

ECAT FOUNDATION

External quality Control for Assays and Tests

With a focus on Thrombosis and Haemostasis

REPORT



SURVEY 2024-L3
Lupus Anticoagulant
Labcode 1492

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ECAT Foundation

Date of Issue : 29-October-2024
Survey : 2024-L3
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 **December 12th, 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.

Ratio Screen/Confirm

Several participants reported a value for the ratio screen/confirm which actually was not likely to be a ratio screen over confirm. Therefore these results were excluded in the statistical analysis.

This report is authorized by:

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

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

ECAT Foundation

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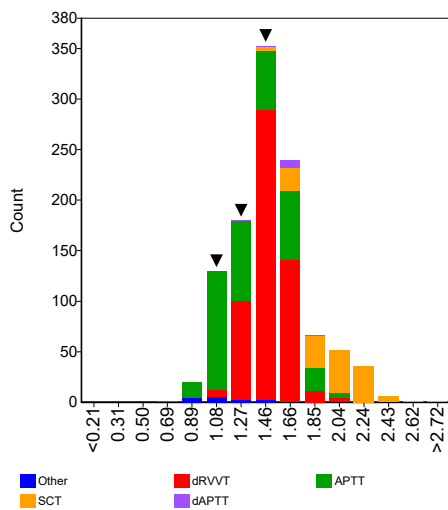
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Appendices are an integral part of the total report.

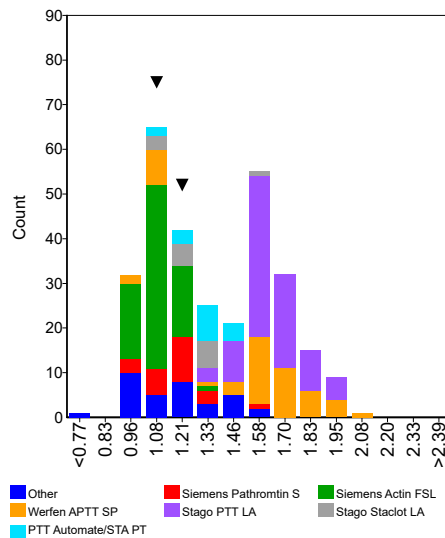
Ratio Normal Plasma

| | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|--------------------------------|-----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 367 | 1.34 | 21.7 | 0.74 - 2.02 | 1 | 1.18 | -0.54 | 1.12 | -0.76 | | |
| Hyphen-Biomed Cephen LS | 10 | 1.50 | 3.7 | 1.42 - 1.58 | | | | | | | |
| Siemens Actin FS | 8 | 0.94 | | 0.74 - 0.97 | | | | | | | |
| Siemens Actin FSL | 75 | 1.08 | 7.4 | 0.93 - 1.38 | 1 | | | 1.12 | 0.47 | | |
| Siemens Pathromtin SL | 23 | 1.16 | 10.9 | 0.96 - 1.54 | 1 | 1.18 | 0.15 | | | | |
| Stago PTT Automate/STA PTT | 17 | 1.32 | 7.2 | 1.08 - 1.47 | | | | | | | |
| Stago PTT LA | 83 | 1.64 | 7.9 | 1.29 - 1.98 | | | | | | | |
| Stago Staclot LA | 15 | 1.27 | 10.0 | 1.02 - 1.52 | | | | | | | |
| Tcoag TriniClot Automated APTT | 7 | 1.23 | | 1.19 - 1.26 | | | | | | | |
| Werfen APTT SP | 51 | 1.58 | 17.1 | 0.98 - 2.02 | | | | | | | |
| Werfen HemosIL SynthAsil | 42 | 1.27 | 8.2 | 1.06 - 1.56 | | | | | | | |
| Werfen MixCon | 16 | 1.15 | 3.9 | 1.08 - 1.28 | | | | | | | |
| dAPTT | 10 | 1.63 | 7.3 | 1.21 - 1.81 | | | | | | | |
| Stago PTT LA | 8 | 1.66 | | 1.51 - 1.81 | | | | | | | |
| dPT | 5 | 1.32 | | 1.10 - 1.47 | | | | | | | |
| dRVVT | 548 | 1.49 | 9.0 | 1.00 - 2.36 | 1 | | | | | 1.52 | 0.23 |
| Hyphen Biomed Hemoclot LA-S | 9 | 1.51 | | 1.31 - 1.65 | | | | | | | |
| Precision Biologic LA check | 7 | 1.41 | | 1.30 - 1.62 | | | | | | | |
| Roche Lupus S | 7 | 1.26 | | 1.10 - 1.41 | | | | | | | |
| Siemens LA1 screen | 212 | 1.47 | 9.1 | 1.00 - 2.09 | 1 | | | | | 1.52 | 0.32 |
| Stago DRVVT screen | 81 | 1.44 | 8.6 | 1.21 - 1.83 | | | | | | | |
| Technoclone LA Screen | 5 | 1.58 | | 1.44 - 1.62 | | | | | | | |
| Werfen HemosIL dRVVT screen | 221 | 1.52 | 8.0 | 1.05 - 2.36 | | | | | | | |
| PT | 6 | 1.00 | | 0.96 - 1.03 | | | | | | | |
| SCT | 144 | 1.99 | 12.2 | 1.45 - 3.37 | | | | | | | |
| Werfen SCT screen | 142 | 1.99 | 12.1 | 1.45 - 2.64 | | | | | | | |

