ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT

SURVEY 2023-L2
Lupus Anticoagulant
Labcode 1492

Date of Issue   :   01-August-2023

Survey   :   2023-L2

Report   :   Lupus Anticoagulant

<u>Note</u>:
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.

<u>General Information</u>

Complaints
Any complaints regarding this survey report should be reported to the ECAT before **September 22nd, 2023**. 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

<u>Note</u>: 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	23.108
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	Ratio
Expiry Date	28-February-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	571

Homogeneity Parameter   LA ratio

Response Rate   92 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	266	148	0	13
dAPTT	15	2	0	2
dPT	6	4	0	0
dRVVT	583	16	0	16
KCT	5	0	0	0
Other	2	1	0	1
PNP	0	0	0	1
PT	1	3	0	0
SCT	141	2	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									

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Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	375	1.30	16.6	0.89 - 2.85	1	1.18	-0.57	1.04	-1.23		
Hyphen-Biomed Cephen LS	7	1.49		1.35 - 1.67							
IL APTT SP	53	1.47	11.8	1.09 - 1.75							
IL HemosIL SynthAsil	45	1.29	7.6	1.08 - 1.48							
IL MixCon	15	1.14	4.0	0.99 - 1.43							
Siemens Actin FS	8	1.04		0.92 - 1.09							
Siemens Actin FSL	78	1.11	6.4	0.89 - 1.52	1			1.04	-0.96		
Siemens Pathromtin SL	28	1.20	9.9	0.97 - 1.50	1	1.18	-0.21				
Stago PTT Automate/STA PTT	17	1.29	9.2	1.05 - 1.48							
Stago PTT LA	78	1.50	7.8	0.97 - 1.90							
Stago Staclot LA	18	1.29	14.0	1.03 - 1.78							
Tcoag TriniClot APTT-HS	6	1.31		1.00 - 1.40							
Tcoag TriniClot Automated APTT	7	1.25		1.23 - 1.30							
dAPTT	13	1.48	11.7	1.07 - 2.37							
Stago PTT LA	9	1.54		1.42 - 1.63							
dPT	6	1.21		1.10 - 1.36							
dRVVT	551	1.51	8.3	0.63 - 2.37	1					1.37	-1.07
Hyphen Biomed Hemoclot LA-S	8	1.72		1.46 - 1.84							
I.L. HemosIL dRVVT screen	197	1.52	7.9	1.08 - 2.27							
Precision Biologic LA check	6	1.37		1.31 - 1.59							
Roche Lupus S	7	1.49		1.38 - 1.60							
Siemens LA1 screen	232	1.53	7.4	0.63 - 2.37	1					1.37	-1.36
Stago DRVVT screen	83	1.44	7.2	1.13 - 1.87							
Technoclone LA Screen	7	1.40		1.35 - 1.46							
SCT	141	1.92	15.0	1.25 - 4.60							
Haematex SACT Reagent	5	3.38		2.55 - 4.60							
IL SCT screen	136	1.90	14.2	1.25 - 2.66							

Assays

APTT

DRVVT

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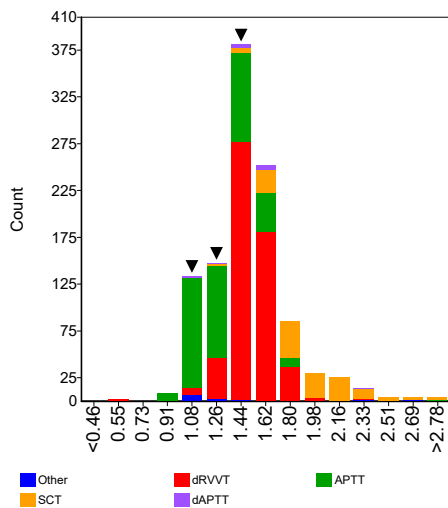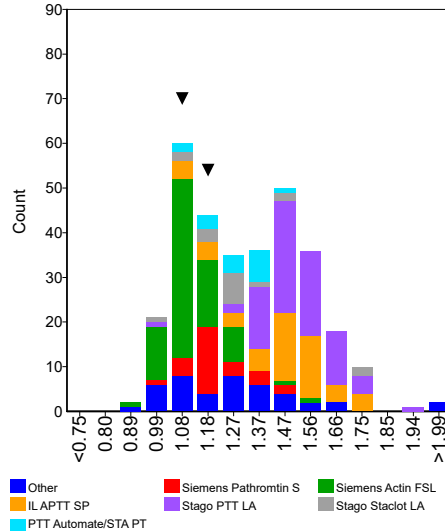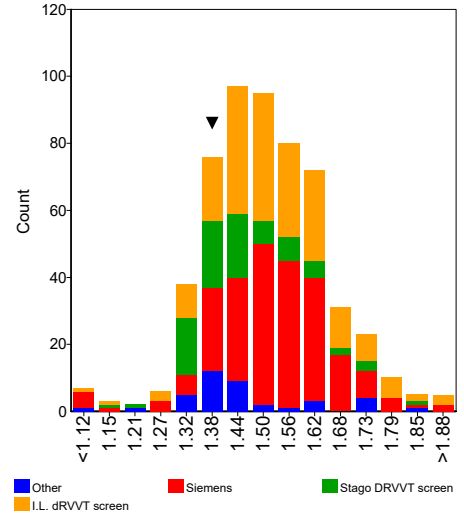
Lupus Anticoagulant

Screening

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	113	1.25	19.2	0.77 - 3.25	1	1.11	-0.58	1.18	-0.30		
IL APTT SP	15	1.44	11.5	1.06 - 1.65							
IL HemosIL SynthAsil	8	1.24		1.05 - 1.43							
Siemens Actin FSL	31	1.05	8.3	0.89 - 1.69	1			1.18	1.39		
Siemens Pathromtin SL	15	1.21	7.0	1.11 - 1.76	1	1.11	-1.19				
Stago PTT Automate/STA PTT	7	1.26		1.12 - 1.33							
Stago PTT LA	15	1.49	9.5	1.28 - 1.66							
Stago Staclot LA	6	1.19		0.90 - 1.71							
dRVVT	131	1.49	9.1	0.65 - 1.90	1					1.58	0.66
I.L. HemosIL dRVVT screen	27	1.53	9.8	1.15 - 1.80							
Siemens LA1 screen	81	1.50	7.8	0.65 - 1.74	1					1.58	0.72
Stago DRVVT screen	12	1.47	11.9	1.29 - 1.90							
SCT	16	1.96	11.5	1.54 - 2.20							
IL SCT screen	16	1.96	11.5	1.54 - 2.20							

