ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2023-L4
Lupus Anticoagulant
Labcode 1492

Date of Issue : 19-January-2024

Survey : 2023-L4

Report : Lupus Anticoagulant

Note:
In the Survey Manual 2023 detailed information is given regarding the ECAT external quality assessment programme , including the statistical evaluation and explanation of the report.
This Survey Manual 2023 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 **March 5th, 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.

Modified report
Because of the changes in the online result report form we have also modified the survey report. For the mixing test it is now possible to report a result separately for a screening and confirmation test. These results are displayed in the report as separate parameters.

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.

This report is authorized by:

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

Note: A printed version of the actual Survey Manual is provided to all participants once a year . This manual can also be downloaded from the member section of the ECAT website .

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Registration number with the Chamber of Commerce (KvK) Gouda : 41174102
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Lupus Anticoagulant

Screening

Sample No 23.213
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Ratio
Expiry Date 30-April-2026
Homogeneity 2.1 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 7.0%** 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.

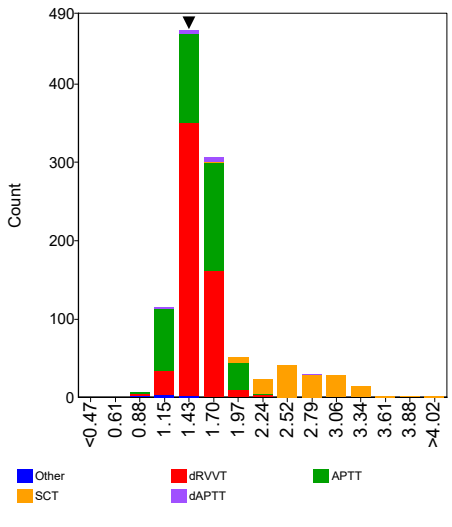
Number of Participants 632
Number of Responders 568 **Response Rate** 90 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	379	39	0	15
dAPTT	16	1	0	0
dPT	6	2	0	0
dRVVT	589	7	0	21
KCT	4	0	0	0
Other	2	1	0	0
PNP	2	0	0	1
PT	1	3	0	0
SCT	144	1	0	8

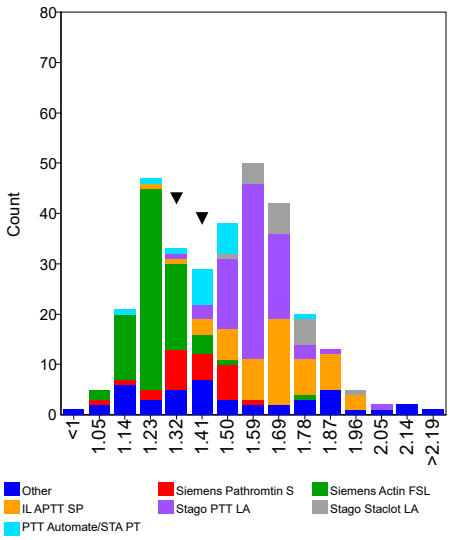
Assay	Your classification								
	Screening 1			Screening 2			Screening 3		
	TS1	TS2	TS3						
APTT	Elevated	Not elevated							
dAPTT									
dPT									
dRVVT			Elevated						
KCT									
Other									
PNP									
PT									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	368	1.52	16.9	0.93 - 2.21	1	1.39	-0.51	1.33	-0.74		
Hyphen-Biomed Cephen LS	7	1.81		1.73 - 1.91							
IL APTT SP	53	1.68	9.1	1.25 - 2.00							
IL HemosIL SynthAsil	44	1.78	7.6	1.52 - 2.11							
IL MixCon	15	1.52	5.6	1.39 - 1.60							
Siemens Actin FS	7	1.13		0.93 - 1.16							
Siemens Actin FSL	78	1.24	6.4	1.07 - 1.75	1			1.33	1.18		
Siemens Pathromtin SL	25	1.37	9.1	1.03 - 1.56	1	1.39	0.13				
Stago CKPrest / APTT Kaolin	5	1.27		1.17 - 1.41							
Stago PTT Automate/STA PTT	17	1.43	7.1	1.15 - 1.75							
Stago PTT LA	75	1.60	5.1	1.32 - 2.09							
Stago Staclot LA	17	1.69	5.4	1.51 - 1.94							
Tcoag TriniClot Automated APTT	7	1.39		1.33 - 1.42							
dAPTT	13	1.55	9.1	1.20 - 2.77							
Stago PTT LA	8	1.57		1.44 - 1.64							
dRVVT	552	1.49	9.2	1.00 - 2.31	1					1.40	-0.65
Hyphen Biomed Hemoclot LA-S	8	1.52		1.35 - 1.76							
I.L. HemosIL dRVVT screen	214	1.56	7.8	1.10 - 2.31							
Precision Biologic LA check	7	1.52		1.40 - 1.63							
Roche Lupus S	7	1.45		1.32 - 1.55							
Siemens LA1 screen	224	1.46	8.2	1.00 - 1.79	1					1.40	-0.44
Stago DRVVT screen	80	1.43	10.2	1.25 - 2.15							
Technoclone LA Screen	6	1.42		1.32 - 1.58							
SCT	145	2.73	15.7	1.70 - 4.61							
Haematex SACT Reagent	6	3.03		2.27 - 4.61							
IL SCT screen	139	2.72	15.3	1.70 - 3.78							