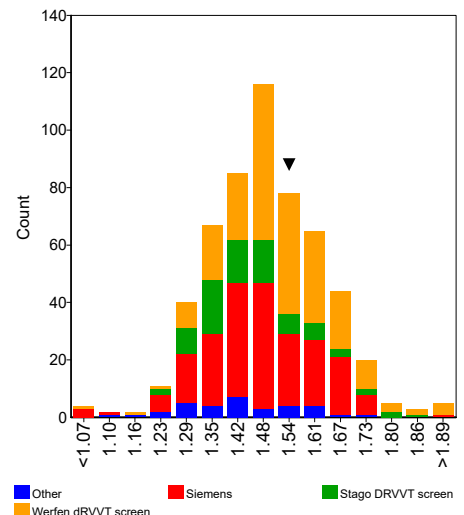
Assays



APTT



DRVVT

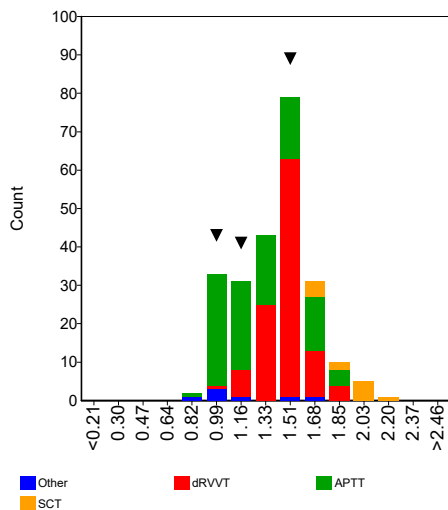


Lupus Anticoagulant

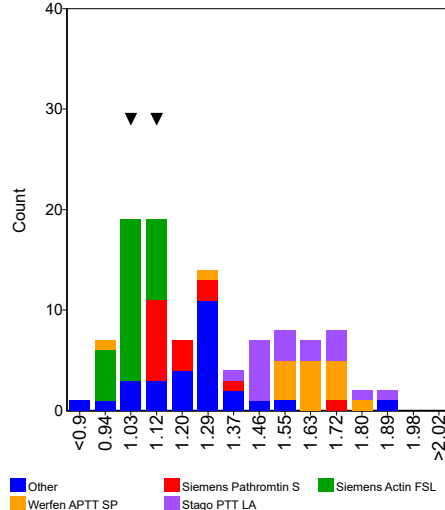
Screening

| Ratio MRI | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|-----------------------------|-----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 105 | 1.28 | 21.7 | 0.90 - 1.92 | 1 | 1.11 | -0.62 | 1.03 | -0.89 | | |
| Siemens Actin FSL | 29 | 1.04 | 4.6 | 0.95 - 1.13 | 1 | | | 1.03 | -0.15 | | |
| Siemens Pathromtin SL | 15 | 1.18 | 7.1 | 1.09 - 1.74 | 1 | 1.11 | -0.89 | | | | |
| Stago PTT Automate/STA PTT | 6 | 1.31 | | 1.20 - 1.37 | | | | | | | |
| Stago PTT LA | 17 | 1.56 | 9.9 | 1.35 - 1.92 | | | | | | | |
| Werfen APTT SP | 16 | 1.61 | 8.1 | 0.98 - 1.77 | | | | | | | |
| Werfen HemosIL SynthAsil | 9 | 1.27 | | 1.19 - 1.90 | | | | | | | |
| dRVVT | 111 | 1.48 | 8.4 | 1.03 - 1.84 | 1 | | | | | 1.54 | 0.51 |
| Siemens LA1 screen | 69 | 1.49 | 6.6 | 1.14 - 1.83 | 1 | | | | | 1.54 | 0.48 |
| Stago DRVVT screen | 12 | 1.40 | 10.4 | 1.20 - 1.67 | | | | | | | |
| Werfen HemosIL dRVVT screen | 23 | 1.49 | 9.1 | 1.22 - 1.66 | | | | | | | |
| SCT | 12 | 1.89 | 10.1 | 1.66 - 2.16 | | | | | | | |
| Werfen SCT screen | 12 | 1.89 | 10.1 | 1.66 - 2.16 | | | | | | | |

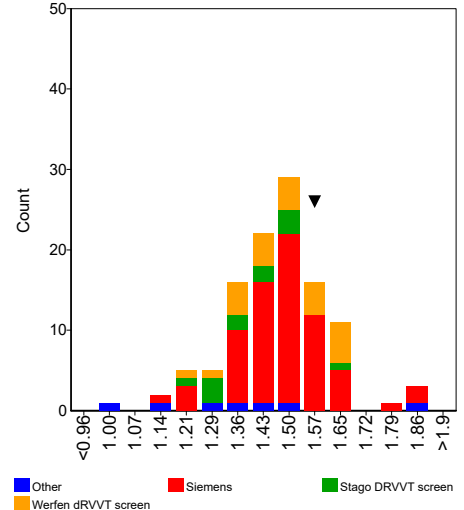
Assays



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

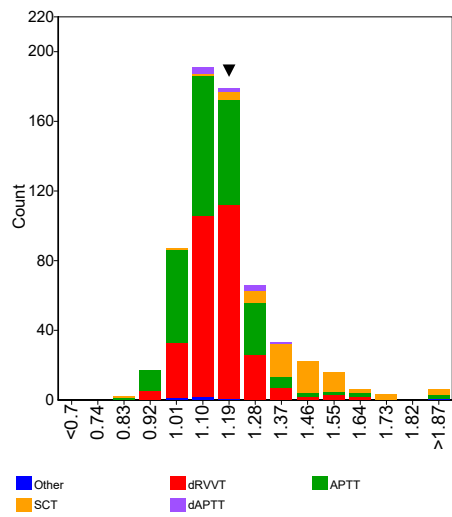
The majority of performed screening tests (> ~85%) were classified as elevated. Interestingly within the assay group dRVVT and SCT 98-100% of the performed screening tests were classified as elevated for this weak positive Lupus Anticoagulant plasma. However, in the assay group APTT only 64% of the screening tests were classified as elevated, which was caused by the lower sensitivity to this weak positive Lupus Anticoagulant plasma for some APTT reagents (like Siemens Actin FSL and Siemens Pathromtin SL).

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

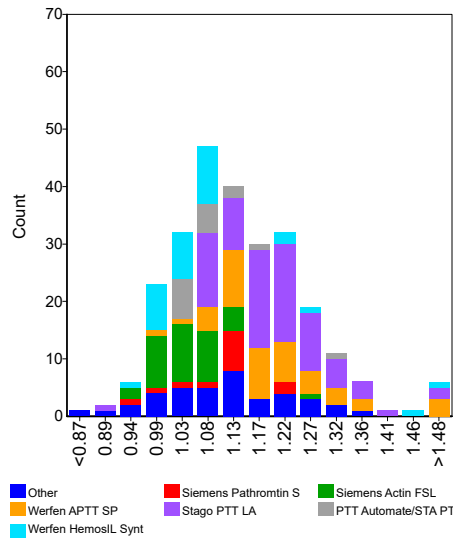
Ratio Normal Plasma

| | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|--------------------------------|-----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 257 | 1.13 | 10.1 | 0.84 - 1.98 | | | | | | | |
| Hyphen-Biomed Cephen LS | 9 | 1.13 | | 1.11 - 1.28 | | | | | | | |
| Siemens Actin FSL | 35 | 1.04 | 5.3 | 0.93 - 1.29 | | | | | | | |
| Siemens Pathromtin SL | 13 | 1.11 | 6.6 | 0.96 - 1.21 | | | | | | | |
| Stago PTT Automate/STA PTT | 16 | 1.07 | 4.4 | 1.02 - 1.32 | | | | | | | |
| Stago PTT LA | 78 | 1.20 | 7.4 | 0.91 - 1.98 | | | | | | | |
| Tcoag TriniClot Automated APTT | 7 | 1.09 | | 1.02 - 1.31 | | | | | | | |
| Werfen APTT SP | 44 | 1.19 | 8.1 | 0.99 - 1.94 | | | | | | | |
| Werfen Hemosil SynthAFax | 5 | 0.99 | | 0.96 - 1.15 | | | | | | | |
| Werfen Hemosil SynthAsil | 32 | 1.05 | 5.9 | 0.96 - 1.51 | | | | | | | |
| Werfen MixCon | 7 | 1.15 | | 0.84 - 1.22 | | | | | | | |
| dAPTT | 11 | 1.20 | 9.7 | 1.07 - 1.37 | | | | | | | |
| Stago PTT LA | 8 | 1.22 | | 1.12 - 1.37 | | | | | | | |
| dRVVT | 307 | 1.15 | 7.1 | 0.93 - 1.62 | 1 | | | | | 1.18 | 0.32 |
| Roche Lupus S | 6 | 1.06 | | 0.93 - 1.17 | | | | | | | |
| Siemens LA1 screen | 136 | 1.14 | 6.8 | 0.95 - 1.39 | 1 | | | | | 1.18 | 0.46 |
| Stago DRVVT screen | 44 | 1.15 | 6.7 | 1.01 - 1.37 | | | | | | | |
| Werfen Hemosil dRVVT screen | 105 | 1.18 | 7.3 | 0.93 - 1.62 | | | | | | | |
| SCT | 74 | 1.44 | 10.2 | 0.86 - 3.37 | | | | | | | |
| Werfen SCT screen | 73 | 1.43 | 9.9 | 0.86 - 1.88 | | | | | | | |

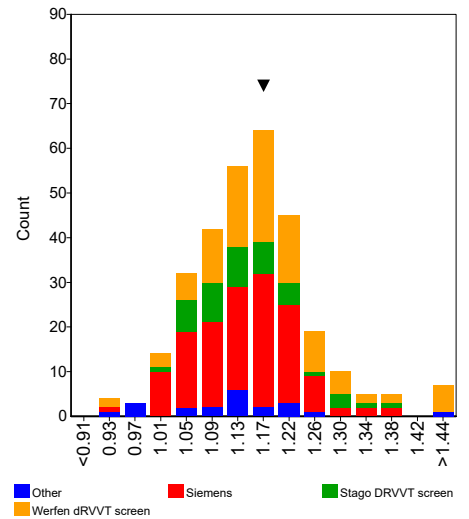
Assays



APTT



DRVVT

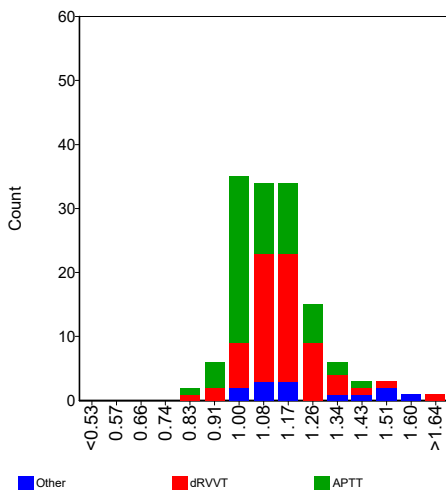


Lupus Anticoagulant

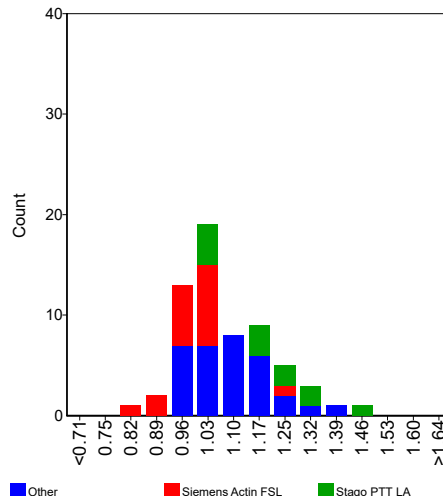
Mixing (screening)

