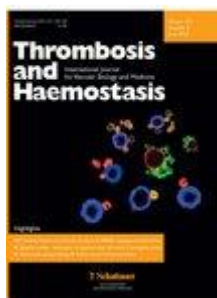


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### External quality assessment (EQA) for CoaguChek monitors

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#### Summary

Anticoagulant control facilities are being overwhelmed by requests for monitoring and large numbers of patients are not therefore receiving treatment. Procedures designed for point-of-care testing have therefore been developed, the most popular being the CoaguChek. The need for external quality assessment (EQA) of monitors used by patients in self-management has been stressed in a European Commission (EC) Directive. It would not however be feasible for all CoaguChek monitors to be enrolled in national or regional EQA schemes which take time to organise and analyse. The European Concerted Action on Anticoagulation (ECAA) has therefore evolved a simpler system. Its value has been assessed in collaboration with the European Concerted Action on Thrombosis (ECAT). 523 monitors were tested at nine clinics which asked patients to bring their CoaguChek instruments to be assessed with the ECAA/ECAT procedure based on a set of 5 plasma samples with certified international normalised ratios (INR). 15% or more deviation from the certified INR on a single certified plasma sample from the set was defined by the ECAA as the limit of acceptable performance. One hundred and six (20.3%) of the monitors tested showed significant deviation and higher than average incidence of significant INR deviations reported with one specific numbered lot of test strips. Recent ECAA/ECAT, Danish and Italian studies report regular EQA of CoaguChek monitors is essential. There is general agreement that this should be performed at reasonably frequent intervals, at six months or whenever there is a change of the manufacturer's test strips.

#### Keywords

accuracy, precision, Oral anticoagulation, external quality assessment, point-of-care monitors, INR deviation