

Section VI. Safety and Efficacy Summary

Performance of the ProTime™ Microcoagulation System was measured by the correlation of the results of the home test to the results obtained in the clinic by the healthcare worker using the ProTime™ System. Forty-five patients were selected from four anticoagulation clinics based on the judgment of the health care professional with regard to the patient's suitability for home testing and his/her ability to perform the test procedure. Patients who agreed to participate in the study received a 30 to 60 minute training session at the clinic which included explanation, demonstration and practice performing the test procedure. The patient was required to demonstrate the ability to perform the assay prior to enrollment in the study.

The performance of the ProTime™ Microcoagulation System was assessed using:

- Correlation of patient ProTime™ test to healthcare professional ProTime™ test
- Correlation of the ProTime™ results to the hospital lab and reference lab
- Comparison of mean differences among PT methods
- Accuracy among methods of appropriate therapeutic classification of patients receiving oral anticoagulants.

Results of the patient self-test and the INR generated by the healthcare professional were highly correlated ($r=0.92$) and the mean difference was small ($-0.05 \text{ INR} \pm 0.33$). Significant and equivalent correlations were demonstrated between the reference lab INR and hospital lab INR ($r=0.88$); the reference lab and the ProTime™ home test ($r=0.89$); and the reference lab to the clinic ProTime™ test ($r=0.91$). Accuracy was further assessed by comparison of mean differences between various INR test methods and the reference laboratory INR. All methods showed mean differences less than 0.2 INR units. ANOVA comparisons of mean differences for the laboratory results and the home and clinic ProTime™ tests were not different. Secondary analysis examined the impact on accuracy of the ProTime™ test for subsets of the data set: individual sites, children who tested themselves, and time effects. The accuracy was equivalent for all subjects examined.

The data was tested for agreement with the reference laboratory within the identified therapeutic range and within specified boundaries. Home ProTime™ results agreed with the reference laboratory with respect to identification of patients in and out of therapeutic range. The accuracy of correctly classifying patients in, above, or below therapeutic target range using the ProTime™ System was equivalent to that when employing the hospital laboratory INR.

Patients experienced some testing faults while using the ProTime™ System at home, but successfully repeated the test to obtain accurate results. An error message is generated in place of test results when the test fails to meet pre-set criteria for the integral reagent controls.

In summary, the ProTime™ Microcoagulation System has been shown to be equivalent to the laboratory PT test. Patients demonstrated the ability to learn the proper procedure to perform the assay and were able to produce accurate results at home. Correlation studies and comparative analysis of the ProTime™ result and reference laboratory result indicate that the ProTime™ System is safe and effective within the boundaries of current prothrombin time test technology. Test results of patients taking oral anticoagulants could be rapidly communicated to the prescribing physician for appropriate adjustments to therapy. Patients rated ProTime™ System easy to use.