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Weqas

GLOBAL PROVIDER OF QUALITY
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Weqas hsTroponin Study

Gareth Davies

Weqas Cardiac Marker Programme

Frequency: Monthly

Samples: 4 (1 mL)

Return Window: 2 weeks

Material: Off the clot human serum spiked with ITC complex

Key Features: Includes challenging samples at limits of detection and diagnostic “99th centile” for hs TnT and TnI. Allows semi-quantitative reporting for PoCT Tn. Liquid human serum samples require no pre-analytical preparation. Linearly related panel covering a clinically relevant range.

Weqas hs Troponin Study

Samples prepared using 3 matrices - serum, EDTA plasma and Lithium Heparin pooled plasma.
All 3 matrices spiked with the same amount of Troponin ITC complex to a Troponin T target of 200 ng/L
Doubling dilutions with base matrix to produce 8 samples per matrix

Base results:

Serum < 3 ng/L

EDTA plasma 4.85 ng/L

LiHep plasma < 3 ng/L

Study to run from August 23 to Jan 24

Aims of the study:

Comparison of performance of different instruments with different matrices

Use the data to update and improve Weqas Troponin EQA programme

Sample Types per Instrument

Lab Instruments:

Roche Troponin T: SST, K2-EDTA, K3-EDTA, LiHep and Na-heparin plasma. Plasma tubes containing separating gel can be used. Plasma (EDTA, heparin) and serum samples should not be used interchangeably.

Abbott Alinity: LiHep plasma

Abbott Architect: EDTA plasma

Beckman Access: Serum & LiHep plasma are preferred samples. EDTA plasma also acceptable. Lithium heparin plasma, EDTA plasma and serum samples should not be used interchangeably. The 99th percentile values presented in the Expected Results section apply to lithium heparin plasma and serum samples. A conversion factor of 0.90 should be applied to the 99th percentile for EDTA plasma samples.

POCT Instruments:

AQT90 flex: venous whole blood and plasma

Siemens Atellica VTLi: Whole blood (lithium heparin), Venous (lithium heparin), Capillary

Abbott i-Stat: LiHep whole blood or plasma, Non-heparinized whole blood samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives

Quidel Ortho Triage True: EDTA whole blood and plasma

Cut-offs per Instrument

Roche: 14 ng/L (9.0 for females and 16.8 for males)

Beckman: 17.5 ng/L (11.6 for women and 19.8 ng/L for men)

Abbott Alinity: 26.2 ng/L (15.6 for women, 34.2 for men) (same for Architect)

AQT90 flex: 0.023 ug/L

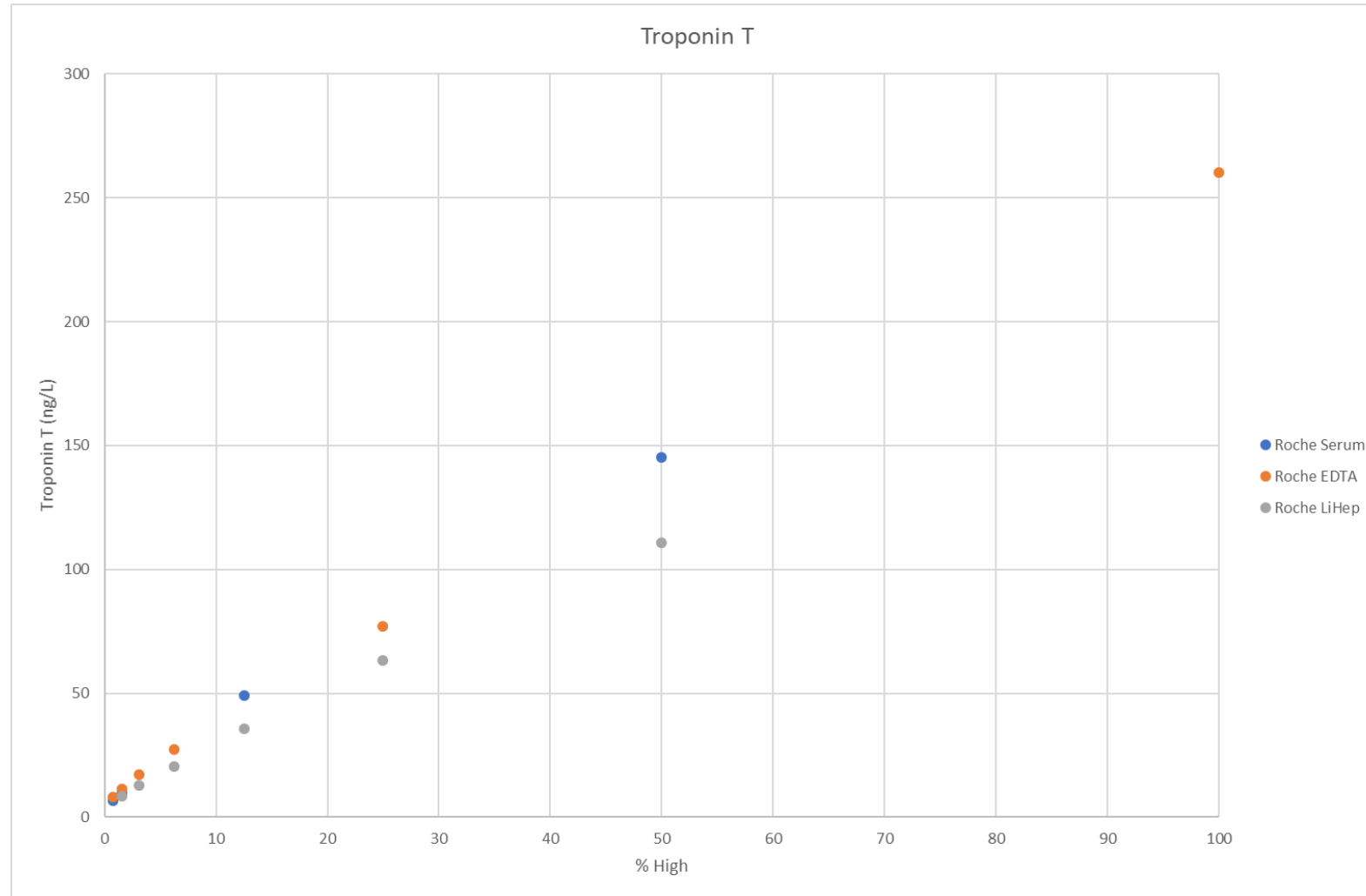
Siemens Atellica VTLi: 22.9 ng/L (18.5 for females, 27.1 for males)

