

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2024-L1
Lupus Anticoagulant
Labcode 1492

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ECAT Foundation

Date of Issue : 16-April-2024
Survey : 2024-L1
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 **June 21st 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.

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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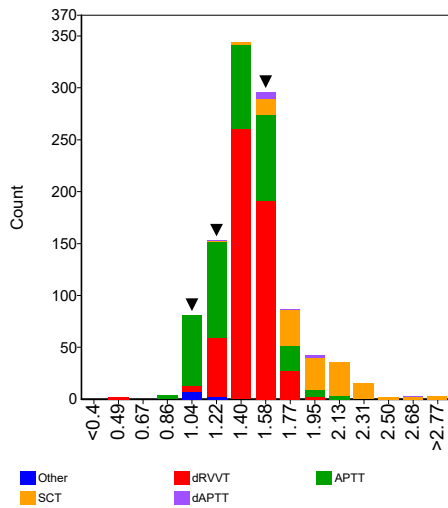
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Appendices are an integral part of the total report.

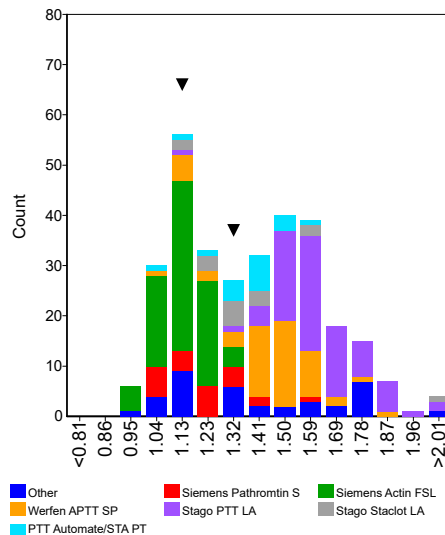
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	361	1.36	18.1	0.92 - 2.19	1	1.28	-0.32	1.13	-0.94		
Hyphen-Biomed Cephen LS	9	1.75		1.58 - 1.81							
Siemens Actin FS	6	1.09		1.01 - 1.12							
Siemens Actin FSL	82	1.13	7.5	0.92 - 1.33	1			1.13	-0.06		
Siemens Pathromtin SL	23	1.20	10.7	1.02 - 1.59	1	1.28	0.62				
Stago PTT Automate/STA PTT	18	1.37	8.2	1.06 - 1.55							
Stago PTT LA	77	1.62	8.1	1.09 - 2.19							
Stago Staclot LA	16	1.34	12.5	1.11 - 2.06							
Tcoag TriniClot Automated APTT	5	1.29		1.28 - 1.31							
Werfen APTT SP	55	1.46	9.0	1.06 - 1.87							
Werfen HemosIL SynthAsil	39	1.40	8.3	1.16 - 1.58							
Werfen MixCon	14	1.16	5.7	1.07 - 1.29							
dAPTT	11	1.68	12.5	1.14 - 2.67							
Stago PTT LA	9	1.67		1.50 - 1.90							
dPT	5	1.17		1.00 - 1.40							
dRVVT	545	1.46	8.8	0.51 - 1.93	1					1.50	0.28
Hyphen Biomed Hemoclot LA-S	9	1.54		1.26 - 1.76							
Precision Biologic LA check	7	1.39		1.29 - 1.73							
Roche Lupus S	7	1.47		1.34 - 1.54							
Siemens LA1 screen	219	1.50	8.0	1.00 - 1.89	1					1.50	-0.01
Stago DRVVT screen	84	1.39	7.6	1.23 - 1.90							
Technoclone LA Screen	5	1.48		1.30 - 1.54							
Werfen HemosIL dRVVT screen	209	1.46	8.1	0.51 - 1.93							
SCT	139	1.95	14.1	1.19 - 4.99							
Werfen SCT screen	136	1.94	13.9	1.19 - 2.91							

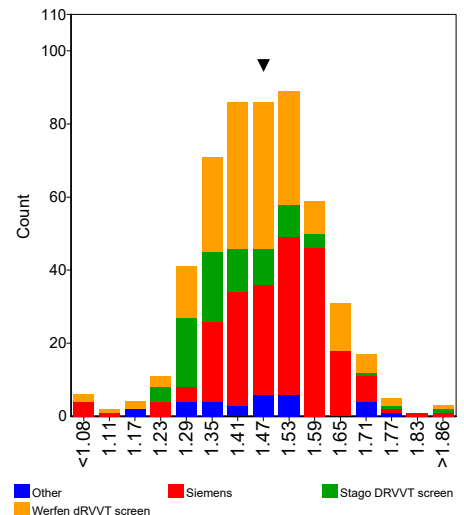
Assays



APTT



DRVVT

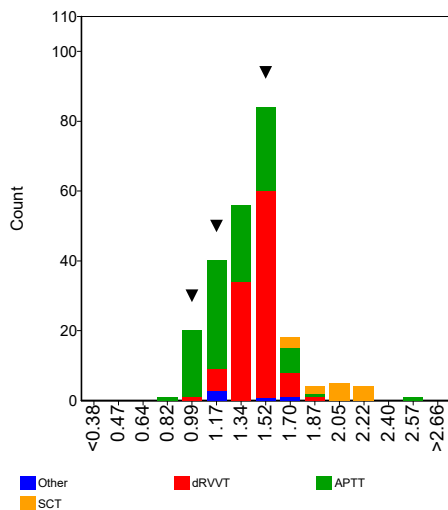


Lupus Anticoagulant

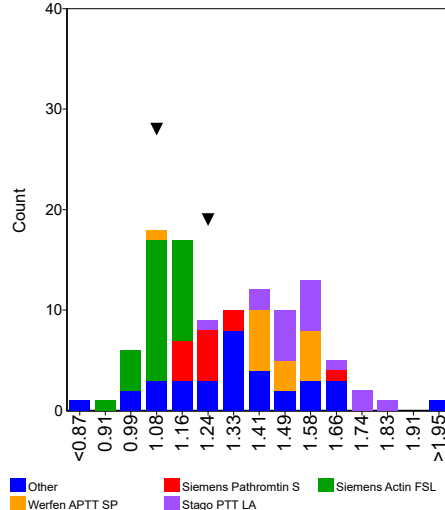
Screening

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	106	1.30	18.2	0.86 - 2.65	1	1.25	-0.22	1.07	-0.98		
Siemens Actin FSL	29	1.09	6.8	0.92 - 1.20	1			1.07	-0.25		
Siemens Pathromtin SL	12	1.24	5.9	1.15 - 1.65	1	1.25	0.14				
Stago PTT Automate/STA PTT	8	1.33		1.19 - 1.54							
Stago PTT LA	17	1.55	8.6	1.22 - 1.85							
Werfen APTT SP	15	1.47	7.4	1.04 - 1.60							
Werfen HemosIL SynthAsil	9	1.45		1.32 - 1.65							
dRVVT	108	1.47	7.0	0.95 - 1.79	1					1.51	0.46
Siemens LA1 screen	67	1.48	6.4	1.18 - 1.79	1					1.51	0.32
Stago DRVVT screen	11	1.36	8.9	1.21 - 1.61							
Werfen HemosIL dRVVT screen	23	1.47	6.2	1.23 - 1.59							
SCT	14	1.97	11.7	1.63 - 2.20							
Werfen SCT screen	14	1.97	11.7	1.63 - 2.20							

