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External Quality Asssurance (EQA) for the Thromboelastometry devices: UK NEQAS BC programme update

DP Kitchen[1] , L Brown[1] , S Munroe-Peart[1] , I Jennings[1] , S Kitchen[1] , ID Walker[1]
UK NEQAS BC, Sheffield, UK

UK NEQAS Blood Coagulation

INTRODUCTION

Thromboelastography and Thromboelastometry are Point of Care testing (POC) technologies for global haemostasis . They measure the elasticity of a developing clot. Thromboelastometry is performed using Rotem ® devices. The Rotem delta device requires samples and reagents to be pipetted whereas the newer Rotem Sigma device uses cartridge based technology with no pipetting required. The TEG devices are used to perform Thromboelastography and can be either TEG5000 which requires samples to be pipetted or TEG6 which is cartridge based. The majority of devices are in theatres and specialist wards and usually operated by staff without laboratory training. UK National External Quality Assurance Service for Blood Coagulation (UK NEQAS BC) has provided External Quality Assurance (EQA) for TEG5000 and Rotem Delta devices for over 5 years.

AIM

To provide EQA for the recently introduced cartridge based thromboelastography/ thromboelastometry methods.

METHOD

One lyophilised citrated plasma sample is distributed to participants three times per year. The sample is supplied with a pre measured volume of diluent and disposable pipette so no laboratory equipment is needed. Participants are allowed 24 days to perform the test and return results. Tests should be run for 30 minutes so the actual time required to process the sample is around 45 minutes which includes reconstituting the sample and performing the test.

Parameters for the Rotem Sigma are required for CT, CFT, A5, A10 and A20 for FibTEM, ExTEM, InTEM and either HepTEM or ApTEM depending on cartridge used.

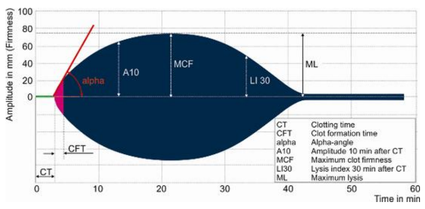
Parameters for the TEG6 are required for R time, K time, Angle and MA for CK, and CKH

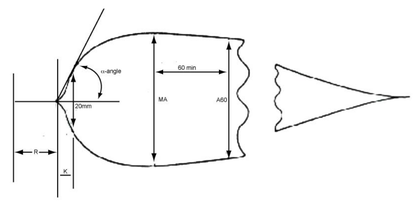
RESULTS

16 surveys of the EQA for Rotem delta and for TEG 5000 have been completed over a 5 year period. An EQA programme was introduced for Rotem Sigma and TEG6 in April 2019 and 3 surveys have been completed. Samples have been of 4 types: Normal donor plasma, Normal donor plasma spiked with heparin, Plasma from patients treated with DOACs and Normal plasma with reduced factor levels to mimic blood loss.

Although all parameters are submitted and medians, CVs and ranges are reported only for the R time for TEG devices and CT for the Rotem devices are scored.

Rotem trace showing parameters





TEG trace showing parameters

Table 1

Rotem Delta CT seconds								TEG 5000 R time minutes			
Sample type	ExTEM	%CV	inTEM	%CV	HepTEM	%CV		Plain cup	%CV	Heparinase cup	%CV
Prolonged clotting	96	73.2	308	17.1	283	10.2		16	25.3	18.5	20.9
Apixaban	92	20.5	195	12.3	214	18.3		10.3	17.4	12.1	25.2
Heparin	57	20.9	223	14.9	154	8.5		Flatline	NA	16.9	59.5
Normal	55.5	18.5	167	7.2	175	8.8		8.1	27.8	8.7	22.7
Prolonged clotting	200.5	69.0	310	18.4	308	19.5		Flatline	NA	Flatline	NA
Heparin low level	49	8.7	242	15.6	191	8.0		Flatline	18.6	7.6	11.7

Results are shown in table 1 for Rotem Delta and TEG 5000 (both pipette based devices) and for Rotem Sigma and TEG6 in table 2 (both cartridge based technology)

Table 2

Rotem Sigma CT seconds												TEG6 R times minutes			
Sample type	FibTEM	%CV	ExTEM	%CV	InTEM	%CV	HepTEM	%CV	ApTEM	%CV		Citrated kaolin	%CV	Citrated kaolin with heparinase	%CV
Normal	106	13.4	111	13.9	261	3.9	258	NA	96	12.7		10.8	13.6	10.6	30.7
Prolonged clotting	299	20.3	307	22.9	499	10.2	484	5.6	285	18.2		Flatline	NA	Flatline	NA
Heparin low level	90.5	7.8	96.5	9.3	406.5	5.4	252	5.1	91	10.4		Flatline	NA	9.1	7.7

NA- not applicable, CV not calculated because of <5 results or results where no clotting was achieved ie “flatline”

Table 3

	Percentage of centres in agreement of sample type			
Sample type	Rotem delta	Rotem Sigma	TEG 5000	TEG6
Normal	98	87.8	74.5	95
Prolonged clotting	93	100	96	100
Heparin low level	81	65.1	95.2	100

As well as the numeric value for parameters we also ask for an interpretation of the results. Interpretation of the sample type by device are shown in table 3 for the 3 samples that were common to both pipette based and cartridge based technology

CONCLUSIONS

Results show CVs ranged from 7.2%- 73.2% for Rotem delta and 17.7%- 59.5% for TEG5000.

CVs for cartridge technology ranged from 3.9%- 22.9% for Rotem Sigma and 7.7%- 30.7% for TEG6, (data from the 3 completed surveys). Cartridge based technology showed an improvement in CVs.

Although not performance assessed interpretations were received from most users. Overall users were in agreement across the sample types with the lowest agreement (65%) with the low level spiked heparin sample on the Rotem Sigma devices.

ACKNOWLEDGEMENT

UK NEQAS BC would like to thank all our participants in the Thromboelastography/ thromboelastometry EQA programme.

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FURTHER READING

Curry et al , BJH 2018 Vol 182 (6) 789-806.
The use of viscoelastic haemostatic assays in the management of major bleeding: A British Society for haematology Guideline.
Kitchen DP et al, JTH 2020 Vol 18(9) 2418-2420. letter in response to “Systematic review of viscoelastic testing(TEG/Rotem) in obstetrics and recommendations form the women’s SSC of the ISTH”

CONTACT INFORMATION

Lead author dianne.kitchen@nhs.net
General email address neqas@coageqa.org.uk.