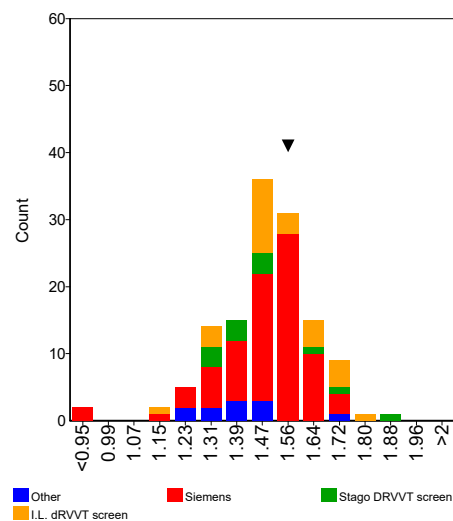### Assays
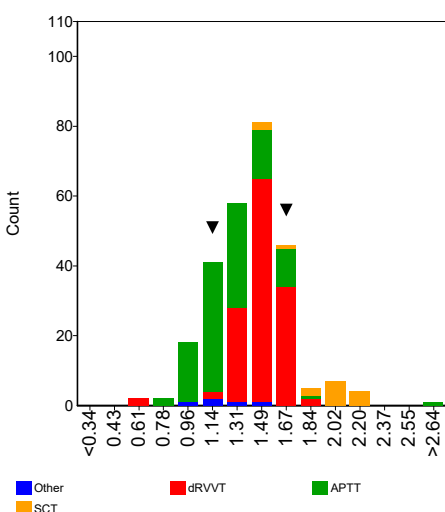
APTT
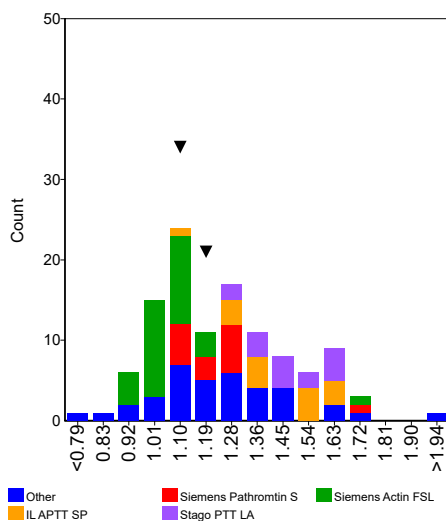
DRVVT

Comments

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

The majority of performed screening tests (> ~85%) were classified as elevated. Interestingly within the assay groups dRVVT and SCT ~98% of the performed screening tests were classified as elevated for this weak positive Lupus Anticoagulant plasma. However, in the assay group APTT 64% of the screening tests was classified as not elevated. Remarkably, 92% of the participants using the APTT reagent Siemens Actin FSL classified the sample as not elevated . This is in line with the lower ratio observed for Siemens Actin FSL compared to the other reagent groups . For the other most frequently used reagents (n≥10) less than 38% of the participants classified the sample as non elevated.
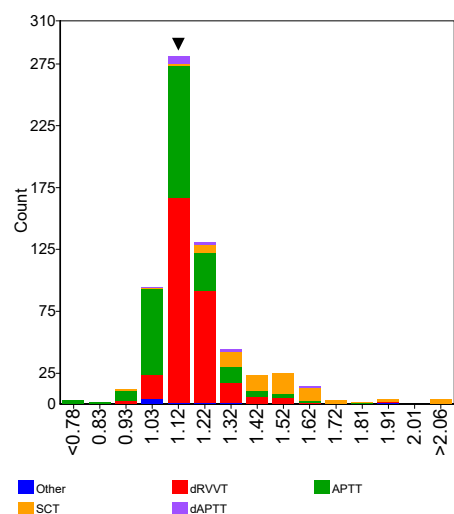
In general, comparable results were observed for the ratio ECAT plasma over Normal Plasma and ratio ECAT plasma over Mean Reference Interval (MRI).
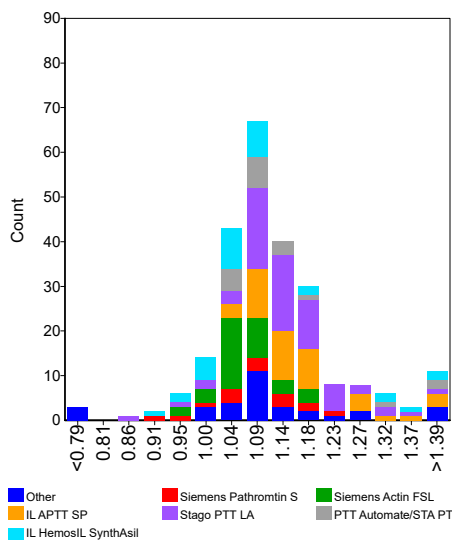
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Lupus Anticoagulant

Mixing (screening)

Sample No	23.108
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	Ratio
Expiry Date	28-February-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	399

Homogeneity Parameter   LA ratio

Response Rate   64 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	66	193	0	8
dAPTT	7	9	0	1
dPT	2	1	0	0
dRVVT	158	158	0	16
KCT	1	2	0	0
Other	1	2	0	0
PNP	0	1	0	0
PT	0	1	0	0
SCT	66	4	0	3

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

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Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	242	1.11	7.5	0.65 - 1.85							
Hyphen-Biomed Cephen LS	5	1.11		0.65 - 1.28							
IL APTT SP	43	1.16	6.7	1.05 - 1.58							
IL HemosIL SynthAsil	32	1.07	8.9	0.90 - 1.45							
Siemens Actin FSL	36	1.07	5.0	0.96 - 1.20							
Siemens Pathromtin SL	15	1.09	7.9	0.93 - 1.21							
Stago PTT Automate/STA PTT	19	1.10	4.7	1.03 - 1.42							
Stago PTT LA	65	1.14	6.2	0.86 - 1.52							
Tcoag TriniClot APTT-HS	5	1.10		1.00 - 1.14							
Tcoag TriniClot Automated APTT	7	1.10		1.08 - 1.12							
dAPTT	12	1.18	10.3	0.99 - 1.58							
Stago PTT LA	7	1.15		1.09 - 1.21							
dRVVT	309	1.16	5.7	0.90 - 1.88	1					1.12	-0.62
I.L. HemosIL dRVVT screen	86	1.16	6.4	0.91 - 1.53							
Siemens LA1 screen	157	1.16	5.2	0.92 - 1.88	1					1.12	-0.72
Stago DRVVT screen	48	1.16	6.2	1.05 - 1.39							
Technoclone LA Screen	5	1.16		1.12 - 1.17							
SCT	71	1.47	13.3	0.91 - 4.60							
IL SCT screen	67	1.45	12.3	0.91 - 2.15							

