ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2024-L2
Lupus Anticoagulant
Labcode 1492

Date of Issue : 09-July-2024

Survey : 2024-L2

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

Complaints
Any complaints regarding this survey report should be reported to the ECAT before **September 19th, 2024**. Complaints received after this date will not be taken into consideration.

Exclusion of results
Results < [value] or > [value] are excluded in the statistical analysis. When other results are excluded in 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.

Webinar
More information about how to report ECAT survey results and explanation of survey report with respect to the Lupus Anticoagulant diagnostics can be found in the following webinar: https://vimeo.com/user158111672/lupus2023

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 24.125

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.8)

Prior Use Prior Use: None

Unit Ratio

Expiry Date 31-January-2027

Homogeneity 0.4 %

Homogeneity Parameter LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 1.3%** 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 623

Number of Responders 560

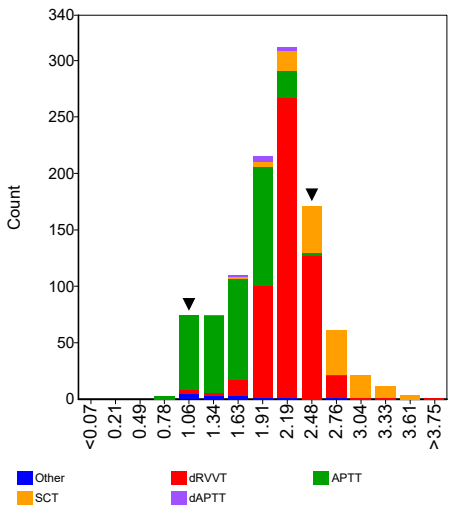
Response Rate 90 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	343	64	0	12
dAPTT	11	1	0	0
dPT	5	3	0	0
dRVVT	583	2	0	20
KCT	5	0	0	0
Other	2	0	0	0
PNP	1	0	0	0
PT	1	5	0	0
SCT	138	0	0	9

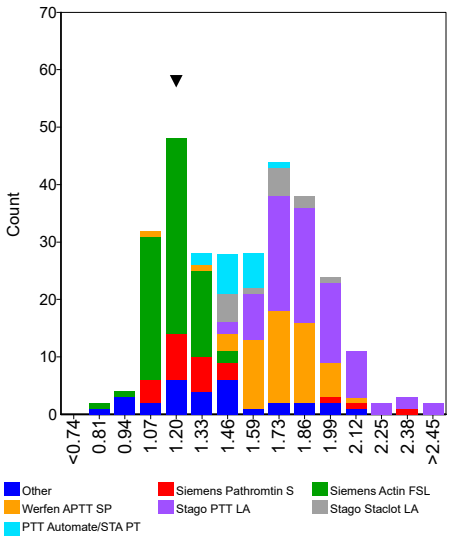
Assay	Your classification								
	Screening 1			Screening 2			Screening 3		
		TS2	TS3						
APTT		Not elevated							
dAPTT									
dPT									
dRVVT			Elevated						
KCT									
Other									
PNP									
PT									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	361	1.60	23.3	0.80 - 2.69	1			1.17	-1.16		
Hyphen-Biomed Cephen LS	12	1.78	5.4	1.55 - 2.13							
Siemens Actin FS	7	1.00		0.80 - 1.17							
Siemens Actin FSL	78	1.19	8.2	0.86 - 1.45	1			1.17	-0.17		
Siemens Pathromtin SL	24	1.28	14.0	1.02 - 2.32							
Stago PTT Automate/STA PTT	16	1.52	4.8	1.38 - 1.74							
Stago PTT LA	78	1.86	10.6	1.45 - 2.69							
Stago Staclot LA	14	1.65	10.9	1.44 - 1.94							
Tcoag TriniClot Automated APTT	7	1.45		1.34 - 1.48							
Werfen APTT SP	54	1.74	9.2	1.12 - 2.08							
Werfen HemosIL SynthAsil	41	1.96	6.1	1.51 - 2.13							
Werfen MixCon	14	1.63	3.5	1.39 - 1.80							
dAPTT	10	1.86	11.1	1.45 - 2.10							
Stago PTT LA	8	1.81		1.65 - 2.06							
dPT	5	1.91		1.28 - 2.85							
dRVVT	535	2.22	10.1	1.00 - 6.17	1					2.36	0.63
Hyphen Biomed Hemoclot LA-S	9	2.12		1.85 - 2.32							
Precision Biologic LA check	7	1.87		1.78 - 2.48							
Roche Lupus S	7	1.88		1.75 - 2.13							
Siemens LA1 screen	219	2.28	9.7	1.00 - 3.47	1					2.36	0.36
Stago DRVVT screen	75	2.14	9.6	1.63 - 2.90							
Technoclone LA Screen	5	2.32		2.14 - 2.44							
Werfen HemosIL dRVVT screen	210	2.21	8.8	1.49 - 6.17							
PT	5	1.03		0.99 - 1.05							
SCT	138	2.66	13.7	1.52 - 3.73							
Werfen SCT screen	136	2.66	13.5	1.52 - 3.73							