Abbott i-Stat: 80 ng/L

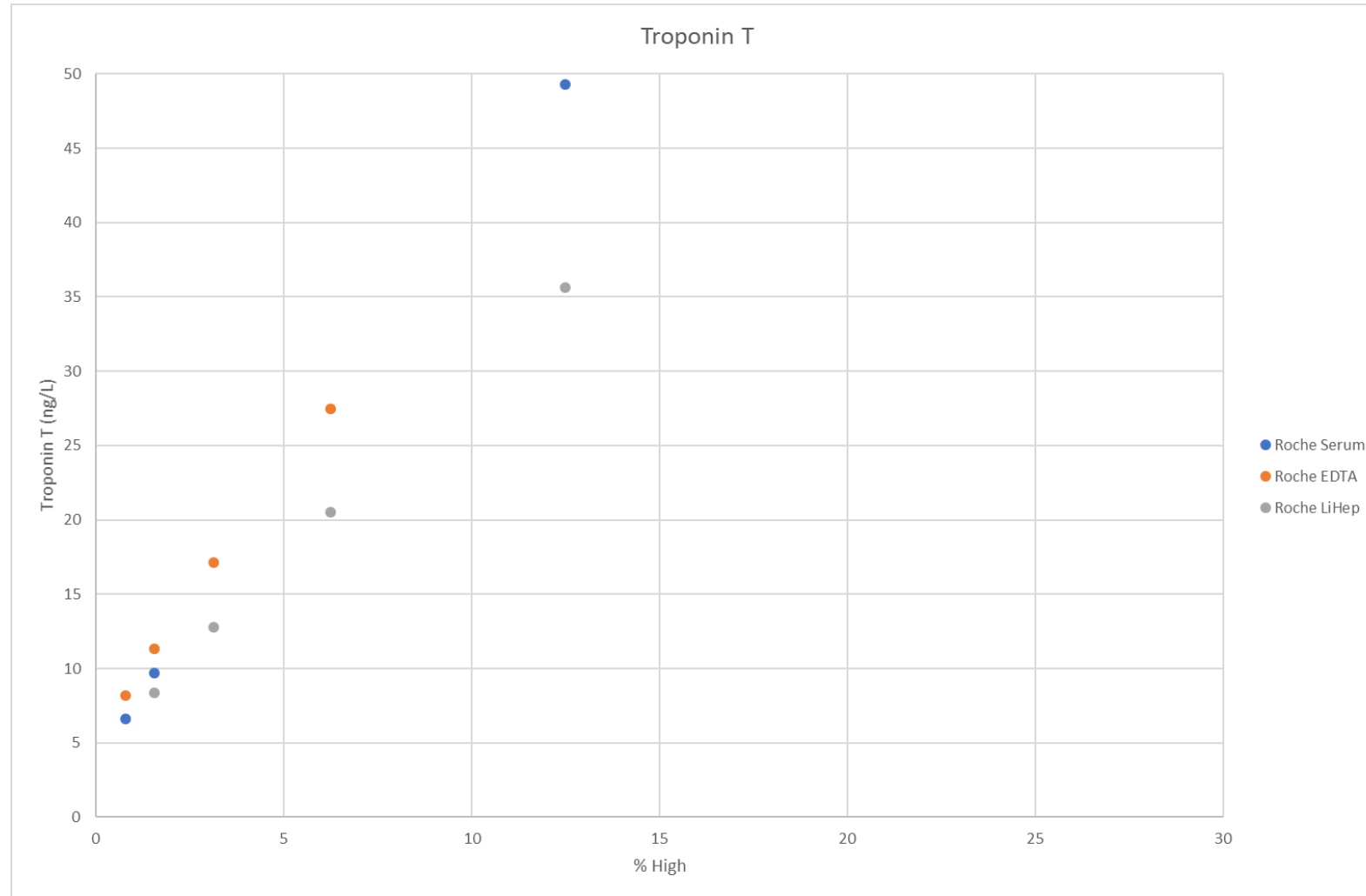
High-sensitivity troponin tests for the early rule out of NSTEMI

