External quality control for CoaguChek XS INR monitors.

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External quality assessment (EQA) of test results is a way of establishing the quality of laboratory testing. The major focus of EQA is to establish whether a laboratory is able to produce accurate results. In addition, it is also a method for establishing the between-laboratory variation for a particular test. EQA is nowadays a well-known and accepted procedure for the assessment of the quality of regular laboratory testing. However, EQA for point-of-care testing (POCT) has not yet been well introduced. One of the problems is the availability of suitable control material. POC monitors are designed for the use of whole blood. Unfortunately it is difficult to distribute stable whole blood samples suitable for measurement of the International Normalised Ratio (INR) to participants.
Fortunately with the CoaguChek XS monitor, the most widely used in Europe, it is also possible to use citrated plasma. The ECAT Foundation therefore designed an EQA programme for the CoaguChek XS INR monitors using lyophilised plasma pools of patients already receiving anticoagulants. Because of the direct relationship between the measured INR value and the treatment of the patient it is important that a POCT can monitor the correct INR value. Therefore in our EQA approach for the CoaguChek XS we focus on the trueness of measurement (accuracy).
The quality set consists of 4 different plasmas, covering the whole therapeutic range (INR 2 – 4.5). The results of all 4 measurements are evaluated in an integrated linear regression model. With this model we are able to assess whether it is possible to obtain accurate results over the entire therapeutic range. Acceptance criteria are based on the deviation of the target value, slope, intercept and correlation coefficient.
The assigned values are established using different lot numbers of test strips as well as different monitors.
Up to now 90 different CoaguChek monitors have been evaluated. Ninety-six per cent of the monitors fulfil the established acceptance criteria.
The between-monitor variation varied between 2.3 and 5.5%. No differences were observed between different lot numbers of test strips.
Because the control samples are stable for up to 6 hours after reconstitution, it is possible to evaluate multiple monitors during the day with the same control set. This makes the use of these control sets in a hospital or a thrombosis service centre setting very practical.
Because of the use of assigned values for the performance evaluation it is also not necessary to perform quality control within a specific time frame. Results can be evaluated at any time they are received by ECAT.
This ECAT EQA programme for CoaguChek monitors is therefore a valuable tool for quality control of POC INR testing.