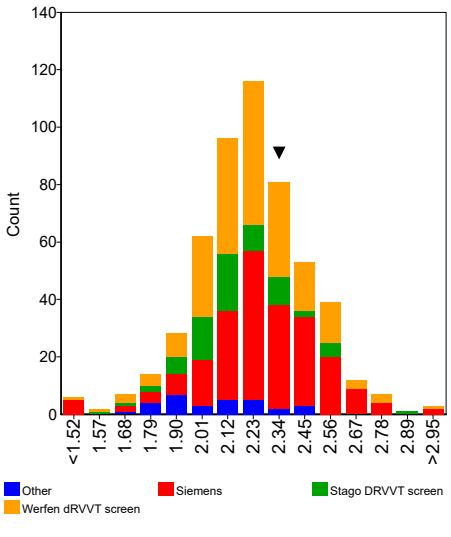
Assays



APTT



DRVVT

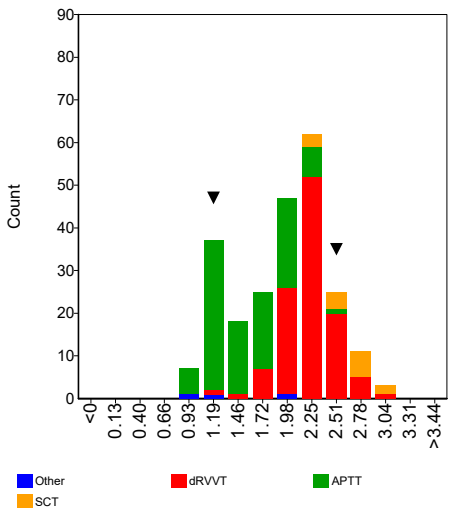


Lupus Anticoagulant

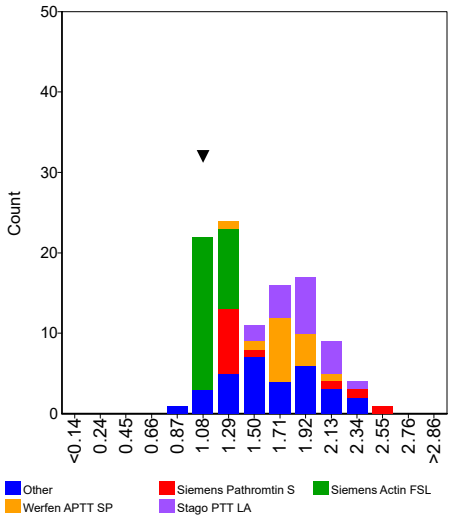
Screening

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	105	1.54	27.0	0.96 - 2.52	1			1.11	-1.04		
Hyphen-Biomed Cephen LS	5	1.58		1.54 - 2.04							
Siemens Actin FSL	29	1.15	7.5	0.99 - 1.36	1			1.11	-0.50		
Siemens Pathromtin SL	12	1.50	30.2	1.25 - 2.52							
Stago PTT Automate/STA PTT	5	1.48		1.38 - 1.68							
Stago PTT LA	18	1.89	11.6	1.42 - 2.31							
Werfen APTT SP	15	1.74	12.0	1.30 - 2.06							
Werfen HemosIL SynthAsil	8	1.90		1.74 - 2.24							
dRVVT	112	2.23	10.4	1.16 - 2.94	1					2.44	0.90
Siemens LA1 screen	71	2.28	10.3	1.38 - 2.94	1					2.44	0.69
Stago DRVVT screen	11	2.10	15.2	1.62 - 2.43							
Werfen HemosIL dRVVT screen	23	2.19	8.6	1.16 - 2.48							
SCT	15	2.62	10.5	2.15 - 2.95							
Werfen SCT screen	15	2.62	10.5	2.15 - 2.95							

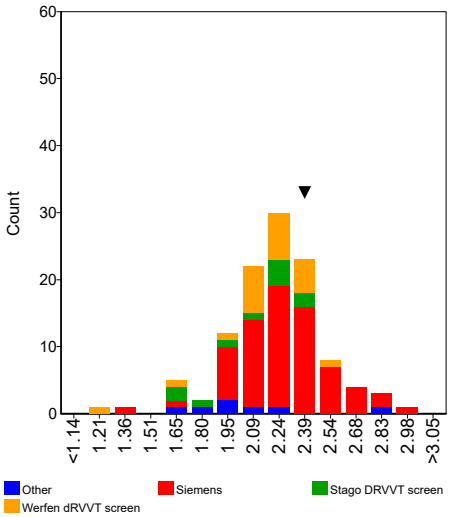
Assays



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 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 a negative value for their reference plasma. Therefore all these results were excluded in the statistical analysis.

The vast majority of performed screening tests (> 94%) 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). A few participants noted that they reported their result after DOAC remove treatment and one participant treated the sample with both hepzyme and DOAC remove before measurement.

Lupus Anticoagulant

Mixing (screening)

Sample No 24.125

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.8)

Prior Use Prior Use: None

Unit Ratio

Expiry Date 31-January-2027

Homogeneity 0.4 %

Homogeneity Parameter LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 1.3%** 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 623

Number of Responders 403

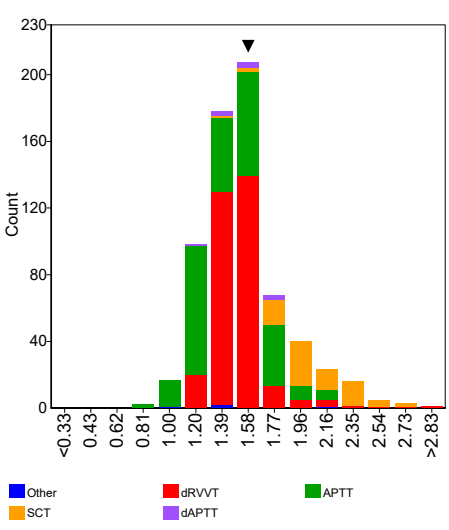
Response Rate 65 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	220	53	0	8
dAPTT	12	0	0	0
dPT	2	0	0	0
dRVVT	323	8	0	8
KCT	1	0	0	0
Other	2	0	0	0
PNP	1	0	0	0
PT	0	1	0	0
SCT	76	0	0	4

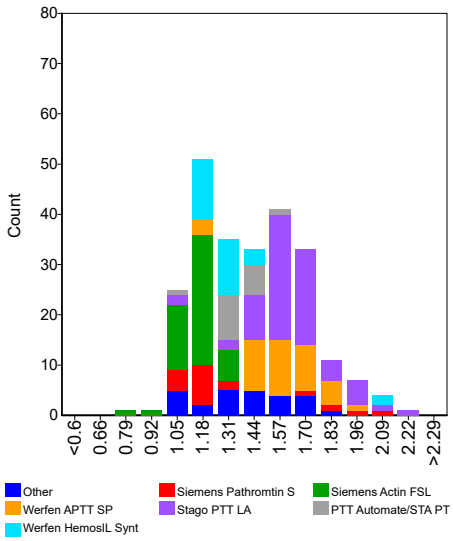
Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Elevated						
KCT									
Other									
PNP									
PT									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	253	1.43	19.3	0.85 - 2.17							
Hyphen-Biomed Cephen LS	10	1.65	12.9	1.42 - 2.16							
Siemens Actin FSL	47	1.16	6.1	0.85 - 1.33							
Siemens Pathromtin SL	18	1.26	17.4	1.04 - 2.14							
Stago PTT Automate/STA PTT	17	1.36	6.6	1.00 - 1.64							
Stago PTT LA	68	1.62	9.4	1.01 - 2.17							
Tcoag TriniClot Automated APTT	7	1.32		1.25 - 1.55							
Werfen APTT SP	39	1.59	10.4	1.17 - 1.95							
Werfen HemosIL SynthAsil	28	1.27	6.7	1.16 - 2.11							
Werfen MixCon	6	1.72		1.03 - 1.80							
dAPTT	10	1.58	14.2	1.23 - 1.85							
Stago PTT LA	7	1.66		1.47 - 1.85							
dRVVT	313	1.49	8.8	1.11 - 3.79	1					1.57	0.59
Roche Lupus S	5	1.31		1.11 - 1.38							
Siemens LA1 screen	154	1.48	9.1	1.17 - 2.79	1					1.57	0.65
Stago DRVVT screen	41	1.46	7.1	1.25 - 1.86							
Werfen HemosIL dRVVT screen	102	1.53	7.7	1.24 - 3.79							
SCT	78	2.06	12.4	1.36 - 2.67							
Werfen SCT screen	77	2.06	12.2	1.36 - 2.67							

