

Lupus Anticoagulant

Mixing

No. of Responders

190

Sample No 16.17
Sample Details Plasma strongly positive for Lupus Anticoagulant
Units: Ratio
Prior Use: None

Stability 31-December-2017

Homogeneity 1.9 %

Homogeneity Parameter

Lupus Anticoagulant ratio

| Assay | Normal | Borderline | Prolonged | No Classification | Your result | | |
|-------|--------|------------|-----------|-------------------|-------------|----------|----------|
| | | | | | Mixing 1 | Mixing 2 | Mixing 3 |
| APTT | 4 | 8 | 230 | 2 | Prolonged | | |
| dAPTT | 1 | 0 | 21 | 0 | | | |
| dPT | 0 | 0 | 5 | 0 | | | |
| dRVVT | 4 | 3 | 238 | 3 | | | |
| KCT | 0 | 0 | 8 | 0 | | | |
| Other | 1 | 0 | 2 | 0 | | | |
| PNP | 1 | 0 | 1 | 0 | | | |
| PT | 0 | 0 | 1 | 0 | | | |
| SCT | 1 | 0 | 37 | 1 | | | |

Ratio n assigned CV (%) range panel 1 z-score panel 2 z-score panel 3 z-score

| Ratio | n | assigned value | CV (%) | range | panel 1 | z-score | panel 2 | z-score | panel 3 | z-score |
|-----------------------------------|-----|----------------|--------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 220 | 1.61 | 17.6 | 0.86 - 4.06 | 2.10 | 1.73 | | | | |
| I.L. APTT SP | 25 | 2.03 | 6.0 | 1.78 - 2.26 | 2.10 | 0.81 | | | | |
| I.L. HemosIL SynthAsil | 19 | 1.77 | 10.1 | 1.47 - 2.32 | | | | | | |
| I.L. MxCon | 12 | 1.64 | 10.5 | 1.27 - 2.00 | | | | | | |
| Siemens Actin FSL | 30 | 1.38 | 9.6 | 0.86 - 4.06 | | | | | | |
| Siemens Pathromtin SL | 16 | 1.27 | 5.3 | 1.16 - 1.37 | | | | | | |
| Stago/Roche PTT | 21 | 1.45 | 8.8 | 1.29 - 1.71 | | | | | | |
| Stago/Roche PTT LA | 64 | 1.66 | 8.9 | 1.29 - 2.22 | | | | | | |
| Trinity Biotech Automated APTT | 8 | 1.40 | | 1.22 - 1.55 | | | | | | |
| Trinity Biotech TriniClot APTT-HS | 7 | 1.61 | | 1.49 - 1.76 | | | | | | |
| dAPTT | 21 | 1.64 | 16.3 | 1.07 - 3.72 | | | | | | |
| Stago/Roche PTT LA | 11 | 1.66 | 10.0 | 1.48 - 1.90 | | | | | | |
| dPT | 5 | 2.80 | | 1.30 - 3.26 | | | | | | |
| dRVVT | 231 | 1.75 | 10.6 | 1.03 - 2.61 | | | | | | |
| I.L. HemosIL dRVVT screen | 36 | 1.81 | 10.0 | 1.20 - 2.20 | | | | | | |
| I.L. LAC screen | 6 | 1.89 | | 1.73 - 2.22 | | | | | | |
| Life Diagnostics LA screen | 7 | 1.90 | | 1.70 - 2.61 | | | | | | |
| Precision Biologic LA check | 8 | 2.18 | | 2.00 - 2.47 | | | | | | |
| Siemens LA1 screen | 100 | 1.69 | 8.3 | 1.17 - 2.33 | | | | | | |
| Siemens LA2 confirmation | 5 | 1.10 | | 1.03 - 1.45 | | | | | | |
| Stago / Roche DRVVT screen | 54 | 1.76 | 9.9 | 1.06 - 2.42 | | | | | | |
| KCT | 7 | 3.18 | | 1.91 - 3.96 | | | | | | |
| Homemade Kaolin | 6 | 3.16 | | 1.91 - 3.96 | | | | | | |
| SCT | 38 | 2.59 | 19.9 | 0.57 - 6.94 | | | | | | |
| Haematex SACT Reagent | 5 | 3.19 | | 0.57 - 6.94 | | | | | | |
| I.L. SCT screen | 32 | 2.56 | 14.5 | 2.09 - 4.75 | | | | | | |

Lupus Anticoagulant

Confirmation

No. of Responders
238

Sample No 16.17
Sample Details Plasma strongly positive for Lupus Anticoagulant
Units: Ratio
Prior Use: None
Stability 31-December-2017
Homogeneity 1.9 %