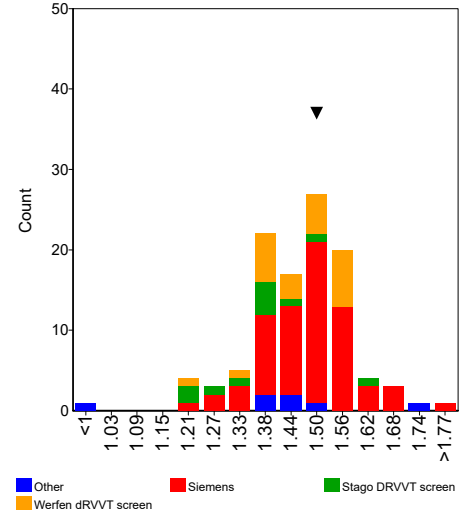
Assays



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. 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.

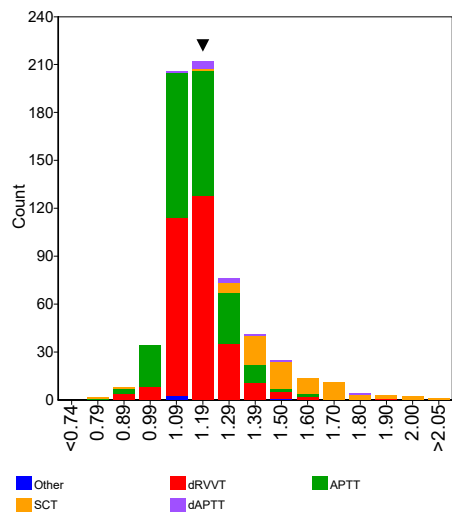
The majority of performed screening tests (approx. 88%) were classified as prolonged.

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

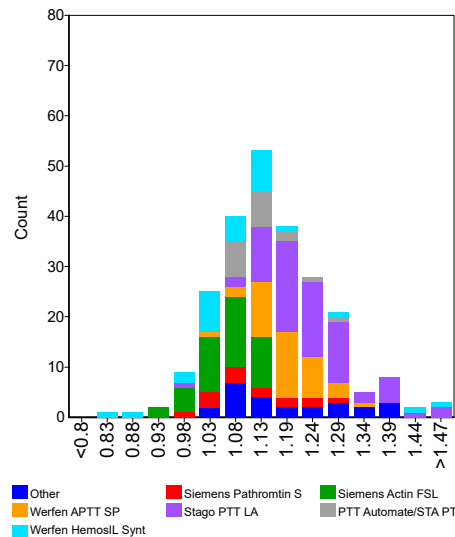
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	246	1.15	8.8	0.80 - 1.60							
Hyphen-Biomed Cephen LS	8	1.28		1.21 - 1.40							
Siemens Actin FSL	42	1.06	5.0	0.93 - 1.14							
Siemens Pathromtin SL	14	1.12	9.6	0.98 - 1.30							
Stago PTT Automate/STA PTT	18	1.14	4.4	1.07 - 1.29							
Stago PTT LA	69	1.22	6.6	0.98 - 1.60							
Tcoag TriniClot Automated APTT	7	1.13		1.08 - 1.41							
Werfen APTT SP	39	1.19	5.3	1.05 - 1.32							
Werfen HemosIL SynthAsil	29	1.09	7.0	0.80 - 1.52							
Werfen MixCon	10	1.14	7.5	0.91 - 1.24							
dAPTT	12	1.27	10.0	1.14 - 1.75							
Stago PTT LA	9	1.29		1.15 - 1.49							
dRVVT	304	1.17	6.6	0.92 - 1.86	1					1.18	0.17
Siemens LA1 screen	148	1.17	5.8	0.93 - 1.61	1					1.18	0.16
Stago DRVVT screen	44	1.15	5.9	1.06 - 1.38							
Werfen HemosIL dRVVT screen	94	1.18	7.6	0.92 - 1.86							
SCT	73	1.52	11.7	0.84 - 2.29							
Werfen SCT screen	72	1.51	11.4	0.84 - 2.05							

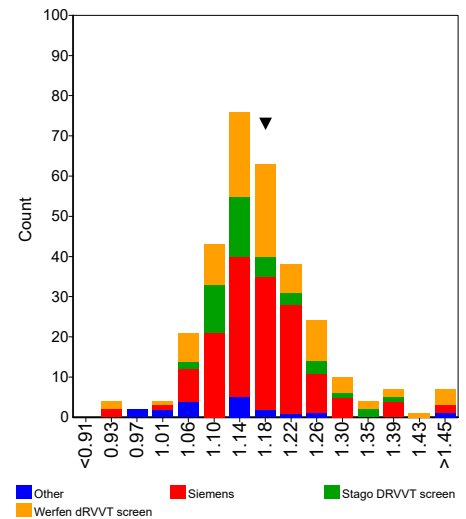
Assays



APTT



DRVVT

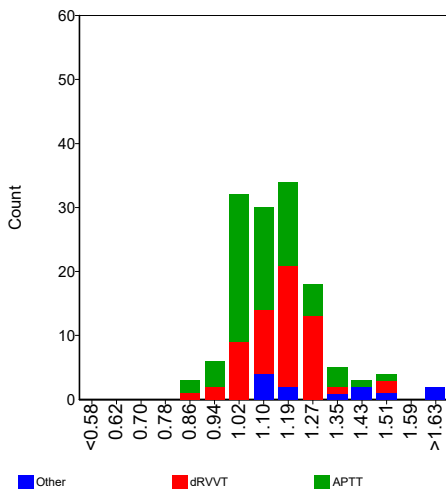


Lupus Anticoagulant

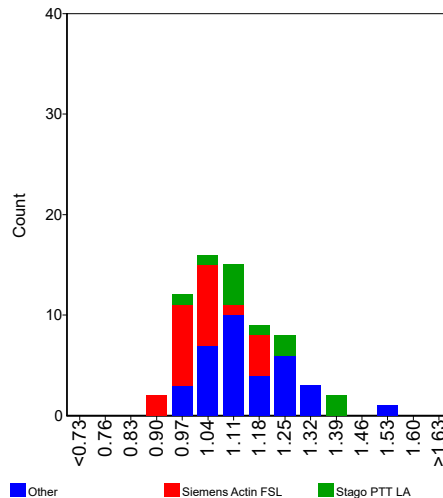
Mixing (screening)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	68	1.11	10.2	0.88 - 1.52							
Siemens Actin FSL	23	1.03	7.9	0.88 - 1.18							
Siemens Pathromtin SL	9	1.14		0.97 - 1.34							
Stago PTT Automate/STA PTT	6	1.08		1.04 - 1.21							
Stago PTT LA	11	1.18	12.8	0.99 - 1.41							
Werfen APTT SP	9	1.13		1.05 - 1.52							
dRVVT	57	1.16	8.9	0.83 - 1.50							
Siemens LA1 screen	38	1.16	8.3	0.91 - 1.50							
Stago DRVVT screen	5	1.17		1.13 - 1.31							
Werfen HemosIL dRVVT screen	8	1.15		1.00 - 1.49							
SCT	5	1.54		1.42 - 1.76							
Werfen SCT screen	5	1.54		1.42 - 1.76							

