

Summary



Summary of an evaluation provided by SKUP

Xprecia Stride™ Coagulation system for measurement of PT (INR)

Manufacturer: Siemens Healthcare Diagnostics INC

Supplier: Abena A/S and Mediq Denmark A/S in Denmark/Siemens Healthcare Diagnostics AS in Norway/Mediq Sweden AB in Sweden

Conclusion

The overall CV was just above 5%, and the quality goal for repeatability was not fulfilled. The quality goal for accuracy was not fulfilled. The quality goal for user-friendliness was fulfilled.

Background

Xprecia Stride™ Coagulation system is an in vitro diagnostic device for determination of prothrombin time, PT (INR). The product is intended for professional use. The sample material is fresh capillary whole blood. The system is produced by Siemens Healthcare Diagnostics INC. The system was launched into the Scandinavian market autumn 2015. The SKUP evaluation was carried out from December 2015 to March 2016 at the request of Siemens Healthcare Diagnostics AS in Norway.

The aim of the evaluation

The aim of the evaluation was to assess the analytical quality and user-friendliness of Xprecia Stride, both when used under optimal conditions by experienced laboratory personnel and when used under real-life conditions by the intended users in primary health care. The analytical results were assessed according to pre-set quality goals.

Materials and methods

Under optimal conditions capillary samples from 101 patients were measured on the Xprecia Stride (modified Quick method). In each of two primary health care centres (PHCCs), capillary samples from 40 patients were measured on Xprecia Stride. Venous samples from the same patients were analysed on a comparison method (Owren's method, STA-R Evolution, STAGO). The quality goal was a repeatability (CV) $\leq 5,0\%$ and for accuracy that $\geq 95\%$ of the results should be within $\pm 20\%$ from the results of the comparison method. The quality goal for the user-friendliness was a total rating of "satisfactory".

Results

At PT (INR) level $< 2,5$, the CV under optimal conditions was 4,7% and under real-life conditions 4,5% and 5,5%, at the two PHCCs respectively. For PT (INR) results $\geq 2,5$, the CV under optimal conditions was 5,3%, and under real-life conditions 6,4% and 7,1%. A negative bias ((-0,09) – (-0,17) INR) between Xprecia Stride and the comparison method was shown both under optimal conditions and under real-life conditions at PT (INR) level $< 2,5$. At PT (INR) level $\geq 2,5$ a bias of -0,23 INR was found in one of the PHCCs. Under optimal conditions, 93% of the results were within the quality goal for accuracy and when handled by the intended users, 92% of the results were within the quality goal for accuracy. The user-friendliness was rated as satisfactory. The fraction of tests wasted caused by technical errors was 0,3%.

Comments from Siemens Healthcare Diagnostics INC

A letter with comment from Siemens Healthcare Diagnostics INC is attached to the report.