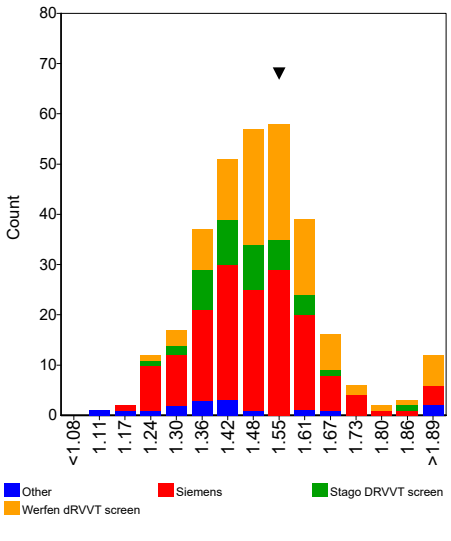
Assays



APTT



DRVVT

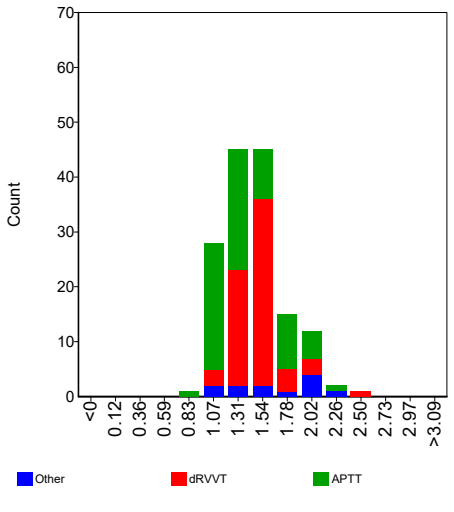


Lupus Anticoagulant

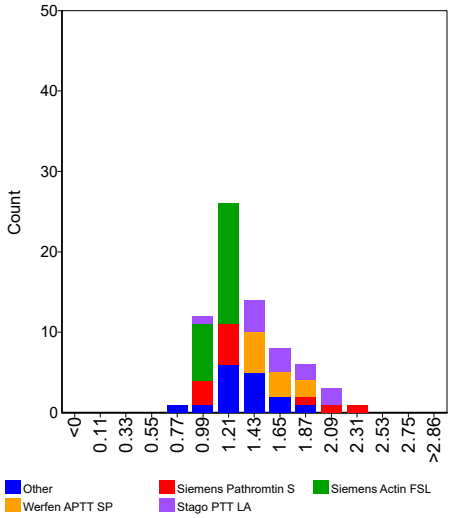
Mixing (screening)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	71	1.35	22.6	0.88 - 2.32							
Siemens Actin FSL	22	1.14	6.6	1.00 - 1.31							
Siemens Pathromtin SL	11	1.41	34.6	1.04 - 2.32							
Stago PTT Automate/STA PTT	5	1.30		1.23 - 1.61							
Stago PTT LA	12	1.63	18.6	1.00 - 2.04							
Werfen APTT SP	10	1.61	11.1	1.43 - 1.79							
dRVVT	66	1.50	11.6	0.95 - 2.57							
Siemens LA1 screen	41	1.49	11.3	1.06 - 2.06							
Stago DRVVT screen	7	1.57		1.35 - 1.63							
Werfen HemosIL dRVVT screen	13	1.59	14.4	0.95 - 2.57							
SCT	6	1.97		1.69 - 2.23							
Werfen SCT screen	6	1.97		1.69 - 2.23							

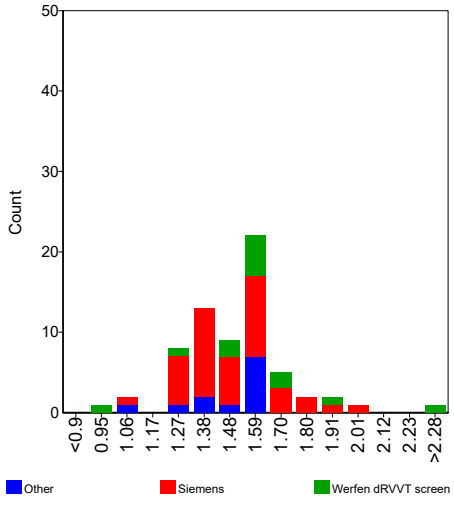
Assays



APTT



DRVVT



Comments

Two 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 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 in the statistical analysis.

The majority of performed mixing tests (> 91%) 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). A few participants noted that they reported their result after DOAC remove treatment and one participant treated the sample with both hepzyme and DOAC remove before measurement.

Lupus Anticoagulant

Confirmation

Sample No 24.125

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.8)

Prior Use Prior Use: None

Unit Ratio

Expiry Date 31-January-2027

Homogeneity 0.4 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 1.3%** 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 623

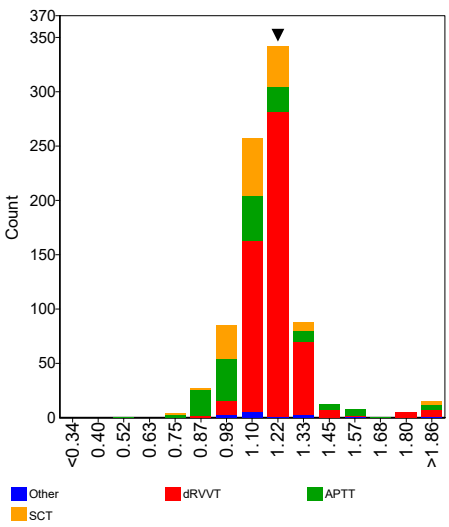
Number of Responders 551 **Response Rate** 88 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	67	110	0	21
dAPTT	5	4	0	1
dPT	2	4	0	1
dRVVT	349	198	0	58
Other	3	0	0	0
PNP	7	0	0	1
SCT	38	90	0	18

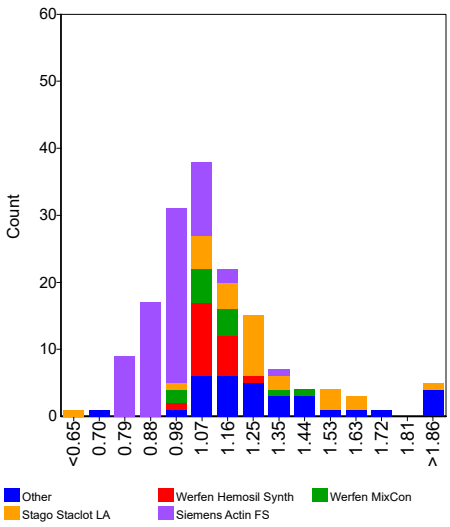
Assay	Your classification								
	Confirmation 1			Confirmation 2			Confirmation 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Elevated						
Other									
PNP									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	158	1.09	17.1	0.57 - 2.51							
Hyphen Biomed Cephen	6	1.09		0.72 - 1.16							
Siemens Actin FS	66	0.95	9.7	0.80 - 1.33							
Stago Staclot LA	28	1.26	16.1	0.57 - 2.05							
Stago/Roche PTT LA	6	1.44		1.10 - 2.03							
Werfen Hemosil SynthAFax	19	1.11	5.4	0.97 - 1.22							
Werfen MixCon	13	1.11	8.3	1.00 - 1.42							
dAPTT	6	1.08		0.95 - 1.61							
dRVVT	539	1.19	6.7	0.89 - 2.42	1					1.19	-0.09
Hyphen Biomed Hemoclot LA-C	9	1.17		1.12 - 1.42							
Precision Biologic LA sure	7	1.08		0.99 - 1.38							
Roche Lupus C	7	1.24		1.21 - 1.37							
Siemens LA2 confirmation	223	1.19	5.8	0.89 - 1.92	1					1.19	-0.04
Stago DRVVT Confirm	71	1.16	5.7	1.05 - 2.02							
Technoclone LA Confirm	7	1.15		1.12 - 1.23							
Werfen HemosIL dRVVT confirm	210	1.21	7.2	0.93 - 2.42							
PNP	5	1.13		1.07 - 8.00							
SCT	134	1.11	9.7	0.80 - 2.36							
Werfen HemosIL SCT confirm	134	1.11	9.7	0.80 - 2.36							

