**Title:**

Quality study to evaluate a recently adopted secondary standard calibrator for intrinsic coagulation factor assays

**Aim:**

RCPA QAP reports in 2020 for our laboratory revealed a positive bias for FIX one-stage clotting assay for the STA Unicalibrator group as compared to other calibrators. At the time, the Unicalibrator was calibrated against the ISTH secondary standard calibrator SSC4 (Uni-SSC4). Our aim was to assess assay performance for intrinsic coagulation factors using a batch of Unicalibrator with values assigned against the more recent SSC5 (Uni-SSC5) and compared against the Uni-SSC4. Two different aPTT reagents were also compared.

**Method:**

Twelve RCPA FIX samples with median assigned values and a further 22 lyophilised samples were tested for factors VIII, IX, XI and XII on a Stago coagulation analyser and compared using both the Uni-SSC4 and Uni-SCC5 calibrators. The samples were tested using Triniclot aPTT S reagent and STA CK Prest reagent in parallel. The results were analysed using linearity graphs and Altman-Bland plots to assess agreement and bias. Where available, the assigned values by RCPA were used as the reference to assess performance of 12 of those samples and Relative Percentage Difference (RPD) was calculated.

**Results:**

There was a strong correlation between results obtained with Uni-SSC4 and Uni-SSC5 for all factors with both reagents. The Coefficient of Determination (r²) was >0.95 and the slope was between 0.90-1.12 with both aPTT reagents. For the Triniclot aPTT S reagent, the FIX calibration using Uni-SSC4 and Uni-SSC5 showed an average RPD of 21% and 18% respectively when the RCPA-assigned FIX values were used as a reference. With the CK Prest reagent, the average RPD 10% and 8% respectively.

**Conclusion:**

Studies confirmed that for the Triniclot aPTT S reagent, the Uni-SSC5 slightly reduced the positive bias seen with Uni-SSC4. However, with the CK Prest reagent, the bias was lowered substantially. Diagnostica Stago has now replaced SSC4 with SSC5 for STA Unicalibrator value assignments and introduced it to all STA immuno-deficient plasma.