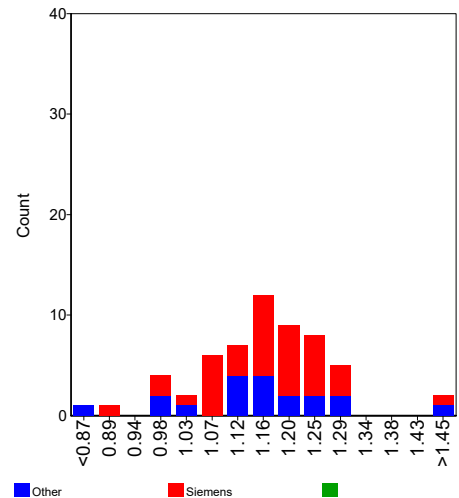
Assays



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. Two 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 and/or the mean of the reference interval could not be correctly calculated. Therefore all these results were excluded from the statistical analysis.

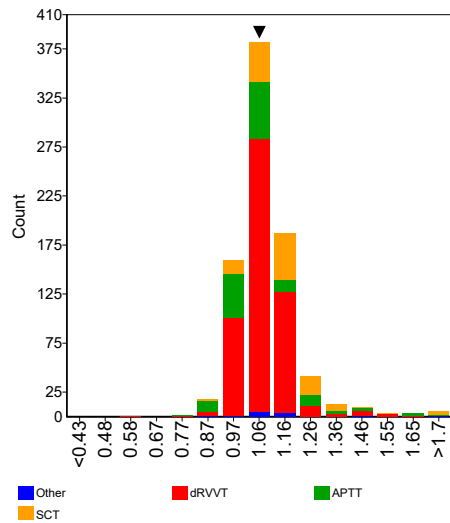
Approximately, half of performed mixing tests (51%) were classified as elevated, which was expected because the sample was weak positive for Lupus Anticoagulant.

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

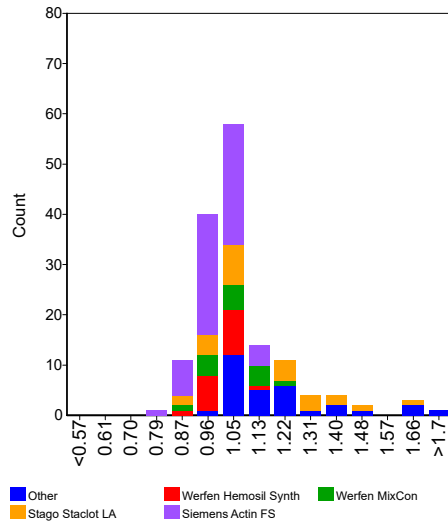
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	149	1.05	10.2	0.79 - 2.12							
Siemens Actin FS	60	1.00	7.5	0.79 - 1.13							
Stago Staclot LA	25	1.13	16.7	0.86 - 1.67							
Stago/Roche PTT LA	7	1.26		1.03 - 1.68							
Werfen Hemosil SynthAFax	18	1.02	4.5	0.89 - 1.12							
Werfen MixCon	15	1.04	9.5	0.87 - 1.21							
dAPTT	7	1.05		0.85 - 2.84							
dRVVT	530	1.07	6.6	0.59 - 1.62	1					1.03	-0.62
Hyphen Biomed Hemoclot LA-C	9	1.04		0.98 - 1.09							
Precision Biologic LA sure	6	0.96		0.92 - 1.21							
Roche Lupus C	7	1.08		1.04 - 1.15							
Siemens LA2 confirmation	216	1.07	5.7	0.78 - 1.62	1					1.03	-0.70
Stago DRVVT Confirm	80	1.04	5.9	0.86 - 1.58							
Technoclone LA Confirm	5	1.04		0.98 - 1.14							
Werfen Hemosil dRVVT confirm	203	1.09	7.3	0.59 - 1.52							
SCT	135	1.14	9.5	0.86 - 2.19							
Werfen Hemosil SCT confirm	135	1.14	9.5	0.86 - 2.19							

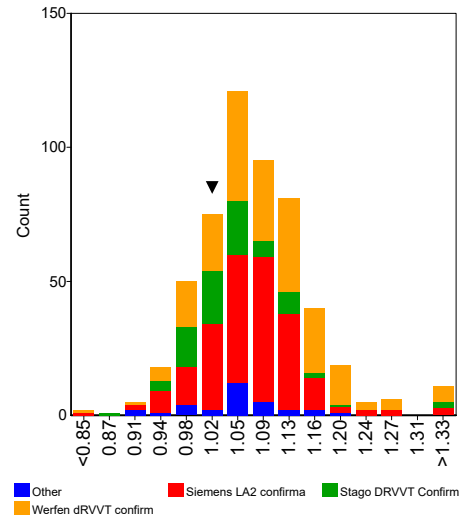
Assays



APTT



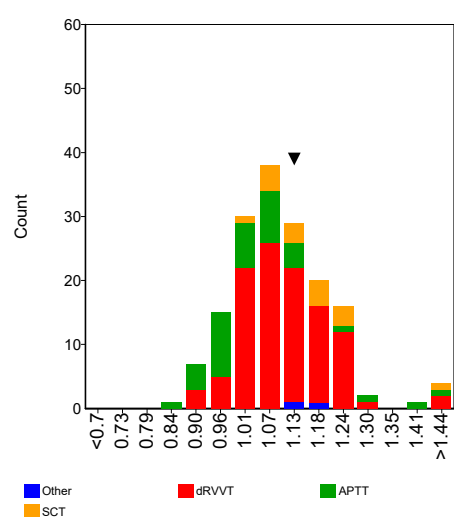
DRVVT



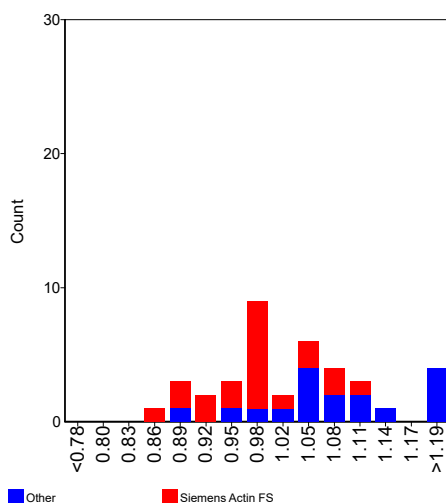
Lupus Anticoagulant **Confirmation**

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	38	1.02	9.2	0.84 - 1.69							
Siemens Actin FS	21	0.98	7.0	0.84 - 1.10							
Stago Staclot LA	7	1.07		0.89 - 1.69							
dRVVT	107	1.10	8.7	0.88 - 1.68	1					1.15	0.47
Siemens LA2 confirmation	64	1.11	9.3	0.91 - 1.68	1					1.15	0.42
Stago DRVVT Confirm	10	1.02	9.2	0.88 - 1.14							
Werfen HemosIL dRVVT confirm	26	1.14	6.6	0.99 - 1.46							
SCT	16	1.15	7.4	1.02 - 1.82							
Werfen HemosIL SCT confirm	16	1.15	7.4	1.02 - 1.82							