Assays

APTT

DRVVT

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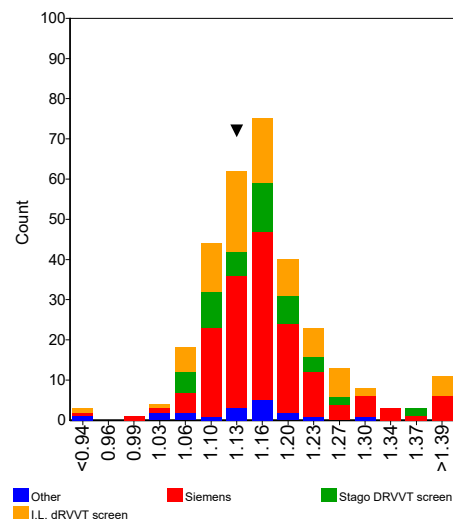
Lupus Anticoagulant | Mixing (screening)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	67	1.08	9.1	0.87 - 1.36							
IL APTT SP	9	1.11		0.98 - 1.19							
IL HemosIL SynthAsil	5	1.05		0.87 - 1.36							
Siemens Actin FSL	20	1.05	9.6	0.91 - 1.34							
Siemens Pathromtin SL	12	1.12	11.5	0.96 - 1.30							
Stago PTT Automate/STA PTT	5	1.05		1.00 - 1.07							
Stago PTT LA	10	1.10	9.4	0.98 - 1.34							
dRVVT	77	1.16	10.2	0.94 - 1.72							
I.L. HemosIL dRVVT screen	11	1.19	13.2	1.00 - 1.72							
Siemens LA1 screen	51	1.15	10.3	0.94 - 1.58							
Stago DRVVT screen	7	1.17		1.01 - 1.37							
SCT	7	1.56		1.38 - 2.15							
IL SCT screen	6	1.58		1.38 - 2.15							

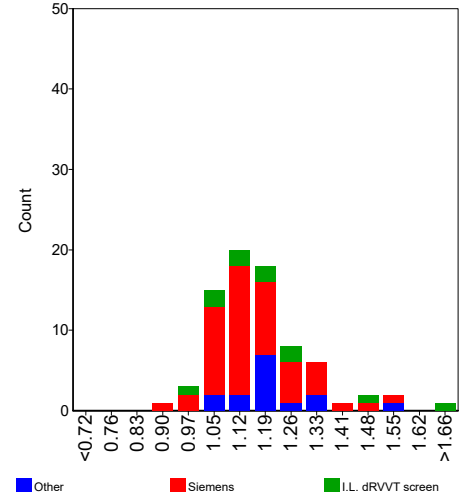### Assays | APTT | DRVVT
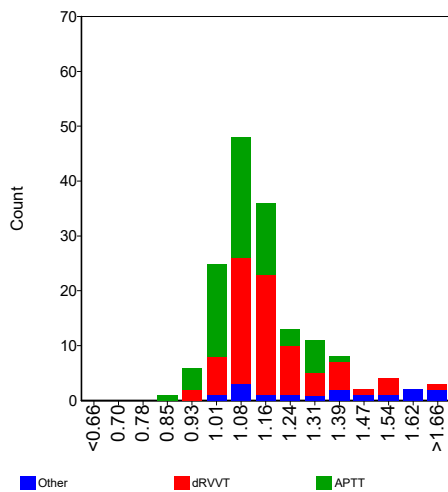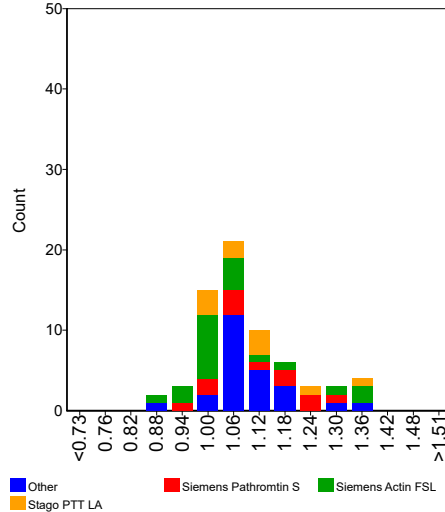
Comments

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

Approximately, half of performed mixing screen tests (45%) were classified as elevated, which was expected because the sample was weak positive for Lupus Anticoagulant. Especially participants using reagents derived from the assay groups APTT showed a large percent of not elevated classifications 75%. This is expected, since a weak positive patient sample was used in this survey and therefore a larger number of not eleveted classifications will be observed compared to the screening test results.

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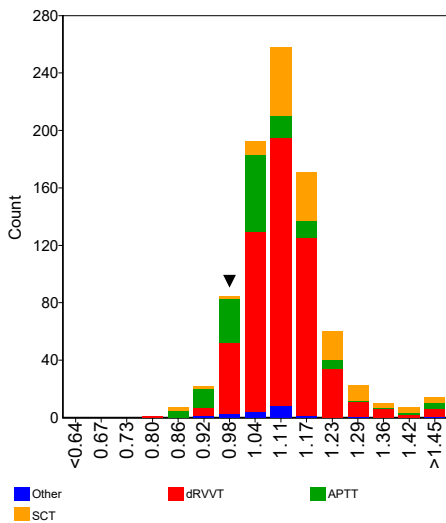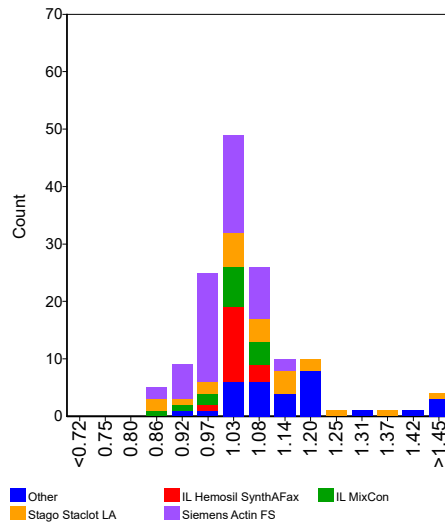
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Lupus Anticoagulant

Confirmation

Sample No	23.108
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	Ratio
Expiry Date	28-February-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	555

Homogeneity Parameter   LA ratio

Response Rate   89 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	30	129	0	20
dAPTT	3	8	0	0
dPT	2	4	0	1
dRVVT	208	343	0	60
Other	2	0	0	1
PNP	2	4	0	2
PT	0	1	0	0
SCT	50	79	0	20

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

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Ratio Normal Plasma	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	142	1.05	8.3	0.85 - 2.57							
IL Hemosil SynthAFax	17	1.03	2.8	0.99 - 1.10							
IL MixCon	15	1.02	5.7	0.88 - 1.11							
Siemens Actin FS	55	1.01	6.8	0.85 - 1.16							
Stago PTT Automate/STA PTT	5	1.21		1.05 - 1.21							
Stago Staclot LA	24	1.08	11.3	0.87 - 1.45							
Stago/Roche PTT LA	5	1.18		1.02 - 1.20							
dAPTT	9	1.09		0.99 - 1.68							
dRVVT	550	1.11	6.7	0.82 - 1.67	1					1.00	-1.42
Hyphen Biomed Hemoclot LA-C	8	1.11		1.00 - 1.19							
IL HemosIL dRVVT confirm	204	1.13	7.1	0.82 - 1.59							
Precision Biologic LA sure	5	1.03		0.90 - 1.18							
Roche Lupus C	7	1.14		1.00 - 1.25							
Siemens LA2 confirmation	229	1.10	6.1	0.89 - 1.67	1					1.00	-1.48
Stago DRVVT Confirm	79	1.07	5.8	0.98 - 1.66							
Technoclone LA Confirm	8	1.05		0.99 - 1.10							
SCT	139	1.16	7.8	0.88 - 1.89							
IL HemosIL SCT confirm	138	1.16	7.7	0.88 - 1.89							

