

## Excellent Performance of the INRatio™ Coagulation Monitor ensures High Retention in the Therapeutic Range after a Short Training Period

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Self management of oral anticoagulation (OAC) supports decreasing complication rates and improves quality of life. Good comparison data between the used self testing device and routinely performed laboratory INR results are a precondition of the successful management of the OAC therapy.

### Method:

This three evaluation centre study compared the results of 76 newly oral anti-coagulated patients, who used the INRatio™ system (Hemosense), with those INR-values determined in the three central labs (CL). After a structured quality-controlled training the patients were monitored over a six weeks period at certain times e.g. T 0 (before training), T1, T2 (after training), W2 (after 2nd week), W4 (after 4th week) and W6 (after 6th week) to determine the quality of the INR scattering within or out of the individual therapeutic range. The INR values from capillary blood samples taken by the patients themselves were measured with INRatio. At the same time plasma samples were determined in the three central labs, one of which laid out as the reference lab (RL) - (Stago Compact/Innovin), where shock-frozen samples were transported to and analysed. The values at T 0 - W6 were compared and evaluated according to Bland/Altman and differences shown in a dissimilarity map. The hit rate within the individual therapeutic range was determined.

### Results:

The comparison between self-testing results (ST) versus RL started with a trend to slightly lower values at T 0, which continuously weakened towards W6; ST

versus CL showed at T 0 not any significant trend but changed into the opposite direction towards W6 to slightly higher values. The 95%- confidence interval of the INR pairs of values is 1.0 INR at T 0, and slightly reduced at later times (0.8) in the comparison of ST vs. RL. All confidence intervals show constant biases of approximately +/- 0.5 to 0.6 INR independent from the measuring time and within the measuring range. The comparative evaluation of the values in the dissimilarity map shows the same Euclidean distance between ST and RL (0.36 INR), ST and CL (0.37) as CL to RL (0.47) at T 0, which is consistent over the different measuring points (0.40-0.54). The hit rate to be within the therapeutic range improved from T 0 of 31.6%, over T2 (33.8%) to over 60.3% at W6.

### Conclusion:

The inaccuracy of self testing results with the INRatio™ compared with well controlled laboratory methods is equal the inaccuracy of results from the same sample determined in two separate central laboratories. The Euclidean distance of less than 0.5 INR demonstrates the excellent accuracy of ST results with lab methods. The accuracy of the measurements is very good already from the beginning of (T 0) and the after training period (T 2) and at the end of the trial period (W6); it has therefore no significant contribution to the improvement of the hit rate to find INR values within the therapeutic range. Small effects can be explained from effects of sample transportation and freezing and defrosting.