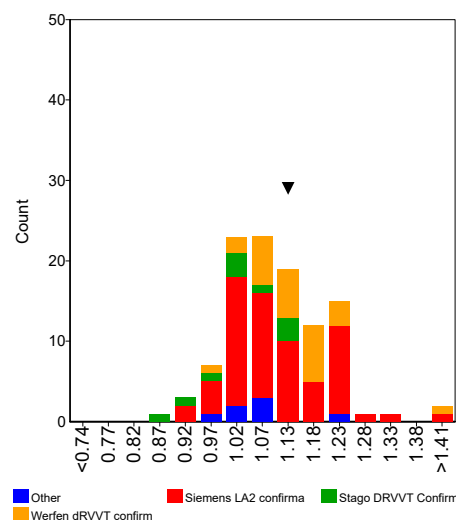
Assays



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. Several participants reported also a confirmation result in Delta Seconds. However the difference in clotting time between the screen and confirmation test (or reagent 1 and reagent 2) should be reported in the interpretation section. All these results were excluded from the statistical analysis.

As expected, the majority of performed confirmation tests (71%) 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	24.67		
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)		
Prior Use	Prior Use: None		
Unit	Ratio		
Expiry Date	31-October-2025		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	616		
Number of Responders	179	Response Rate	29 %

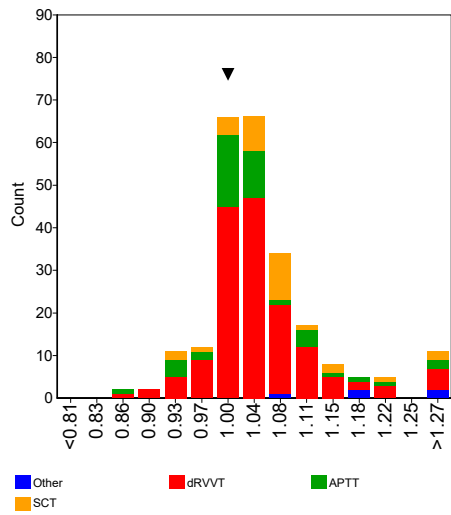
Assay	Elevated	Not elevated	Borderline	No Classification
APTT	8	38	0	5
dAPTT	7	1	0	0
dPT	0	0	0	1
dRVVT	32	130	0	10
SCT	6	25	0	2

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

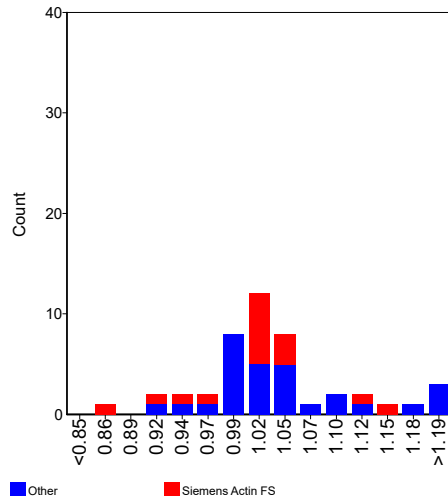
Ratio Normal Plasma

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	45	1.03	6.0	0.86 - 1.40							
Siemens Actin FS	16	1.02	5.6	0.86 - 1.16							
Werfen Hemosil SynthAFax	7	1.00		0.92 - 1.17							
Werfen MixCon	6	1.02		1.00 - 1.11							
dRVVT	157	1.04	4.8	0.86 - 1.38	1					1.01	-0.55
Siemens LA2 confirmation	88	1.04	3.4	0.92 - 1.38	1					1.01	-0.75
Stago DRVVT Confirm	16	1.05	7.1	0.91 - 1.37							
Werfen Hemosil dRVVT confirm	47	1.03	6.7	0.86 - 1.22							
SCT	32	1.06	4.8	0.92 - 1.34							
Werfen Hemosil SCT confirm	32	1.06	4.8	0.92 - 1.34							

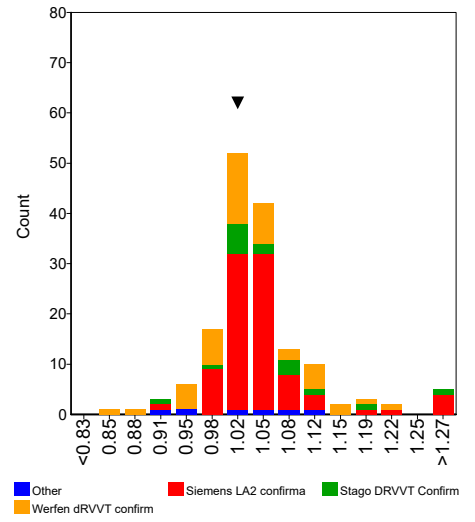
Assays



APTT



DRVVT

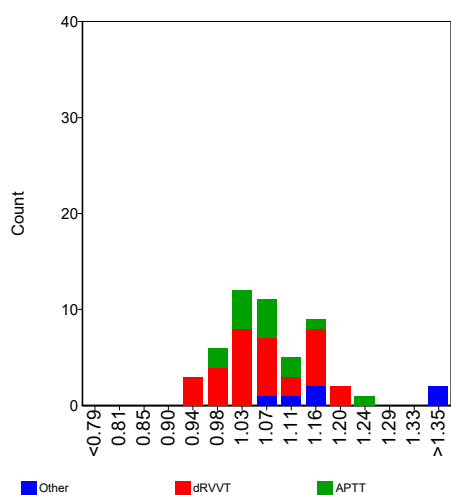


Lupus Anticoagulant

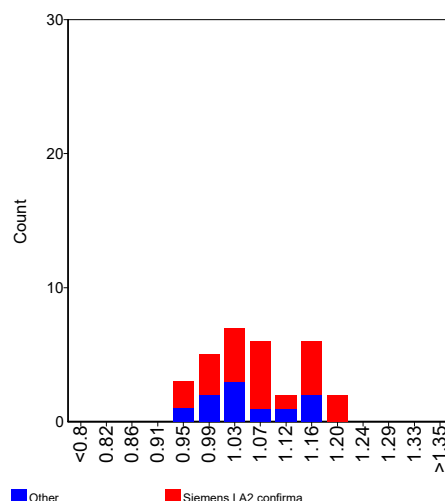
Mixing (confirm)

Ratio MRI	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	14	1.06	5.7	0.98 - 1.23							
Siemens Actin FS	5	1.04		0.98 - 1.17							
dRVVT	31	1.06	7.9	0.94 - 1.21							
Siemens LA2 confirmation	21	1.07	8.5	0.94 - 1.21							
Werfen HemosIL dRVVT confirm	8	1.05		0.98 - 1.15							

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. One participant reported also the Rösner index as mixing confirm result instead of a ratio. All these results were excluded from the statistical analysis.