Assays

APTT

DRVVT

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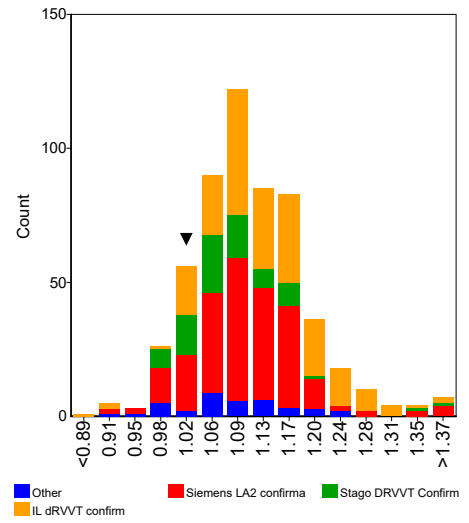
Lupus Anticoagulant

Confirmation

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	38	1.02	9.6	0.82 - 2.40							
Siemens Actin FS	23	0.98	5.3	0.82 - 1.05							
Stago Staclot LA	7	1.10		0.91 - 2.40							
dRVVT	121	1.14	7.8	0.82 - 1.44	1					1.12	-0.16
IL HemosIL dRVVT confirm	24	1.16	5.5	1.00 - 1.33							
Siemens LA2 confirmation	74	1.15	8.4	0.82 - 1.34	1					1.12	-0.27
Stago DRVVT Confirm	13	1.08	8.4	0.94 - 1.20							
SCT	14	1.14	10.2	0.90 - 1.30							
IL HemosIL SCT confirm	14	1.14	10.2	0.90 - 1.30							

Assays
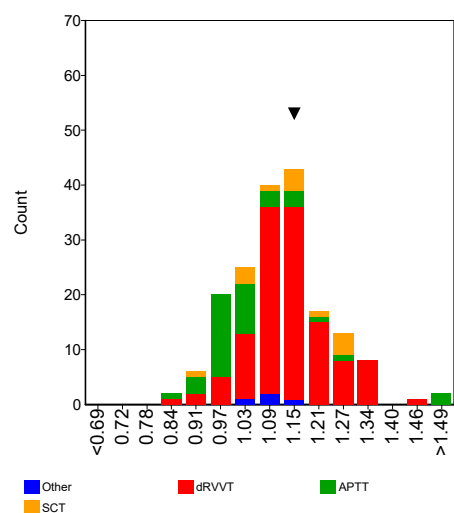
APTT
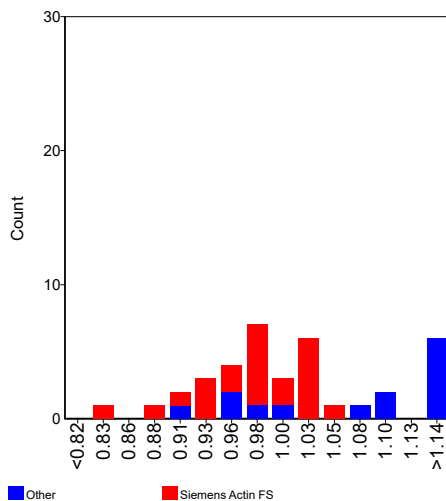
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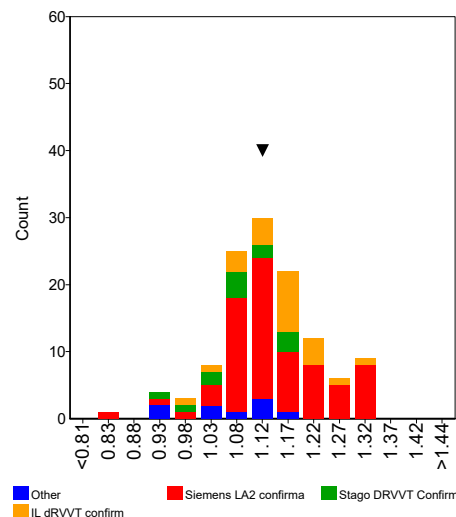
Comments

Several participants selected the wrong unit, e.g. ratio while the result was likely to be in seconds or vice versa. Other participants reported their result for the ECAT plasma in seconds while the result for their reference plasma or the mean of the reference interval was reported as a ratio or vice versa. In all these cases the ratio between the ECAT plasma and the laboratories own reference plasma and/or the mean of the reference interval could not be correctly calculated. Several participants reported also a confirmtion result in Delta Seconds. However the difference in clotting time between the screen and confirmation test (or reagent 1 and reagent 2) should be reported in the Interpretation section. All these results were excluded from the statistical analysis.

As expected, the majority of performed confirmation tests (66%) 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).

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Lupus Anticoagulant   Mixing (confirm)

Sample No	23.108
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	Ratio
Expiry Date	28-February-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	155

Homogeneity Parameter   LA ratio

Response Rate   25 %

Assay	Elevated	Not elevated	Borderline	No Classification
APTT	7	31	0	4
dAPTT	2	2	0	0
dPT	0	0	0	0
dRVVT	41	101	0	12
PNP	0	0	0	0
SCT	7	21	0	2

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

Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	36	1.03	7.6	0.92 - 1.84							
IL Hemosil SynthAFax	5	1.00		0.96 - 1.15							
Siemens Actin FS	14	0.99	5.0	0.92 - 1.06							
dRVVT	145	1.06	4.6	0.96 - 1.62	1					1.00	-1.21
IL HemosIL dRVVT confirm	38	1.05	4.3	0.97 - 1.23							
Siemens LA2 confirmation	89	1.06	4.8	0.96 - 1.62	1					1.00	-1.19
Stago DRVVT Confirm	14	1.06	4.2	1.00 - 1.19							
SCT	29	1.08	5.4	1.00 - 1.22							
IL HemosIL SCT confirm	29	1.08	5.4	1.00 - 1.22							

