

CoaguChek XS

Summary of an evaluation under the direction of SKUP Report SKUP/2007/55



Background

The new CoaguChek® XS System is designed for use in patient self testing of prothrombin time (PT). It will be the successor of the current CoaguChek® S System. The detection principle is based on an amperometric measurement of the thrombin activity initiated by starting the coagulation cascade using a human recombinant thromboplastin. CoaguChek XS is based on the Quick method, while the methods used in Scandinavian hospitals are based on the Owren method. The sample material is capillary whole blood and the sample volume is 10 µL. The PT result is ready within one minute and displayed in INR. Measuring range for PT (INR) is from 0,8 to 8,0.

The aim of the evaluation

The aim of the evaluation of CoaguChek XS was to

- Get a measure of the analytical quality achieved under standardised and optimal conditions by experienced laboratory trained people in a hospital laboratory
- Get a measure of the analytical quality achieved by the users in primary health care
- Evaluate the user-friendliness

Materials and methods

Samples from 72 outpatients on long-term oral anticoagulation therapy were collected in the outpatient clinic at the hospital laboratory. Of these patients, 24 also contributed with a second sample at a second occasion, giving a total of 96 samples. For CoaguChek XS, the samples were capillary samples in duplicate, and for the comparison method venous citrate samples were collected. At the primary care centre, samples from 40 patients were collected.

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 CoaguChek XS is good. The repeatability CV is approximately 3 % under standardised and optimal conditions in a hospital laboratory as well as in a primary health care centre. The quality goal for the repeatability is attained. No systematic difference between the measurements on CoaguChek XS and the comparison method is pointed out. The main impression of the accuracy of CoaguChek XS is good. Four results clearly deviate from the rest, with high results on CoaguChek XS relative to the comparison method. The four deviating results are the reason why CoaguChek XS does not fulfil the quality goal for the total error set by SKUP. The deviating results are not a result of a trend or a general systematic deviation. The deviating results are reproducible and can most probably be explained by matrix effects in the samples from the individual patients. If these results are disregarded, the quality goal is fulfilled.

The users in this evaluation find CoaguChek XS easy to use and are pleased with the device.

Conclusion

The analytical quality of CoaguChek XS is good and so is the user-friendliness. CoaguChek XS seems well suited for use in the primary health care.

Comments from the manufacturer

For comments and additional information from Roche, please see attachment 6 and 7.

The complete report is found at www.skup.nu