As expected, the majority of performed mixing confirmation tests (79%) 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.

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

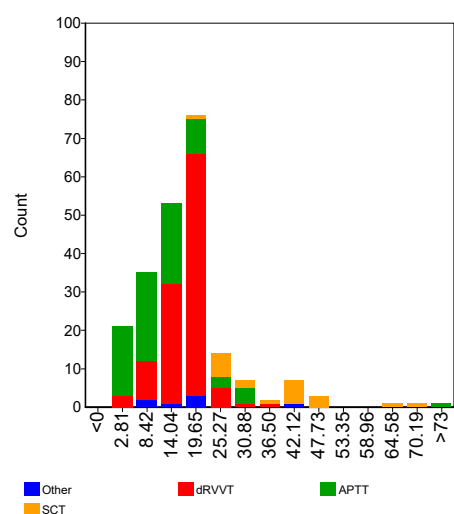
Lupus Anticoagulant

Interpretation

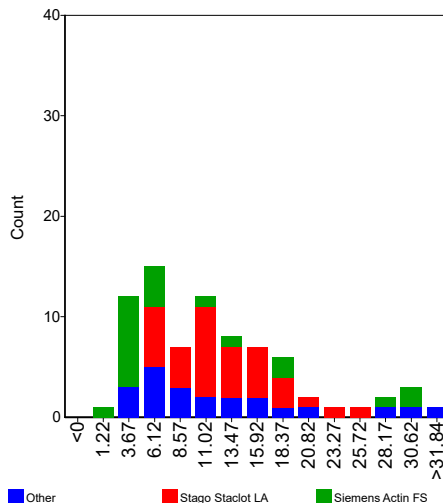
Delta Seconds

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	79	11.21	60.0	1.70 - 91.40							
Siemens Actin FS	21	8.70	88.6	1.70 - 30.20							
Stago Staclot LA	35	12.41	41.6	5.20 - 26.80							
dRVVT	5	17.00		8.30 - 43.20							
dRVVT	114	17.11	22.7	5.30 - 38.00							
Siemens LA2 confirmation	56	17.98	18.3	5.50 - 31.90							
Stago DRVVT Confirm	10	14.12	24.1	9.40 - 38.00							
Werfen HemosIL dRVVT confirm	42	17.28	18.6	5.30 - 23.50							
SCT	21	36.99	32.5	17.70 - 67.40							
Werfen HemosIL SCT confirm	21	36.99	32.5	17.70 - 67.40							

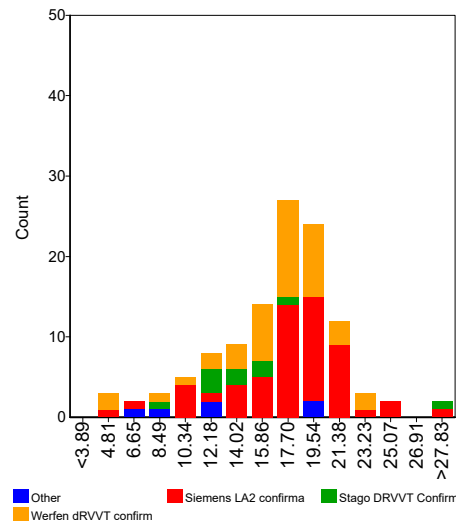
Assays



APTT



DRVVT



Comments

It is not clear whether all results submitted for Delta Seconds reflect in all cases the difference in clotting time between the screen and confirmation test (or reagent 1 and reagent 2).

Please submit for Delta Seconds only the value which is the difference in clotting time between the screen and confirmation test (or difference between reagent 1 and reagent 2).

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 a deviating result which was excluded in the statistical evaluation:

1401 : 0.40

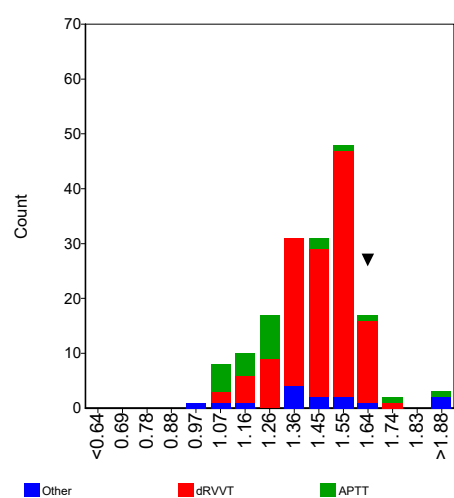
Lupus Anticoagulant

Interpretation

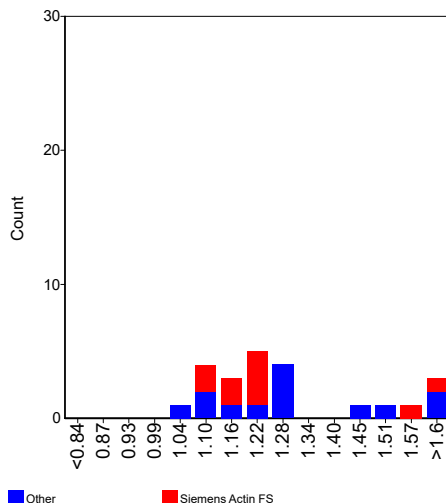
Ratio Screen/Confirmation - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	23	1.27	15.2	1.06 - 2.31							
Siemens Actin FS	10	1.22	10.4	1.08 - 2.31							
Stago Staclot LA	6	1.25		1.06 - 1.48							
dRVVT	131	1.46	8.4	1.05 - 1.70	1					1.63	1.37
Siemens LA2 confirmation	85	1.51	6.0	1.19 - 1.70	1					1.63	1.32
Stago DRVVT Confirm	14	1.37	5.4	1.28 - 1.48							
Werfen HemosIL dRVVT confirm	19	1.38	8.9	1.05 - 1.63							
SCT	6	1.60		1.40 - 2.60							
Werfen HemosIL SCT confirm	6	1.60		1.40 - 2.60							