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Assays

APTT

DRVVT

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

Version: 1.0.0

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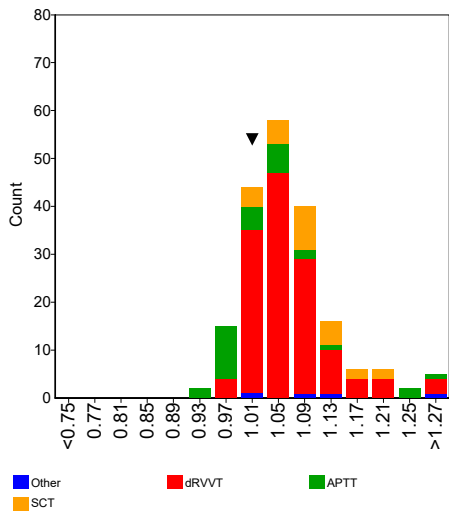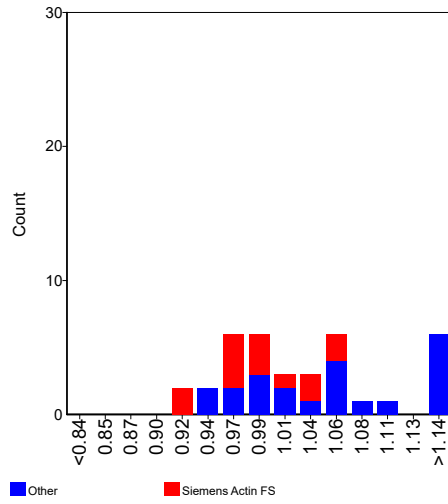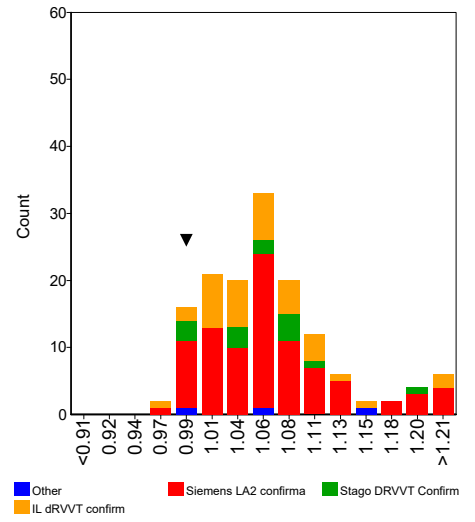
Lupus Anticoagulant		**Mixing (confirm)**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	12	1.05	9.9	0.93 - 1.23							
Siemens Actin FS	7	1.00		0.96 - 1.08							
dRVVT	36	1.11	7.3	1.00 - 1.37							
IL HemosIL dRVVT confirm	6	1.09		1.05 - 1.15							
Siemens LA2 confirmation	28	1.11	8.1	1.00 - 1.37							

Assays
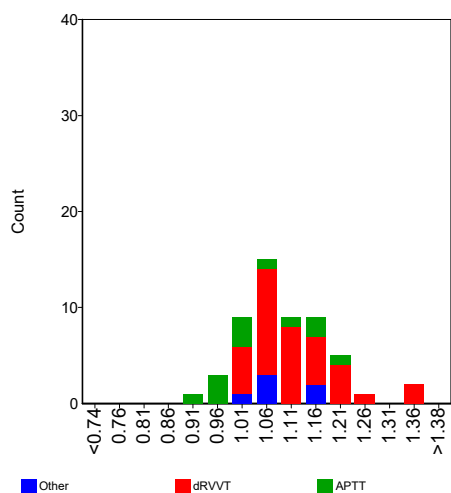
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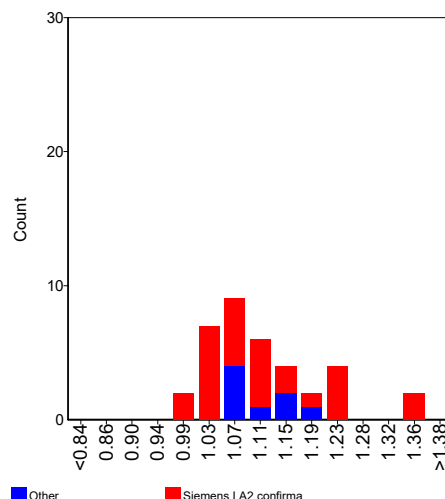
Comments

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

As expected, the majority of performed mixing confirm tests (73%) 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 confirm test. Interestingly, mixing confirm 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).

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Lupus Anticoagulant	Interpretation

Delta Seconds

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	78	7.95	72.8	0.10 - 128.70							
IL Hemosil SynthAFax	6	4.50		2.74 - 6.10							
Siemens Actin FS	20	8.48	86.8	2.10 - 30.90							
Stago Staclot LA	33	7.25	58.1	0.20 - 13.00							
dAPTT	5	7.70		2.20 - 21.00							
dRVVT	127	16.74	24.4	1.05 - 67.40							
IL HemosIL dRVVT confirm	36	15.97	21.4	5.70 - 23.80							
Siemens LA2 confirmation	69	17.66	19.1	2.00 - 55.40							
Stago DRVVT Confirm	12	16.17	26.6	10.60 - 25.10							
SCT	20	41.67	35.1	22.90 - 133.20							
IL HemosIL SCT confirm	19	40.05	31.9	22.90 - 75.70							

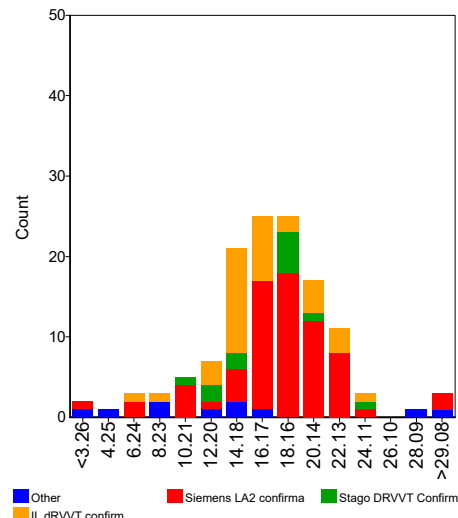### Assays
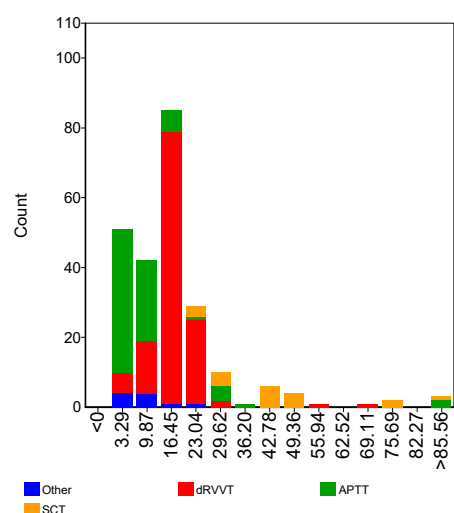
APTT
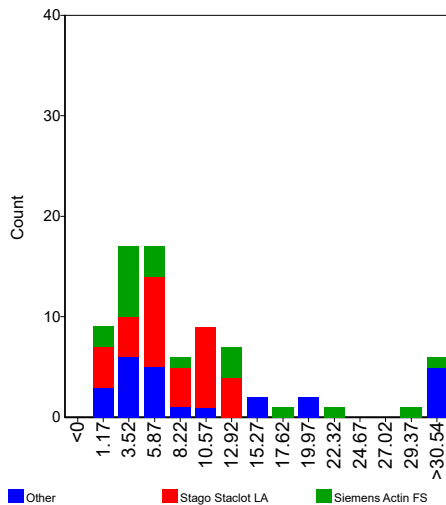
DRVVT

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.

