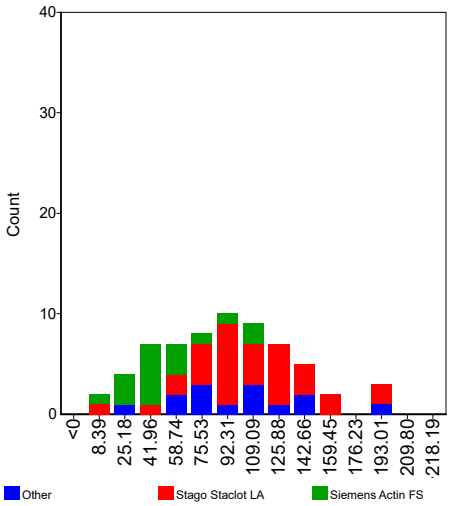
Delta Seconds

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	66	89.34	51.6	8.60 - 201.30							
Siemens Actin FS	17	49.73	50.6	16.40 - 116.00							
Stago Staclot LA	33	106.71	34.8	8.60 - 201.30							
dRVVT	97	117.17	28.1	3.31 - 222.00							
Siemens LA2 confirmation	54	119.24	26.3	3.31 - 222.00							
Stago DRVVT Confirm	9	100.00		5.60 - 167.30							
Werfen HemosIL dRVVT confirm	29	120.76	25.9	39.30 - 210.80							
PNP	6	47.35		17.77 - 67.20							
SCT	12	194.37	43.8	13.20 - 328.00							
Werfen HemosIL SCT confirm	12	194.37	43.8	13.20 - 328.00							

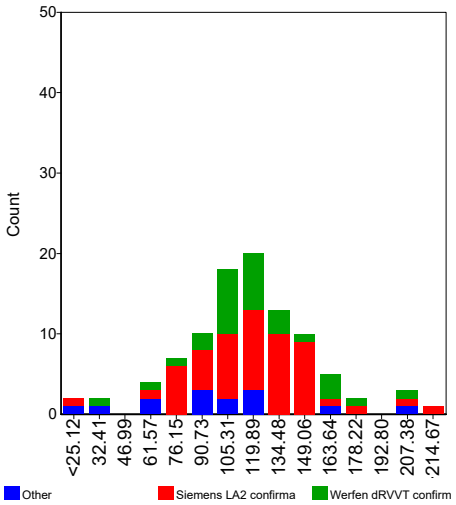
Assays



APTT



DRVVT



Comments

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

The submitted results were a mix of measurements derived from undiluted ECAT plasma and ECAT plasma diluted with normal pooled plasma. This resulted in most cases in a wide range of delta seconds.

