

EQA results for POCT INR testing

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Introduction

Because of the direct relationship between the measured INR and the treatment of a patient with vitamin K antagonists an accurate measurement of the INR is necessary. Today for the measurement of INR the CoaguChek point-of-care monitor is widely used. 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 assigned INR value ranging between 2 and 4.5. 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.

Results

A summary of the results obtained since 2012 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: 716)	Assigned Value	2.0	2.8	3.6	4.4
	Mean	2.0	2.8	3.6	4.6
	Coeff. Variation	2.8%	3.2%	4.6%	4.1%
	Average regression line	$Y = 1.08 X - 0.20$			
Batch 241B00 (number of monitors: 226)	Assigned Value	2.0	2.7	3.8	4.2
	Mean	2.0	2.7	3.8	4.2
	Coeff. Variation	3.6%	3.2%	3.7%	3.9%
	Average regression line	$Y = 0.99 X - 0.01$			

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.

Discussion and conclusion

Up to now almost 1100 monitors have been evaluated showing a good comparability, with on average a between-monitor variability of less than 4%. It can be concluded that the CoaguChek XS POC monitors measure accurately the INR over the entire therapeutic interval.