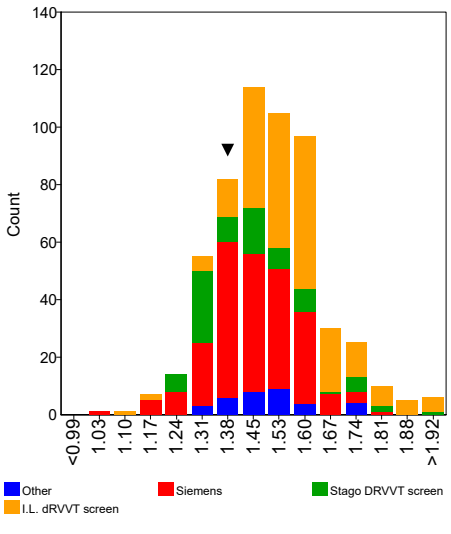
Assays



APTT



DRVVT

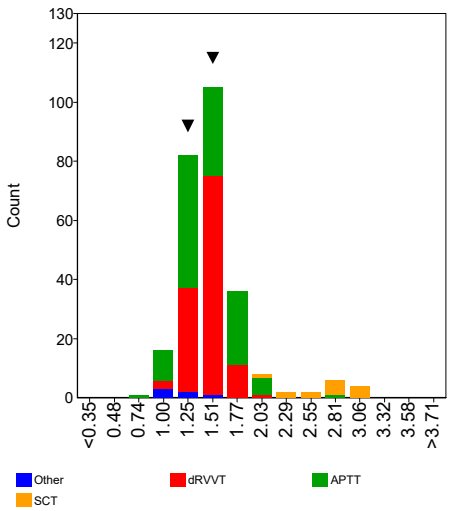


Lupus Anticoagulant

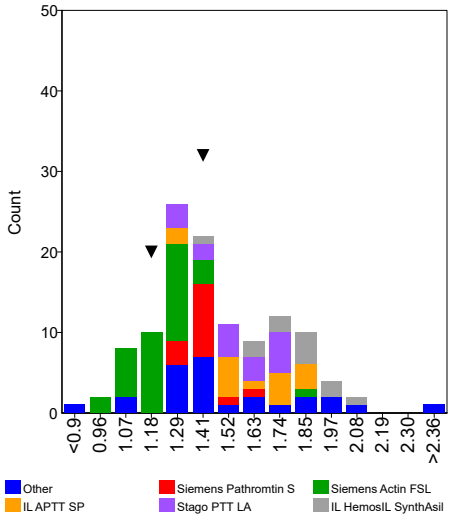
Screening

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	118	1.45	19.7	0.87 - 2.88	1	1.41	-0.14	1.13	-1.12		
IL APTT SP	15	1.62	11.7	1.32 - 1.82							
IL HemosIL SynthAsil	12	1.81	10.0	1.45 - 2.13							
Siemens Actin FSL	34	1.21	8.5	1.00 - 1.86	1			1.13	-0.74		
Siemens Pathromtin SL	14	1.39	4.7	1.24 - 1.66	1	1.41	0.29				
Stago PTT Automate/STA PTT	7	1.40		1.25 - 1.57							
Stago PTT LA	17	1.55	11.8	1.28 - 1.76							
dRVVT	124	1.45	8.5	1.04 - 2.11	1					1.52	0.54
I.L. HemosIL dRVVT screen	24	1.56	10.2	1.26 - 2.11							
Siemens LA1 screen	78	1.43	7.2	1.04 - 1.73	1					1.52	0.92
Stago DRVVT screen	11	1.47	11.2	1.28 - 1.82							
SCT	14	2.73	11.9	2.05 - 3.04							
IL SCT screen	14	2.73	11.9	2.05 - 3.04							

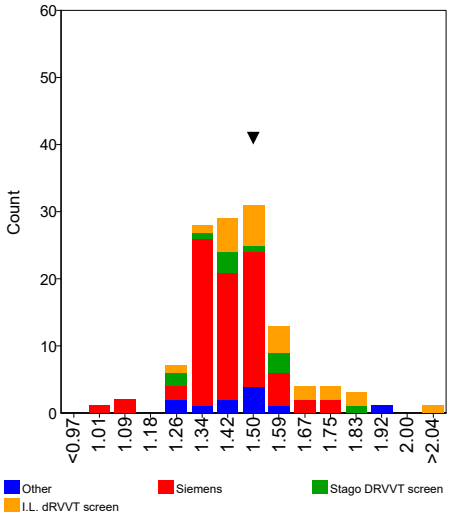
Assays



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. One participant reported a negative value for the reference plasma. All these results were excluded in the statistical analysis.

The vast majority of performed screening tests (95%) 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 (screening)

Sample No 23.213
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Ratio
Expiry Date 30-April-2026
Homogeneity 2.1 %
Homogeneity Parameter LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 7.0%** 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.

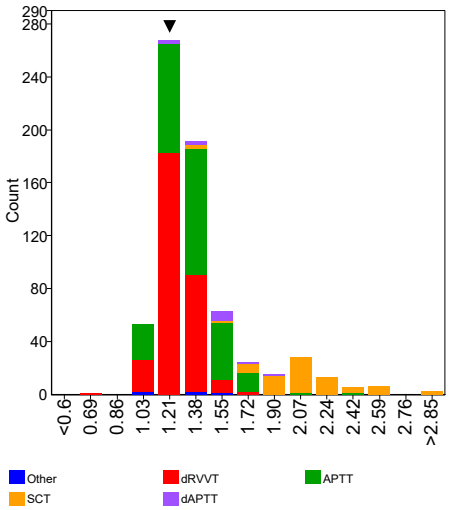
Number of Participants 632
Number of Responders 408
Response Rate 65 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	224	63	0	9
dAPTT	16	1	0	2
dPT	2	0	0	0
dRVVT	257	68	0	12
KCT	2	0	0	0
Other	2	0	0	0
PNP	0	0	0	0
PT	0	2	0	0
SCT	78	0	0	1

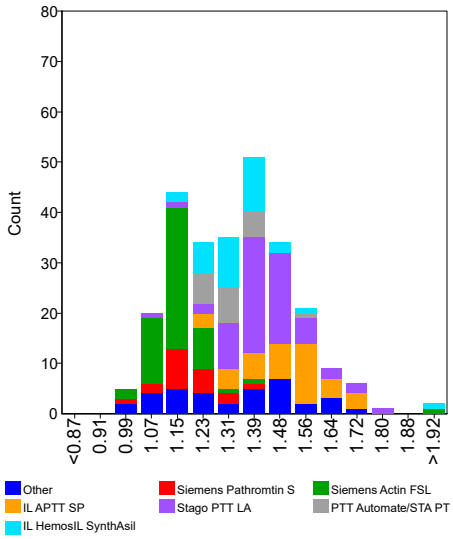
Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			No Classifica						
KCT									
Other									
PNP									
PT									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	264	1.33	13.6	0.96 - 2.44							
Hyphen-Biomed Cephen LS	5	1.50		1.42 - 1.67							
IL APTT SP	38	1.50	9.4	1.25 - 1.71							
IL HemosIL SynthAsil	33	1.33	7.3	1.14 - 2.01							
IL MixCon	7	1.42		0.96 - 1.65							
Siemens Actin FSL	54	1.14	4.7	0.99 - 2.44							
Siemens Pathromtin SL	19	1.19	8.8	0.96 - 1.40							
Stago PTT Automate/STA PTT	19	1.32	5.6	1.20 - 1.55							
Stago PTT LA	64	1.42	6.1	1.09 - 1.76							
Tcoag TriniClot Automated APTT	7	1.25		1.22 - 1.51							
dAPTT	15	1.46	14.6	1.13 - 1.93							
Stago PTT LA	7	1.38		1.13 - 1.73							
dRVVT	308	1.25	7.4	0.71 - 1.79	1					1.27	0.19
I.L. HemosIL dRVVT screen	96	1.32	6.2	0.96 - 1.79							
Siemens LA1 screen	151	1.21	5.3	0.71 - 1.58	1					1.27	0.86
Stago DRVVT screen	43	1.25	8.1	1.09 - 1.60							
SCT	77	2.07	12.5	1.30 - 4.15							
Haematex SACT Reagent	5	2.19		1.60 - 4.15							
IL SCT screen	71	2.06	11.8	1.30 - 3.73							

