Results

- Only samples that provided valid results in all 3 laboratories were used for statistical analysis. 43/50 samples met this criteria and were used for statistical analysis.
- No outliers were identified.
- Variance decomposition using these samples, along with previously calculated variance component estimates, demonstrated a site-to-site variability of 0.115 CCP Score units (CCPsu) (Table 1).
- As acceptance criterion for the overall reproducibility, a standard deviation of at most 0.31 CCPsu was defined as it leads to a clinically relevant absolute shift of disease-specific mortality risk at the active surveillance threshold of less than 1%.
- The overall reproducibility for the Prolaris test was 0.184 CCPsu, which fulfilled the defined acceptance criterion (Table 1).

Conclusions

- The variance in CCP Scores across the three external sites was within the acceptable range, indicating that Prolaris kit results are reliable and reproducible when performed locally by trained laboratory staff.