Simple Simon PT

Summary of an evaluation under the direction of SKUP Report SKUP/2007/57*

Background
The Simple Simon® PT System is a measurement system for prothrombin time (PT), designed for near-patient testing. Simple Simon PT is a wet chemistry analysis procedure based on the Owren method. The Owren method is used in Scandinavian hospital laboratories. Simple Simon measures the activity of the vitamin-K dependent factors II, VII and X. The reagent comes freeze dried and is reconstituted in a buffer. The clot is detected optically. The sample is citrate anti-coagulated plasma or blood, or native whole blood. The sample volume is 10 µL. The measuring time is typically 60 seconds. The measuring range for PT (INR) is from 0,8 to 8,0.
A calibrated Simple Simon Reader, reagent components, tubes, stoppers, pipettes and pipette tips are delivered as a package deal product. When 1200 tests have been performed, a new lot of the complete product is put into use and the exhausted reader with its pipettes is returned for service.

The aim of the evaluation
The aim of the evaluation of Simple Simon PT is to assess the analytical quality achievable under standardised and optimal conditions by experienced laboratory trained personnel. Simple Simon PT was not evaluated under primary care conditions, as indicated by the asterisk behind the evaluation number.

Materials and methods
Blood samples of 73 outpatients on long-term oral anticoagulation therapy were collected in evacuated plastic tubes containing citrate anticoagulant. Of these patients, 23 also contributed a second sample at a second occasion, giving a total of 96 patient samples. The blood of the samples were analysed in duplicate on Simple Simon, the corresponding plasmas in duplicate on a comparison method. The first 29 samples were analysed on a lot of Simple Simon calibrated with samples of in-patients at one hospital laboratory, the remaining 67 samples on a lot calibrated with samples of out-patients at eight hospital laboratories. All data was used in assessing precision, but only those of the second lot in assessing bias and accuracy. The designated comparison method was a PT method with SPA reagent on a STA Compact instrument, both from Stago, calibrated with calibrators from EQUALIS.
The analytical quality goal of SKUP for PT is: Repeatability CV <5 % and a total error <±20 %.

Results
The precision of Simple Simon PT was good, with a repeatability CV of approximately 3 % for INR values >2, slightly higher at INR values <2. Simple Simon showed a small positive bias relative to the comparison method. The bias (in INR) was approximately +0,1 in the therapeutic range. The accuracy was good, in spite of the small bias. The analytical quality goals of SKUP were attained.

Conclusion
The analytical quality of Simple Simon PT is good, as demonstrated by skilled laboratory personnel under optimal conditions. The analytical quality goals of SKUP are attained. The user-friendliness is good, but the system requires some training to attain optimal analytical quality. The performance of Simple Simon PT in the hands of primary care users was not examined.

Comments from the manufacturer
For comments from Zafena AB, please see attachment 5 in the report.

The complete report is found at www.skup.nu