

## **INRatio2, a system for measurement of P—PT (INR)**

### **Summary of an evaluation under the direction of SKUP Report SKUP/2010/80**

#### **Background**

Triolab turned to SKUP in 2009 for an evaluation of INRatio2, an instrument for determination of P—PT (INR) in capillary samples only. The evaluation was performed in the hospital laboratory in Hillerød and in two primary health care centres.

#### **The aim of the evaluation**

- Determination of the within-series-imprecision with samples from 101 patients in the hospital laboratory and 40 patients in each primary care centre
- Comparison of the INRatio2 hospital laboratory results with results from frozen plasma samples measured with the comparison method in the Roskilde hospital laboratory
- Comparison of the INRatio2 primary care results with results from fresh plasma samples measured with the comparison method in the Hillerød hospital laboratory
- Evaluation of the user-friendliness
- Investigation of the influence on the result from haematocrit

#### **Materials and methods**

The comparison method for the hospital laboratory evaluation was run on an Instrumentation Laboratory ACL TOP instrument in the department of Clinical Biochemistry, Roskilde. For the primary health care the comparison method was run on a Sysmex CA 7000 in the department of Clinical Biochemistry, Hillerød. Four INRatio2 instruments and three lot numbers were used for the analysing of samples from totally 181 patients.

#### **Results**

The imprecision of INRatio in the hospital laboratory was 6,3%. The mean imprecision for the lowest tertile was 5,9%, 5,6% for the middle, and 7,4% for the highest tertile. The bias of INRatio was less than 6% in all concentration levels and the total bias was +2,3% (-2,2 to +5,7%) compared to Roskilde.

In total four of the 101 hospital results deviated more than  $\pm 20\%$  from the comparison method results, one deviated  $>50\%$  in both duplicates. Haematocrit did not seem to influence on the measurements.

In the primary care evaluation one practitioner had a CV of 5,1%, the other had a CV of 8,6%. Significant differences of imprecision were observed due to used lot numbers. The total error goal ( $<\pm 20\%$ ) was fulfilled in the hospital laboratory evaluation and in primary care centres. The user friendliness was satisfying. It was noticed that it was difficult to know when the test strip was properly filled with blood. External quality assurance is not possible with INRatio2 but two built-in controls are included in each strip. Eight measurements out of 362 failed of different reasons.

#### **Conclusion**

The quality goal for total error goal ( $<\pm 20,0\%$ ) was fulfilled in all evaluation sites. The quality goal for imprecision ( $<5,0\%$  CV) was not fulfilled neither in the hospital laboratory nor in the two primary care centres. Bias was less than 6%. The frequency of failed measurements in the evaluation was 2,2%. Thus the quality goal of less than 2,0% failed measurements was almost fulfilled. The user friendliness was satisfying; however, there were comments about the application of the sample.

#### **Comments from Alere**

A letter with comments from Alere is attached to the report.

The complete report is found at [www.skup.nu](http://www.skup.nu).