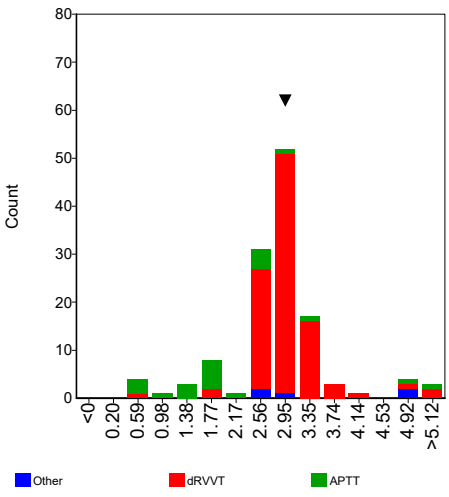
Lupus Anticoagulant

Interpretation

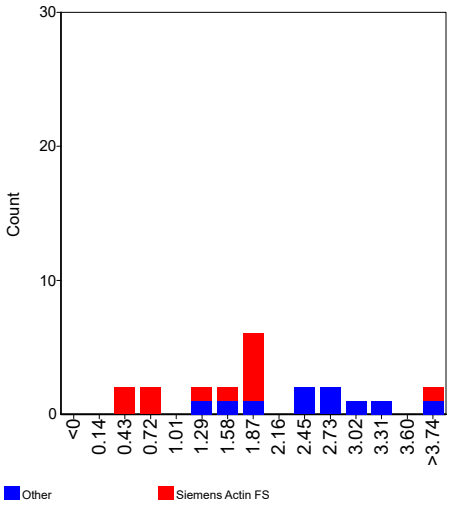
Ratio Screen/Confirmation - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	22	1.98	52.7	0.51 - 14.50							
Siemens Actin FS	12	1.46	51.9	0.51 - 5.10							
dRVVT	101	2.92	11.2	0.67 - 7.92	1					2.85	
dRVVT	101	2.92	11.2	0.67 - 7.92	2					2.94	
Siemens LA2 confirmation	73	2.87	9.1	1.81 - 7.92	1					2.85	
Siemens LA2 confirmation	73	2.87	9.1	1.81 - 7.92	2					2.94	
Stago DRVVT Confirm	7	2.65		2.48 - 5.73							
Werfen HemosIL dRVVT confirm	15	3.37	12.9	0.67 - 4.87							
SCT	5	3.12		2.40 - 5.04							
Werfen HemosIL SCT confirm	5	3.12		2.40 - 5.04							

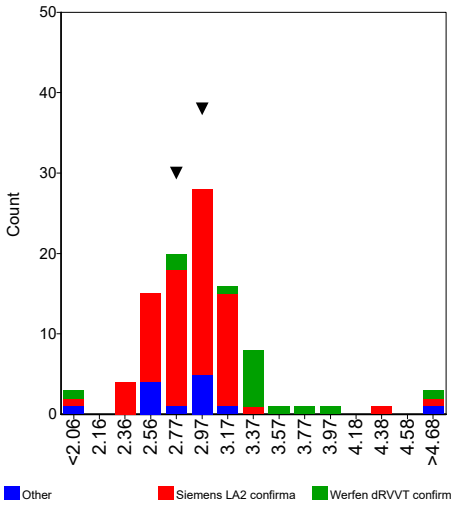
Assays



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. >2.0). For the assay type "APTT" the LA ratio is slightly lower compared to the other assay types.

The submitted ratio screen / confirmation was a mix of measurements derived from undiluted ECAT plasma and ECAT plasma diluted with normal pooled plasma. This resulted in most cases in a wide range of ratio's.

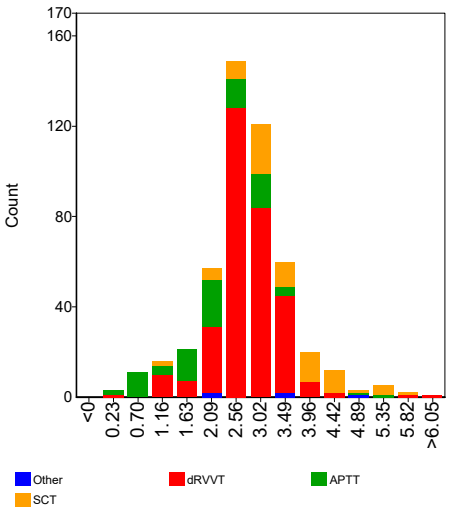
Lupus Anticoagulant

Interpretation

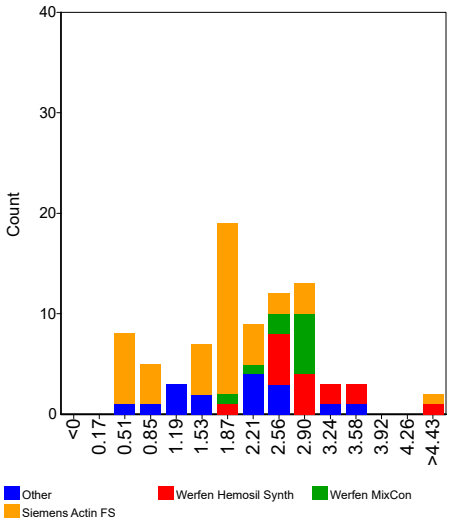
Ratio Screen/Confirmation - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	86	2.11	42.7	0.38 - 5.54							
Siemens Actin FS	43	1.66	47.0	0.38 - 5.54							
Werfen Hemosil SynthAFax	15	2.93	17.1	1.93 - 4.95							
Werfen MixCon	10	2.75	11.1	2.01 - 3.03							
dRVVT	313	2.76	17.3	0.42 - 6.82							
Hyphen Biomed Hemoclot LA-C	7	2.96		1.26 - 3.54							
Roche Lupus C	6	2.99		2.72 - 4.23							
Siemens LA2 confirmation	107	2.64	9.2	0.42 - 3.70							
Stago DRVVT Confirm	59	2.46	11.0	1.05 - 2.98							
Werfen HemosIL dRVVT confirm	128	3.06	17.2	1.24 - 6.82							
SCT	77	3.41	25.9	1.19 - 5.61							
Werfen HemosIL SCT confirm	77	3.41	25.9	1.19 - 5.61							