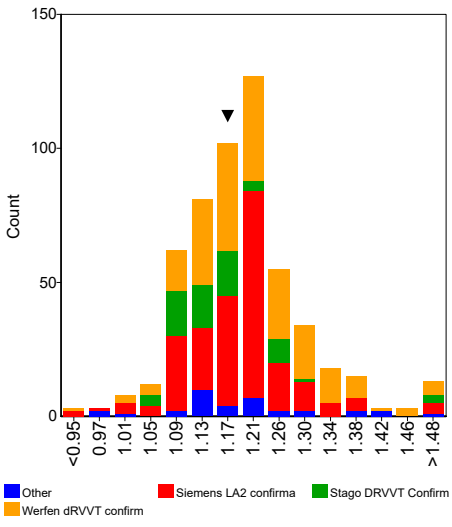
Assays



APTT



DRVVT

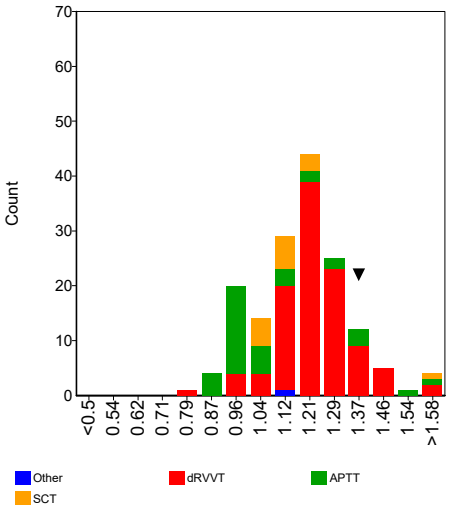


Lupus Anticoagulant

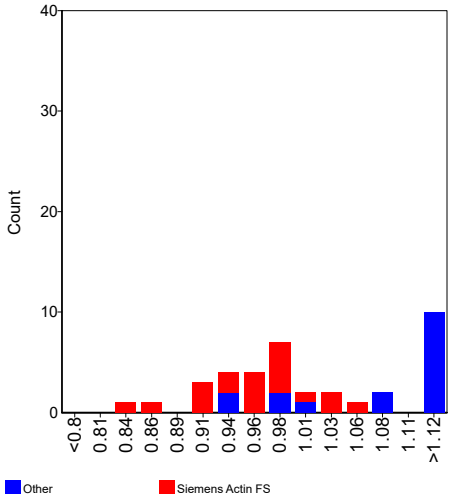
Confirmation

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	37	1.04	14.6	0.84 - 1.76							
Siemens Actin FS	20	0.96	5.4	0.84 - 1.06							
dRVVT	106	1.22	8.2	0.81 - 2.50	1					1.33	1.09
Siemens LA2 confirmation	67	1.23	8.8	0.94 - 1.48	1					1.33	1.00
Stago DRVVT Confirm	11	1.16	6.2	1.02 - 1.24							
Werfen HemosIL dRVVT confirm	21	1.26	7.5	0.81 - 2.50							
SCT	15	1.11	7.0	1.00 - 2.36							
Werfen HemosIL SCT confirm	15	1.11	7.0	1.00 - 2.36							

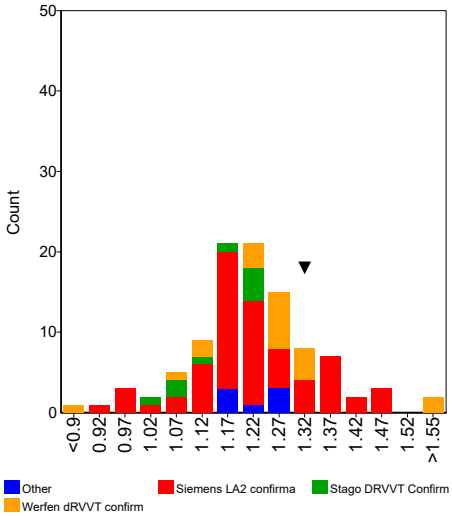
Assays



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 was reported as a ratio or delta seconds. 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 (54%) 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). A few participants noted that they reported their result after DOAC remove treatment and one participant treated the sample with both hepzyme and DOAC remove before measurement.

Lupus Anticoagulant

Mixing (confirm)

Sample No 24.125

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.8)

Prior Use Prior Use: None

Unit Ratio

Expiry Date 31-January-2027

Homogeneity 0.4 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 1.3%** 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 623

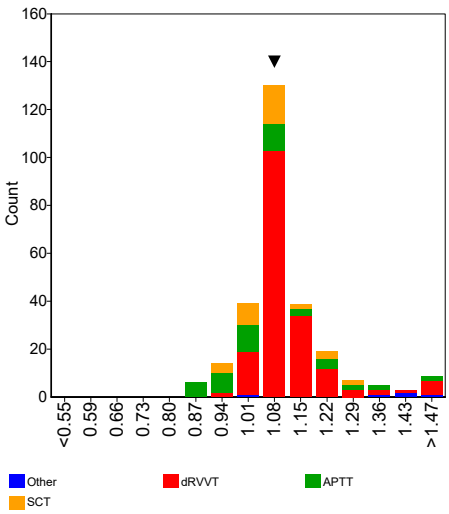
Number of Responders 192 **Response Rate** 31 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	17	33	0	6
dAPTT	7	1	0	1
dPT	1	0	0	0
dRVVT	66	121	0	9
SCT	6	29	0	2

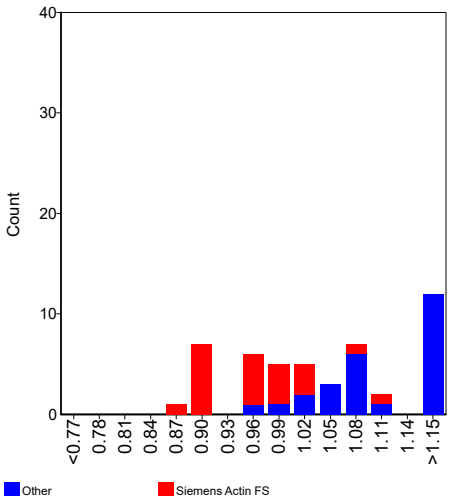
Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Not elevated						
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	49	1.06	12.9	0.89 - 1.56							
Siemens Actin FS	22	0.96	6.5	0.89 - 1.10							
Werfen Hemosil SynthAFax	8	1.09		1.03 - 1.56							
Werfen MixCon	5	1.06		1.03 - 1.48							
dRVVT	181	1.10	4.8	0.92 - 1.99	1					1.09	-0.19
Siemens LA2 confirmation	101	1.11	4.3	0.95 - 1.99	1					1.09	-0.36
Stago DRVVT Confirm	16	1.09	5.6	1.00 - 1.76							
Werfen HemosIL dRVVT confirm	55	1.09	4.8	0.92 - 1.36							
SCT	36	1.07	7.6	0.94 - 1.30							
Werfen HemosIL SCT confirm	36	1.07	7.6	0.94 - 1.30							

