

ProTime InRhythm PT (INR) system



Summary of an evaluation under the direction of SKUP Report SKUP/2014/104

Background

The ProTime InRhythm™ System (InRhythm) is an in vitro diagnostic device for the quantitative measurement of Prothrombin Time / International Normalized Ratio (PT/INR) from capillary whole blood or fresh venous whole blood collected with no additives. The test system is intended for use by point of care healthcare professionals in the management of patients treated with oral vitamin K antagonist therapy.

The system is produced by International Technidyne Corporation (ITC), and has not been launched onto the Scandinavian market yet. The SKUP evaluation was carried out from January to March 2014 at the request of Medic24 in Norway.

The aim of the evaluation

- Estimation of the imprecision of InRhythm in a hospital laboratory (standardised and optimal conditions) and in primary health care centres
- comparing the InRhythm results achieved in a hospital laboratory and by two primary health care centres (intended users) with the results from an established hospital laboratory method for PT (INR)
- examination of the variation between three lots of test cuvettes
- evaluation of the user-friendliness of the InRhythm system and its user manual

Materials and methods

Capillary blood samples (third blood drop) from 102 patients on oral vitamin K antagonist treatment were measured on the InRhythm system at the hospital laboratory. Additionally, a total of 80 capillary samples (second blood drop) were tested at two primary health care centres (PHCCs). Three lots of test cuvettes were used. All results from the InRhythm were compared with the routine method of PT (INR) measurements at the hospital laboratory using citrated venous plasma samples (referred to as “the comparison method”). The quality goal for the imprecision was a repeatability CV of <5%. The quality goal for the accuracy was a deviation of ≤20% in the individual result from the comparison method result for 95% of the individual PT (INR) results.

Results

- For PT (INR) results <2,5 the repeatability CV was 3,4% in the hospital laboratory and 3,7 and 4,3% in the two PHCCs. For results ≥2,5 INR the CV was 4,9% (hospital), and 4,6 and 5,4% in PHCCs. In the therapeutic range 2,0 – 3,0 INR the CV was 4,1%.
- PT (INR) results <2,5 achieved on InRhythm in the hospital laboratory were on average 0,1 INR (-5,5%) lower than the results on the comparison method. No bias was observed with results <2,5 INR collected from the two PHCCs. For PT (INR) results ≥2,5 there was no bias observed.
- In the hospital laboratory 94% of the results with three lots of test cuvettes were within the limits for allowable deviation. For PHCCs the proportion of results within the limits was 89% (one lot of test cuvettes). Only small deviations between the three lots of test cuvettes appeared (visual inspection).
- The reproducibility CV achieved with the internal quality control solution *directCHECK* Whole blood Control for InRhythm was 18% in the hospital laboratory and 13% in the PHCCs.
- The percentage of technical errors was 0,8%. In addition it was recorded 2,5% errors related to too large blood drops.

- The users were satisfied with the user manual. The operation facilities were assessed as both satisfactory and intermediate. The time factors related to the InRhythm method were assessed as satisfactory and the quality control possibilities were assessed as unsatisfactory.

Conclusion

For PT (INR) results $<2,5$ the quality goal with a repeatability CV $<5\%$ was fulfilled for measurement performed at the hospital laboratory and most likely fulfilled for PHCCs. For PT (INR) results $\geq 2,5$ the quality goal most likely was fulfilled for the hospital laboratory measurements and for the measurements at one of the PHCCs. For the other PHCC the quality goal most likely was not fulfilled. In the therapeutic range $2,0 - 3,0$ the quality goal for repeatability was fulfilled (results from the hospital laboratory).

In the hospital laboratory InRhythm gave results $5,5\%$ lower results than the comparison method for PT (INR) results $<2,5$. The quality goal for accuracy was neither fulfilled for the hospital laboratory nor for the PHCCs. The percentage of technical errors fulfilled the goal ($\leq 2\%$).

The whole blood internal quality control material from the manufacturer was assessed as unsatisfactory. The control showed poor reproducibility, and should therefore not be used for analytical quality control.

The manual and time factors were assessed as satisfactory. The operations facilities of InRhythm were assessed partly as satisfactory and partly as intermediate due to the system's sensitivity for large drops of blood leading to the error message "Sample too large". Another comment mentioned was that the system must be placed stable when analysing samples. Overall the users found the InRhythm system fast and easy to handle.

Comments from Accriva Diagnostics (representing ITC and Accumetrics)

A letter with comments from Accriva Diagnostics is attached to the report.

The complete report is found at www.skup.nu.