

RESULTS OF EXTERNAL QUALITY CONTROL FOR THE COAGUCHEK XS INR POINT-OF-CARE MONITOR USING A CONTROL SET WITH ASSIGNED VALUES.

Piet Meijer¹, Renata Sanders², Kees C.J. van de Brugge² and Moniek P.M. de Maat^{1,3}

- 1) ECAT Foundation, Voorschoten, The Netherlands
- 2) Vlietland Hospital, Schiedam, The Netherlands
- 3) Erasmus University Medical Center, Rotterdam, The Netherlands

Introduction

Treatment with Vitamin K antagonists, such as Warfarin, has to be controlled by the measurement of the prothrombin time, expressed as the International Normalised Ratio (INR). Nowadays the use of a point-of-care (POC) monitor for the measurement of the INR has been widely introduced and is used by either patients for self-monitoring or by professionals within the setting of an anticoagulation clinic or care homes for the elderly. In The Netherlands the Roche CoaguChek XS monitor is the most widely used POC monitor. Because of the direct relationship between the measured INR and the treatment of the patient an accurate measurement of the INR is necessary. The ECAT Foundation has therefore developed an external quality control programme using control samples with an assigned value for the CoaguChek XS. The results of this quality control programme are presented below.

Materials and Methods

The control set contains 4 lyophilised plasma samples, prepared from pools of plasma of anticoagulated patients with an INR ranging between 2 and 4.5. The assigned values were established by the Dutch Reference Laboratory for Anticoagulation (RELAC) using different CoaguChek XS monitors and different lot numbers of test strips, from which one is calibrated against the international reference preparation for recombinant human thromboplastin (rTF/09). The relative uncertainty of the control samples varies between 0.6 and 1.3%. After reconstitution, the control samples are stable for at least 6 hours at room temperature. The quality performance of a CoaguChek XS monitor was assessed by integrated comparison of the INR measured and the value assigned using a linear regression model. For each of the control samples a tolerance range of $\pm 15\%$ of the assigned value was used. Acceptance criteria for the slope, intercept and coefficient of regression were established. A CoaguChek XS is regarded as passing the quality control criteria when all the test results were within the tolerance range and the acceptance criteria were met.

Results

This external quality control programme was introduced by the ECAT Foundation in 2012. From the beginning 3 lot numbers of control sets were used. A summary of the results obtained is given in the table below.

Control Set		Sample 1	Sample 2	Sample 3	Sample 4
Batch 211B00 (number of monitors: 160)	Assigned Value	1.9	2.8	3.8	4.2
	Mean	2.0	2.8	4.1	4.3
	Coeff. Variation	6.3%	2.5%	3.8%	2.9%
	Average regression line	$Y = 1.06 X - 0.06$			
Batch 221B00 (number of monitors: 370)	Assigned Value	2.0	2.8	3.6	4.4
	Mean	2.0	2.8	3.6	4.6
	Coeff. Variation	3.2%	2.8%	3.3%	3.9%
	Average regression line	$Y = 1.08 X - 0.18$			
Batch 221B00 (number of monitors: 180)	Assigned Value	2.1	2.7	3.8	4.3
	Mean	2.1	2.7	3.8	4.2
	Coeff. Variation	3.7%	3.3%	3.2%	4.0%
	Average regression line	$Y = 0.99 X$			

Small, non-clinically relevant differences between lot numbers of test strips were observed. More than 95% of the monitors passed the quality control acceptance criteria.

During a one-year period every month two monitors, which are used in a care home for the elderly, were checked. On all occasions both monitors passed the quality control. The average test results for both monitors were similar. The between-occasion coefficient of variation varied between 2.7% and 4.5%.

Discussion and conclusion

The external quality control programme of the ECAT Foundation has been shown to be a useful tool for performance assessment of the CoaguChek XS POC monitors. Up to now more than 700 monitors have been evaluated showing a good comparability, with on average a between-monitor variability of less than 5%. It can

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be concluded that the CoaguChek XS POC monitors measure accurately the INR over the entire therapeutic interval.