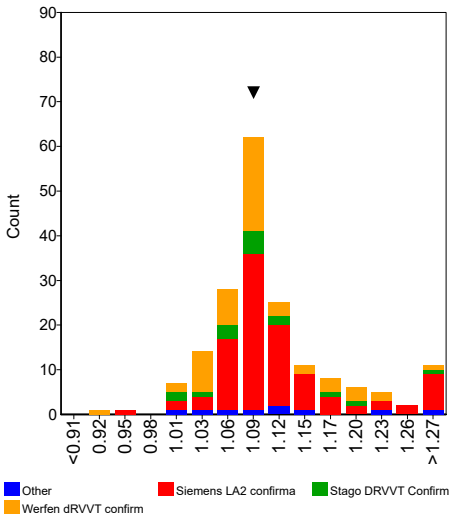
Assays



APTT



DRVVT

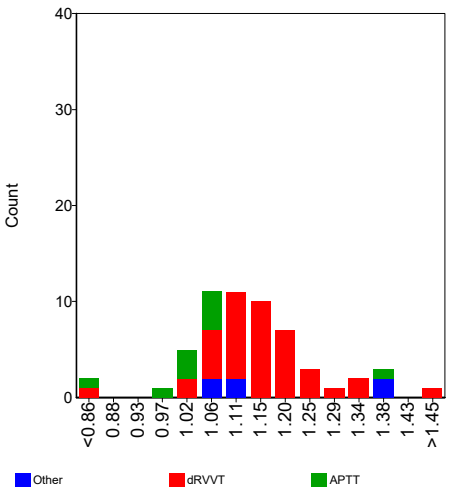


Lupus Anticoagulant

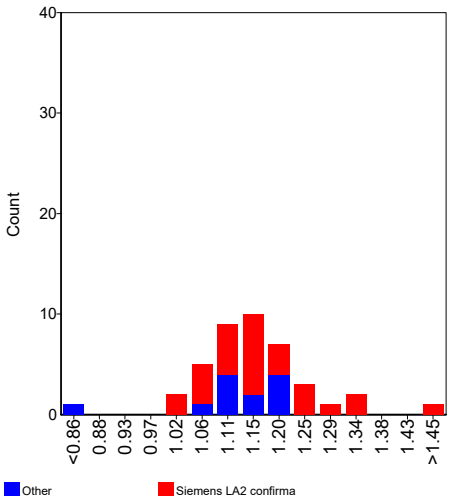
Mixing (confirm)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	10	1.04	5.8	0.85 - 1.38							
Siemens Actin FS	8	1.03		0.85 - 1.07							
dRVVT	41	1.15	7.2	0.79 - 1.73							
Siemens LA2 confirmation	29	1.16	8.4	1.01 - 1.73							
Werfen HemosIL dRVVT confirm	9	1.15		0.79 - 1.22							

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 (65%) 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).

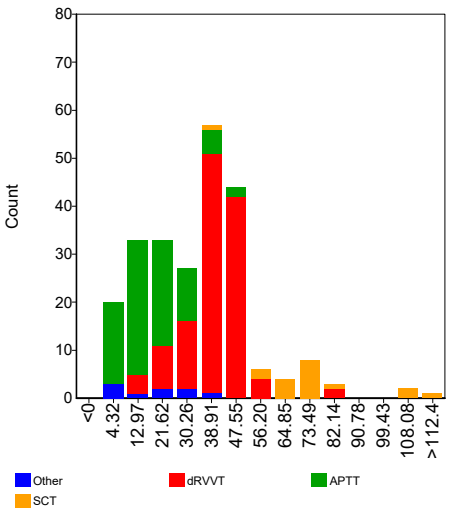
Lupus Anticoagulant

Interpretation

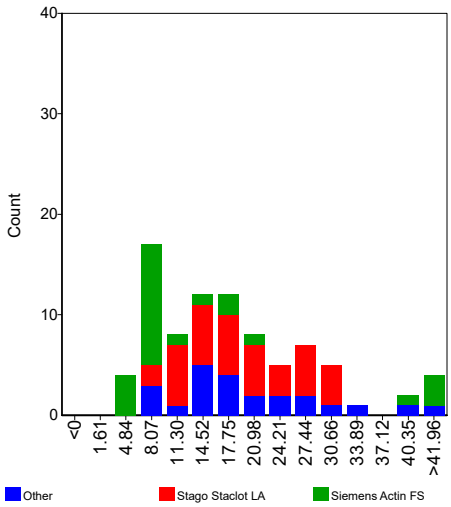
Delta Seconds

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	85	17.61	53.6	5.40 - 50.10							
Precision Biologic CRYOcheck Hex LA Cor	5	29.00		6.70 - 39.00							
Siemens Actin FS	25	11.42	63.2	5.40 - 50.10							
Stago Staclot LA	37	19.43	38.7	7.00 - 30.90							
Werfen Hemosil SynthAFax	6	14.90		9.12 - 19.10							
dRVVT	125	40.89	19.5	9.00 - 80.30							
Siemens LA2 confirmation	70	43.59	15.8	17.10 - 80.30							
Stago DRVVT Confirm	9	34.30		18.60 - 43.50							
Werfen HemosIL dRVVT confirm	40	39.48	14.4	9.00 - 49.60							
SCT	19	71.91	18.8	42.10 - 113.80							
Werfen HemosIL SCT confirm	19	71.91	18.8	42.10 - 113.80							

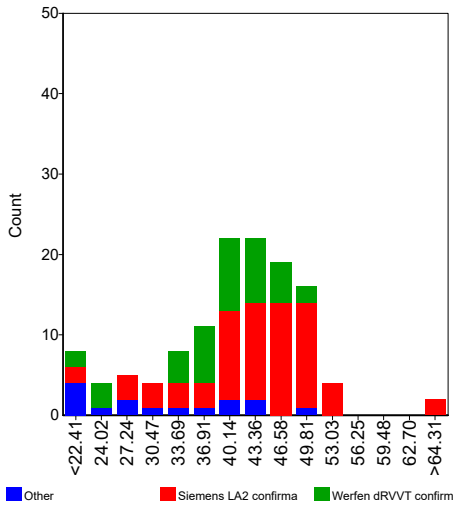
Assays



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).

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

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

967 (instr. 1): 0.8
967 (instr. 2): 0.5
9905: 1.21
9907139: 1.73
9907274: 0.9

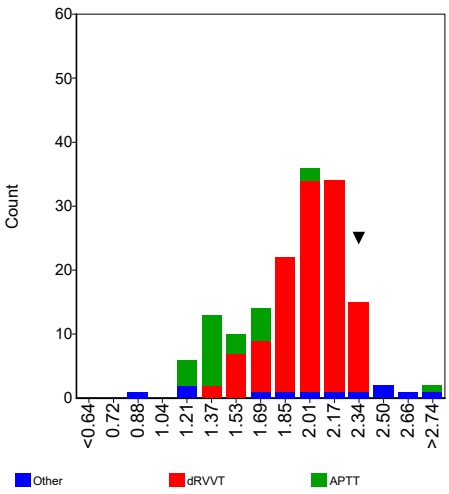
Lupus Anticoagulant

Interpretation

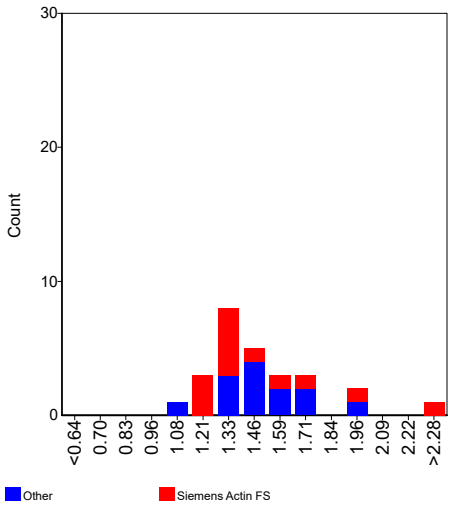
Ratio Screen/Confirmation - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	26	1.47	15.4	1.14 - 3.57							
Siemens Actin FS	13	1.46	18.7	1.22 - 3.57							
dRVVT	118	2.02	10.9	1.30 - 2.40	1					2.26	1.11
Siemens LA2 confirmation	80	2.08	8.7	1.30 - 2.40	1					2.26	0.99
Stago DRVVT Confirm	12	1.88	9.6	1.63 - 2.27							
Werfen HemosIL dRVVT confirm	16	1.88	10.6	1.58 - 2.18							
SCT	8	2.35		1.79 - 3.00							
Werfen HemosIL SCT confirm	8	2.35		1.79 - 3.00							