Diagnostics guidance [DG40]Published: 26 August 2020

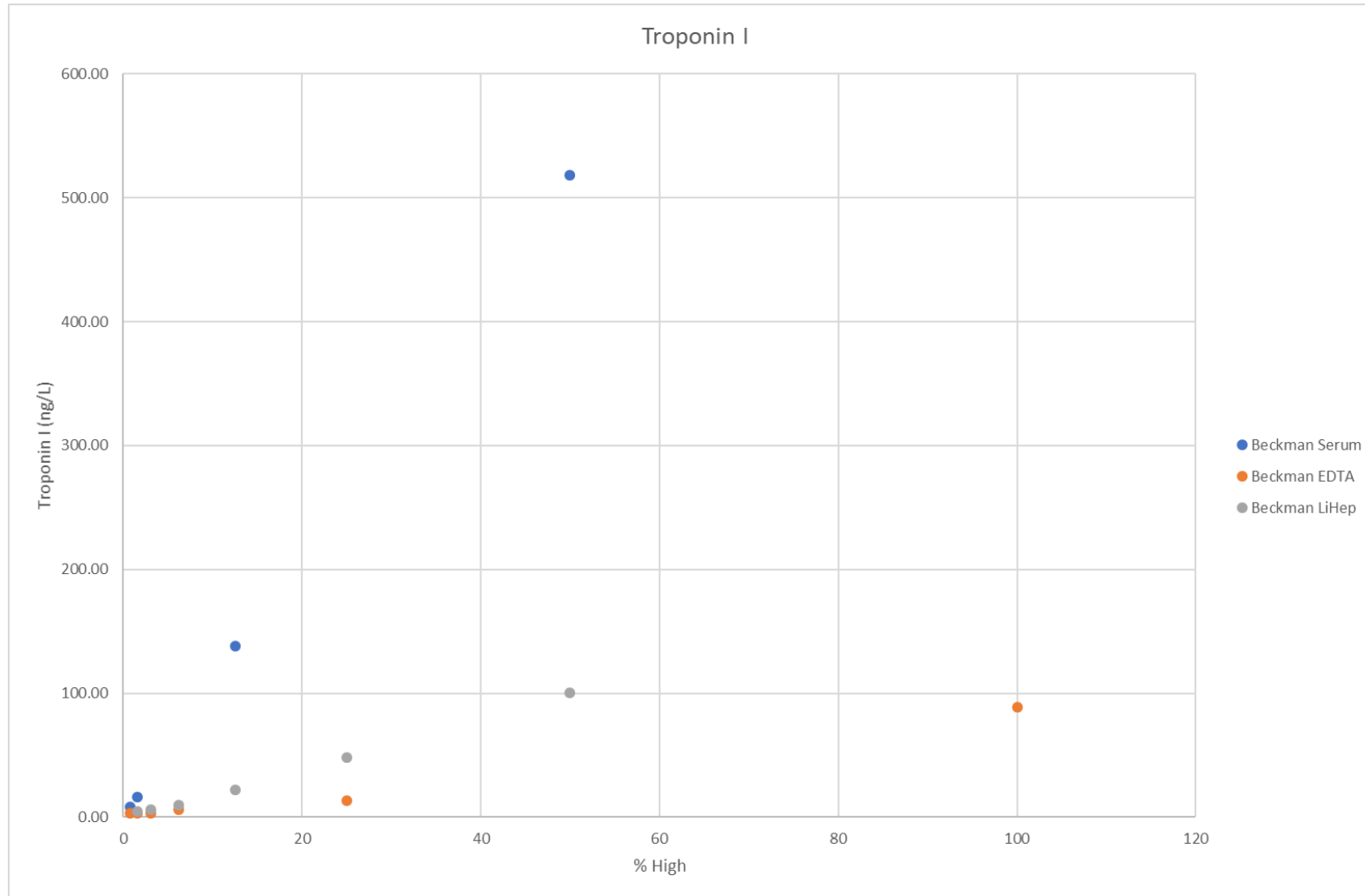
Roche Troponin T



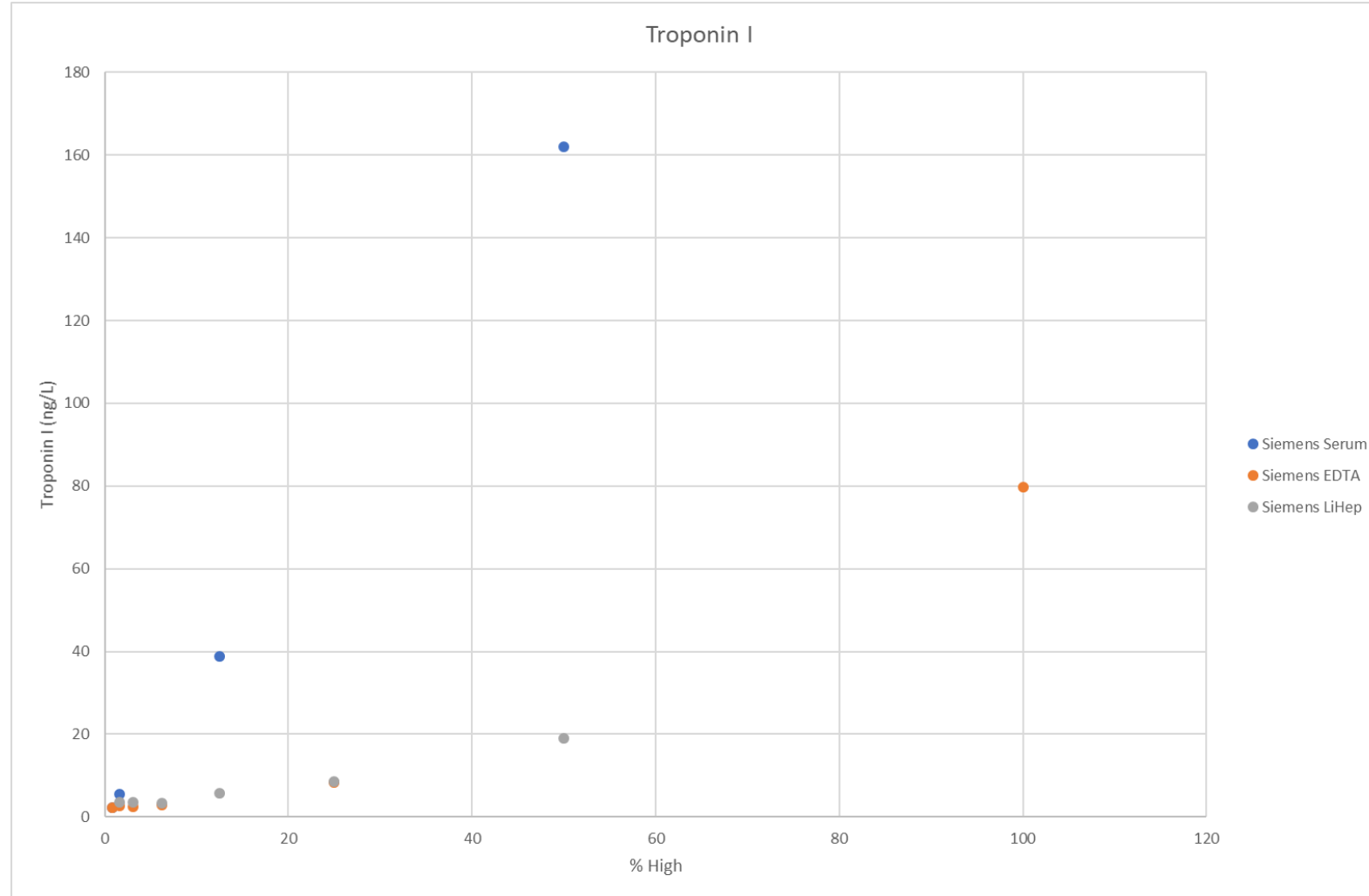
Roche Troponin T