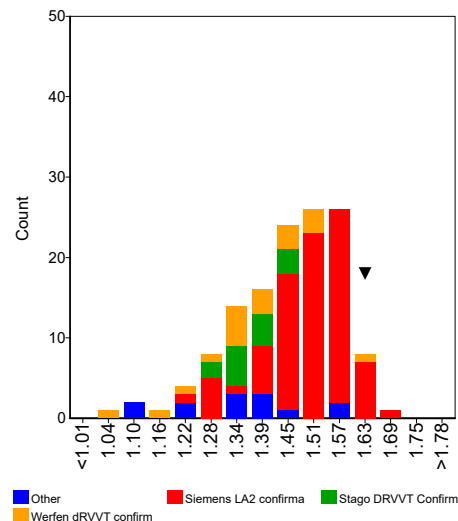
Assays



APTT



DRVVT



Comments

Some participants did not indicate which type of ratio screen/confirmation they reported (standard ratio or normalised ratio). These results have been excluded in the evaluation. **Don't forget to select the type of ratio in the next survey.**

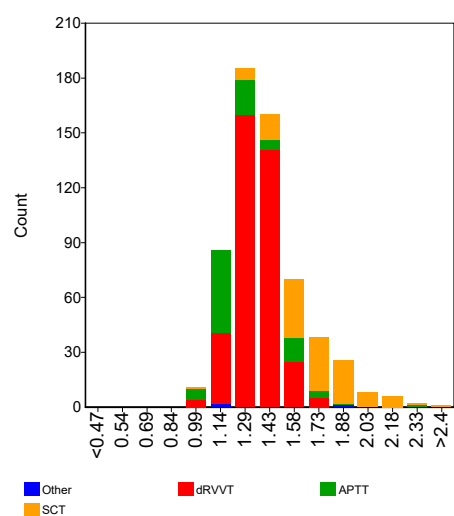
The average ratio screen / confirmation is in general in line with the expected LA ratio (approx. 1.6). For the assay type "APTT" the LA ratio is slightly lower compared to the other assay types.

Lupus Anticoagulant	Interpretation
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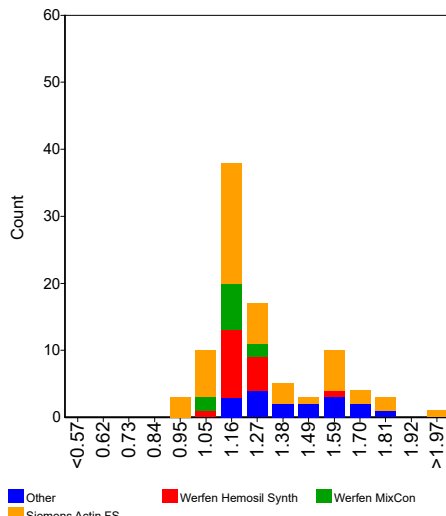
Ratio Screen/Confirmation - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	94	1.26	15.6	1.00 - 2.27							
Siemens Actin FS	49	1.27	18.4	1.00 - 2.27							
Werfen Hemosil SynthAFax	17	1.19	6.2	1.06 - 1.62							
Werfen MixCon	11	1.17	6.0	1.03 - 1.26							
dRVVT	374	1.35	8.0	0.97 - 1.80							
Hyphen Biomed Hemoclot LA-C	7	1.39		1.05 - 1.66							
Siemens LA2 confirmation	124	1.39	8.2	1.08 - 1.80							
Stago DRVVT Confirm	58	1.33	5.4	1.10 - 1.71							
Werfen HemosIL dRVVT confirm	177	1.33	7.8	0.97 - 1.58							
SCT	122	1.70	13.8	1.01 - 2.43							
Werfen HemosIL SCT confirm	122	1.70	13.8	1.01 - 2.43							

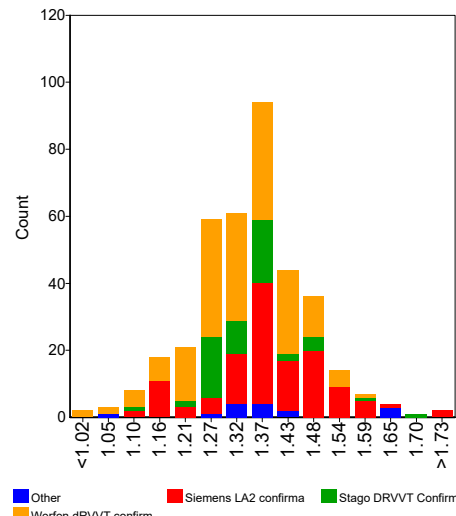
Assays



APTT



DRVVT



Comments

Some participants did not indicate which type of ratio screen/confirmation they reported (standard ratio or normalised ratio). These results have been excluded in the evaluation. **Don't forget to select the type of ratio in the next survey.**

The average ratio screen / confirmation is in general in line with the expected LA ratio (approx. 1.6). 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".

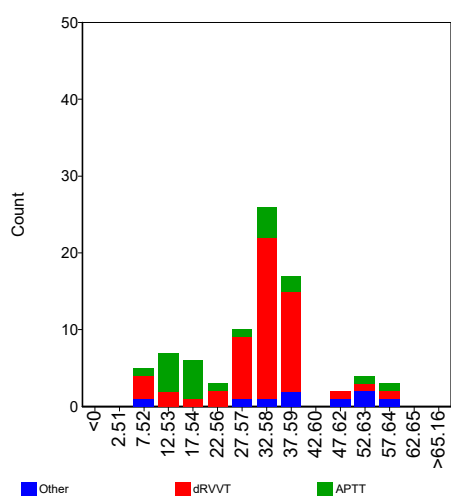
Lupus Anticoagulant

Interpretation

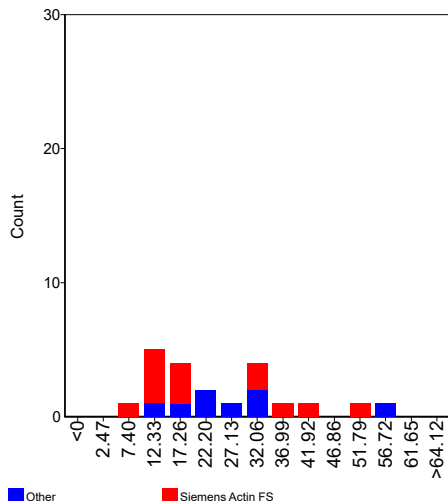
Percentage Correction - Standard

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	21	23.69	54.4	5.90 - 58.00							
Siemens Actin FS	13	22.64	61.1	5.90 - 52.30							
dRVVT	53	32.57	17.3	6.25 - 58.00							
Siemens LA2 confirmation	39	33.26	14.0	6.25 - 53.99							
Werfen HemosIL dRVVT confirm	6	35.15		29.60 - 58.00							
SCT	7	49.70		30.10 - 56.50							
Werfen HemosIL SCT confirm	7	49.70		30.10 - 56.50							