| Ratio MRI | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|-----------------------------|----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 62 | 1.08 | 11.0 | 0.84 - 1.46 | | | | | | | |
| Siemens Actin FSL | 18 | 1.00 | 5.7 | 0.84 - 1.23 | | | | | | | |
| Siemens Pathromtin SL | 9 | 1.12 | | 0.97 - 1.36 | | | | | | | |
| Stago PTT LA | 12 | 1.18 | 13.2 | 1.00 - 1.46 | | | | | | | |
| Werfen APTT SP | 9 | 1.10 | | 0.98 - 1.19 | | | | | | | |
| dRVVT | 65 | 1.14 | 9.0 | 0.85 - 1.96 | | | | | | | |
| Siemens LA1 screen | 40 | 1.14 | 9.1 | 0.93 - 1.47 | | | | | | | |
| Stago DRVVT screen | 8 | 1.17 | | 1.01 - 1.23 | | | | | | | |
| Werfen HemosIL dRVVT screen | 11 | 1.18 | 11.4 | 1.00 - 1.96 | | | | | | | |
| SCT | 5 | 1.51 | | 1.37 - 1.61 | | | | | | | |
| Werfen SCT screen | 5 | 1.51 | | 1.37 - 1.61 | | | | | | | |

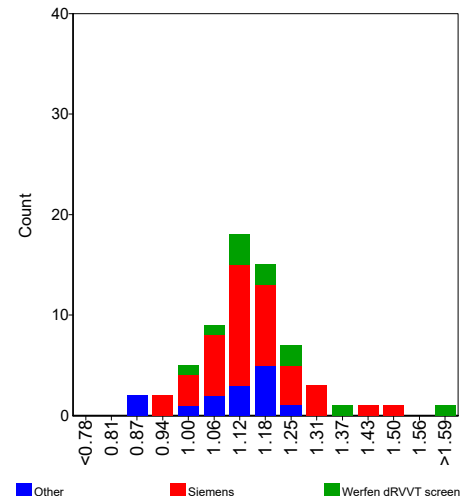
Assays



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 reference plasma or the mean of the reference interval was reported as a ratio. In all these cases the ratio between the ECAT plasma and the laboratories own reference plasma and/or the mean of the reference interval could not be correctly calculated. Therefore all these results were excluded in the statistical analysis.

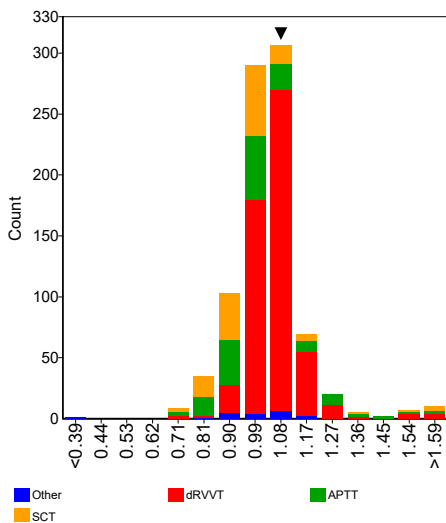
For a sample with a weak positive result in the screening test, it is expected that a more heterogeneous classification pattern will be observed in the mixing screen test due to different sensitivity to Lupus Anticoagulant. Approximately, half of performed mixing tests (44%) were classified as elevated. Especially participants using reagents derived from the assay group APTT showed a large percent of not elevated classifications 68%. This is expected, since a weak positive patient sample was used in this survey and therefore a larger number of not elevated 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).

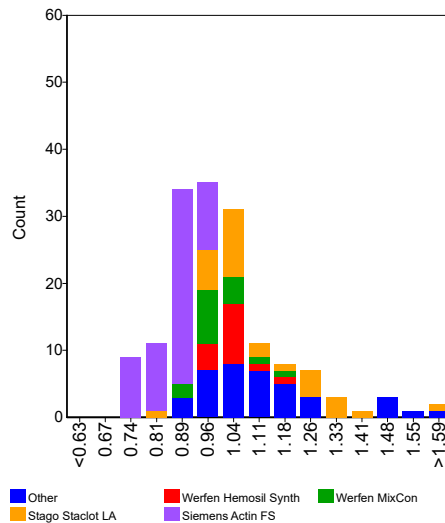
Ratio Normal Plasma

| | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|---|-----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 156 | 0.99 | 13.7 | 0.72 - 2.65 | | | | | | | |
| Precision Biologic CRYOcheck Hex LA Cor | 5 | 1.08 | | 1.05 - 1.54 | | | | | | | |
| Siemens Actin FS | 58 | 0.87 | 8.4 | 0.72 - 1.00 | | | | | | | |
| Stago Staclot LA | 29 | 1.11 | 14.5 | 0.82 - 1.85 | | | | | | | |
| Stago/Roche PTT LA | 7 | 1.16 | | 0.87 - 1.51 | | | | | | | |
| Werfen Hemosil SynthAFax | 15 | 1.02 | 4.5 | 0.96 - 1.16 | | | | | | | |
| Werfen MixCon | 16 | 0.99 | 6.2 | 0.90 - 1.17 | | | | | | | |
| dAPTT | 6 | 0.93 | | 0.88 - 1.21 | | | | | | | |
| dRVVT | 540 | 1.05 | 6.2 | 0.99 - 1.69 | 1 | | | | | 1.05 | -0.07 |
| Hyphen Biomed Hemoclot LA-C | 8 | 0.97 | | 0.93 - 1.00 | | | | | | | |
| Precision Biologic LA sure | 7 | 0.96 | | 0.99 - 1.15 | | | | | | | |
| Roche Lupus C | 7 | 1.04 | | 0.95 - 1.15 | | | | | | | |
| Siemens LA2 confirmation | 207 | 1.05 | 5.6 | 0.82 - 1.35 | 1 | | | | | 1.05 | -0.01 |
| Stago DRVVT Confirm | 77 | 1.04 | 4.9 | 0.92 - 1.69 | | | | | | | |
| Technoclone LA Confirm | 7 | 1.06 | | 1.01 - 1.10 | | | | | | | |
| Werfen Hemosil dRVVT confirm | 221 | 1.07 | 6.5 | 0.71 - 1.68 | | | | | | | |
| PNP | 6 | 1.02 | | 0.09 - 1.20 | | | | | | | |
| SCT | 142 | 0.96 | 9.7 | 0.67 - 2.16 | | | | | | | |
| Werfen Hemosil SCT confirm | 142 | 0.96 | 9.7 | 0.67 - 2.16 | | | | | | | |

