Clinical Validation of the ProTime InRhythm PT/INR in Professional Use Settings

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Introduction: The ProTime InRhythm™ (InRhythm) System is a point-of-care device for monitoring 446 paired samples; e.g. linear regression analysis of FS was r = 0.99, slope y = 0.99 (95% CI: 0.95 – 1.01), intercept x = -0.01 (95% CI: 0.01 – 0.16). Reproducibility of duplicate FS and VWB samples was determined at different INR ranges (0.80 to > 4.5). Estimate of imprecision of duplicate samples evaluated at 6 INR levels yielded a %CV of 3% to 5% suggesting reproducibility performance of ≤5%. Both FS and VWB samples correlated well with the laboratory Innovin/Sysmex system using linear regression and weighted Deming analyses on 446 paired samples; e.g. linear regression analysis of FS was r = 0.93, slope = 1.0 (95% CI: 0.97 – 1.04) and intercept = -0.03 (95% CI: -0.14 – 0.07). Similar results were observed with Deming analysis. In the therapeutic range (>2.5 – 3.5 INR), there was 94.3% clinical agreement based on recognized standards. This level of agreement was observed across all sites participating in this study. In the aggregate (INR range: 0.90 to 8.9), total clinical agreement of 91.7% was observed which compares well with point of care expectations.

Conclusion: This study demonstrates that the InRhythm System, in the hands of professional users, is safe and effective in monitoring VKA therapy.