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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	25	1.26	18.1	0.73 - 2.52							
Siemens Actin FS	12	1.28	24.6	0.73 - 2.10							
dRVVT	132	1.43	8.5	0.84 - 1.76	1					1.50	0.57
IL HemosIL dRVVT confirm	20	1.37	12.5	1.13 - 1.76							
Siemens LA2 confirmation	85	1.46	5.5	1.14 - 1.69	1					1.50	0.44
Stago DRVVT Confirm	13	1.40	9.2	1.20 - 1.57							
Technoclone LA Confirm	5	1.40		1.12 - 1.51							
SCT	11	1.67	21.3	0.90 - 2.09							
IL HemosIL SCT confirm	10	1.62	20.8	0.90 - 2.05							

Assays
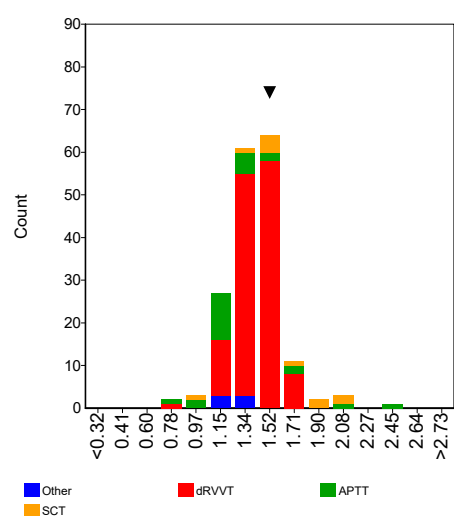
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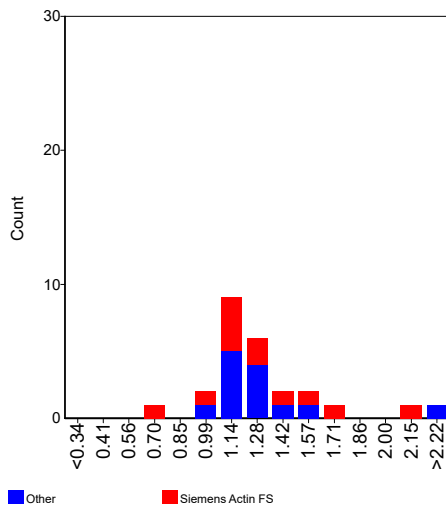
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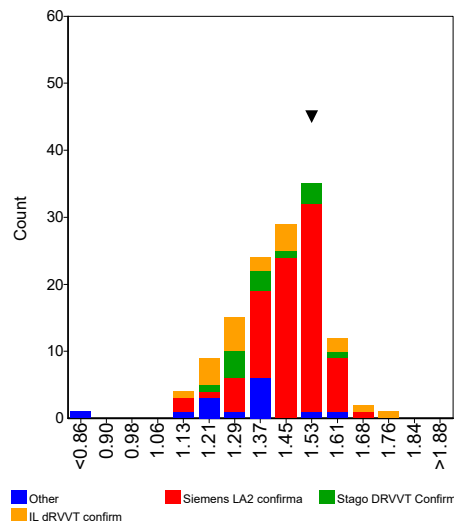
Comments

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. 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. 1.4).

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Lupus Anticoagulant	Interpretation

Ratio Screen/Confirmation - Normalised

|	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	90	1.19	14.4	0.94 - 4.00							
IL Hemosil SynthAFax	14	1.12	2.7	1.04 - 1.16							
IL MixCon	11	1.11	4.4	1.05 - 1.22							
Siemens Actin FS	45	1.22	16.6	0.98 - 2.00							
dRVVT	392	1.36	7.7	0.94 - 1.74							
Hyphen Biomed Hemoclot LA-C	8	1.55		1.33 - 1.73							
IL HemosIL dRVVT confirm	172	1.34	7.7	0.97 - 1.74							
Siemens LA2 confirmation	136	1.38	6.5	0.94 - 1.57							
Stago DRVVT Confirm	61	1.34	7.2	1.21 - 1.64							
SCT	117	1.64	13.7	1.02 - 2.20							
IL HemosIL SCT confirm	117	1.64	13.7	1.02 - 2.20							

Assays
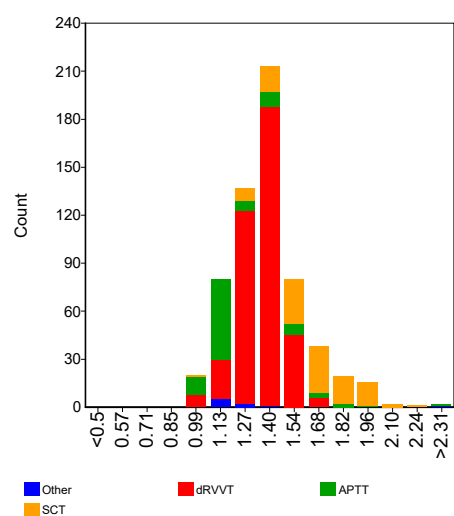
APTT
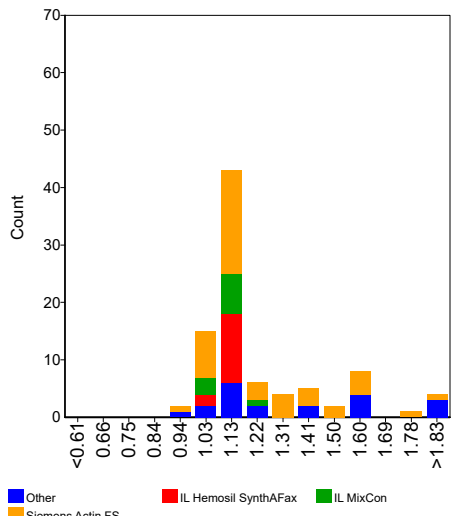
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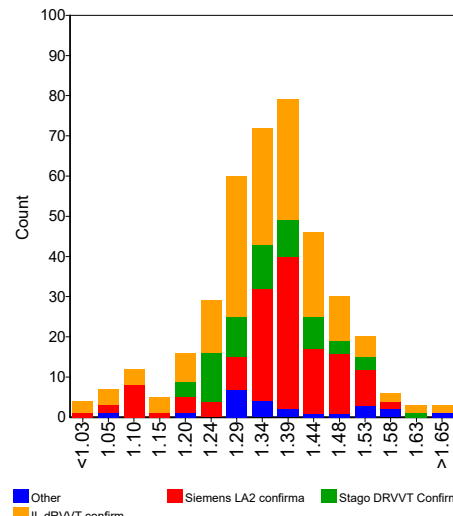
Comments

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The average ratio screen / confirmation is in general in line with the expected LA ratio (approx. 1.4).