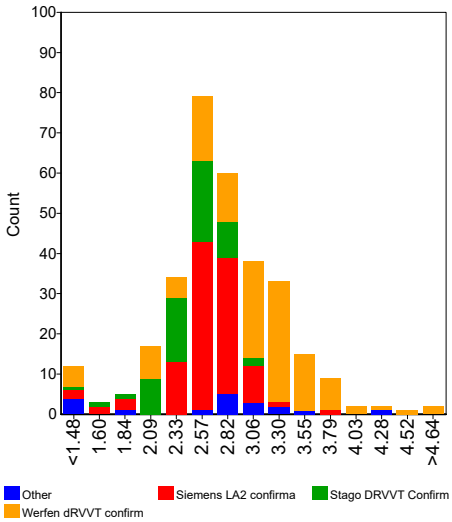
Assays



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. >2.0). For the assay type "APTT" and method type "Siemens Actin FS" the LA ratio is slightly lower compared to the other assay types and other methods within the assay type "APTT". The observed results are comparable to the observations seen for the parameter: "Ratio Screen/Confirmation - Standard".

The submitted ratio screen / confirmation was a mix of measurements derived from undiluted ECAT plasma and ECAT plasma diluted with normal pooled plasma. This resulted in most cases in a wide range of ratio's.

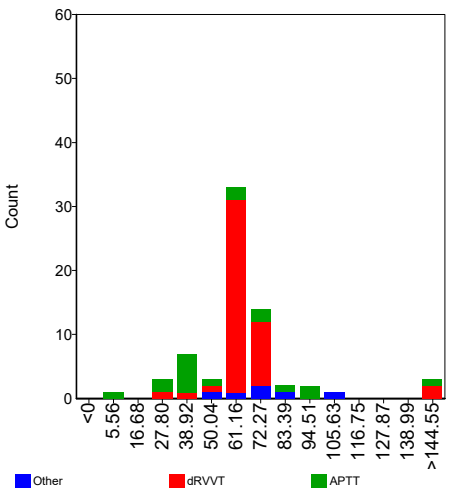
Lupus Anticoagulant

Interpretation

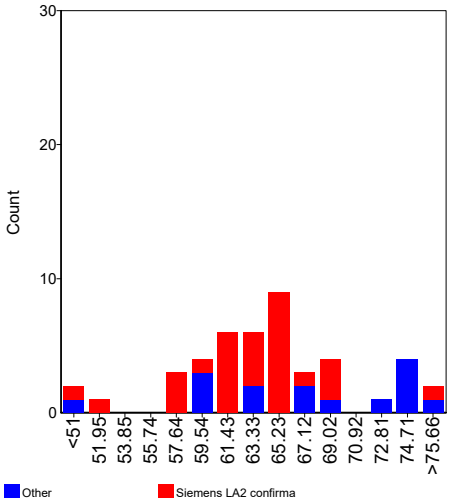
Percentage Correction - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	18	54.92	54.4	11.00 - 264.00							
Siemens Actin FS	9	37.80		11.00 - 94.00							
dRVVT	45	64.45	8.8	33.00 - 256.00							
Siemens LA2 confirmation	30	63.33	6.5	35.73 - 219.00							
Stago DRVVT Confirm	7	62.80		59.20 - 68.30							
Werfen HemosIL dRVVT confirm	6	74.45		66.70 - 256.00							

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 in the statistical evaluation. Don't forget to select the type of correction in the next survey.