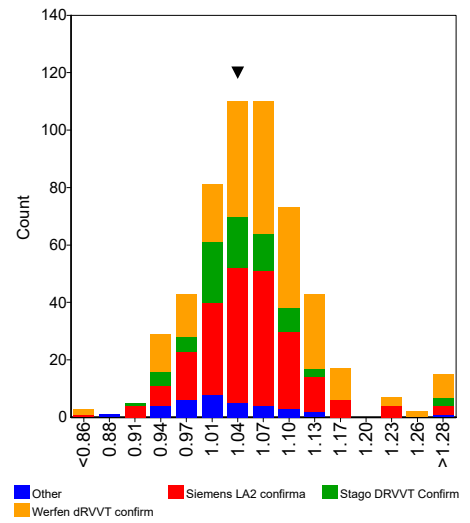
Assays



APTT



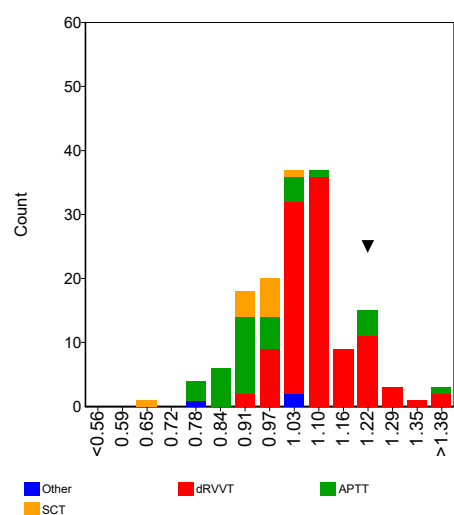
DRVVT



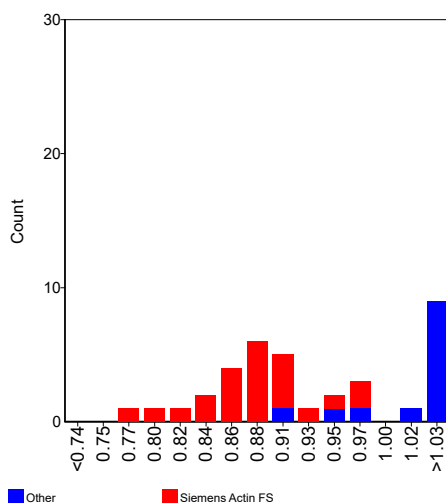
Lupus Anticoagulant **Confirmation**

| Ratio MRI | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|------------------------------|-----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 36 | 0.94 | 11.5 | 0.78 - 1.61 | | | | | | | |
| Siemens Actin FS | 23 | 0.88 | 5.5 | 0.78 - 0.97 | | | | | | | |
| Stago Staclot LA | 5 | 1.03 | | 0.96 - 1.24 | | | | | | | |
| dRVVT | 103 | 1.09 | 7.4 | 0.89 - 1.69 | 1 | | | | | 1.25 | 1.94 |
| Siemens LA2 confirmation | 65 | 1.11 | 8.3 | 0.94 - 1.45 | 1 | | | | | 1.25 | 1.51 |
| Stago DRVVT Confirm | 11 | 1.01 | 8.1 | 0.89 - 1.09 | | | | | | | |
| Werfen HemosIL dRVVT confirm | 20 | 1.10 | 5.5 | 0.95 - 1.69 | | | | | | | |
| SCT | 12 | 0.94 | 6.5 | 0.63 - 1.03 | | | | | | | |
| Werfen HemosIL SCT confirm | 12 | 0.94 | 6.5 | 0.63 - 1.03 | | | | | | | |

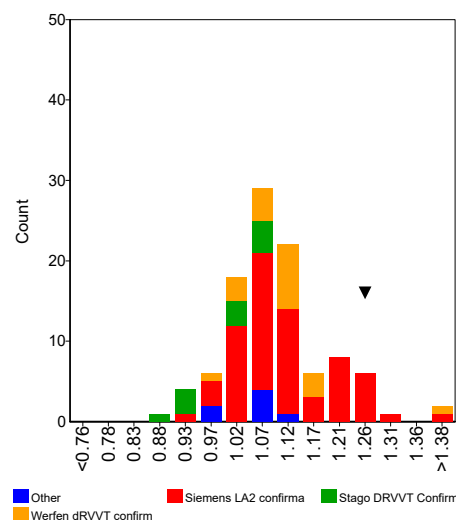
Assays



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. Some 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 in the statistical analysis.

As expected, the majority of performed confirmation tests (81%) 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 | 24.182 | | |
| Sample Details | Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.5) | | |
| Prior Use | Prior Use: None | | |
| Unit | Ratio | | |
| Expiry Date | 30-April-2027 | | |
| Homogeneity | 0.0 % | Homogeneity Parameter | LA ratio |
| Number of Participants | 624 | | |
| Number of Responders | 175 | Response Rate | 28 % |

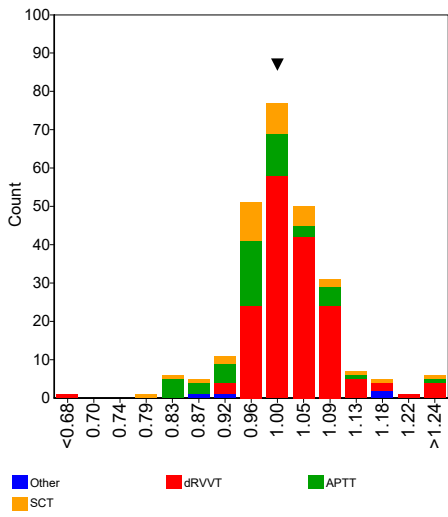
| Assay | Elevated | Not elevated | Borderline | No Classification |
|-------|----------|--------------|------------|-------------------|
| APTT | 8 | 40 | 0 | 7 |
| dAPTT | 2 | 5 | 0 | 1 |
| dPT | 0 | 0 | 0 | 0 |
| dRVVT | 24 | 138 | 0 | 13 |
| PNP | 1 | 0 | 0 | 0 |
| SCT | 2 | 30 | 0 | 2 |

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

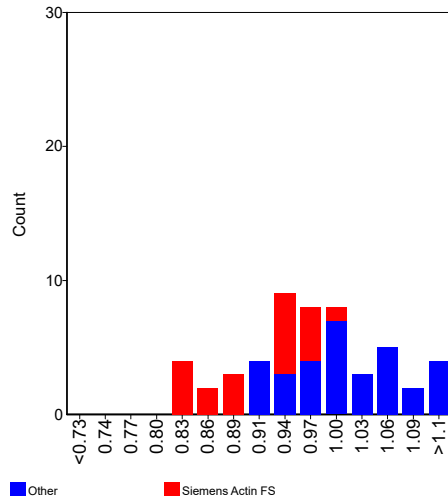
Ratio Normal Plasma

| | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|------------------------------|-----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 52 | 0.97 | 8.2 | 0.83 - 1.60 | | | | | | | |
| Siemens Actin FS | 20 | 0.92 | 6.8 | 0.83 - 1.00 | | | | | | | |
| Stago/Roche PTT LA | 5 | 0.93 | | 0.91 - 1.07 | | | | | | | |
| Werfen HemosIL APTT-SP | 5 | 1.05 | | 1.00 - 1.24 | | | | | | | |
| Werfen Hemosil SynthAFax | 7 | 0.97 | | 0.95 - 1.14 | | | | | | | |
| Werfen MixCon | 5 | 1.02 | | 0.95 - 1.60 | | | | | | | |
| dRVVT | 164 | 1.03 | 4.8 | 0.97 - 1.45 | 1 | | | | | 1.02 | -0.17 |
| Siemens LA2 confirmation | 82 | 1.02 | 3.5 | 0.94 - 1.45 | 1 | | | | | 1.02 | -0.08 |
| Stago DRVVT Confirm | 18 | 1.04 | 4.6 | 0.99 - 1.41 | | | | | | | |
| Werfen HemosIL dRVVT confirm | 56 | 1.04 | 6.5 | 0.66 - 1.32 | | | | | | | |
| SCT | 33 | 0.99 | 6.9 | 0.80 - 1.68 | | | | | | | |
| Werfen HemosIL SCT confirm | 33 | 0.99 | 6.9 | 0.80 - 1.68 | | | | | | | |

