# External Quality Assessment for activated clotting time: UK NEQAS study on GEM Hemochron 100

L.Brown, D.P.Kitchen, I. Jennings, I. Walker
UK NEQAS for Blood Coagulation, 463A Glossop, Sheffield, S10 2QD United Kingdom

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## INTRODUCTION

GEM Hemochron 100 is a point of care (POC) device for monitoring unfractionated heparin (UFH) therapy via activated clotting time testing (ACT) with cartridge – based technology to measure ACT at two levels high (ACT+) and low (ACT LR) heparin doses.
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. One of UK NEQAS BC goals is to develop EQA programmes for the newly introduced to the market devices or tests designated for coagulation testing.

## AIM

UK NEQAS BC conducted pilot studies where whole blood EQA material containing a range of doses of UFH was evaluated for ACT on the GEM Hemochron 100 with a view to establishing a POC EQA programme.

## METHOD

- Whole blood samples containing low and high doses of UFH which had been previously used in established UK NEQAS BC EQA programmes for ACT (ACT+ EQA, ACTLR EQA) on Hemochron Signature Elite devices were selected for the pilot studies.
- These samples were distributed in two consecutive pilot surveys to the users of GEM Hemochron 100 to test with ACT+ and ACT LR cartridges.
- Precision was evaluated via calculated coefficient of variation (CV %) in each pilot.
- Calculated medians in each pilot were compared to the established ACT EQA programme's medians.
- Although performance in the pilots was not assessed, % deviation from the median was calculated for the consensus information only

## RESULTS

Results of testing on the GEM Hemochron 100 with ACT+ cartridge shown variable between – centre precision with CV% ranging from 8 – 17 on samples with low dose of UFH. However, samples with high dose UFH demonstrated improved between - centre precision (CV% range 3.5 – 4.2) while using the same cartridges (table 1).

Higher variation of results was observed between centres while testing low dose UFH samples on ACT LR cartridges with result %CV range 21 - 31. Tested with the same cartridge samples with high dose of UFH demonstrated CV% range 12 – 25 however (table 1). A higher result variation of low and high doses of UFH samples tested on ACT LR cartridges have been caused by the presence of few outliers which were possibly caused by operating errors.

When comparing results from this pilot with same samples tested in the established ACT programmes, GEM Hemochron 100 ACT+ medians for low and high doses of UFH compared well with the ACT+ medians for samples sent in the ACT+ EQA programme (10.8% and 3.2% difference). Nevertheless, for ACT LR, larger differences were observed (GEM Hemochron 100 ACT LR *vs* ACTLR EQA: 35.8% and 27%) (table 2).

| | GEM Hemochron 100 ACT+ cartridge | | | | GEM Hemochron 100 ACT LR cartridge | | | |
|---|---|---|---|---|---|---|---|---|
| **Sample type** | Pilot | Median ACT (sec) | CV%* | Range of results | Pilot | Median ACT (sec) | CV%* | Range of results |
| **Low dose UFH**** | 1 | 181 (n = 22) | 8 | 159 – 217 | 1 | 176 (n = 17) | 31 | 66 – 207 |
| | 2 | 156 (n = 35) | 17 | 71 – 186 | 2 | 136 (n = 17) | 21 | 65 – 173 |
| **High dose UFH**** | 1 | 438 (n = 22) | 3.5 | 408 – 457 | 1 | 267 (n = 16) | 25 | 161 – 377 |
| | 2 | 444 (n = 35) | 4.2 | 422 – 498 | 2 | 285 (n = 17) | 12 | 232 – 351 |

Table 1. Summary of results obtained in two pilot studies of ACT testing on GEM Hemochron 100
*Coefficient of variation, **Unfractionated heparin

| | GEM Hemochron 100 ACT+ cartridge | | | GEM Hemochron 100 ACT LR cartridge | | |
|---|---|---|---|---|---|---|
| **Sample type** | ACT+ EQA Median (sec) | GEM Hemochron 100 Median ACT (sec) | (% Difference) | ACTLR EQA Median (sec) | GEM Hemochron 100 Median ACT (sec) | (% Difference) |
| **Low dose UFH*** | 165 | 181 | 10.8 | 113 | 176 | 35.8 |
| **High dose UFH*** | 424 | 438 | 3.2 | 195 | 267 | 26.97 |

Table 2. Comparison of the ACT+ and ACTLR EQA medians and GEM Hemochron 100 medians calculated in the pilots.
*Unfractionated heparin

## CONCLUSION

- Results of evaluation ACT EQA material tested on GEM Hemochron 100 in two pilots showed a better precision in samples with high dose UFH with ACT + cartridges in comparison to the results obtained on samples with low dose UFH
- Results of evaluation ACT EQA material tested on GEM Hemochron 100 showed significantly higher variation while testing low and high UFH samples on ACT LR cartridges
- GEM Hemochron 100 ACT+ medians for low and high doses of UFH were found to be comparable to the medians for samples sent in ACT+ EQA programmes
- Larger differences were observed on GEM Hemochron 100 ACT LR between the medians for both levels of UFH and samples sent in ACT LR EQA programmes
- Studies demonstrated an overall suitability of whole blood samples for testing on GEM Hemochron 100
- However, further work needs to be conducted with the samples for testing on ACT LR cartridges.

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## CONTACT INFORMATION

neqas@coagegqa.org.uk Lilia.Brown@nhs.net