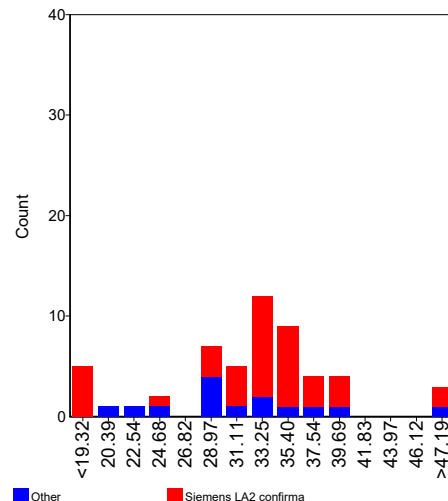
Assays



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.**

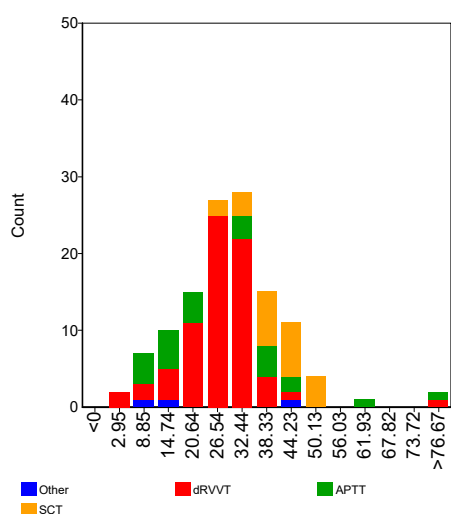
Lupus Anticoagulant

Interpretation

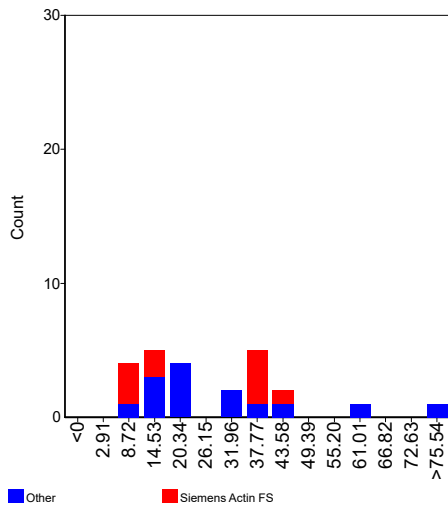
Percentage Correction - Normalised

	n	assigned value	CV (%)	Range	Test System	Panel 1	Z-score	Panel 2	Z-score	Panel 3	Z-score
APTT	24	26.51	58.1	8.30 - 77.00							
Siemens Actin FS	10	25.39	65.9	8.30 - 44.70							
dRVVT	72	26.98	25.8	4.90 - 93.00							
Siemens LA2 confirmation	29	28.32	22.6	7.07 - 37.74							
Stago DRVVT Confirm	9	25.05		22.90 - 32.00							
Werfen HemosIL dRVVT confirm	32	26.74	28.8	4.90 - 93.00							
SCT	23	40.88	19.3	25.24 - 51.60							
Werfen HemosIL SCT confirm	23	40.88	19.3	25.24 - 51.60							

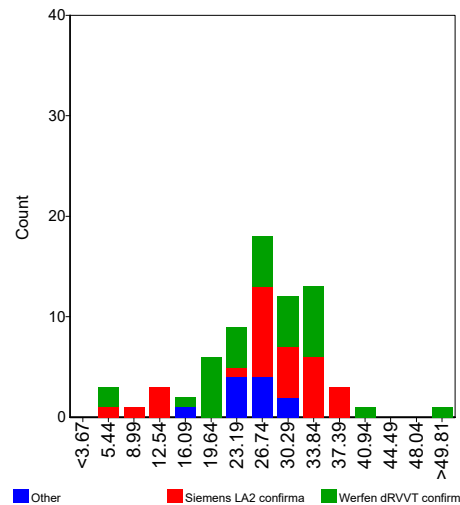
Assays



APTT



DRVVT



Comments

Some participants did not indicate which type of correction they have reported (standard correction or normalised correction). A few participants reported a ratio as percentage correction result. These results have been excluded in the evaluation. **Don't forget to select the type of correction in the next survey.**

Lupus Anticoagulant

Final Conclusion

Testing Strategies	Classification				Your Classification			
	Equivocal	LA detected	LA not detected	No conclusion	Test System	Panel 1	Panel 2	Panel 3
Screen test only	2	9	13	8	1			
					2			
					3			
Screen and mixing test	9	25	40	10	1			
					2			
					3			
Screen and confirm test	21	417	35	7	1			
					2			
					3			
Screen, mixing and confirm test	16	196	43	6	1			LA detected
					2			
					3			
Screen, confirm, mixing test	6	108	40	5	1			
					2			
					3			
Mixing - confirmation	2	11	13	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			
438	34	25	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 497 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 88% classified the sample as positive. Five percent classified the sample as equivocal. Thus, the vast majority of the participants correctly classified this sample as positive. A minority (7%) of the participants classified this sample as negative, this does not seem 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 weakly positive for lupus anticoagulant but in real clinical practice this should be confirmed in a new sample after 12 weeks. One participant advised to repeat the measurement within 3 weeks. Some participants indicated that the presence of direct oral anticoagulants and/or factor deficiency should be excluded.

Lupus Anticoagulant

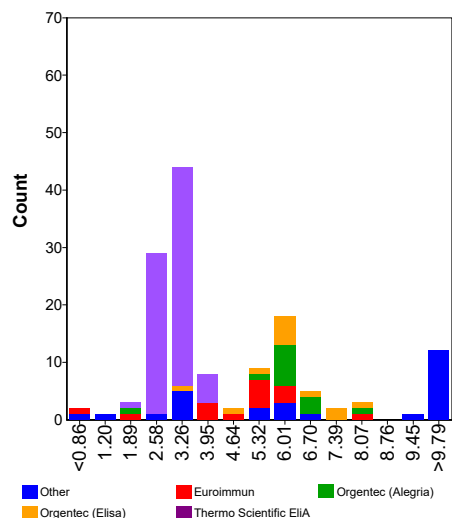
AntiCardiolipin Antibodies IgG

Sample No	24.67		
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)		
Prior Use	Prior Use: None		
Unit	GPL, U/mL, µg/mL, CU/mL		
Expiry Date	31-October-2025		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	616		
Number of Responders	223	Response Rate	36 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	136	22	55	10	2	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	139	4.2	45.8	0.0 - 55.7						
Biorad Bioplex	7	53.0		49.4 - 54.7						
Euroimmun	15	4.8	27.4	0.5 - 8.0						
Orgentec (Alegria)	13	6.1	11.3	2.2 - 8.3						
Orgentec (Elisa)	12	6.1	20.5	3.6 - 7.8						
Thermo Scientific EliA	72	3.0	12.4	2.0 - 4.1						
Werfen INOVA Quanta Lite	6	5.8		0.0 - 6.4						
CU/mL	78	23.8	9.9	19.8 - 29.0						
Werfen Acustar / INOVA Quanta Flash	77	23.7	9.8	19.8 - 29.0						

GPL, U/mL, µg/mL



Comments

Most of the participants reported a negative classification.