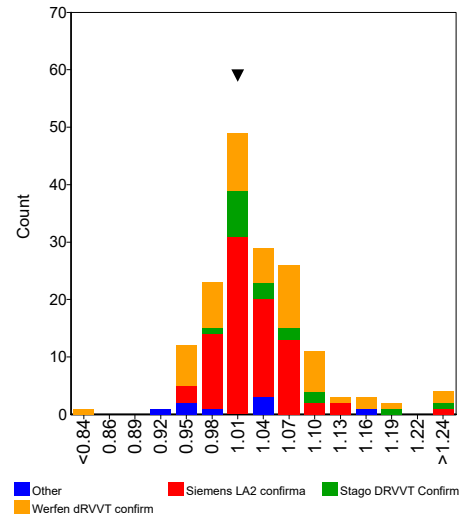
Assays



APTT



DRVVT

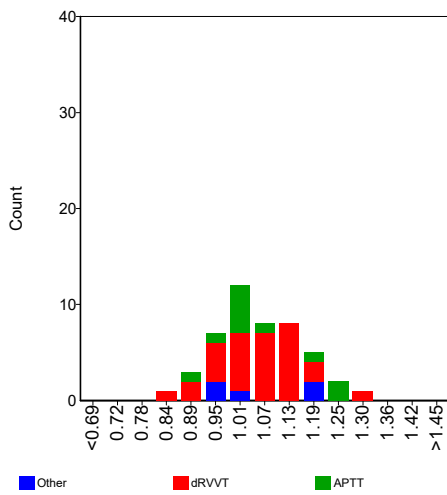


Lupus Anticoagulant

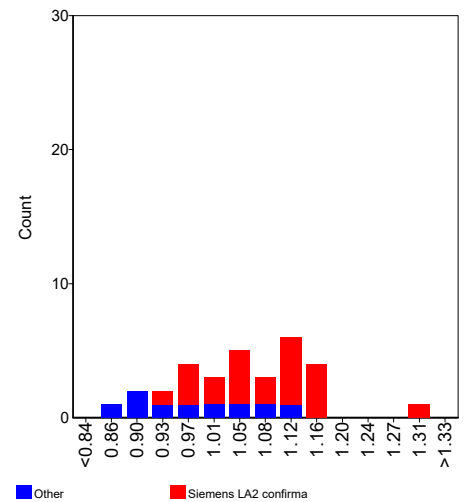
Mixing (confirm)

| Ratio MRI | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|------------------------------|----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 11 | 1.07 | 11.9 | 0.90 - 1.24 | | | | | | | |
| Siemens Actin FS | 6 | 1.02 | | 0.90 - 1.02 | | | | | | | |
| dRVVT | 31 | 1.05 | 9.2 | 0.85 - 1.30 | | | | | | | |
| Siemens LA2 confirmation | 22 | 1.08 | 7.5 | 0.94 - 1.30 | | | | | | | |
| Werfen HemosIL dRVVT confirm | 6 | 1.00 | | 0.85 - 1.12 | | | | | | | |

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 in the statistical analysis.

As expected, the majority of performed mixing confirmation tests (85%) 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).

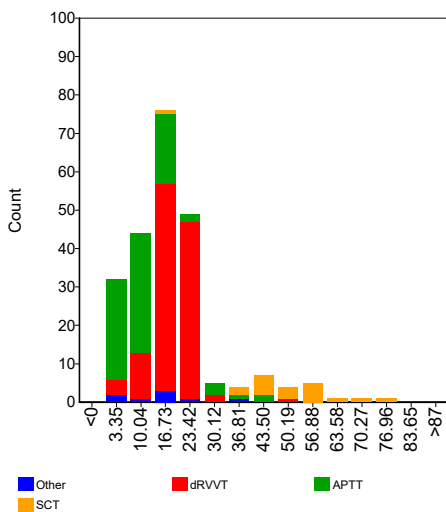
Lupus Anticoagulant

Interpretation

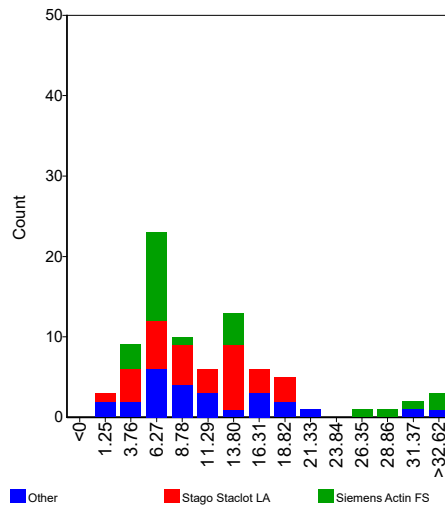
Delta Seconds

| | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|---|-----|----------------|--------|---------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 83 | 10.43 | 57.8 | 1.80 - 42.80 | | | | | | | |
| Precision Biologic CRYOcheck Hex LA Cor | 6 | 17.10 | | 11.00 - 22.00 | | | | | | | |
| Siemens Actin FS | 24 | 10.60 | 69.2 | 4.00 - 42.80 | | | | | | | |
| Stago Staclot LA | 33 | 10.44 | 52.4 | 2.50 - 18.40 | | | | | | | |
| dRVVT | 119 | 18.98 | 20.5 | 1.41 - 52.30 | | | | | | | |
| Siemens LA2 confirmation | 60 | 18.17 | 18.9 | 4.40 - 52.30 | | | | | | | |
| Stago DRVVT Confirm | 13 | 16.72 | 30.3 | 1.80 - 22.10 | | | | | | | |
| Werfen HemosIL dRVVT confirm | 39 | 21.27 | 12.3 | 9.20 - 28.90 | | | | | | | |
| SCT | 19 | 49.95 | 24.7 | 19.30 - 79.40 | | | | | | | |
| Werfen HemosIL SCT confirm | 19 | 49.95 | 24.7 | 19.30 - 79.40 | | | | | | | |

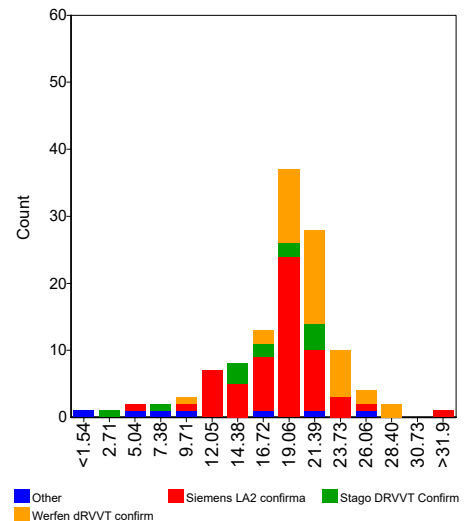
Assays



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).

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

9039 : 0.1

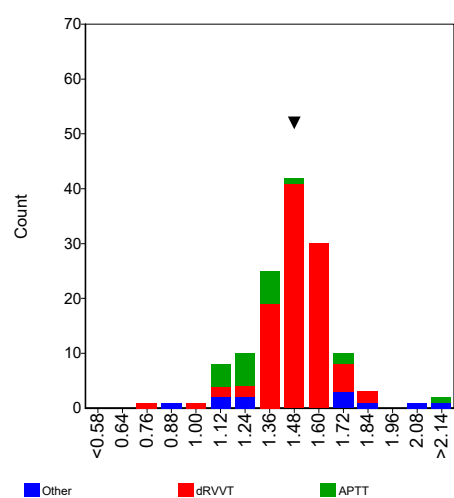
Lupus Anticoagulant

Interpretation

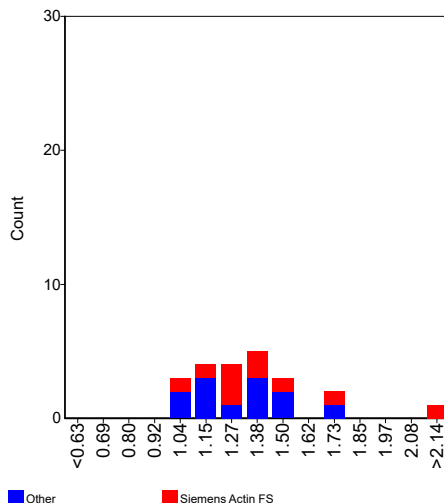
Ratio Screen/Confirmation - Standard

| | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|------------------------------|-----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 23 | 1.33 | 16.0 | 1.06 - 3.13 | | | | | | | |
| Siemens Actin FS | 10 | 1.39 | 18.1 | 1.08 - 3.13 | | | | | | | |
| Stago Staclot LA | 5 | 1.20 | | 1.06 - 1.39 | | | | | | | |
| dRVVT | 116 | 1.49 | 8.0 | 0.80 - 1.82 | 1 | | | | | 1.53 | 0.36 |
| Siemens LA2 confirmation | 77 | 1.50 | 6.7 | 1.11 - 1.70 | 1 | | | | | 1.53 | 0.27 |
| Stago DRVVT Confirm | 11 | 1.43 | 5.2 | 1.34 - 1.60 | | | | | | | |
| Werfen HemosIL dRVVT confirm | 18 | 1.52 | 12.4 | 1.19 - 1.82 | | | | | | | |
| SCT | 8 | 1.74 | | 0.86 - 2.17 | | | | | | | |
| Werfen HemosIL SCT confirm | 8 | 1.74 | | 0.86 - 2.17 | | | | | | | |