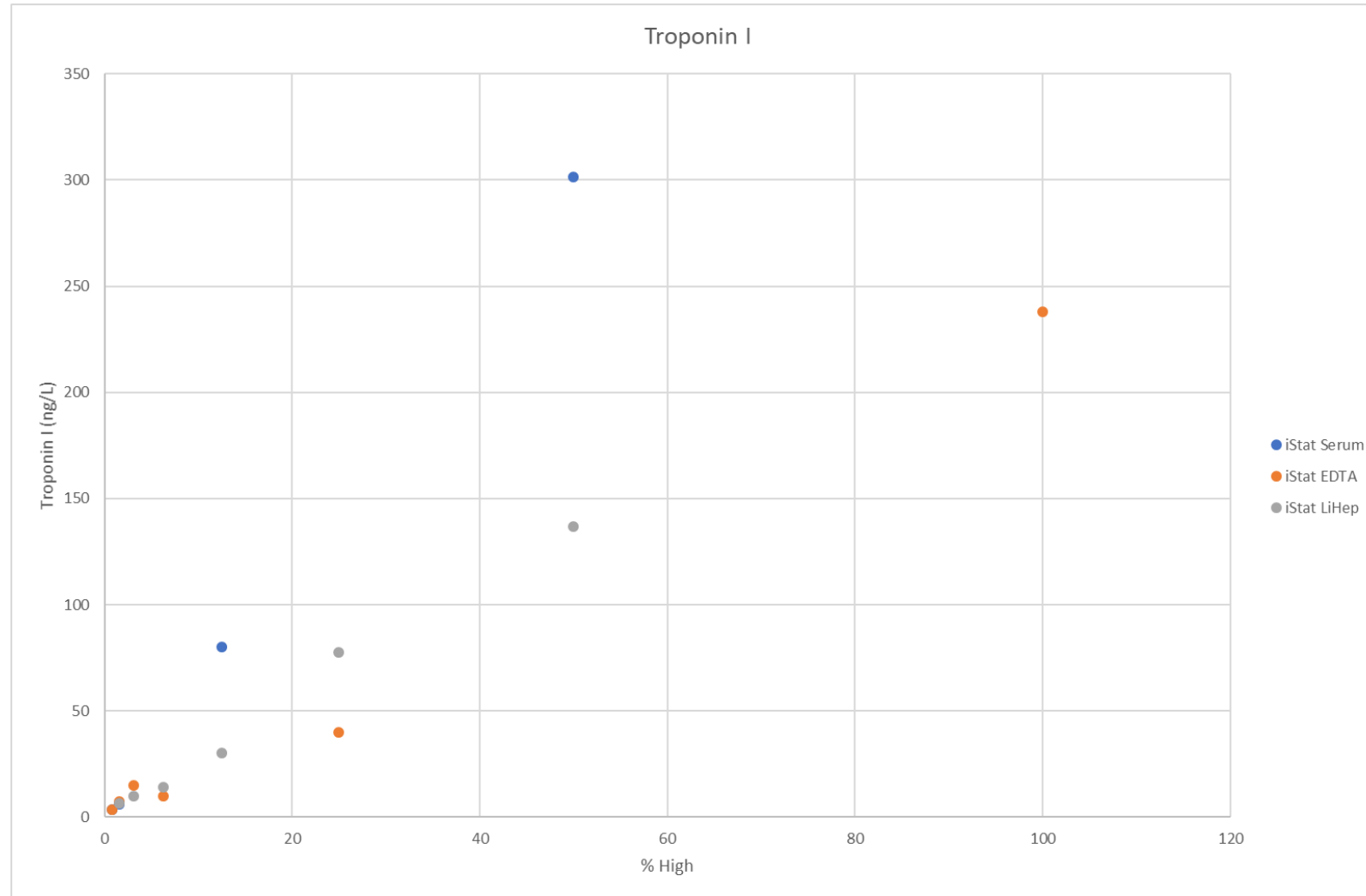
Beckman



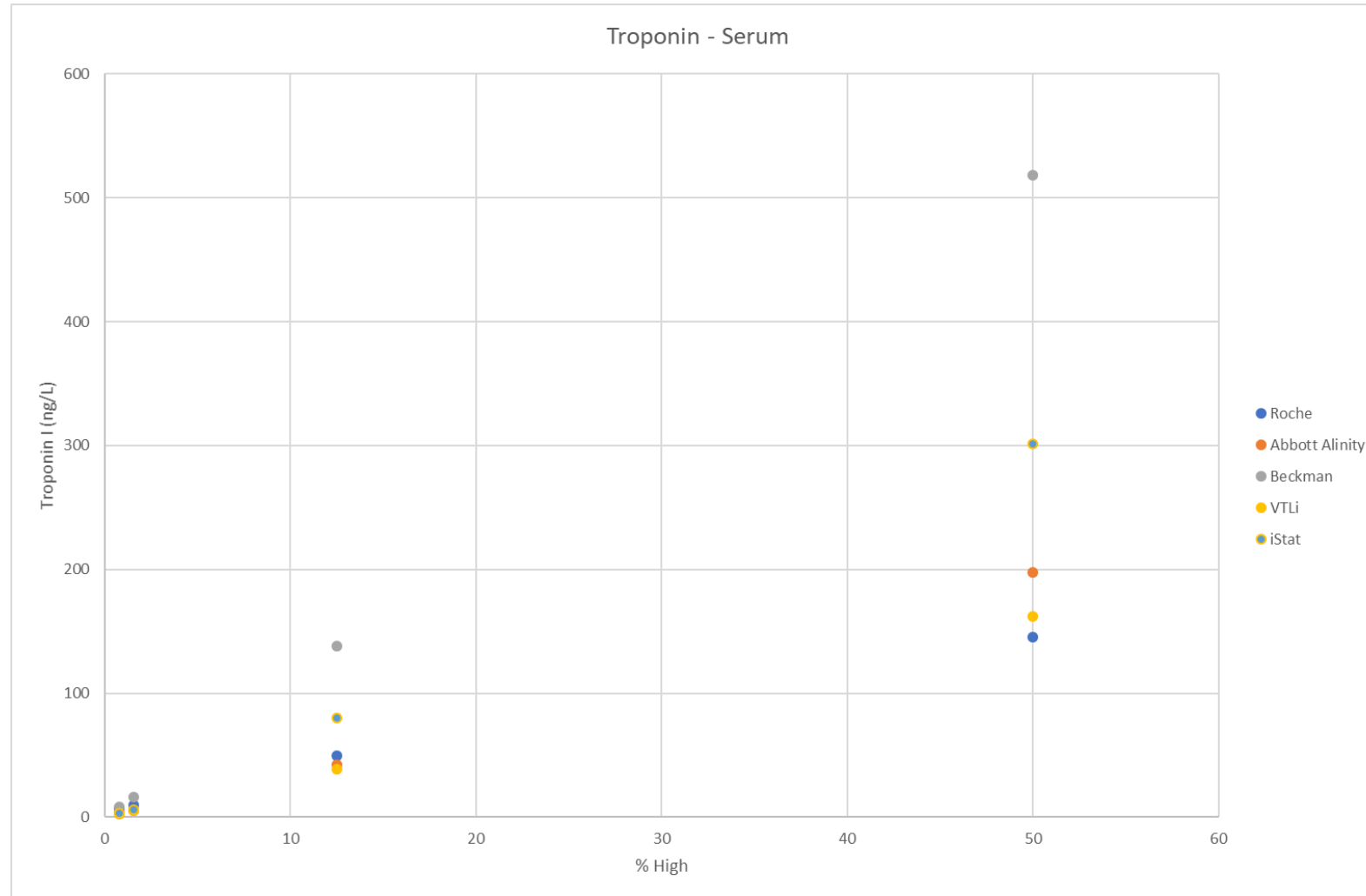
Siemens Atellica VTLi



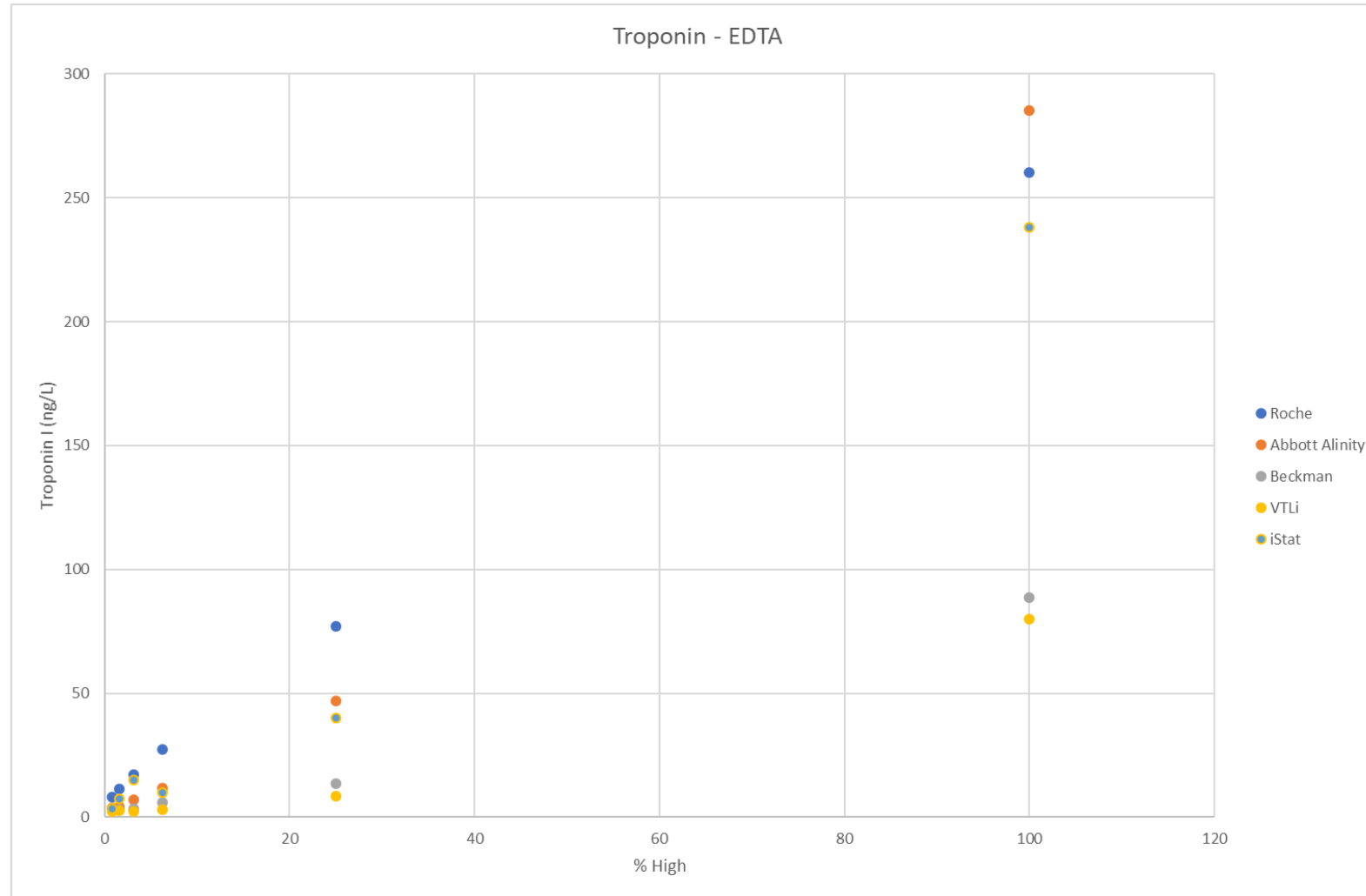
Abbott i-Stat