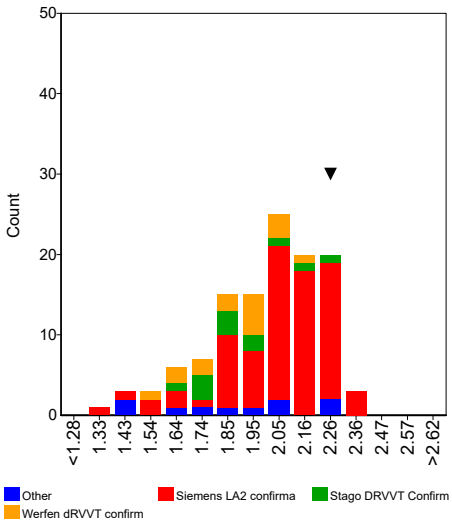
Assays



APTT



DRVVT



Comments

Some participants did not indicate which type of ratio screen / confirmation they reported (standard ratio or normalised ratio). One participant reported a ratio, which was likely to be the result in percentage or delta seconds. These results have been excluded in the statistical 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. 1.8). For the assay type "APTT" the LA ratio is slightly lower compared to the other assay types, as also was observed for the parameter: "Ratio Screen / Confirmation - Normalised".

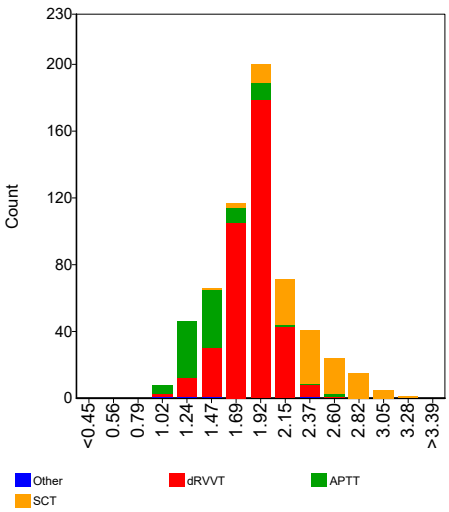
Lupus Anticoagulant

Interpretation

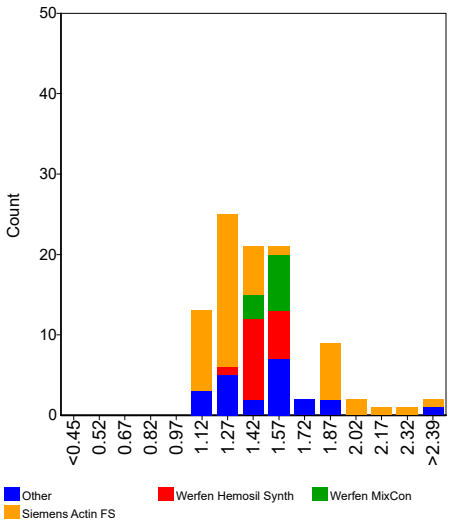
Ratio Screen/Confirmation - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	97	1.44	17.0	1.10 - 2.53							
Hyphen Biomed Cephen	5	1.61		1.36 - 1.67							
Siemens Actin FS	48	1.42	22.8	1.10 - 2.53							
Werfen Hemosil SynthAFax	17	1.48	4.7	1.30 - 1.62							
Werfen MixCon	10	1.50	4.3	1.40 - 1.59							
dRVVT	377	1.84	9.9	1.07 - 2.50							
Hyphen Biomed Hemoclot LA-C	7	1.82		1.51 - 1.97							
Roche Lupus C	6	1.53		1.26 - 1.68							
Siemens LA2 confirmation	129	1.90	8.8	1.07 - 2.42							
Stago DRVVT Confirm	54	1.86	9.2	1.53 - 2.40							
Werfen HemosIL dRVVT confirm	175	1.81	9.7	1.14 - 2.50							
SCT	116	2.39	13.8	1.54 - 3.23							
Werfen HemosIL SCT confirm	116	2.39	13.8	1.54 - 3.23							

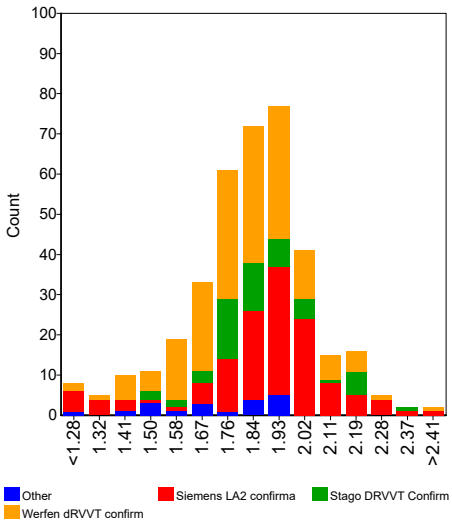
Assays



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 statistical 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. 1.8). For the assay type "APTT" the LA ratio is slightly lower compared to the other assay types, as also was observed for the parameter: "Ratio Screen / Confirmation - Standard".

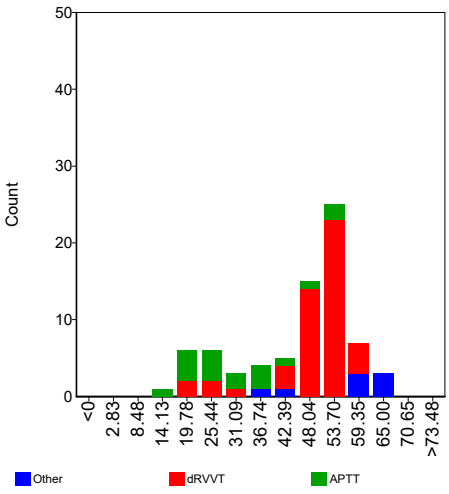
Lupus Anticoagulant

Interpretation

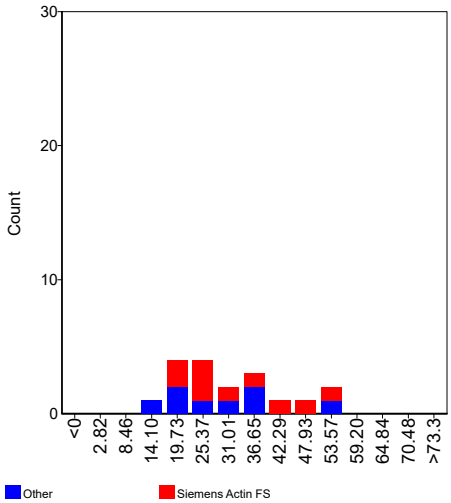
Percentage Correction - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	18	31.40	43.0	15.00 - 56.00							
Siemens Actin FS	10	32.98	40.8	18.57 - 51.00							
dRVVT	49	50.45	9.2	21.60 - 57.10							
Siemens LA2 confirmation	37	51.32	7.5	21.60 - 57.10							
Werfen HemosIL dRVVT confirm	5	48.60		23.00 - 54.20							
SCT	6	62.10		58.36 - 67.20							
Werfen HemosIL SCT confirm	6	62.10		58.36 - 67.20							