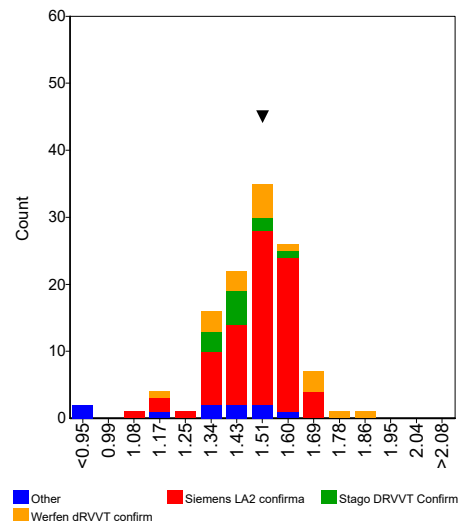
Assays



APTT



DRVVT



Comments

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

296A (instr. 1) : 13.1

296A (instr. 2) : 16.5

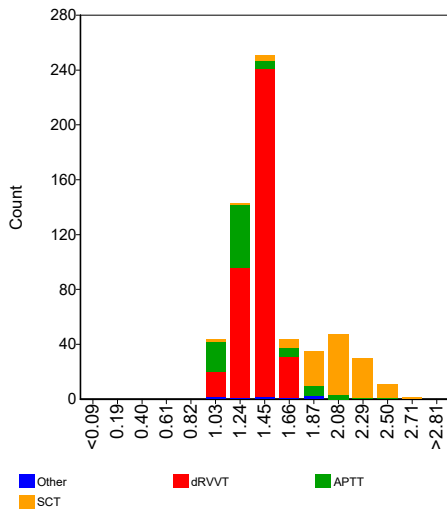
Lupus Anticoagulant

Interpretation

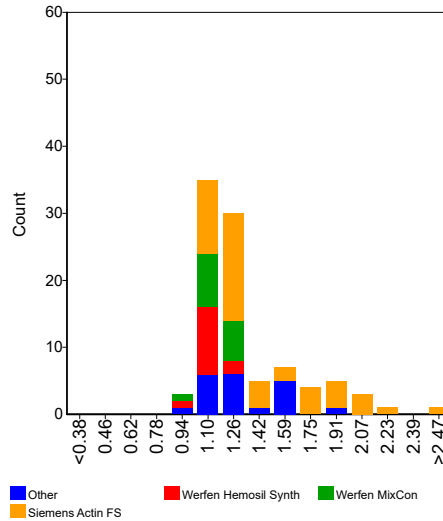
Ratio Screen/Confirmation - Normalised

| | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|------------------------------|-----|----------------|--------|-------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 94 | 1.28 | 16.6 | 1.01 - 2.49 | | | | | | | |
| Siemens Actin FS | 46 | 1.42 | 24.5 | 1.04 - 2.49 | | | | | | | |
| Werfen Hemosil SynthAFax | 13 | 1.14 | 3.3 | 1.01 - 1.33 | | | | | | | |
| Werfen MixCon | 15 | 1.17 | 4.4 | 1.02 - 1.28 | | | | | | | |
| dRVVT | 382 | 1.40 | 8.2 | 0.98 - 1.74 | | | | | | | |
| Hyphen Biomed Hemoclot LA-C | 8 | 1.57 | | 1.41 - 1.67 | | | | | | | |
| Roche Lupus C | 7 | 1.27 | | 0.99 - 1.34 | | | | | | | |
| Siemens LA2 confirmation | 118 | 1.39 | 8.0 | 0.98 - 1.62 | | | | | | | |
| Stago DRVVT Confirm | 58 | 1.39 | 7.2 | 1.09 - 1.74 | | | | | | | |
| Werfen Hemosil dRVVT confirm | 184 | 1.41 | 8.3 | 1.00 - 1.69 | | | | | | | |
| SCT | 122 | 2.08 | 11.7 | 1.00 - 2.69 | | | | | | | |
| Werfen Hemosil SCT confirm | 122 | 2.08 | 11.7 | 1.00 - 2.69 | | | | | | | |

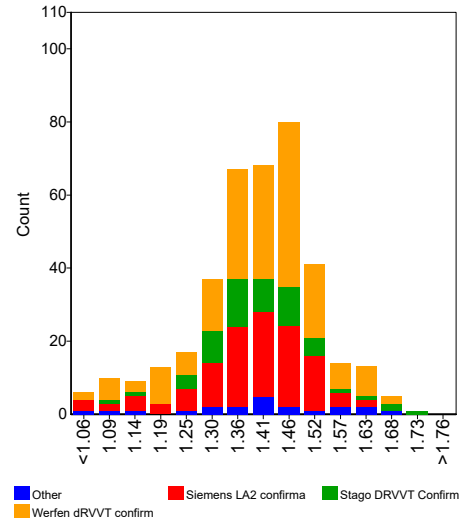
Assays



APTT



DRVVT



Comments

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

4561 : 11.7

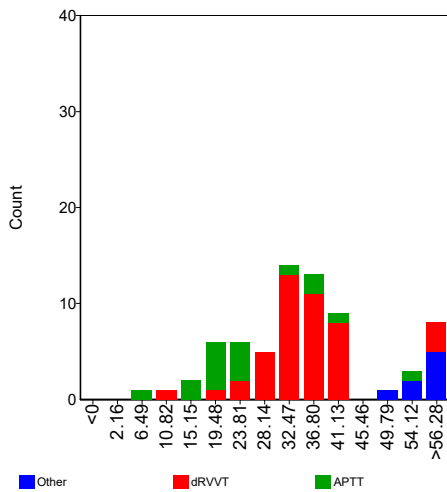
Lupus Anticoagulant

Interpretation

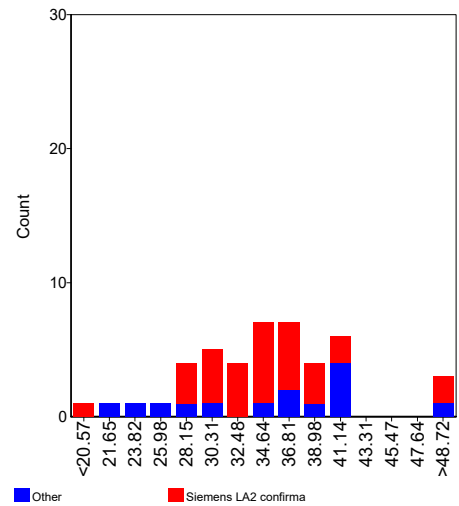
Percentage Correction - Standard

| | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|------------------------------|----|----------------|--------|---------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 17 | 24.93 | 41.9 | 5.80 - 52.38 | | | | | | | |
| Siemens Actin FS | 9 | 23.50 | | 19.00 - 52.38 | | | | | | | |
| dRVVT | 44 | 34.83 | 16.5 | 11.20 - 69.00 | | | | | | | |
| Siemens LA2 confirmation | 30 | 34.65 | 13.5 | 11.20 - 63.78 | | | | | | | |
| Werfen HemosIL dRVVT confirm | 7 | 40.50 | | 34.60 - 69.00 | | | | | | | |
| SCT | 8 | 59.13 | | 50.60 - 62.40 | | | | | | | |
| Werfen HemosIL SCT confirm | 8 | 59.13 | | 50.60 - 62.40 | | | | | | | |

Assays



DRVVT



Comments

Some participants reported a ratio instead of a percentage correction result and were excluded in the statistical evaluation.

