Near patient international normalised ratio (INR) measurement in Anticoagulation clinics and Emergency departments is important for monitoring over-anticoagulation and under-anticoagulation. The benefits of POC INR testing are enhanced convenience, faster turnaround time, potentially allowing faster clinical decision-making, improved clinical outcomes, and reduced health care resource use. It also offers convenience to patients, single finger prick test rather than blood test requiring larger volume sample, phlebotomists and transportation to laboratory. This provides a streamlined approach to managing patients wherever testing takes place. The test works on the electrochemical detection after activation of the blood coagulation with human recombinant thromboplatin. Careful monitoring of patients on warfarin therapy is important; under-anticoagulation increases the risk of stroke, while over-anticoagulation increases the risk of bleeding episodes.

Here we compared the Coaguchek Pro II with the in use Coaguchek XSPro and a laboratory method, ACLTOP350. The Pro II system offers multiple enhancements over the Coaguchek XS Pro and Coaguchek XS Pro systems: a broader operating temperature range, an extended menu including an activated partial thromboplatin time (aPTT) test as well as a new strip for prothrombin time (PT) measurement, displayed as International Normalized Ratio (INR) and Wi-Fi enabled.

### Materials & Methods

**Imprecision**
Within batch and between batch imprecision were calculated for Level 1 and Level 2 IQC material

**Accuracy**
This was assessed by
- Analysing anonymised patient samples
- Comparing Coaguchek Pro II method with Coaguchek XS Pro and laboratory method ACLTOP350

**User Variability**
This was assessed by 7 different members of staff, who were a mixture of laboratory, nursing and phlebotomist staff, running IQC Level 1 and IQC Level 2 on the Coaguchek Pro II analyser.

### Results
**Impression studies using IQC materials**

<table>
<thead>
<tr>
<th></th>
<th>IQC LEVEL 1</th>
<th>IQC LEVEL 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>% CV (within batch)</td>
<td>1.1</td>
<td>2.87</td>
</tr>
<tr>
<td>%CV (between batch)</td>
<td>1.1</td>
<td>2.88</td>
</tr>
<tr>
<td>Total analytical Imprecision (%)</td>
<td>0.00</td>
<td>2.42</td>
</tr>
</tbody>
</table>

Table 1: Within-batch and between-batch imprecision for the measurement of IQC levels (n= 20). The total acceptable imprecision is ± Capillary +/- 5 and venous: ±10. ISO Std 5: This was met by both levels of IQC.

**Accuracy studies using anonymised patient samples**

Fig 1: Difference plot for Coaguchek XS-Pro (current use monitor) vs laboratory method (ACLTOP 350)

Fig 2: Difference plot for Coaguchek Pro II (new monitor) vs. Coaguchek XS Pro (currently used monitor)

Fig 3: Method comparison plot Coaguchek Xs Pro (current use monitor) vs laboratory method (ACLTOP 350)

Fig 4: Method comparison plot Coaguchek Pro II (new monitor) vs. Coaguchek Xs Pro (current use monitor)

The above figures show the acceptable accuracy. This is variable depending on the level of INR. In general +/- 0.1 % INR (Results from two methods) (British Society of Haematology)

**User variability**

<table>
<thead>
<tr>
<th></th>
<th>IQC LEVEL 1</th>
<th>IQC LEVEL 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>1.1</td>
<td>2.86</td>
</tr>
<tr>
<td>SD</td>
<td>0</td>
<td>0.053</td>
</tr>
<tr>
<td>%CV</td>
<td>0.00</td>
<td>1.87</td>
</tr>
</tbody>
</table>

Table 5: User variability check with different members of staff who were of different backgrounds, results for both levels were comparable and therefore the desirable imprecision of 10% is met

### Discussion

- **Impression:** 20 tests were carried out for within batch and between batch imprecision tests and were found to be comparable, within laboratory ± 5% and venous ±4.6%.
- **Accuracy:** 20 anonymised patient samples were tested for accuracy, from the graph above, and majority of the data lies within ±5%, mean difference, which is acceptable. This method compares and shows a 95% confidence interval, between the 2 groups concluding that there is no significant difference. Between the methods, so both can be used interchangeably. Thus desirable accuracy is met.
- **User variability:** This involved 7 different users, running level 1 and level 2 QC on the Coaguchek Pro II, results were comparable and the desirable imprecision of 10% is met.
- **Sample stability:** Since finger samples are used on Roche Coaguchek Pro II, stability check is not required.

### Conclusion

The results of the validation show that the Roche Coaguchek Pro II fits with the criteria of a point of care device effectively and they are comparable with the previously used device and laboratory method.

### References