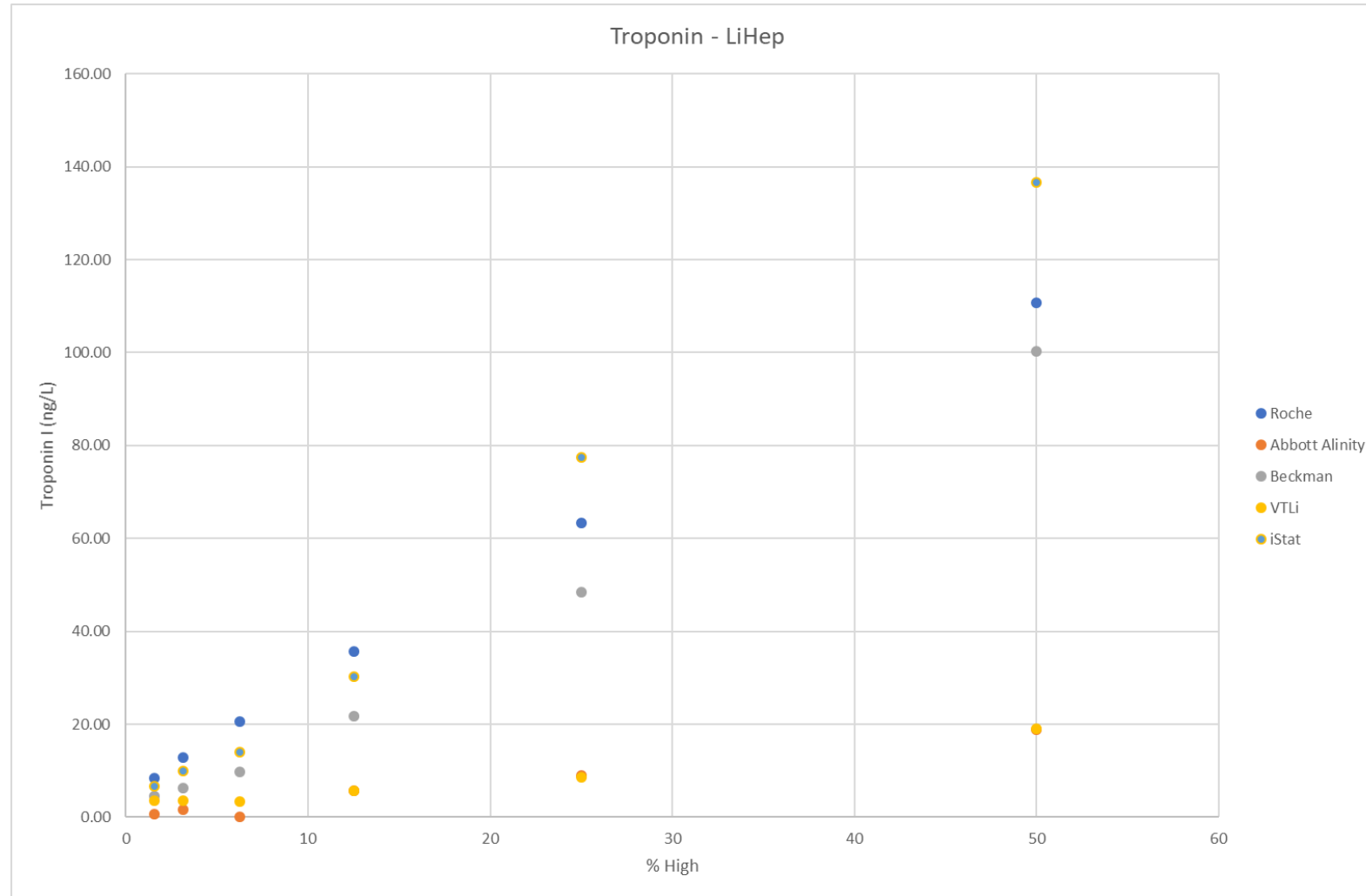
Serum – All Instruments



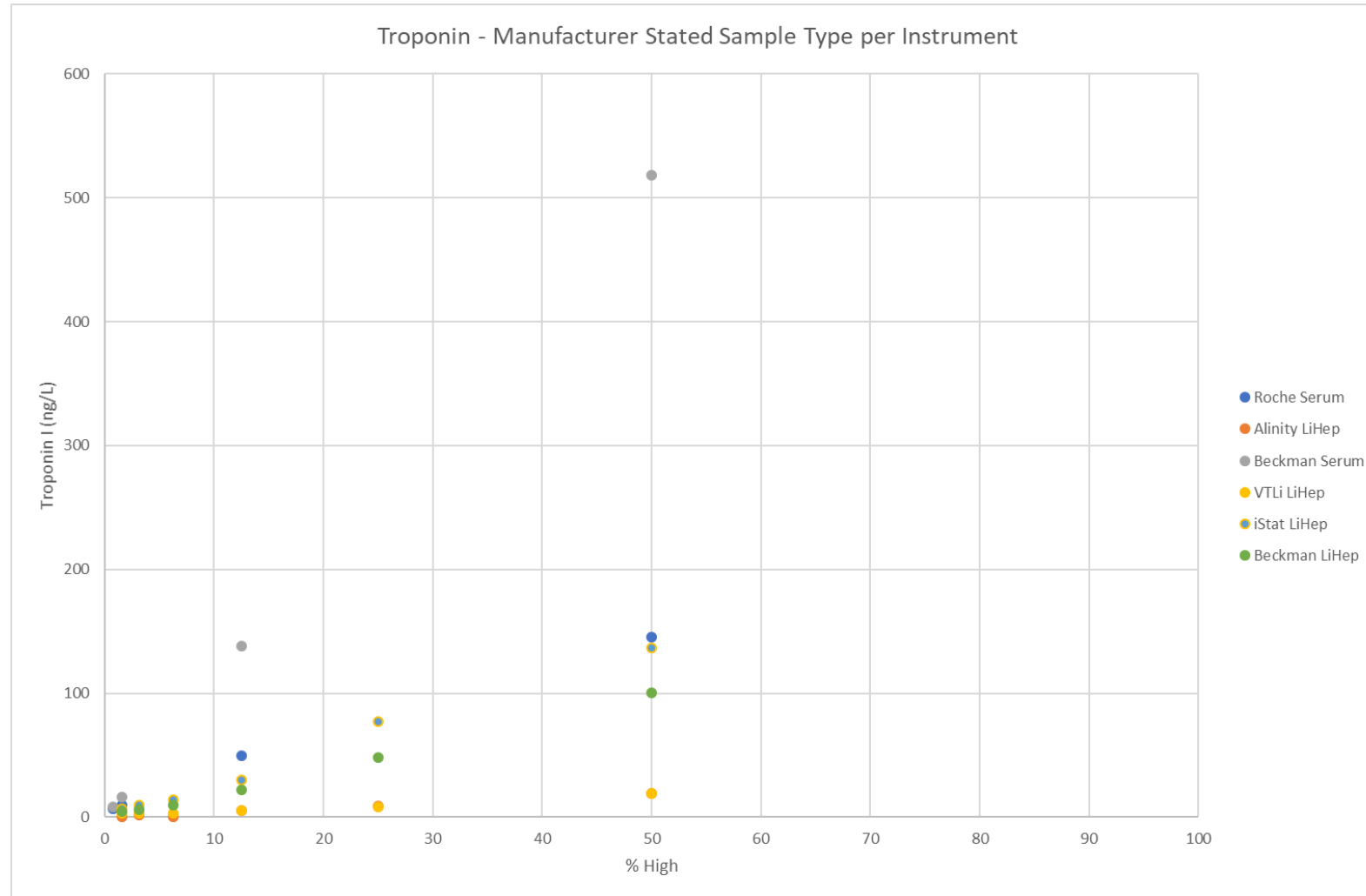
EDTA plasma – All Instruments



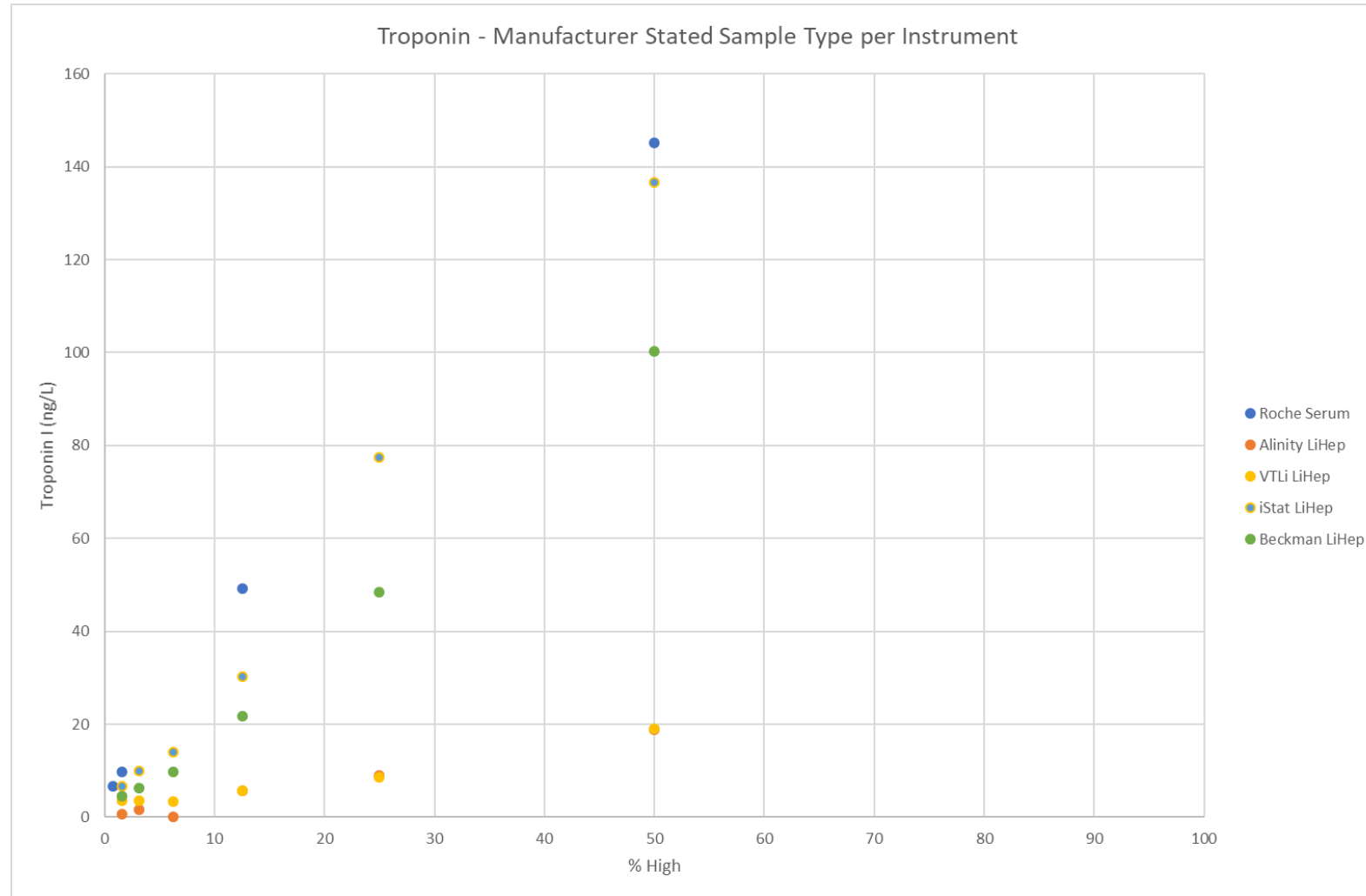