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Lupus Anticoagulant

Interpretation

Percentage Correction - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	16	18.98	67.2	1.36 - 35.10							
Siemens Actin FS	9	23.81		1.36 - 34.50							
dRVVT	55	32.08	20.4	10.00 - 100.00							
IL HemosIL dRVVT confirm	6	30.58		28.22 - 63.00							
Siemens LA2 confirmation	38	32.94	16.3	13.50 - 100.00							
Stago DRVVT Confirm	8	32.90		10.00 - 44.80							
SCT	8	45.92		39.84 - 54.28							
IL HemosIL SCT confirm	7	42.74		39.84 - 54.28							

Assays
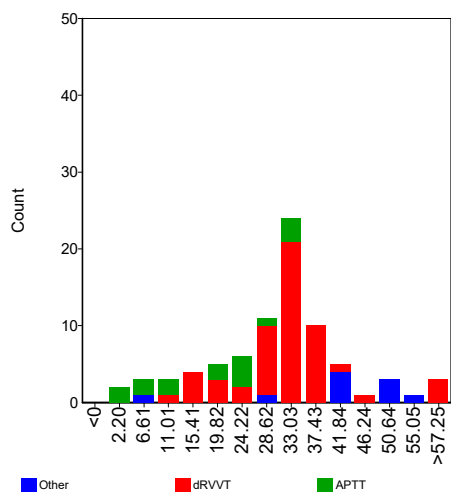
DRVVT
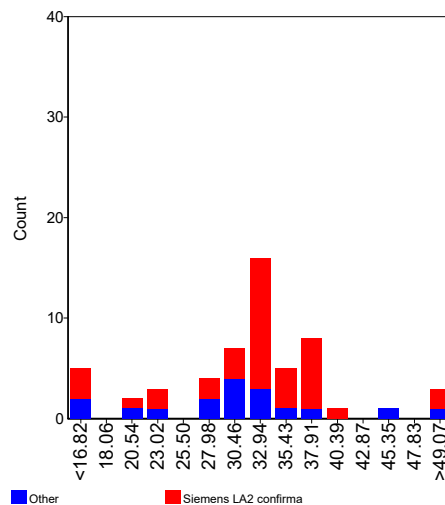
Comments

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.

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Lupus Anticoagulant

Interpretation

Percentage Correction - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	28	21.42	83.8	0.23 - 74.50							
Siemens Actin FS	13	24.93	82.0	1.92 - 74.50							
dRVVT	71	27.08	21.3	1.25 - 61.43							
IL HemosIL dRVVT confirm	26	24.65	20.5	4.90 - 39.80							
Siemens LA2 confirmation	33	29.11	16.9	12.00 - 61.43							
Stago DRVVT Confirm	11	27.73	22.6	1.25 - 50.00							
SCT	21	39.99	35.3	15.00 - 58.80							
IL HemosIL SCT confirm	21	39.99	35.3	15.00 - 58.80							

Assays

APTT
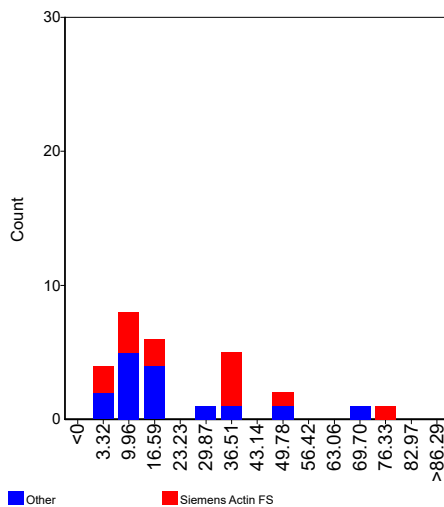
DRVVT

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 statistical evaluation. Don't forget to select the type of correction in the next survey.
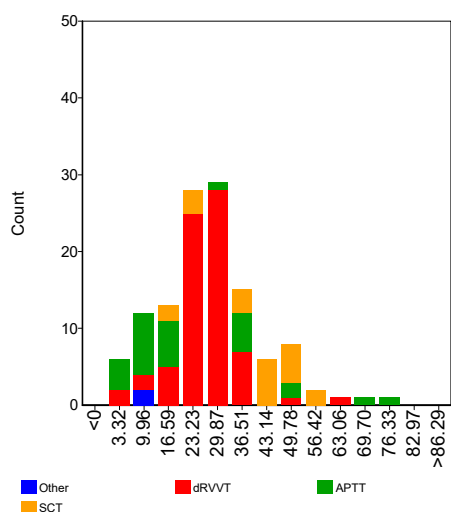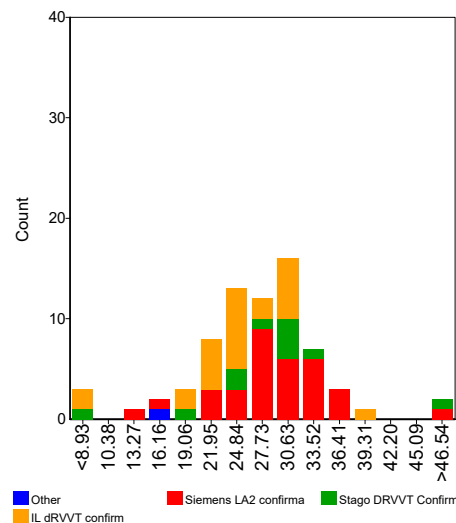
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Lupus Anticoagulant | Final Conclusion

Testing Strategies	Classification				Your Classification			
	Equivocal	LA detected	LA not detected	No conclusion	Test System	Panel 1	Panel 2	Panel 3
Screen test only	1	7	20	15	1			
					2			
					3			
Screen and mixing test	7	16	45	16	1			
					2			
					3			
Screen and confirm test	37	386	66	6	1			
					2			
					3			
Screen, mixing and confirm test	23	198	51	5	1			LA detected
					2			
					3			
Screen, confirm, mixing test	6	101	44	0	1			
					2			
					3			
Mixing - confirmation	0	13	15		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			
417	49	45	6	LA detected		

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

In total 511 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 80% classified the sample as positive. Nine percent classified the sample as equivocal. Thus, the vast majority of the participants correctly classified this sample as positive. A minority (10%) 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).

Several participants stated that there is an indication that this sample is weak 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.

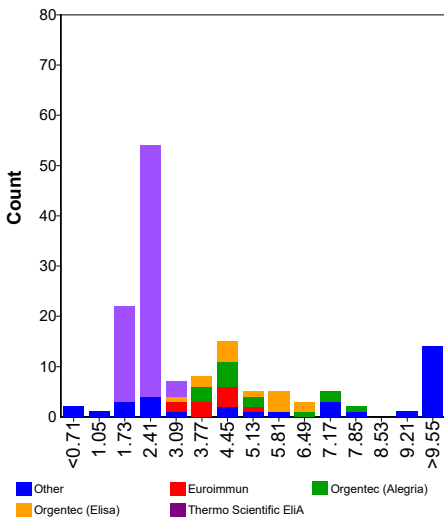**External quality Control for Assays and Tests**
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Lupus Anticoagulant

AntiCardiolipin Antibodies IgG

Sample No	23.108
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	GPL, U/mL, µg/mL, CU/mL
Expiry Date	28-February-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	228

Homogeneity Parameter   LA ratio

Response Rate   37 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	170	25	27	7	2	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	144	3.5	56.1	0.0 - 47.6						
Aeskulisa Diagnotic GmbH	7	2.6		1.0 - 7.0						
Biorad Bioplex	7	45.7		43.3 - 47.6						
Euroimmun	10	4.1	17.7	3.0 - 5.0						
Orgentec (Alegria)	14	5.1	28.7	3.8 - 7.9						
Orgentec (Elisa)	14	5.0	25.8	2.8 - 6.6						
Other	5	4.2		2.0 - 40.8						
Thermo Scientific EliA	72	2.3	13.8	1.4 - 3.3						
Werfen INOVA Quanta Lite	7	4.8		0.0 - 25.0						
CU/mL	81	20.2	11.2	15.9 - 24.0						
I.L. Acustar / INOVA Quanta Flash	80	20.2	11.2	15.9 - 24.0						

GPL, U/mL, µg/mL

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

Comments

A negative classification has been observed for the majority of participants (74%).