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

The following participant reported a deviating result which was excluded in the statistical evaluation:
1480 : 2.35%

The submitted results were a mix of measurements derived from undiluted ECAT plasma and ECAT plasma diluted with normal pooled plasma. This resulted in most cases in a wide range of percentage corrections.

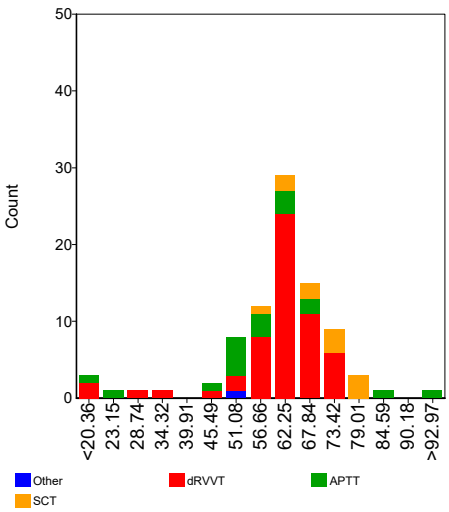
Lupus Anticoagulant

Interpretation

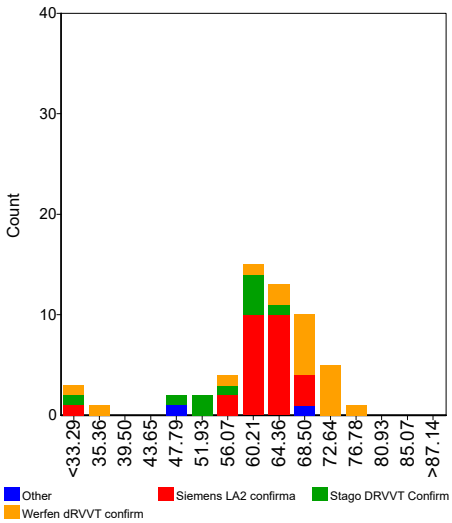
Percentage Correction - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	18	56.32	21.3	8.00 - 104.25							
Siemens Actin FS	9	53.80		8.00 - 104.25							
dRVVT	56	62.60	10.8	3.65 - 76.01							
Siemens LA2 confirmation	26	62.05	5.0	29.80 - 67.90							
Stago DRVVT Confirm	10	55.51	13.3	4.60 - 64.09							
Werfen HemosIL dRVVT confirm	18	67.88	9.5	3.65 - 76.01							
SCT	11	70.74	10.5	57.20 - 80.20							
Werfen HemosIL SCT confirm	11	70.74	10.5	57.20 - 80.20							

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 in the statistical evaluation. Don't forget to select the type of correction in the next survey.

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

The following participants reported deviating results which were excluded in the statistical evaluation:

163 : 1%
1327: 0%
1604: 0.34%
9119: -1.8%
9907339: 0.1%

The submitted results were a mix of measurements derived from undiluted ECAT plasma and ECAT plasma diluted with normal pooled plasma. This resulted in most cases in a wide range of percentage corrections.

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	0	13	0	11	1			
					2			
					3			
Screen and mixing test	5	56	1	13	1			
					2			
					3			
Screen and confirm test	2	326	9	27	1			
					2			
					3			
Screen, mixing and confirm test	6	251	8	11	1			LA detected
					2			LA detected
					3			
Screen, confirm, mixing test	3	177	2	10	1			
					2			
					3			
Mixing - confirmation	0	46	1	4	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			
451	5	9	21	LA detected	LA detected	

Comments

The sample used in this survey was plasma derived from a patient diagnosed with Lupus Anticoagulant (LA Ratio > approx. 2.0). In addition, based on the information known from this plasma sample, this patient was also treated with a vitamine K antagonist and not with a DOAC.