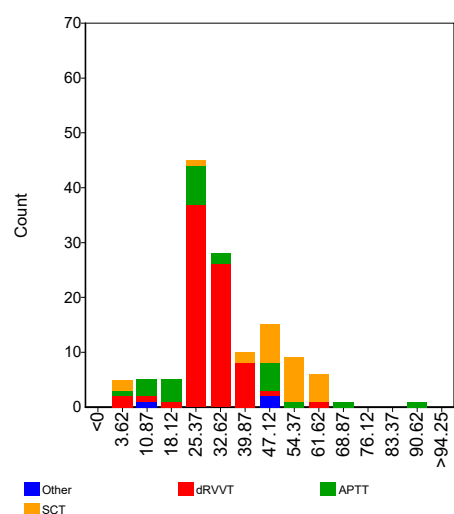
Lupus Anticoagulant

Interpretation

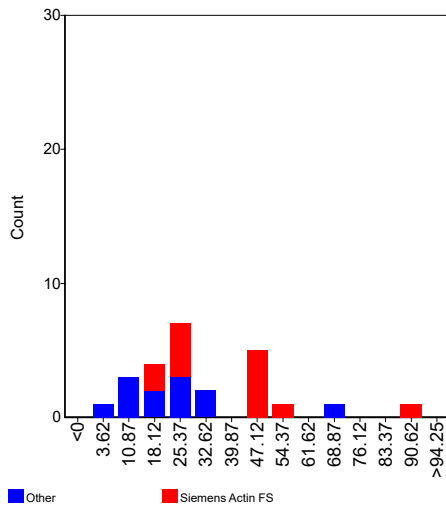
Percentage Correction - Normalised

| | n | assigned value | CV (%) | Range | Test System | Panel 1 | Z-score | Panel 2 | Z-score | Panel 3 | Z-score |
|------------------------------|----|----------------|--------|---------------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 25 | 30.17 | 62.0 | 5.40 - 90.00 | | | | | | | |
| Siemens Actin FS | 13 | 38.09 | 49.1 | 14.56 - 90.00 | | | | | | | |
| dRVVT | 77 | 29.45 | 20.7 | 6.60 - 64.50 | | | | | | | |
| Siemens LA2 confirmation | 35 | 29.58 | 21.4 | 6.60 - 64.50 | | | | | | | |
| Stago DRVVT Confirm | 10 | 28.73 | 12.7 | 24.00 - 34.00 | | | | | | | |
| Werfen HemosIL dRVVT confirm | 30 | 30.47 | 23.8 | 9.00 - 42.00 | | | | | | | |
| SCT | 25 | 50.71 | 16.8 | 0.00 - 63.70 | | | | | | | |
| Werfen HemosIL SCT confirm | 25 | 50.71 | 16.8 | 0.00 - 63.70 | | | | | | | |

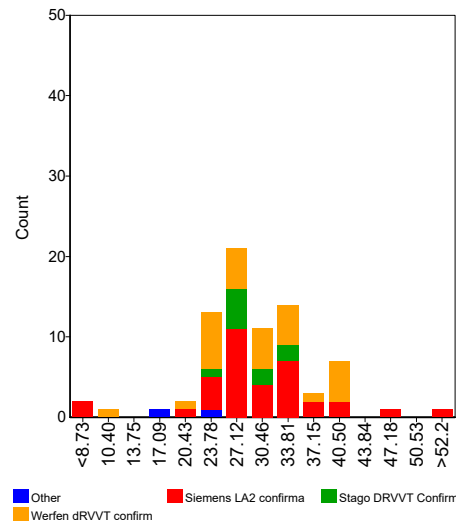
Assays



APTT



DRVVT



Comments

Some participants reported a ratio instead of a percentage correction result and were excluded in the statistical evaluation.

The following participants reported results for the normalised percentage correction which were probably no percentage correction result and were therefore excluded in the statistical evaluation:

141 : 0
653A : 0

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 | 0 | 7 | 15 | 10 | 1 | | | |
| | | | | | 2 | | | |
| | | | | | 3 | | | |
| Screen and mixing test | 4 | 20 | 52 | 20 | 1 | | | |
| | | | | | 2 | | | |
| | | | | | 3 | | | |
| Screen and confirm test | 16 | 412 | 47 | 2 | 1 | | | |
| | | | | | 2 | | | |
| | | | | | 3 | | | |
| Screen, mixing and confirm test | | 226 | 34 | 8 | 1 | | | LA detected |
| | | | | | 2 | | | |
| | | | | | 3 | | | |
| Screen, confirm, mixing test | 11 | 94 | 41 | 5 | 1 | | | |
| | | | | | 2 | | | |
| | | | | | 3 | | | |
| Mixing - confirmation | 3 | 19 | 9 | 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 | | | |
| 412 | 43 | 31 | 8 | LA detected | | |

Comments

The sample used in this survey was plasma from a patient diagnosed with Lupus Anticoagulant (LA Ratio = approx. 1.5). This patient might be under anticoagulation treatment.

In total 486 participants gave a final conclusion. Of the participants who gave a final conclusion, approximately 85% classified the sample as positive. Six percent classified the sample as equivocal. Thus, the vast majority of the participants correctly classified this sample as positive. A minority (9%) of the participants classified this sample as negative, which was observed especially for participants using the "Screen test only" and "Screen and mixing test" only.

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. Some participants indicated that the presence of direct oral anticoagulants and/or factor deficiency should be excluded. Other participants indicated an anti-Xa activity level of ~0.1 IU/mL.

Lupus Anticoagulant

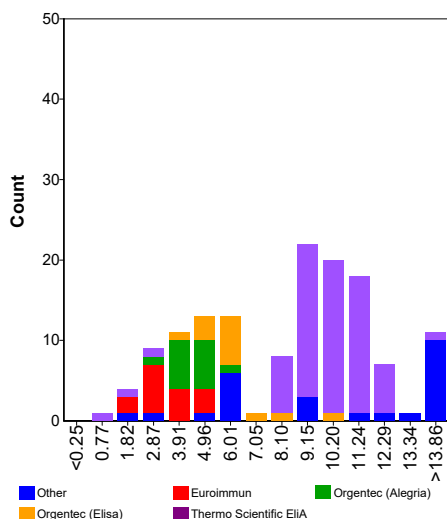
AntiCardiolipin Antibodies IgG

| | | | |
|-------------------------------|---|------------------------------|----------|
| Sample No | 24.182 | | |
| Sample Details | Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.5) | | |
| Prior Use | Prior Use: None | | |
| Unit | GPL, U/mL, µg/mL, CU/mL | | |
| Expiry Date | 30-April-2027 | | |
| Homogeneity | 0.0 % | Homogeneity Parameter | LA ratio |
| Number of Participants | 624 | | |
| Number of Responders | 226 | Response Rate | 36 % |

| Classification | Negative | Borderline | Low Positive | Medium Positive | High Positive | No Conclusion |
|----------------|----------|------------|--------------|-----------------|---------------|---------------|
| Total | 104 | 37 | 72 | 10 | 4 | 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 | 139 | 8.3 | 46.0 | 1.1 - 91.0 | | | | | | |
| Biorad Bioplex | 7 | 78.3 | | 75.1 - 91.0 | | | | | | |
| Euroimmun | 15 | 3.6 | 31.0 | 2.0 - 5.1 | | | | | | |
| Orgentec (Alegria) | 14 | 4.3 | 17.5 | 3.2 - 5.6 | | | | | | |
| Orgentec (Elisa) | 13 | 5.9 | 21.7 | 4.0 - 10.6 | | | | | | |
| Thermo Scientific ELIA | 72 | 9.9 | 13.2 | 1.1 - 14.0 | | | | | | |
| CU/mL | 83 | 24.9 | 9.2 | 4.2 - 31.6 | | | | | | |
| Werfen Acustar / INOVA Quanta Flash | 82 | 24.8 | 9.2 | 4.2 - 31.6 | | | | | | |

GPL, U/mL, µg/mL



Comments

A heterogeneous pattern in the classification has been observed.