The following participant reported a deviating result which was excluded in the statistical evaluation:
1480 : 1.8 CU/mL

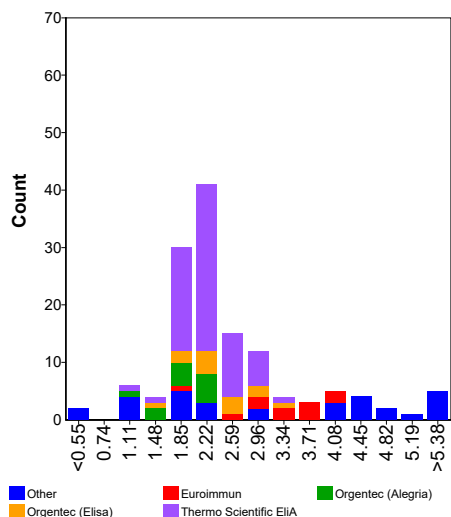**External quality Control for Assays and Tests**
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Lupus Anticoagulant	AntiCardiolipin Antibodies IgM

Sample No 23.108

Sample Details Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)

Prior Use Prior Use: None

Unit MPL, U/mL, µg/mL, CU/mL

Expiry Date 28-February-2025

Homogeneity 0.0 %   **Homogeneity Parameter** LA ratio

Number of Participants 623

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

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	214	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	134	2.4	30.6	0.0 - 17.0						
Aeskulisa Diagnotic GmbH	7	1.7		1.0 - 3.0						
Biorad Bioplex	7	4.3		4.0 - 5.0						
Euroimmun	11	3.3	20.9	2.0 - 4.0						
Orgentec (Alegria)	12	1.9	23.6	1.1 - 2.4						
Orgentec (Elisa)	13	2.4	20.7	1.6 - 3.4						
Thermo Scientific EliA	67	2.2	17.4	1.2 - 3.5						
Werfen INOVA Quanta Lite	6	7.5		0.0 - 17.0						
CU/mL	76	4.0	10.7	3.0 - 5.4						
I.L. Acustar / INOVA Quanta Flash	76	4.0	10.7	3.0 - 5.4						

MPL, U/mL, µg/mL

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

Comments

Most of the participants reported a negative classification.

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Lupus Anticoagulant ## ß2-Glycoprotein I Antibodies IgG

Sample No	23.108
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	U, U/mL, µg/mL, CU/mL
Expiry Date	28-February-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	216

Homogeneity Parameter	LA ratio
Response Rate	35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	125	4	23	36	30	2

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U, U/mL, µg/mL	135	3.6	29.1	0.0 - 88.7	3.7	0.13				
Aeskulisa Diagnotic GmbH	7	3.0		1.6 - 9.0						
Biorad Bioplex	7	82.0		81.1 - 88.7						
Euroimmun	9	4.7		3.0 - 10.0						
Orgentec (Alegria)	13	3.4	12.0	3.0 - 4.6						
Orgentec (Elisa)	14	4.1	40.4	2.0 - 7.2	3.7	-0.23				
Thermo Scientific EliA	69	3.2	12.7	1.4 - 7.0						
Werfen INOVA Quanta Lite	6	6.0		0.0 - 11.0						
CU/mL	81	70.1	12.8	41.0 - 90.2						
I.L. Acustar / INOVA Quanta Flash	80	70.0	12.9	41.0 - 90.2						

U, U/mL, µg/mL
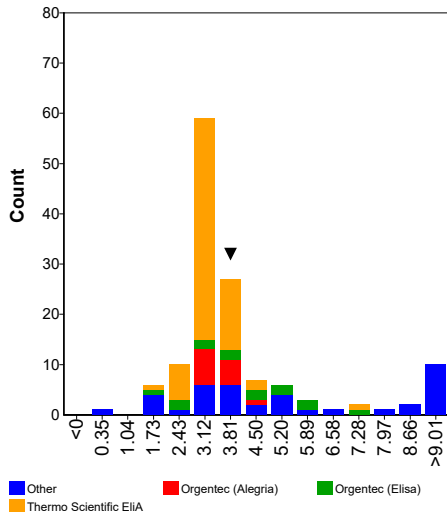
Comments

A heterogeneous pattern in the classification has been observed.

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Lupus Anticoagulant | ß2-Glycoprotein I Antibodies IgM

Sample No	23.108
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.4)
Prior Use	Prior Use: None
Unit	U, U/mL, µg/mL, CU/mL
Expiry Date	28-February-2025
Homogeneity	0.0 %
Number of Participants	623
Number of Responders	196

Homogeneity Parameter   LA ratio

Response Rate   31 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	198	0	1	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, U/mL, µg/mL	96	3.1	61.5	0.0 - 14.0	2.3	-0.43				
Aeskulisa Diagnotic GmbH	7	3.5		1.0 - 6.0						
Biorad Bioplex	7	6.2		5.9 - 7.0						
Euroimmun	8	9.1		1.7 - 11.0						
Orgentec (Alegria)	12	1.5	19.7	1.0 - 1.9						
Orgentec (Elisa)	13	2.2	20.5	1.8 - 14.0	2.3	0.21				
Thermo Scientific EliA	37	2.5	17.0	0.0 - 7.0						
Werfen INOVA Quanta Lite	5	3.8		0.0 - 4.0						
CU/mL	72	2.1	12.4	1.5 - 2.8						
I.L. Acustar / INOVA Quanta Flash	72	2.1	12.4	1.5 - 2.8						

U, U/mL, µg/mL

Legend: Other (blue), Orgentec (Alegria) (red), Orgentec (Elisa) (green), Thermo Scientific EliA (orange)
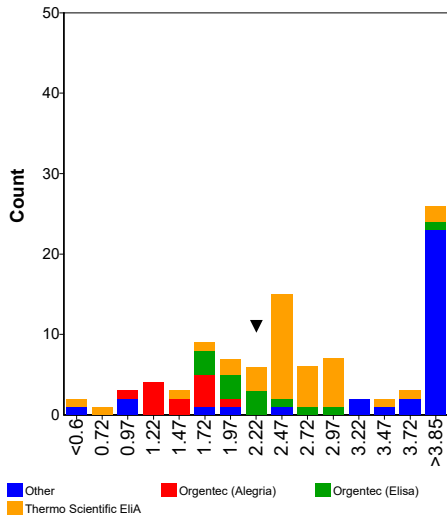
Comments

A negative pattern in the classification has been observed.

The following participant reported a deviating result which was excluded in the statistical evaluation:
1480 : 18.9 CU/mL