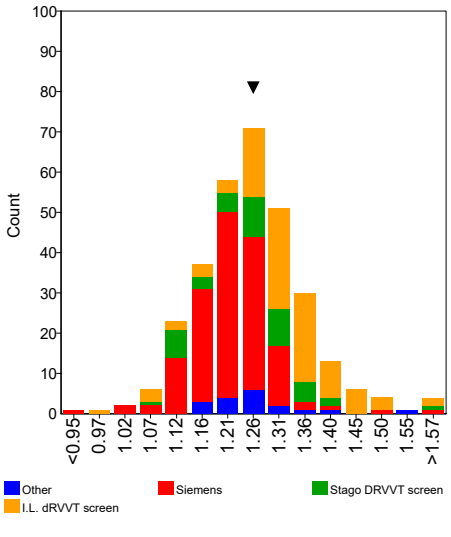
Assays



APTT



DRVVT

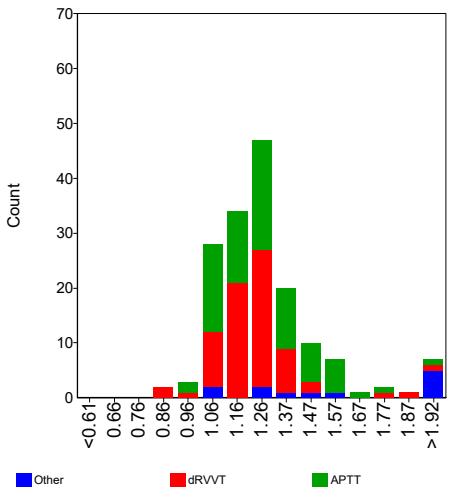


Lupus Anticoagulant

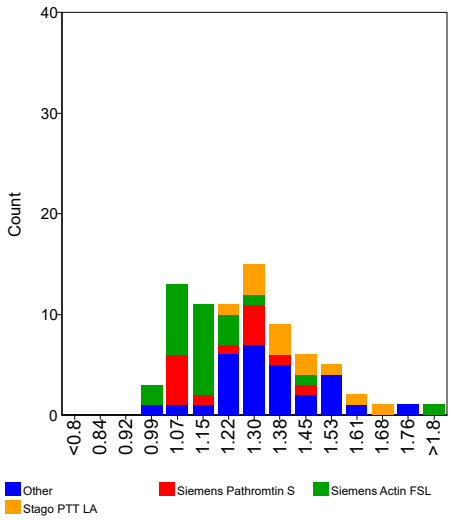
Mixing (screening)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	78	1.26	13.8	0.99 - 2.73							
IL APTT SP	8	1.39		1.20 - 1.57							
IL HemosIL SynthAsil	7	1.34		1.00 - 1.60							
Siemens Actin FSL	24	1.14	7.5	0.99 - 2.73							
Siemens Pathromtin SL	13	1.20	11.2	1.04 - 1.47							
Stago PTT Automate/STA PTT	6	1.27		1.21 - 1.43							
Stago PTT LA	12	1.40	9.7	1.24 - 1.70							
dRVVT	72	1.22	9.6	0.88 - 2.00							
I.L. HemosIL dRVVT screen	11	1.34	13.0	1.14 - 2.00							
Siemens LA1 screen	48	1.18	9.6	0.88 - 1.48							
Stago DRVVT screen	5	1.27		1.20 - 1.33							
SCT	5	2.10		2.02 - 2.52							
IL SCT screen	5	2.10		2.02 - 2.52							

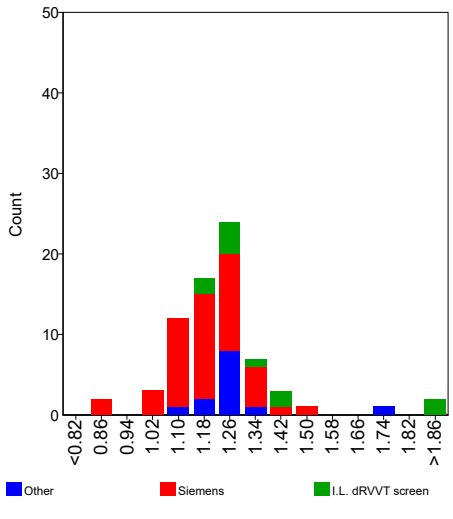
Assays



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 mean of the reference interval (MRI) was reported as a ratio. One participant reported their result for the ECAT plasma in seconds while the result for their reference plasma was reported in delta seconds. All these results were excluded in the statistical analysis.

The majority of performed mixing screening tests (81%) 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 23.213

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.6)

Prior Use Prior Use: None

Unit Ratio

Expiry Date 30-April-2026

Homogeneity 2.1 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 7.0%** 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 632

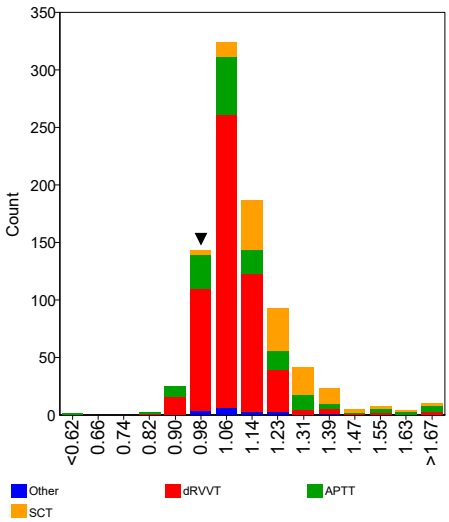
Number of Responders 557 **Response Rate** 88 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	73	103	0	27
dAPTT	8	4	0	1
dPT	2	3	0	1
dRVVT	166	385	0	64
Other	2	2	0	0
PNP	3	3	0	3
PT	0	0	0	0
SCT	80	49	0	21

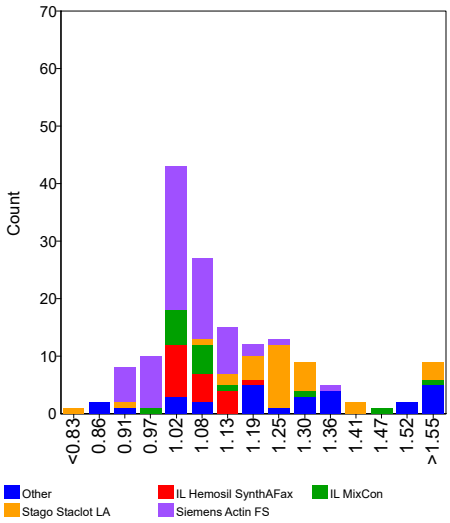
Assay	Your classification								
	Confirmation 1			Confirmation 2			Confirmation 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Not elevated						
Other									
PNP									
PT									
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	159	1.11	12.6	0.47 - 2.33							
IL Hemosil SynthAFax	19	1.07	4.6	1.00 - 1.16							
IL MixCon	16	1.07	7.6	0.97 - 1.71							
Siemens Actin FS	66	1.04	6.5	0.89 - 1.37							
Stago Staclot LA	30	1.25	8.1	0.47 - 1.73							
Stago/Roche PTT LA	6	1.33		1.04 - 1.62							
dAPTT	9	1.10		0.98 - 1.38							
dRVVT	548	1.07	6.6	0.81 - 1.87	1					1.02	-0.72
Hyphen Biomed Hemoclot LA-C	7	1.03		0.92 - 1.16							
IL HemosIL dRVVT confirm	226	1.10	7.5	0.87 - 1.70							
Precision Biologic LA sure	5	0.94		0.90 - 1.11							
Roche Lupus C	8	1.10		1.00 - 1.17							
Siemens LA2 confirmation	217	1.06	5.2	0.81 - 1.57	1					1.02	-0.71
Stago DRVVT Confirm	75	1.04	5.6	0.94 - 1.87							
Technoclone LA Confirm	6	1.01		0.95 - 1.12							
SCT	142	1.22	8.8	1.00 - 2.87							
IL HemosIL SCT confirm	141	1.22	8.7	1.00 - 2.87							