On the other hand, within the method groups Biorad Bioplex (100%) and Werfen Acustar/INOVA Quanta Flash (73%) the majority of participants classified this sample as positive, corresponding with the higher titer observed in these method groups.

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

- 618** : 63 U/mL
- 1282** : 107.9 CU/mL

Lupus Anticoagulant

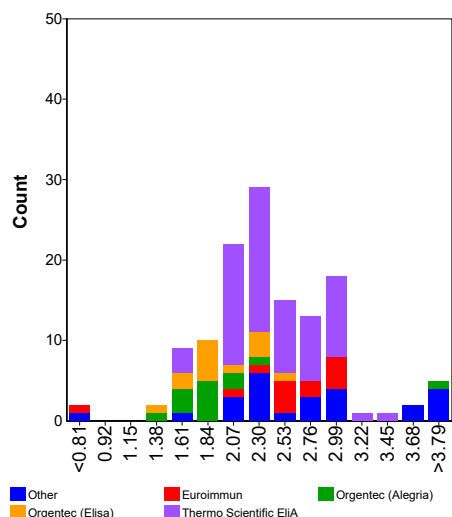
AntiCardiolipin Antibodies IgM

Sample No	24.67		
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)		
Prior Use	Prior Use: None		
Unit	MPL, U/mL, µg/mL, CU/mL		
Expiry Date	31-October-2025		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	616		
Number of Responders	211	Response Rate	34 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	211	0	0	1	1	0

IgG	n	assigned value	CV (%)	range	Test System 1 Result	z-score	Test System 2 Result	z-score	Test System 3 Result	z-score
U/mL, µg/mL, GPL/MPL	129	2.4	22.3	0.0 - 9.0						
Aeskulisa Diagnostik GmbH	5	3.0		2.0 - 9.0						
Biorad Bioplex	7	2.3		2.0 - 3.0						
Euroimmun	13	2.6	15.0	0.2 - 3.0						
Orgentec (Alegria)	13	1.9	17.1	1.3 - 8.1						
Orgentec (Elisa)	13	1.9	19.2	1.3 - 2.5						
Thermo Scientific ELIA	65	2.4	16.8	1.7 - 3.4						
CU/mL	72	3.3	12.4	2.5 - 4.1						
Werfen Acustar / INOVA Quanta Flash	72	3.3	12.4	2.5 - 4.1						

MPL, U/mL, µg/mL



Comments

Most of the participants reported a negative classification.

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

737 : 80 CU/mL

1282 : 93.4 CU/mL

Lupus Anticoagulant

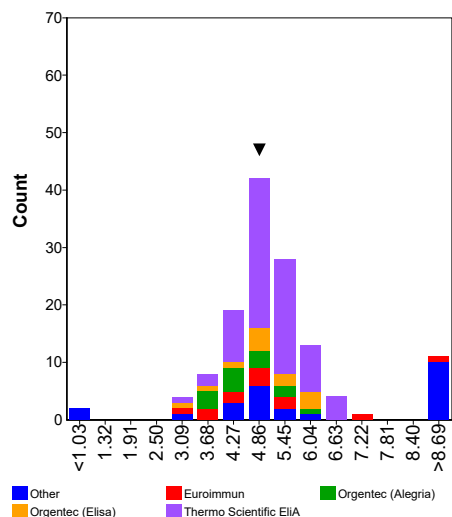
β2-Glycoprotein I Antibodies IgG

Sample No	24.67		
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)		
Prior Use	Prior Use: None		
Unit	U, U/mL, µg/mL, CU/mL		
Expiry Date	31-October-2025		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	616		
Number of Responders	214	Response Rate	35 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	118	8	22	39	29	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	132	5.1	17.7	0.0 - 111.3	4.9	-0.21				
Aeskulisa Diagnostik GmbH	6	4.8		4.0 - 10.0						
Biorad Bioplex	7	106.8		98.4 - 111.3						
Euroimmun	12	4.9	26.3	3.0 - 12.0						
Orgentec (Alegria)	13	4.5	17.9	3.4 - 5.9						
Orgentec (Elisa)	12	5.0	20.8	2.9 - 6.2	4.9	-0.08				
Thermo Scientific ELIA	70	5.1	11.8	3.3 - 6.7						
Werfen INOVA Quanta Lite	5	4.8		0.0 - 5.9						
CU/mL	79	82.7	14.1	61.0 - 437.8						
Werfen Acustar / INOVA Quanta Flash	78	82.7	14.3	61.0 - 437.8						

U, U/mL, µg/mL



Comments

Most of the participants reported a negative classification.

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

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

737 : 3 CU/mL

Lupus Anticoagulant

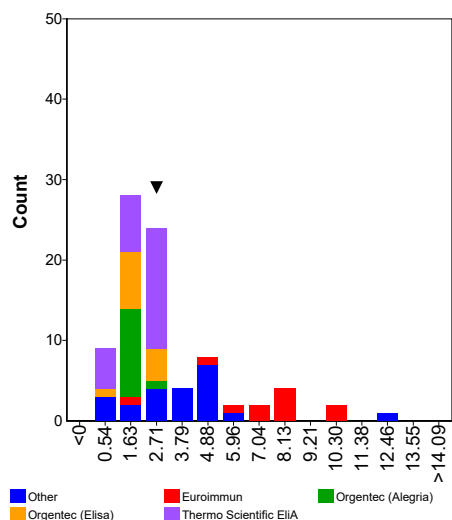
β2-Glycoprotein I Antibodies IgM

Sample No	24.67		
Sample Details	Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.6)		
Prior Use	Prior Use: None		
Unit	U, U/mL, µg/mL, CU/mL		
Expiry Date	31-October-2025		
Homogeneity	0.0 %	Homogeneity Parameter	LA ratio
Number of Participants	616		
Number of Responders	195	Response Rate	32 %

Classification	Negative	Borderline	Low Positive	Medium Positive	High Positive	No Conclusion
Total	196	0	0	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	84	2.7	64.5	0.0 - 12.0	2.3	-0.23				
Aeskulisa Diagnostic GmbH	6	5.0		1.5 - 5.6						
Biorad Bioplex	7	4.4		3.4 - 5.0						
Euroimmun	11	7.4	30.0	1.9 - 10.3						
Orgentec (Alegria)	12	1.5	20.0	1.2 - 2.8						
Orgentec (Elisa)	12	1.8	36.1	1.0 - 3.0	2.3	0.68				
Thermo Scientific ELIA	27	2.1	35.3	0.0 - 3.1						
CU/mL	70	1.9	15.2	1.3 - 2.6						
Werfen Acustar / INOVA Quanta Flash	70	1.9	15.2	1.3 - 2.6						

U, 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:

1282 : 98.4 CU/mL