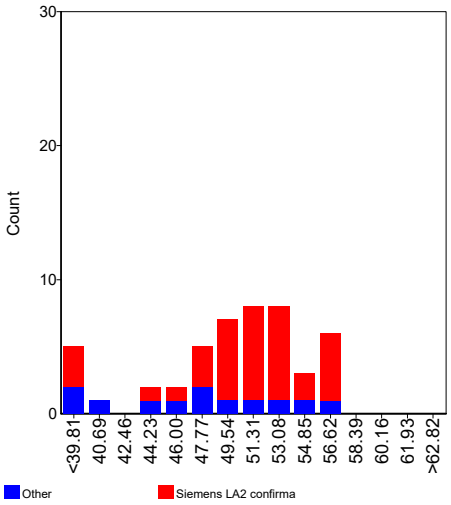
Assays



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

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

568: 1.41

967: 1.6

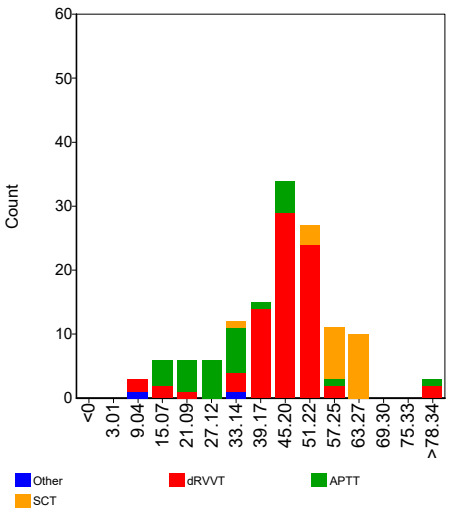
Lupus Anticoagulant

Interpretation

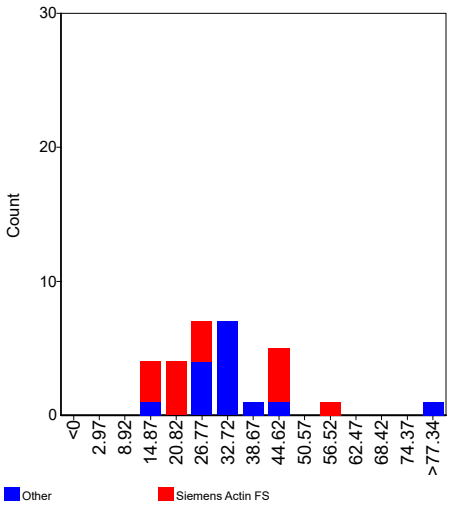
Percentage Correction - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	30	30.78	42.0	13.50 - 80.00							
Siemens Actin FS	15	29.78	53.2	13.50 - 56.50							
dRVVT	79	45.70	13.5	7.00 - 95.00							
Siemens LA2 confirmation	34	47.09	11.8	7.00 - 56.00							
Stago DRVVT Confirm	9	46.80		37.20 - 52.70							
Werfen HemosIL dRVVT confirm	34	45.21	13.3	17.39 - 95.00							
SCT	22	59.79	8.8	35.95 - 65.10							
Werfen HemosIL SCT confirm	22	59.79	8.8	35.95 - 65.10							

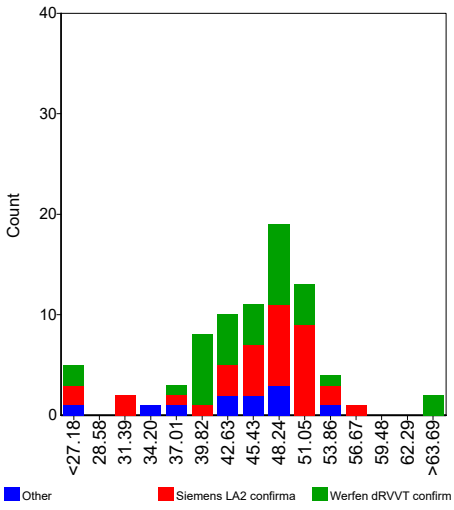
Assays



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

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

195: 1.5

9907255: 2.04

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	15	4	10	1			
					2			
					3			
Screen and mixing test	5	54		15	1			
					2			
					3			
Screen and confirm test	6	426	11	2	1			
					2			
					3			
Screen, mixing and confirm test	7	273	13	0	1			
					2			
					3			
Screen, confirm, mixing test	3	150	6	5	1			LA detected
					2			
					3			
Mixing - confirmation	0	34	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			
467		5	8	LA detected		

Comments

The sample used in this survey was a pooled plasma derived from two patient donors diagnosed with Lupus Anticoagulant. One patient was under Rivaroxaban treatement and one patient was under LMWH treatment. This pooled plasma resulted in an anti-Xa result of approx. 0.3 IU/mL (LA Ratio = approx. 1.8).

In total 472 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 99% indicated Lupus Anticoagulant was detected. About 1% classified the sample as equivocal. Thus, the vast majority of the participants correctly classified this sample as a Lupus Anticoagulant positive.

Lupus Anticoagulant

AntiCardiolipin Antibodies IgG

Sample No 24.125

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.8)

Prior Use Prior Use: None

Unit GPL, U/mL, µg/mL, CU/mL

Expiry Date 31-January-2027

Homogeneity 0.4 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 1.3%** 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.

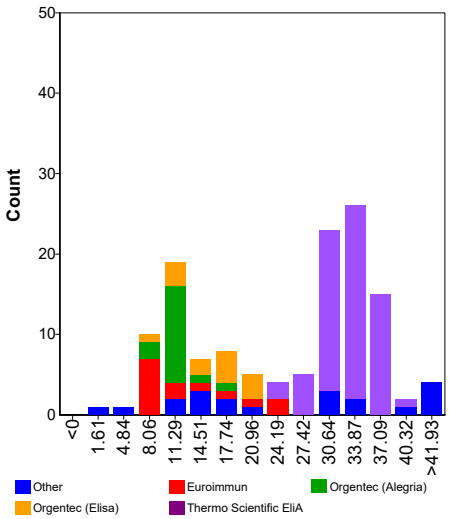
Number of Participants 623

Number of Responders 219 **Response Rate** 35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	25	16	73	73	35	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	130	25.3	48.5	3.0 - 160.0						
Aeskulisa Diagnotic GmbH	5	35.0		3.0 - 56.8						
Euroimmun	14	12.7	51.0	7.2 - 25.0						
Orgentec (Alegria)	16	11.2	12.4	9.2 - 16.7						
Orgentec (Elisa)	13	15.8	31.1	8.8 - 21.8						
Thermo Scientific EliA	67	33.1	8.9	23.0 - 39.0						
Werfen INOVA Quanta Lite	6	16.4		13.0 - 20.0						
CU/mL	81	72.0	10.7	59.0 - 92.0						
Werfen Acustar / INOVA Quanta Flash	80	71.9	10.6	59.0 - 92.0						

GPL, U/mL, µg/mL



Comments
A positive classification has been observed by the majority of participants.