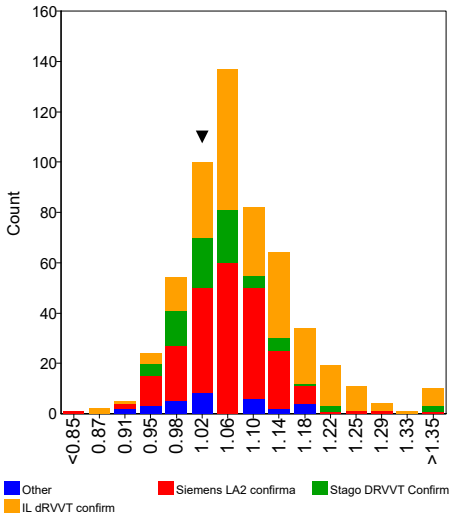
Assays



APTT



DRVVT

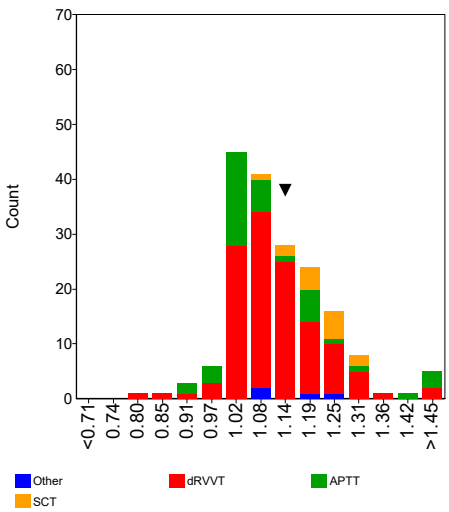


Lupus Anticoagulant

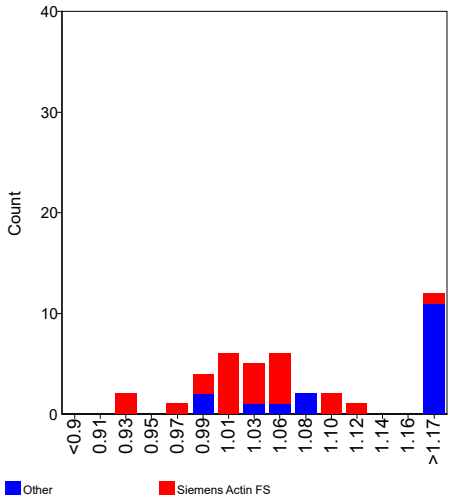
Confirmation

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	41	1.08	10.0	0.93 - 1.83							
Siemens Actin FS	24	1.03	4.4	0.93 - 1.18							
Stago Staclot LA	6	1.34		1.09 - 1.82							
dRVVT	121	1.10	8.0	0.79 - 1.68	1					1.15	0.52
IL HemosIL dRVVT confirm	24	1.15	7.3	1.00 - 1.38							
Siemens LA2 confirmation	78	1.10	7.8	0.79 - 1.58	1					1.15	0.62
Stago DRVVT Confirm	10	1.06	8.6	0.91 - 1.17							
SCT	14	1.21	6.5	1.07 - 1.32							
IL HemosIL SCT confirm	14	1.21	6.5	1.07 - 1.32							

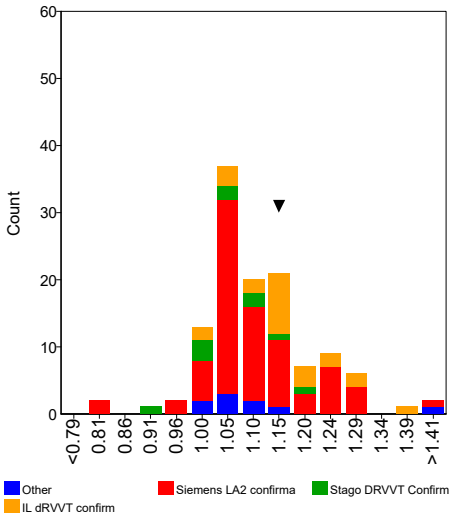
Assays



APTT



DRVVT



Comments

Several participants selected the wrong unit, e.g. ratio while the result was likely to be in seconds or vice versa. Other participants reported their result for the ECAT plasma in seconds while the result for their reference plasma or the mean of the reference interval was reported as a ratio or vice versa. In all these cases the ratio between the ECAT plasma and the laboratories own reference plasma and/or the mean of the reference interval could not be correctly calculated.

As expected, the majority of performed confirmation tests (62%) were classified as not elevated. For a weak positive Lupus Anticoagulant plasma, it is expected that the test result (almost) fully normalised in the confirmation test.

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

Lupus Anticoagulant

Mixing (confirm)

Sample No 23.213
Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.6)
Prior Use Prior Use: None
Unit Ratio
Expiry Date 30-April-2026
Homogeneity 2.1 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 7.0%** 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.

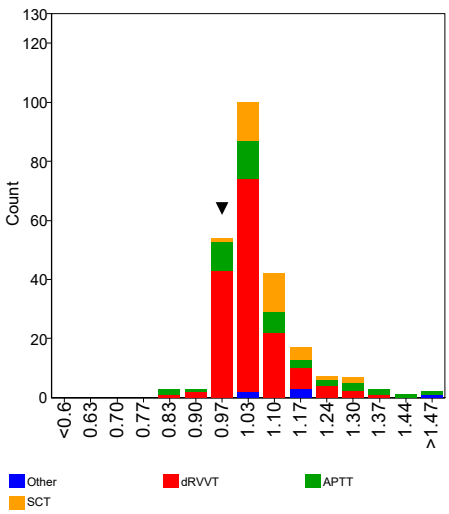
Number of Participants 632
Number of Responders 174 **Response Rate** 28 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	18	28	0	7
dAPTT	6	0	0	2
dPT	0	0	0	0
dRVVT	32	124	0	11
SCT	7	27	0	1

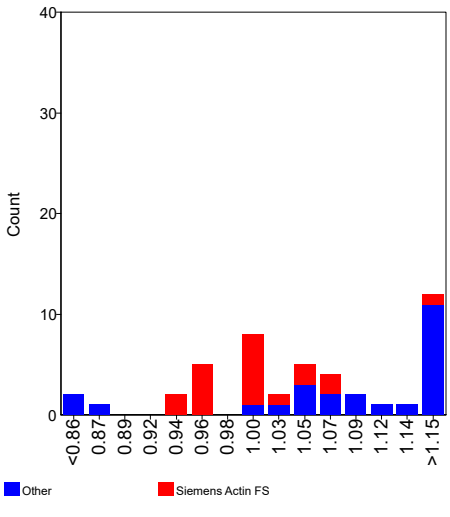
Assay	Your classification								
	Mixing 1			Mixing 2			Mixing 3		
			TS3						
APTT									
dAPTT									
dPT									
dRVVT			Not elevated						
SCT									

Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	45	1.07	12.5	0.82 - 1.55							
IL Hemosil SynthAFax	5	1.13		1.06 - 1.38							
Siemens Actin FS	20	1.00	4.8	0.94 - 1.17							
Siemens Pathromtin SL	6	0.99		0.82 - 1.33							
dAPTT	6	1.14		1.02 - 1.52							
dRVVT	155	1.04	4.7	0.81 - 1.47	1					1.00	-0.73
IL HemosIL dRVVT confirm	43	1.05	7.3	0.81 - 1.47							
Siemens LA2 confirmation	91	1.03	3.6	0.94 - 1.30	1					1.00	-0.80
Stago DRVVT Confirm	15	1.08	9.1	0.95 - 1.31							
SCT	34	1.08	5.7	0.96 - 1.28							
IL HemosIL SCT confirm	33	1.08	5.2	0.96 - 1.27							

