Evaluation of External Quality Assessment material for activated clotting time on point of care devices i – Stat1 and i– Stat Alinity: UK NEQAS for Blood Coagulation pilot studies.

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INTRODUCTION

United Kingdom National External Quality Assessment Scheme for Blood Coagulation (UK NEQAS BC) is an external quality assessment (EQA) schemes provider for haemostasis related tests with more than 4000 devices participating in Point of Care EQA programmes. One of UK NEQAS BC goals is to develop new EQA programmes for the newly introduced to the market devices or tests designated for coagulation testing.

i – Stat1 and i – Stat Alinity are point of care (POC) devices which use cartridge-based technology for activated clotting time (ACT) testing to monitor patients on heparin therapy.

AIM

United Kingdom National External Quality Assessment Scheme for Blood Coagulation (UK NEQAS BC) conducted a series of pilot studies for ACT testing with lyophilised plasma samples. These samples were evaluated for suitability to be used for external quality assessment with a view to establish a new POC EQA programme for users of kaolin-based cartridges for ACT testing on I – Stat1 and I – Stat Alinity point of care devices.

METHOD

- Pooled plasma was spiked with 0.35 IU/ml (**sample 1**), 0.5 IU/ml (**sample 2**) and 0.83 IU/ml (**sample 3**) of unfractionated heparin (UFH) and lyophilised in aliquots
- These were distributed to the users of i – stat Alinity and i – Stat1 POC ACT devices in three consecutive pilot studies.
- Samples were distributed together with a diluent containing calcium chloride and a stated optimum time for sample reconstitution.
- Precision was evaluated via calculated coefficient of variation (CV %) in each pilot.
- Device specific medians calculated in each pilot were compared.
- Although performance in the pilots was not assessed, 20% deviation from the median was calculated for the consensus information only

RESULTS

A reasonable precision with CV% range 2.8 – 4.8 for i – Stat Alinity and CV% range 3.1 – 9.1 for i – Stat1 was observed in three pilot studies.

Results for sample 2 showed slightly higher variation (CV 4.8 %) in comparison to the results for samples 1 and 3 obtained on i – Stat Alinity.

Even higher result variation (CVs 8.3% and 9.1%) was observed for samples 1 and 3 respectively on the I – Stat1 when compared to the CV% for the results obtained for sample 2 (table 1).

Higher % CVs for the results obtained on I – Stat1 for samples 1 and 3 are due to single outlying results, possibly caused by operating errors.

Overall results demonstrated linear correlation with the level of UFH present in plasma samples.

Device specific medians were found comparable between the two devices with 3.6%, 1.3% and 5.4 % difference for three samples respectively as shown in table 1.

	i - Stat Alinity			i - Stat 1			
ACT* Sample	Median ACT (sec.)	CV%**	Range of results	Median ACT (sec.)	CV%**	Range of results	Median Alinity *vs*. Median i – Stat1 (% difference)
Sample 1	227 (n = 16)	2.8	221 - 239	219 (n=20)	8.3	144 - 233	3.6
Sample 2	400 (n = 17)	4.8	382 - 480	395 (n = 21)	3.1	377 - 420	1.3
Sample 3	609 (n = 18)	2.9	567 - 631	578 (n=19)	9.1	373 - 602	5.4

Table 1. Summary of results obtained in three pilot studies of ACT testing on I – Stat Alinity and i- Stat1
*ACT – activated clotting time **Coefficient of variation

CONCLUSION

- Results of evaluation ACT EQA material obtained on I – Stat Alinity and I – Stat1 devices in three pilots for ACT testing showed acceptable precision
- Results demonstrated linear correlation with the level of unfractionated heparin present in lyophilised plasma
- Device specific calculated medians were found to be comparable between the two platforms
- These studies demonstrated the suitability of UK NEQAS BC lyophilised plasma samples for testing on I – Stat1 and I – Stat Alinity
- UK NEQAS BC can provide a point of care ACT EQA programme for these platforms

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