LiHep plasma – All Instruments



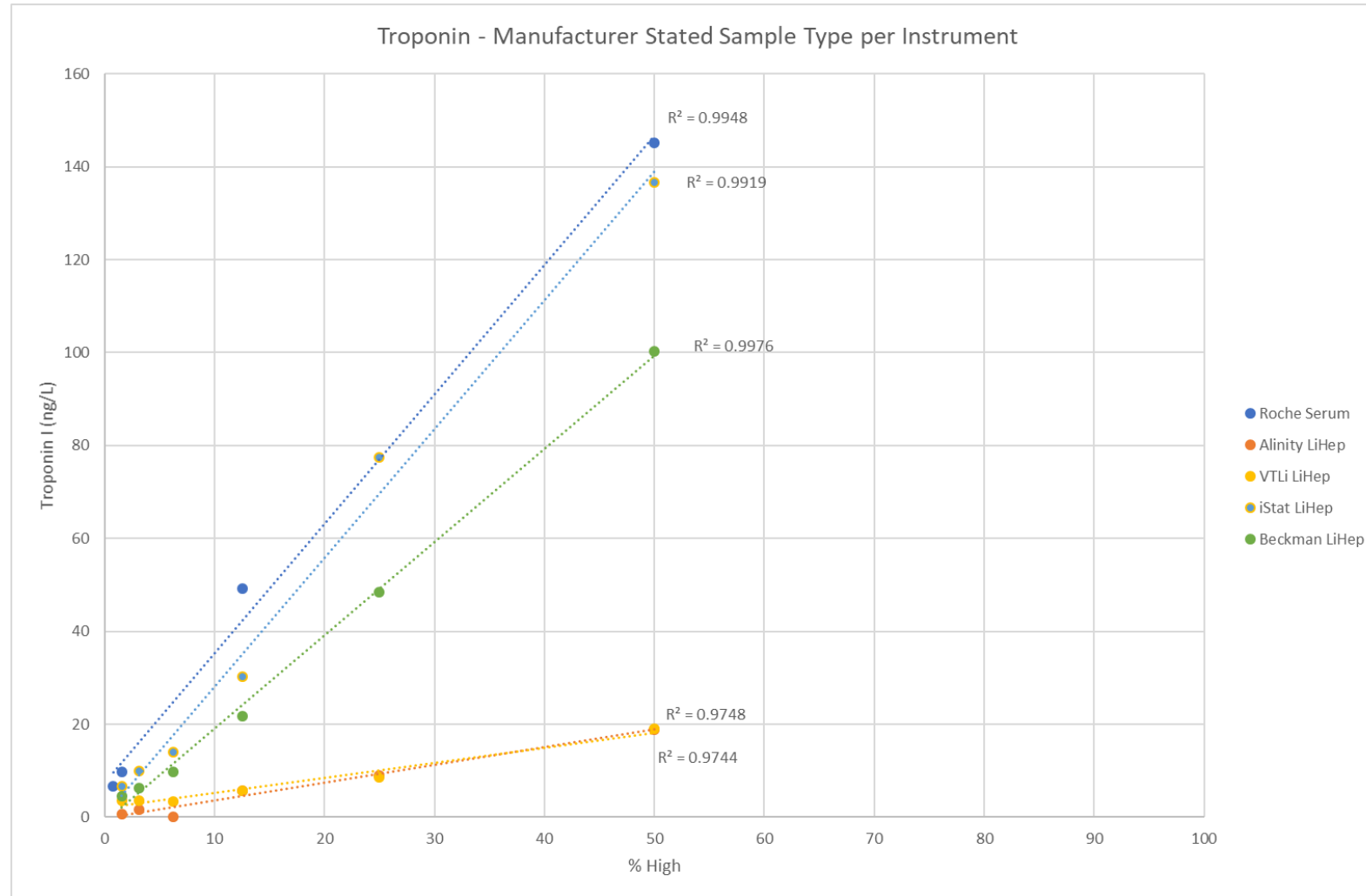
Manufacturer Stated Sample Type Per Instrument



Manufacturer Stated Sample Type Per Instrument



Manufacturer Stated Sample Type Per Instrument



Further Work

Study still has 2 months remaining

Data to be collated and analysed

Decision to be made on matrix for EQA programme going forward

Samples from this study are available for participants and manufacturers

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Thank you

Any Questions?