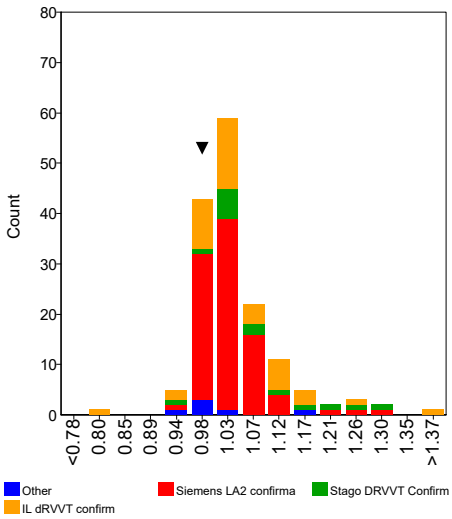
Assays



APTT



DRVVT

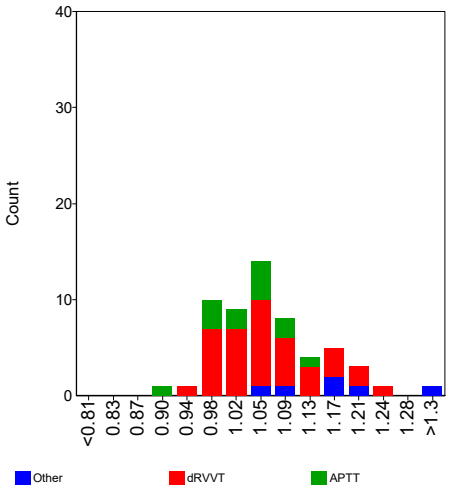


Lupus Anticoagulant

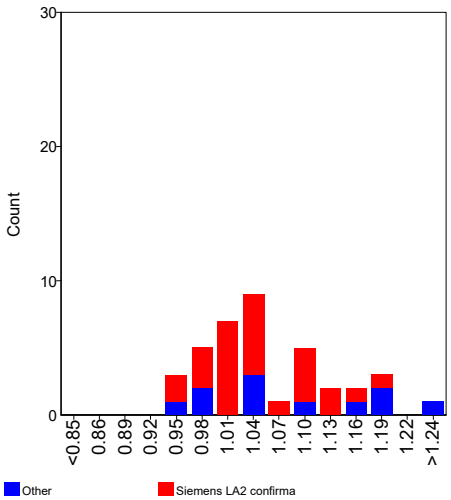
Mixing (confirm)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	13	1.03	5.9	0.92 - 1.12							
Siemens Actin FS	9	1.05		0.92 - 1.09							
dRVVT	38	1.06	7.4	0.95 - 1.25							
IL HemosIL dRVVT confirm	9	1.11		0.96 - 1.25							
Siemens LA2 confirmation	27	1.05	6.2	0.95 - 1.21							

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.

As expected, the majority of performed mixing confirmation tests (74%) were classified as not elevated. For a weak positive Lupus Anticoagulant plasma, it is expected that the test result (almost) fully normalised in the mixing confirmation test. Mixing confirmation tests were performed less frequently (~3 times less) compared to mixing screen tests.

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

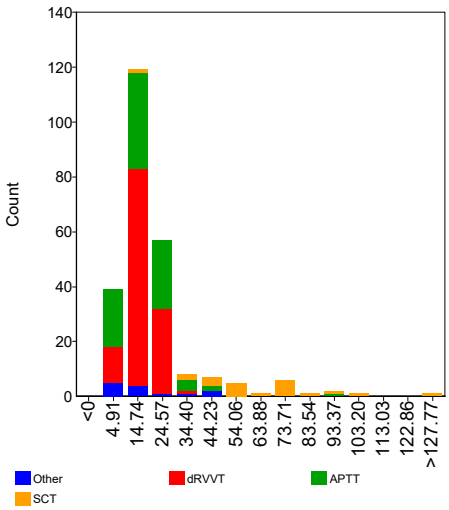
Lupus Anticoagulant

Interpretation

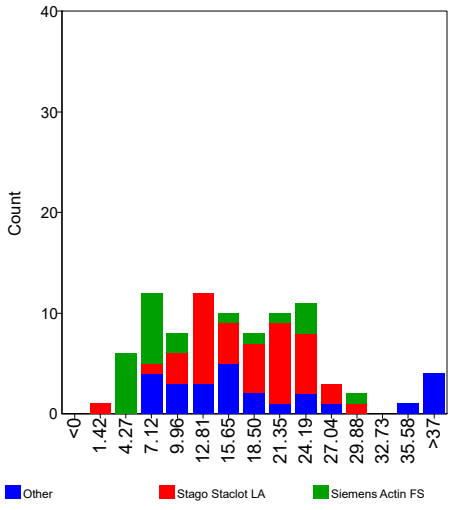
Delta Seconds

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	88	16.28	51.4	0.00 - 89.20							
IL Hemosil SynthAFax	8	13.60		10.71 - 27.10							
Siemens Actin FS	22	11.43	74.6	4.00 - 29.80							
Stago Staclot LA	40	18.03	34.2	0.00 - 30.80							
dAPTT	7	19.60		6.20 - 48.00							
dRVVT	124	17.13	27.4	0.90 - 30.00							
IL HemosIL dRVVT confirm	43	20.04	18.7	0.90 - 30.00							
Siemens LA2 confirmation	60	16.26	20.1	1.00 - 26.30							
Stago DRVVT Confirm	13	15.51	31.2	10.60 - 22.90							
SCT	22	62.37	35.0	16.70 - 153.70							
IL HemosIL SCT confirm	21	60.35	32.0	16.70 - 103.00							

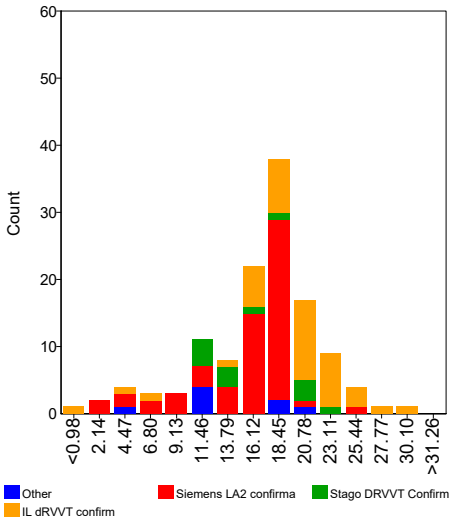
Assays



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).