Homogeneity Parameter Lupus Anticoagulant ratio

| Assay | Positive | Borderline | Negative | No Classification | Your result | | |
|-------|----------|------------|----------|-------------------|-------------|-------------|-------------|
| | | | | | Confirm 1 | Confirm 2 | Confirm 3 |
| APTT | 133 | 4 | 5 | 0 | | | |
| dAPTT | 12 | 0 | 1 | 0 | | | |
| dPT | 7 | 0 | 0 | 0 | | | |
| dRVVT | 456 | 8 | 2 | 0 | | LA Positive | |
| Other | 1 | 0 | 0 | 0 | | | |
| PNP | 14 | 0 | 0 | 0 | | | |
| PT | 1 | 0 | 0 | 0 | | | |
| SCT | 70 | 0 | 1 | 0 | | | LA Positive |

| Ratio | n | assigned value | CV (%) | range | panel 1 | z-score | panel 2 | z-score | panel 3 | z-score |
|--------------------------------------|-----|----------------|--------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 84 | 1.36 | 16.2 | 0.84 - 2.81 | | | | | | |
| I.L. Hemosil SynthAFax | 14 | 1.28 | 9.3 | 1.14 - 1.68 | | | | | | |
| I.L. MixCon | 10 | 1.50 | 28.4 | 1.09 - 2.14 | | | | | | |
| Siemens Actin FS | 34 | 1.26 | 10.6 | 0.84 - 1.87 | | | | | | |
| Stago/Roche Staclot LA | 7 | 1.34 | | 1.20 - 1.98 | | | | | | |
| Technoclone Lupus Anticoagulant Test | 5 | 2.74 | | 1.79 - 2.81 | | | | | | |
| dAPTT | 8 | 1.29 | | 1.24 - 2.93 | | | | | | |
| dPT | 7 | 1.72 | | 1.30 - 3.40 | | | | | | |
| dRVVT | 394 | 1.23 | 9.3 | 0.43 - 3.30 | | | 1.26 | 0.26 | | |
| American Diagnostics DVVconfirm | 6 | 1.36 | | 1.09 - 1.82 | | | | | | |
| I.L. Hemosil dRVVT confirm | 104 | 1.22 | 9.7 | 0.76 - 2.10 | | | 1.26 | 0.33 | | |
| I.L. LAC confirm | 20 | 1.24 | 9.2 | 1.08 - 2.59 | | | | | | |
| Life Diagnostics LA confirm | 10 | 1.27 | 14.7 | 1.10 - 1.90 | | | | | | |
| Precision Biologic LA sure | 14 | 1.37 | 24.0 | 1.05 - 2.64 | | | | | | |
| Siemens LA2 confirmation | 143 | 1.21 | 8.0 | 0.43 - 2.10 | | | | | | |
| Stago/Roche DRVVT Confirm | 79 | 1.24 | 8.7 | 0.89 - 2.00 | | | | | | |
| Technoclone LA Confirm | 7 | 1.22 | | 1.09 - 1.33 | | | | | | |
| SCT | 69 | 1.53 | 9.0 | 1.20 - 2.12 | | | | | 1.45 | -0.61 |
| I.L. SCT confirm | 69 | 1.53 | 9.0 | 1.20 - 2.12 | | | | | 1.45 | -0.61 |

Lupus Anticoagulant

Ratio Screening/Confirmation

No. of Responders
481

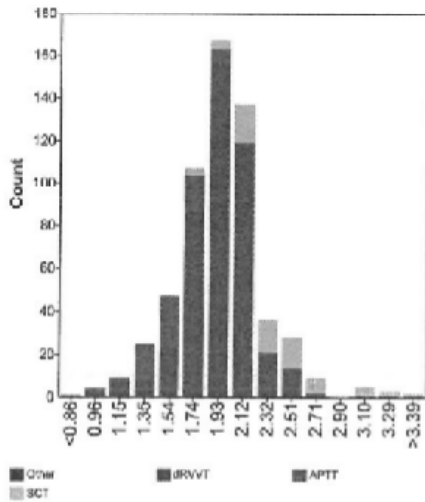
Sample No 16.17
Sample Details Plasma strongly positive for Lupus Anticoagulant
Units: Ratio
Prior Use: None

Stability 31-December-2017

Homogeneity 1.9 % Homogeneity Parameter Lupus Anticoagulant ratio

| Ratio Screening/Confirmation | n | assigned value | CV (%) | range | panel 1 | z-score | panel 2 | z-score | panel 3 | z-score |
|------------------------------|-----|----------------|--------|-------------|---------|---------|---------|---------|---------|---------|
| APTT | 77 | 1.61 | 15.5 | 0.88 - 3.90 | | | | | | |
| dAPTT | 8 | 1.35 | | 1.24 - 1.79 | | | | | | |
| dRVVT | 435 | 1.94 | 10.4 | 0.79 - 3.33 | | | 1.78 | -0.81 | | |
| SCT | 69 | 2.37 | 14.4 | 1.67 - 6.00 | | | | | 2.76 | 1.15 |

Assays



Lupus Anticoagulant
Final Conclusion

| Final Conclusion | Negative | Borderline | Positive | No Conclusion | Your Result |
|------------------|----------|------------|----------|---------------|-------------|
| Total | 1 | 4 | 435 | 41 | Positive |

Comments

In total 440 participants gave a final conclusion. Forty-one participants (9%) gave no final conclusion.

The sample used in this survey was plasma from a patient diagnosed with strong Lupus Anticoagulant. The patient was not under treatment at the time of blood sampling.

Of the participants who gave a final conclusion, 99% classified the sample correctly as positive.

Several participants stated that there is an indication that this sample is positive for lupus anticoagulant but in real clinical practice this should be confirmed in a new sample after 12 weeks.

Also a number of participants indicated that the positivity of the lupus anticoagulant test could also be caused by treatment of the patient with direct anticoagulants. This should be excluded.