The challenge in this plasma sample with strongly prolonged clotting time was, how to ultimately distinguish between coagulation deficiency and LA inhibitors. By additionally diluting the plasma more than normally done, clarity could be obtained. Most participants observed both prolonged screen and confirm tests (with and without mixing with normal pooled plasma), indicating the presence of a strong lupus anticoagulant. Also, multiple participants could not measure the screening test in undiluted plasma, due to the presence of a strong lupus anticoagulant.

Many participants experienced the diagnostics of this patient plasma as a challenge, resulting in a variety of test approaches with a diversity in used dilution factors and as such in a wide range of reported test results. Therefore, no performance assessment was performed.

In total 451 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 97% classified the sample as positive. Two percent classified the sample as equivocal. Thus, the vast majority of the participants correctly classified this sample as positive. A minority of the participants classified this sample as negative, this could be due to failed coagulation tests. This failed coagulation test could be caused by the presence of high LA inhibitors titers.

Several participants stated 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 patient was suspicious of treatment with a vitamine K antagonist, because of an increased INR value.

Lupus Anticoagulant

AntiCardiolipin Antibodies IgG

Sample No 24.238

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. >2.0)

Prior Use Prior Use: None

Unit GPL, U/mL, µg/mL, CU/mL

Expiry Date 31-July-2026

Homogeneity 0.2 %

Homogeneity Parameter LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 0.7%** 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 626

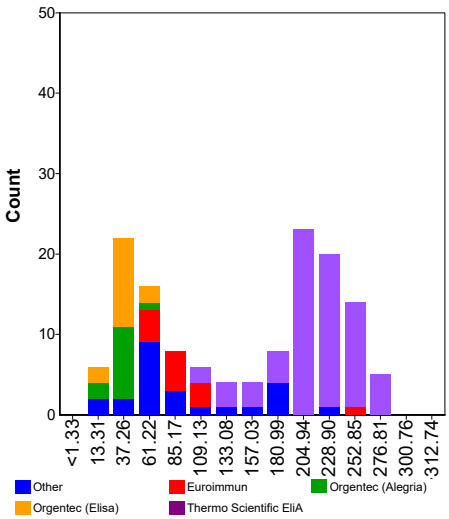
Number of Responders 227

Response Rate 36 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	0	0	12	45	170	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	136	147.1	66.1	13.7 - 285.0						
Aeskulisa Diagnotic GmbH	6	56.3		17.0 - 143.4						
Euroimmun	13	87.1	26.2	60.8 - 248.0						
Orgentec (Alegria)	12	28.5	22.4	15.4 - 52.0						
Orgentec (Elisa)	15	37.6	32.1	13.7 - 60.7						
Thermo Scientific EliA	72	219.4	14.2	108.0 - 285.0						
Werfen INOVA Quanta Lite	8	69.6		61.0 - 78.1						
CU/mL	81	192.7	12.5	106.1 - 236.7						
Werfen Acustar / INOVA Quanta Flash	80	193.3	12.2	106.1 - 236.7						

GPL, U/mL, µg/mL



Comments
A positive classification has been observed by all participants, most paticipants (75%)classificated the sample as "High Positive".

Please be aware of the selection of the correct unit for the method group “Werfen Acustar / INOVA Quanta Flash". Since there is an order of magnitude difference between the results of the method "IL Acustar / INOVA Quanta Flash" from the other methods, it is expressed in the report as CU/mL instead of U/mL. For all other methods the unit U/mL should be seleceted.

The following participants reported deviating results which were excluded in the statistical evaluation:
176 : 2.6 CU/mL
907268: 340 U/mL

The result of 1 participant **(labcode 1353)** was excluded because they reported the result with an incorrect unit (ratio instead U/mL).

Because it is unknown whether participants have used undiluted or diluted ECAT plasma to measure Anti-Cardiolipin Antibodies IgG, no performance assessment was performed.