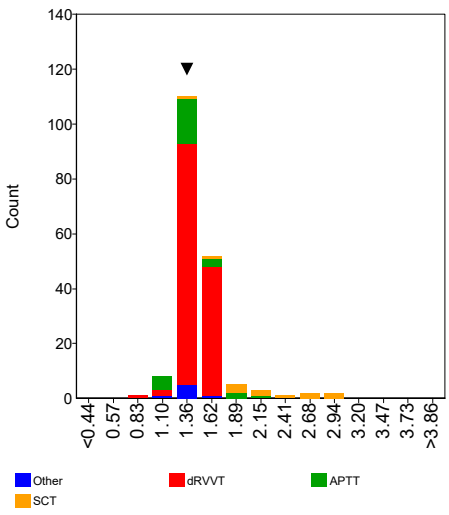
Lupus Anticoagulant

Interpretation

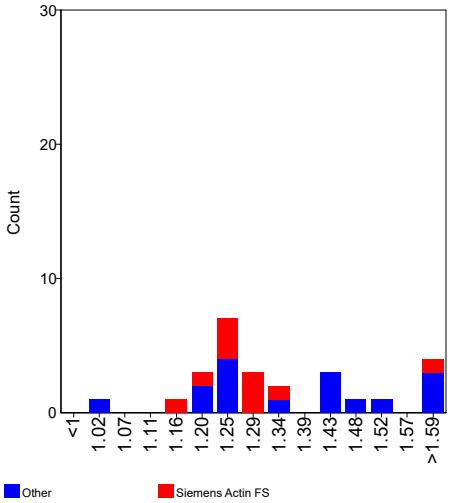
Ratio Screen/Confirmation - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	27	1.35	13.2	1.00 - 2.22							
Siemens Actin FS	11	1.30	7.6	1.18 - 2.22							
Stago Staclot LA	8	1.30		1.19 - 1.46							
dRVVT	138	1.45	7.4	0.91 - 1.73	1					1.40	-0.45
IL HemosIL dRVVT confirm	22	1.46	13.4	0.91 - 1.73							
Precision Biologic LA sure	5	1.55		1.48 - 1.63							
Siemens LA2 confirmation	87	1.45	5.6	1.09 - 1.64	1					1.40	-0.56
Stago DRVVT Confirm	15	1.47	9.4	1.29 - 1.67							
SCT	12	2.18	25.7	1.48 - 2.91							
IL HemosIL SCT confirm	11	2.11	24.5	1.48 - 2.90							

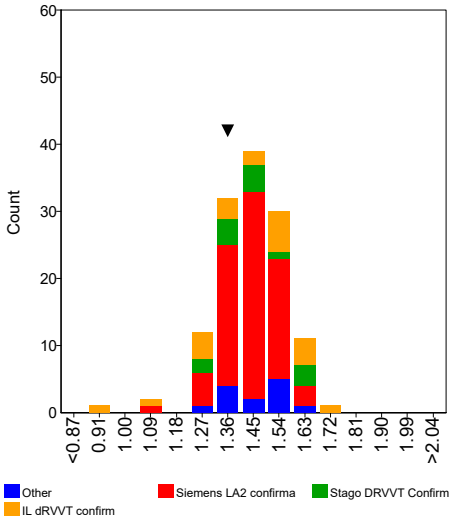
Assays



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 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. 1.6).

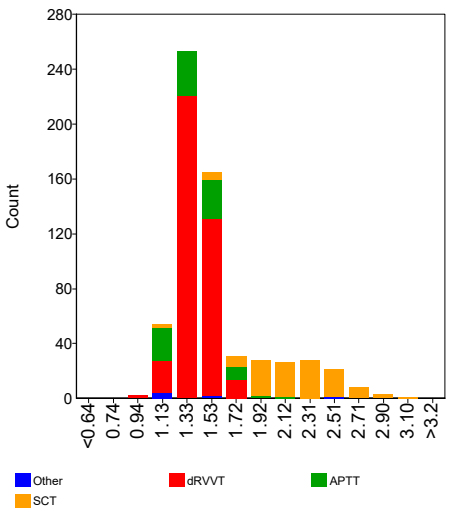
Lupus Anticoagulant

Interpretation

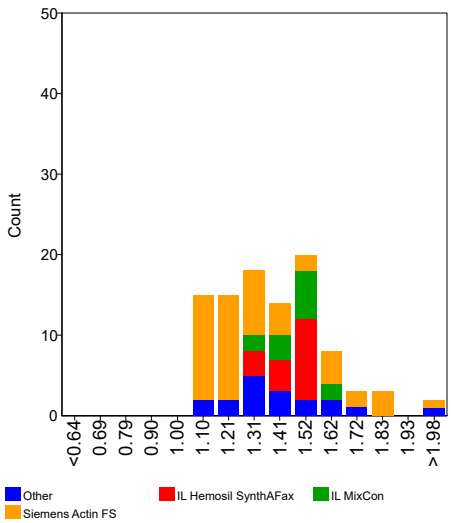
Ratio Screen/Confirmation - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	98	1.37	15.1	1.07 - 2.20							
IL Hemosil SynthAFax	17	1.45	5.8	1.30 - 1.54							
IL MixCon	13	1.47	8.0	1.29 - 1.66							
Siemens Actin FS	50	1.31	17.0	1.07 - 2.20							
Stago/Roche PTT LA	5	1.30		1.08 - 1.62							
dRVVT	389	1.39	8.0	1.00 - 1.74							
Hyphen Biomed Hemoclot LA-C	8	1.51		1.29 - 1.71							
IL HemosIL dRVVT confirm	188	1.42	7.4	1.03 - 1.74							
Roche Lupus C	6	1.33		1.24 - 1.39							
Siemens LA2 confirmation	122	1.36	6.9	1.00 - 1.57							
Stago DRVVT Confirm	58	1.36	9.8	1.16 - 1.65							
SCT	126	2.19	15.5	1.10 - 3.10							
IL HemosIL SCT confirm	126	2.19	15.5	1.10 - 3.10							

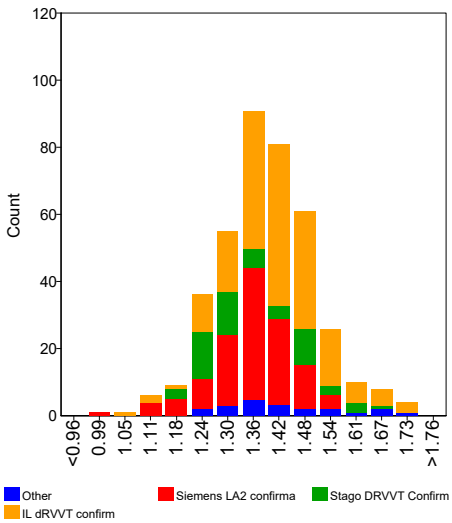
Assays



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 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. 1.6).