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

- 365:** 129.1 CU/mL
- 1353 :** 0.28 (ratio)
- 9907155 :** 0 U/mL

Lupus Anticoagulant

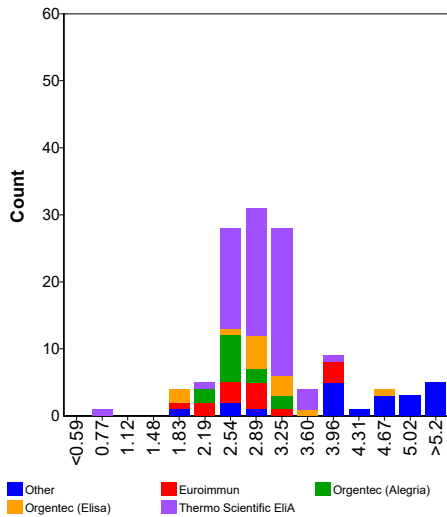
AntiCardiolipin Antibodies IgM

| | | | |
|-------------------------------|---|------------------------------|----------|
| Sample No | 24.182 | | |
| Sample Details | Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.5) | | |
| Prior Use | Prior Use: None | | |
| Unit | MPL, U/mL, µg/mL, CU/mL | | |
| Expiry Date | 30-April-2027 | | |
| Homogeneity | 0.0 % | Homogeneity Parameter | LA ratio |
| Number of Participants | 624 | | |
| Number of Responders | 213 | Response Rate | 34 % |

| Classification | Negative | Borderline | Low Positive | Medium Positive | High Positive | No Conclusion |
|----------------|----------|------------|--------------|-----------------|---------------|---------------|
| Total | 212 | 1 | 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/mL, µg/mL, GPL/MPL | 124 | 3.1 | 20.9 | 0.9 - 7.3 | | | | | | |
| Biorad Bioplex | 6 | 5.0 | | 4.1 - 5.2 | | | | | | |
| Euroimmun | 14 | 2.9 | 26.6 | 2.0 - 4.0 | | | | | | |
| Orgentec (Alegria) | 13 | 2.6 | 11.8 | 2.3 - 3.2 | | | | | | |
| Orgentec (Elisa) | 13 | 3.0 | 21.8 | 1.8 - 4.6 | | | | | | |
| Thermo Scientific EliA | 62 | 3.0 | 12.4 | 0.9 - 3.8 | | | | | | |
| CU/mL | 79 | 6.2 | 10.2 | 2.6 - 7.6 | | | | | | |
| Werfen Acustar / INOVA Quanta Flash | 78 | 6.2 | 10.0 | 3.0 - 7.6 | | | | | | |

MPL, U/mL, µg/mL



Comments

A negative pattern in the classification has been observed.

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

- 359:** 36 U/mL
- 1353 :** 0.1 (ratio)
- 9907155 :** 0 U/mL

Lupus Anticoagulant

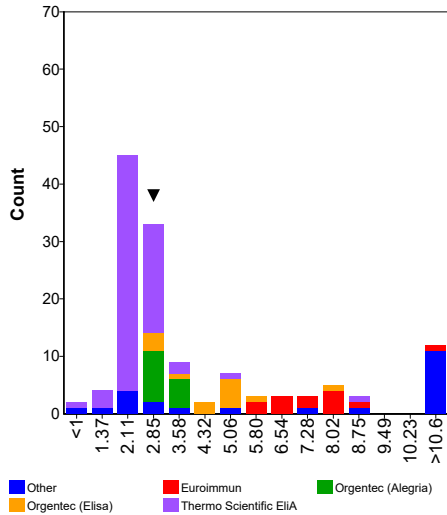
β2-Glycoprotein I Antibodies IgG

| | | | |
|-------------------------------|---|------------------------------|----------|
| Sample No | 24.182 | | |
| Sample Details | Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.5) | | |
| Prior Use | Prior Use: None | | |
| Unit | U, U/mL, µg/mL, CU/mL | | |
| Expiry Date | 30-April-2027 | | |
| Homogeneity | 0.0 % | Homogeneity Parameter | LA ratio |
| Number of Participants | 624 | | |
| Number of Responders | 219 | Response Rate | 35 % |

| Classification | Negative | Borderline | Low Positive | Medium Positive | High Positive | No Conclusion |
|----------------|----------|------------|--------------|-----------------|---------------|---------------|
| Total | 117 | 5 | 11 | 37 | 49 | 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 | 131 | 3.5 | 56.6 | 0.6 - 84.0 | 3.2 | -0.13 | | | | |
| Aeskulisa Diagnostic GmbH | 5 | 2.0 | | 1.0 - 11.5 | | | | | | |
| Biorad Bioplex | 7 | 71.6 | | 64.9 - 84.0 | | | | | | |
| Euroimmun | 13 | 7.3 | 15.1 | 5.7 - 25.6 | | | | | | |
| Orgentec (Alegria) | 14 | 3.1 | 13.6 | 2.5 - 3.6 | | | | | | |
| Orgentec (Elisa) | 13 | 4.4 | 25.8 | 3.0 - 7.7 | 3.2 | -1.07 | | | | |
| Thermo Scientific ELIA | 68 | 2.3 | 15.2 | 0.8 - 8.6 | | | | | | |
| CU/mL | 84 | 128.5 | 12.4 | 98.2 - 186.0 | | | | | | |
| Werfen Acustar / INOVA Quanta Flash | 83 | 128.4 | 12.5 | 98.2 - 186.0 | | | | | | |

U, U/mL, µg/mL



Comments

Most of the participants reported a negative classification, except for participants using the methods Biorad Bioplex and Werfen Acustar / INOVA Quanta Flash, who 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:

9907155 : 0 U/mL

Lupus Anticoagulant

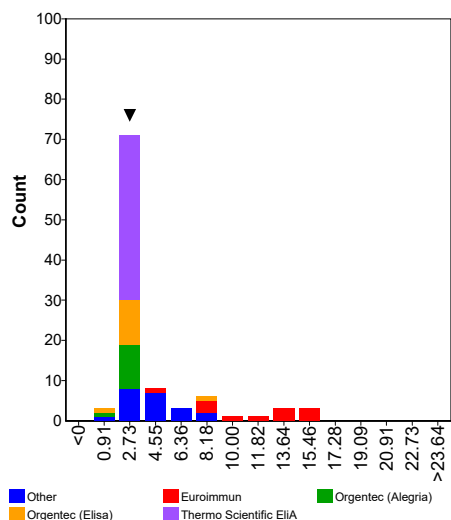
β2-Glycoprotein I Antibodies IgM

| | | | |
|-------------------------------|---|------------------------------|----------|
| Sample No | 24.182 | | |
| Sample Details | Plasma weak positive for Lupus Anticoagulant (LA Ratio approx. 1.5) | | |
| Prior Use | Prior Use: None | | |
| Unit | U, U/mL, µg/mL, CU/mL | | |
| Expiry Date | 30-April-2027 | | |
| Homogeneity | 0.0 % | Homogeneity Parameter | LA ratio |
| Number of Participants | 624 | | |
| Number of Responders | 197 | Response Rate | 32 % |

| Classification | Negative | Borderline | Low Positive | Medium Positive | High Positive | No Conclusion |
|----------------|----------|------------|--------------|-----------------|---------------|---------------|
| Total | 195 | 1 | 1 | 0 | 1 | 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 | 99 | 3.2 | 41.7 | 0.2 - 16.3 | 2.1 | -0.82 | | | | |
| Aeskulisa Diagnostik GmbH | 5 | 3.5 | | 2.1 - 5.0 | | | | | | |
| Biorad Bioplex | 6 | 5.4 | | 5.1 - 6.1 | | | | | | |
| Euroimmun | 12 | 11.5 | 34.9 | 3.9 - 16.3 | | | | | | |
| Orgentec (Alegria) | 12 | 2.1 | 13.1 | 1.4 - 2.6 | | | | | | |
| Orgentec (Elisa) | 13 | 2.8 | 24.9 | 1.0 - 7.6 | 2.1 | -0.95 | | | | |
| Thermo Scientific ELIA | 41 | 2.7 | 12.2 | 2.0 - 3.3 | | | | | | |
| CU/mL | 76 | 2.7 | 16.1 | 2.0 - 15.1 | | | | | | |
| Werfen Acustar / INOVA Quanta Flash | 76 | 2.7 | 16.1 | 2.0 - 15.1 | | | | | | |

U, U/mL, µg/mL



Comments

A negative pattern in the classification has been observed.

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

856 : 0.0 U/mL

9907155 : 0 U/mL