A heterogeneous pattern in the classification has been observed.

All participants using the method Biorad Bioplex (n=8) reported a result higher than the upper limit of their method (> 112 or >160). These results were excluded in the statistical evaluation.

The following participants reported deviating results which were excluded in the statistical evaluation:
538 : 2.4
1353 : 0.83

Lupus Anticoagulant

AntiCardiolipin Antibodies IgM

Sample No 24.125

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.8)

Prior Use Prior Use: None

Unit MPL, U/mL, µg/mL, CU/mL

Expiry Date 31-January-2027

Homogeneity 0.4 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 1.3%** 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.

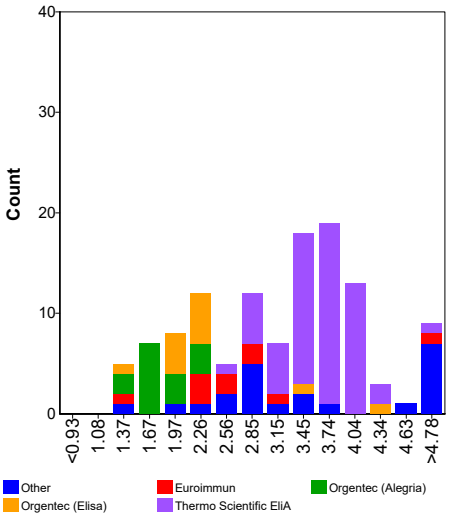
Number of Participants 623

Number of Responders 207 **Response Rate** 33 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	208	0	1	1	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	119	3.2	30.6	1.3 - 7.0						
Aeskulisa Diagnotic GmbH	5	6.0		1.5 - 7.0						
Biorad Bioplex	7	2.6		2.0 - 3.0						
Euroimmun	10	2.6	21.3	1.3 - 6.4						
Orgentec (Alegria)	15	1.9	15.5	1.5 - 2.4						
Orgentec (Elisa)	12	2.3	19.7	1.4 - 4.3						
Thermo Scientific EliA	60	3.6	10.9	2.6 - 4.8						
CU/mL	77	5.1	14.0	3.2 - 9.3						
Werfen Acustar / INOVA Quanta Flash	77	5.1	14.0	3.2 - 9.3						

MPL, U/mL, µg/mL



Comments

Most of the participants reported a negative classification.

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

1353 : 0.29

Lupus Anticoagulant

ß2-Glycoprotein I Antibodies IgG

Sample No 24.125

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.8)

Prior Use Prior Use: None

Unit U, U/mL, µg/mL, CU/mL

Expiry Date 31-January-2027

Homogeneity 0.4 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 1.3%** 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.

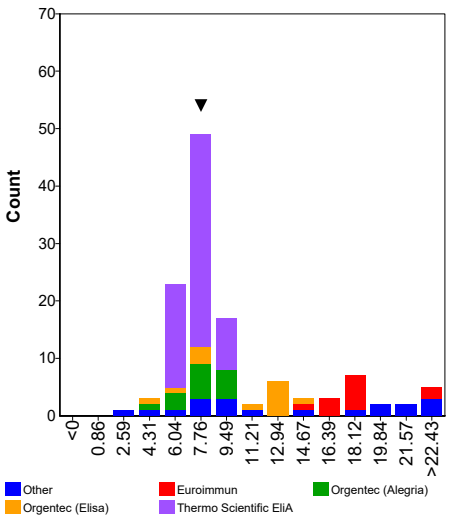
Number of Participants 623

Number of Responders 210 **Response Rate** 34 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	52	36	31	10	83	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	123	8.9	34.2	3.0 - 426.1	8.2	-0.22				
Aeskulisa Diagnotic GmbH	5	8.9		3.0 - 10.0						
Euroimmun	12	17.6	9.0	14.0 - 33.0						
Orgentec (Alegria)	15	7.7	21.8	4.7 - 9.9						
Orgentec (Elisa)	13	10.7	34.6	4.6 - 15.0	8.2	-0.68				
Thermo Scientific EliA	64	7.5	13.2	5.4 - 9.5						
Werfen INOVA Quanta Lite	6	18.9		11.0 - 21.8						
CU/mL	80	457.5	14.5	339.0 - 609.5						
Werfen Acustar / INOVA Quanta Flash	79	457.5	14.6	339.0 - 609.5						

U, U/mL, µg/mL



Comments
A heterogeneous pattern in the classification has been observed.

Especially within the method groups Biorad Bioplex (100%) and Werfen Acustar/INOVA Quanta Flash (99%) the majority of participants classified this sample as positive, corresponding with the higher titer observed in these method groups.

All participants using the method Biorad Bioplex (n=8) reported a result higher than the upper limit of their method (> 112 or >160). These results were excluded in the statistical evaluation.

The following participant reported a deviating result which was excluded in the statistical evaluation:
246 : 15.0

Lupus Anticoagulant

ß2-Glycoprotein I Antibodies IgM

Sample No 24.125

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.8)

Prior Use Prior Use: None

Unit U, U/mL, µg/mL, CU/mL

Expiry Date 31-January-2027

Homogeneity 0.4 %

Homogeneity Parameter LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 1.3%** 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 623

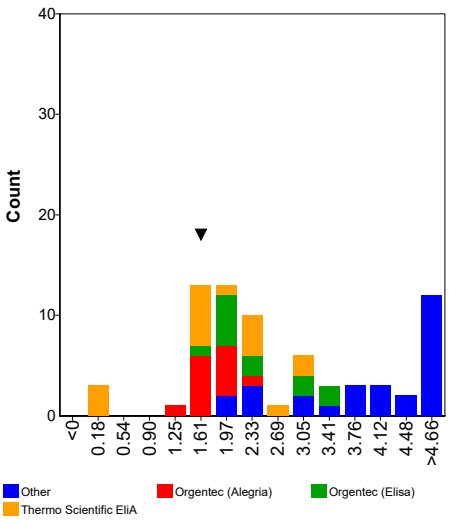
Number of Responders 190

Response Rate 30 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	191	0	1	1	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	70	2.8	53.7	0.0 - 13.3	1.7	-0.75				
Aeskulisa Diagnotic GmbH	5	7.0		2.5 - 10.0						
Biorad Bioplex	7	3.7		3.3 - 4.4						
Euroimmun	9	9.0		7.6 - 13.3						
Orgentec (Alegria)	13	1.8	17.6	1.3 - 2.2						
Orgentec (Elisa)	12	2.5	30.0	1.7 - 3.5	1.7	-1.03				
Thermo Scientific EliA	17	1.8	49.0	0.0 - 2.9						
CU/mL	74	2.2	16.2	1.5 - 3.0						
Werfen Acustar / INOVA Quanta Flash	74	2.2	16.2	1.5 - 3.0						

U, U/mL, µg/mL



Comments

A negative pattern in the classification has been observed.

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

538 : 75