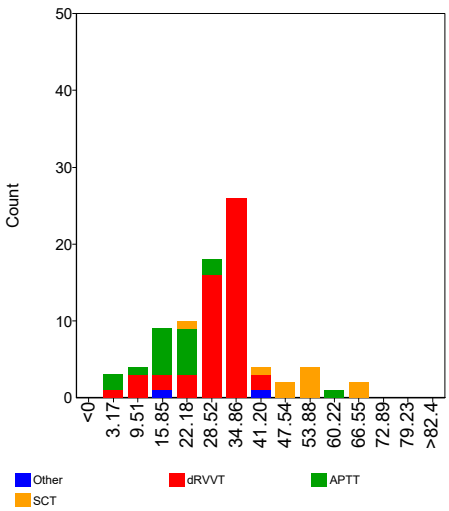
Lupus Anticoagulant

Interpretation

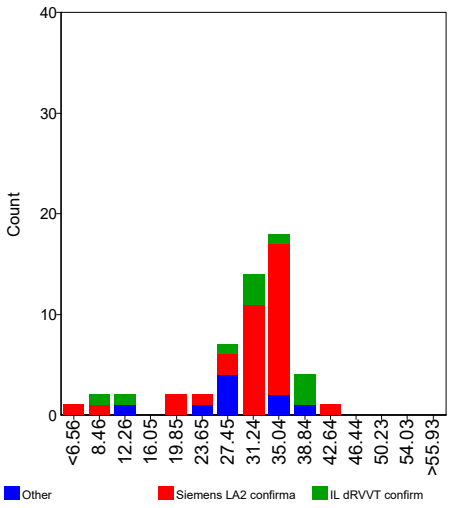
Percentage Correction - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	18	18.98	40.2	4.90 - 60.30							
Siemens Actin FS	8	19.25		5.00 - 60.30							
dRVVT	53	31.15	18.1	2.00 - 41.40							
IL HemosIL dRVVT confirm	10	31.25	26.3	10.00 - 38.60							
Siemens LA2 confirmation	34	31.80	12.8	2.00 - 41.40							
Stago DRVVT Confirm	6	27.40		22.18 - 37.90							
SCT	10	52.65	18.8	22.10 - 65.70							
IL HemosIL SCT confirm	9	52.40		22.10 - 64.90							

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

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

4505 : 0.05

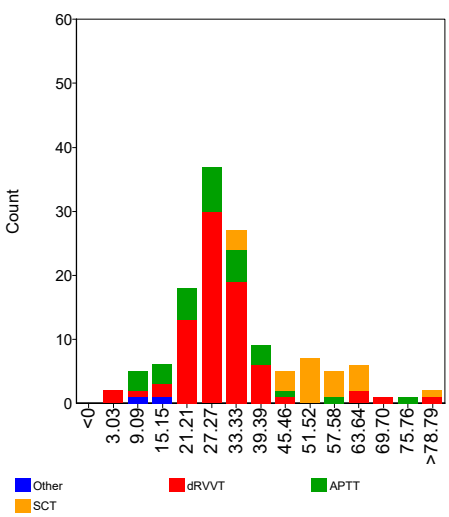
Lupus Anticoagulant

Interpretation

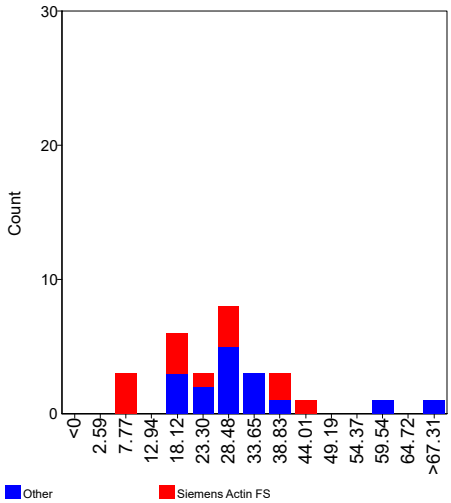
Percentage Correction - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	29	27.27	43.2	6.36 - 77.00							
Siemens Actin FS	13	23.91	60.5	6.36 - 45.50							
dRVVT	78	28.93	22.9	2.94 - 92.00							
IL HemosIL dRVVT confirm	34	31.25	27.9	2.94 - 92.00							
Siemens LA2 confirmation	32	28.09	19.2	5.00 - 69.65							
Stago DRVVT Confirm	8	28.55		15.63 - 33.10							
SCT	22	53.17	16.1	33.00 - 100.00							
IL HemosIL SCT confirm	22	53.17	16.1	33.00 - 100.00							

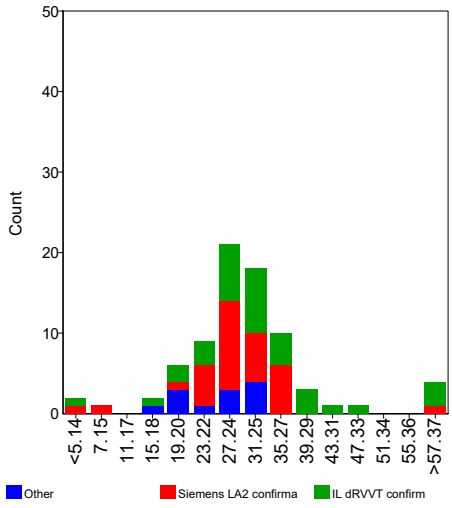
Assays



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

9907255 : 1.62

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	1	8	8	10	1			
					2			
					3			
Screen and mixing test	4	65	4	16	1			
					2			
					3			
Screen and confirm test	19	453	21	3	1			
					2			
					3			
Screen, mixing and confirm test	9	247	17		1			LA detected
					2			
					3			
Screen, confirm, mixing test	7	138	12	4	1			
					2			
					3			
Mixing - confirmation	1	26	3	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			
475	18	13	2	LA detected		

Comments
The sample used in this survey was plasma from a patient diagnosed with Lupus Anticoagulant (LA Ratio = approx. 1.6).
No other types of inhibitors were present.

In total 506 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 94% classified the sample as positive. Three percent classified the sample as equivocal. Thus, the vast majority of the participants correctly classified this sample as positive. A minority (4%) of the participants classified this sample as negative, this does not seems to be affected by the test strategy but is probably caused by the sensitivity of the reagent and the local interpretation of the result (e.g. local cut-off value used).

Participants stated that there is an indication that this sample is positive for lupus anticoagulant but in real clinical practice this should be confirmed in a new sample after 12 weeks.
Some participants indicated that the presence of direct oral anticoagulants and/or factor deficiency should be excluded.
One participant indicated that pretreatment with DOAC STOP left the parameters unchanged and concluded that there was no indication for the presence of DOACs in the sample.

Lupus Anticoagulant

AntiCardiolipin Antibodies IgG

Sample No 23.213

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.6)

Prior Use Prior Use: None

Unit GPL, U/mL, µg/mL, CU/mL

Expiry Date 30-April-2026

Homogeneity 2.1 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 7.0%** 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.

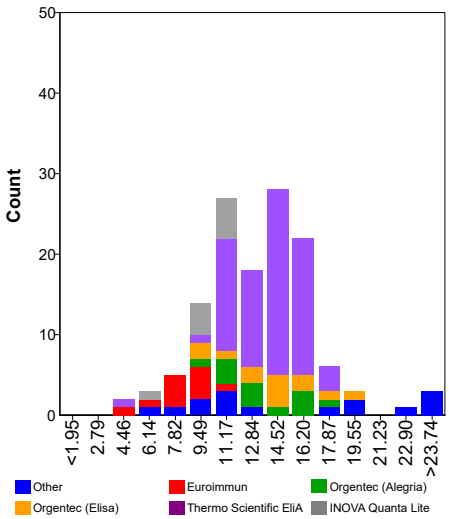
Number of Participants 632

Number of Responders 220 **Response Rate** 35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	38	22	79	45	38	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	132	13.3	24.7	4.4 - 160.0						
Aeskulisa Diagnotic GmbH	5	11.3		5.9 - 24.7						
Euroimmun	11	8.3	25.5	5.2 - 11.6						
Orgentec (Alegria)	12	13.5	21.4	9.6 - 17.5						
Orgentec (Elisa)	13	14.3	22.1	9.8 - 19.0						
Thermo Scientific EliA	71	14.1	15.2	4.4 - 18.0						
Werfen INOVA Quanta Lite	10	10.0	13.9	6.0 - 11.7						
CU/mL	81	84.7	10.1	61.6 - 145.1						
I.L. Acustar / INOVA Quanta Flash	80	84.5	10.0	61.6 - 145.1						

GPL, U/mL, µg/mL



Comments

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

3625 : 1.19

7770049 : 63

A heterogeneous pattern in the classification has been observed. A positive classification has been observed by the majority of participants.