Lupus Anticoagulant

AntiCardiolipin Antibodies IgM

Sample No 24.238

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. >2.0)

Prior Use Prior Use: None

Unit MPL, U/mL, µg/mL, CU/mL

Expiry Date 31-July-2026

Homogeneity 0.2 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 0.7%** 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.

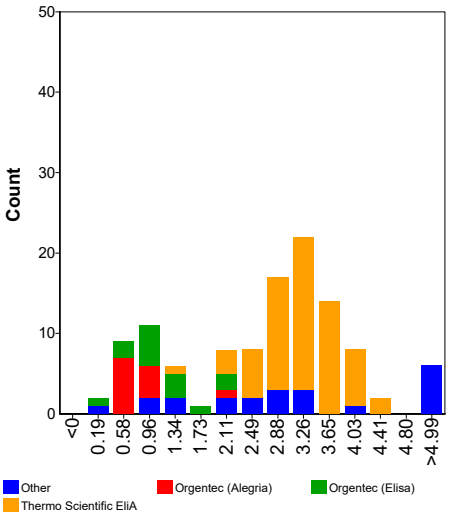
Number of Participants 626

Number of Responders 218 **Response Rate** 35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	218	0	1	0	0	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/mL, µg/mL, GPL/MPL	114	2.7	50.8	0.2 - 10.0						
Aeskulisa Diagnotic GmbH	6	3.0		1.2 - 10.0						
Orgentec (Alegria)	12	0.8	21.1	0.5 - 2.2						
Orgentec (Elisa)	14	1.1	48.5	0.2 - 2.1						
Thermo Scientific EliA	66	3.3	17.7	1.5 - 4.3						
CU/mL	77	2.6	15.3	1.8 - 6.1						
Werfen Acustar / INOVA Quanta Flash	77	2.6	15.3	1.8 - 6.1						

MPL, U/mL, µg/mL



Comments
Most of the participants reported a negative classification.

Please be aware of the selection of the correct unit for the method group “Werfen Acustar / INOVA Quanta Flash". Since there is an order of magnitude difference between the results of the method "IL Acustar / INOVA Quanta Flash" from the other methods, it is expressed in the report as CU/mL instead of U/mL. For all other methods the unit U/mL should be seleceted.

The following participant reported a deviating result which was excluded in the statistical evaluation:
176 : 201.8 CU/mL

The result of 1 participant **(labcode 1353)** was excluded because they reported the result with an incorrect unit (ratio instead U/mL).

Because it is unknown whether participants have used undiluted or diluted ECAT plasma to measure Anti-Cardiolipin Antibodies IgM, no performance assessment was performed.

Lupus Anticoagulant

ß2-Glycoprotein I Antibodies IgG

Sample No 24.238

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. >2.0)

Prior Use Prior Use: None

Unit U, U/mL, µg/mL, CU/mL

Expiry Date 31-July-2026

Homogeneity 0.2 %

Homogeneity Parameter LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 0.7%** 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 626

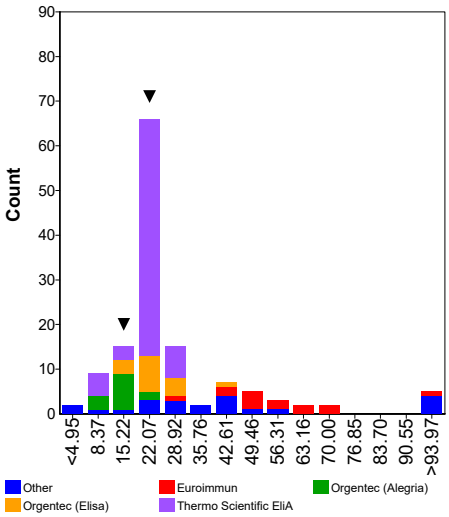
Number of Responders 220

Response Rate 35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	6	6	44	55	111	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	133	24.6	36.7	2.0 - 467.6	18.5		20.6			
Aeskulisa Diagnotic GmbH	6	17.8		2.0 - 57.5						
Euroimmun	14	55.3	23.3	26.6 - 421.3						
Orgentec (Alegria)	13	16.1	23.0	8.8 - 19.9						
Orgentec (Elisa)	16	23.5	23.1	15.1 - 41.4	18.5		20.6			
Thermo Scientific EliA	68	22.6	12.1	8.1 - 30.0						
Werfen INOVA Quanta Lite	8	40.9		25.0 - 50.7						
CU/mL	81	1069.4	14.1	503.0 - 1470.9						
Werfen Acustar / INOVA Quanta Flash	79	1071.2	13.8	503.0 - 1470.9						

U, U/mL, µg/mL



Comments

A positive classification has been observed by the majority of participants (95%), half of the paticipants classificated the sample as "High Positive".