Lupus Anticoagulant

AntiCardiolipin Antibodies IgM

Sample No 23.213

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.6)

Prior Use Prior Use: None

Unit MPL, U/mL, µg/mL, CU/mL

Expiry Date 30-April-2026

Homogeneity 2.1 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 7.0%** 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.

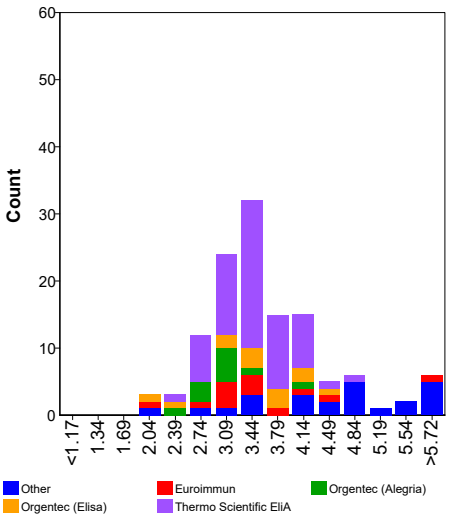
Number of Participants 632

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

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	207	0	2	0	0	1

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U/mL, µg/mL, GPL/MPL	124	3.6	20.0	2.0 - 9.9						
Aeskulisa Diagnotic GmbH	5	4.4		2.6 - 4.9						
Biorad Bioplex	6	5.3		4.6 - 6.0						
Euroimmun	13	3.4	22.0	2.0 - 9.9						
Orgentec (Alegria)	11	3.0	12.0	2.5 - 4.0						
Orgentec (Elisa)	13	3.5	19.3	2.2 - 4.5						
Thermo Scientific EliA	63	3.5	14.0	2.5 - 4.8						
Werfen INOVA Quanta Lite	5	6.0		3.5 - 9.0						
CU/mL	76	6.3	9.9	4.1 - 7.7						
I.L. Acustar / INOVA Quanta Flash	76	6.3	9.9	4.1 - 7.7						

MPL, U/mL, µg/mL



Comments

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

1617 : 18.0

9907155 : 0

Almost all participants reported a negative classification.

Lupus Anticoagulant

ß2-Glycoprotein I Antibodies IgG

Sample No 23.213

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.6)

Prior Use Prior Use: None

Unit U, U/mL, µg/mL, CU/mL

Expiry Date 30-April-2026

Homogeneity 2.1 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 7.0%** 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.

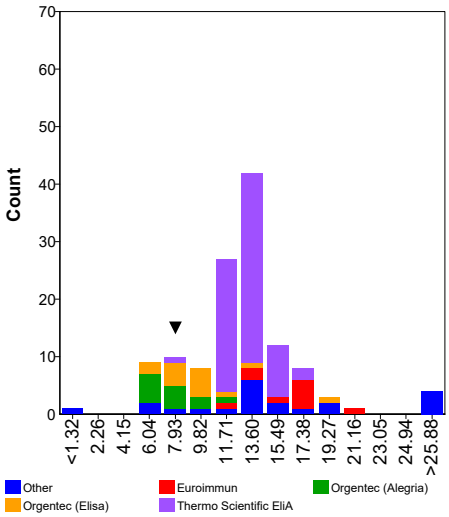
Number of Participants 632

Number of Responders 213 **Response Rate** 34 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	29	11	67	28	80	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	125	12.6	25.8	0.4 - 160.0	8.8	-1.16				
Aeskulisa Diagnotic GmbH	5	15.0		5.2 - 28.9						
Euroimmun	10	16.1	20.2	11.1 - 21.6						
Orgentec (Alegria)	12	7.5	27.4	5.5 - 11.4						
Orgentec (Elisa)	14	9.2	25.1	6.0 - 20.1	8.8	-0.17				
Thermo Scientific EliA	68	13.1	11.3	8.2 - 17.0						
Werfen INOVA Quanta Lite	8	13.5		8.7 - 19.0						
CU/mL	81	408.0	13.8	250.8 - 576.3						
I.L. Acustar / INOVA Quanta Flash	80	406.9	13.6	250.8 - 576.3						

U, U/mL, µg/mL



Comments

The following participants reported deviating results which were excluded in the statistical evaluation:
7770049 : 111.10
9907155 : 0

A heterogeneous pattern in the classification has been observed. A positive classification has been observed by the majority of participants.

Lupus Anticoagulant

ß2-Glycoprotein I Antibodies IgM

Sample No 23.213

Sample Details Plasma positive for Lupus Anticoagulant (LA Ratio approx. 1.6)

Prior Use Prior Use: None

Unit U, U/mL, µg/mL, CU/mL

Expiry Date 30-April-2026

Homogeneity 2.1 % **Homogeneity Parameter** LA ratio

For any method used for the measurement of this parameter with a **CV ≤ 7.0%** 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.

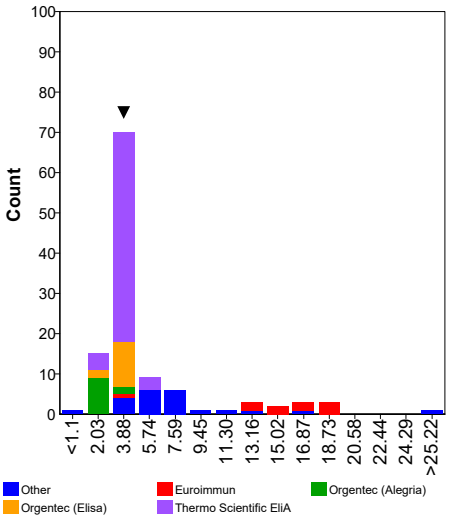
Number of Participants 632

Number of Responders 194 **Response Rate** 31 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	190	4	3	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	115	4.3	37.3	0.1 - 26.0	3.8	-0.32				
Aeskulisa Diagnotic GmbH	5	6.6		6.1 - 12.0						
Biorad Bioplex	6	7.3		5.9 - 8.0						
Euroimmun	10	15.8	19.9	3.8 - 19.1						
Orgentec (Alegria)	11	2.4	18.0	2.0 - 3.7						
Orgentec (Elisa)	13	3.4	15.6	2.0 - 4.0	3.8	0.68				
Thermo Scientific EliA	59	3.9	16.7	2.4 - 5.7						
CU/mL	74	4.8	14.3	2.4 - 6.9						
I.L. Acustar / INOVA Quanta Flash	74	4.8	14.3	2.4 - 6.9						

U, U/mL, µg/mL



Comments

The following participants reported deviating results which were excluded in the statistical evaluation:
3625 : 1.53
9907155 : 0

Most of the participants reported a negative classification.