Please be aware of the selection of the correct unit for the method group “Werfen Acustar / INOVA Quanta Flash". Since there is an order of magnitude difference between the results of the method "IL Acustar / INOVA Quanta Flash" from the other methods, it is expressed in the report as CU/mL instead of U/mL.

The following participants reported deviating results which were excluded in the statistical evaluation:

174 : 11 CU/mL

310 : 2.8 U/mL

Because it is unknown whether participants have used undiluted or diluted ECAT plasma to measure Anti-beta2-Glycoprotein I Antibodies IgG, no performance assessment was performed.

Lupus Anticoagulant

ß2-Glycoprotein I Antibodies IgM

Sample No	24.238
Sample Details	Plasma positive for Lupus Anticoagulant (LA Ratio approx. >2.0)
Prior Use	Prior Use: None
Unit	U, U/mL, µg/mL, CU/mL
Expiry Date	31-July-2026
Homogeneity	0.2 %
Homogeneity Parameter	LA ratio

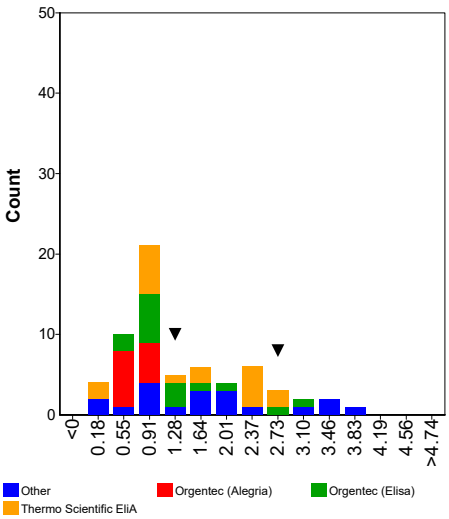
For any method used for the measurement of this parameter with a **CV ≤ 0.7%** the criterion for homogeneity could not be met and the Z-scores should be interpreted with caution. See for further details the paragraph on the statistical evaluation in the Survey Manual.

Number of Participants	626		
Number of Responders	202	**Response Rate**	32 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	203	0	1	0	0	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	64	1.3	68.5	0.0 - 3.9	1.2		2.6			
Aeskulisa Diagnotic GmbH	6	2.0		1.0 - 3.4						
Euroimmun	5	2.0		1.0 - 3.9						
Orgentec (Alegria)	12	0.7	14.1	0.4 - 0.8						
Orgentec (Elisa)	15	1.2	45.6	0.6 - 3.0	1.2		2.6			
Thermo Scientific EliA	18	1.5	68.7	0.0 - 2.9						
CU/mL	45	1.1	10.8	0.8 - 2.4						
Werfen Acustar / INOVA Quanta Flash	45	1.1	10.8	0.8 - 2.4						

U, U/mL, µg/mL



Comments
Most of the participants reported a negative classification.

Please be aware of the selection of the correct unit for the method group “Werfen Acustar / INOVA Quanta Flash". Since there is an order of magnitude difference between the results of the method "IL Acustar / INOVA Quanta Flash" from the other methods, it is expressed in the report as CU/mL instead of U/mL.

The following participant reported a deviating result which was excluded in the statistical evaluation:
9907261 : 26.8 U/mL

Because it is unknown whether participants have used undiluted or diluted ECAT plasma to measure Anti-beta2-Glycoprotein I Antibodies IgM, no performance assessment was performed.