

UK National External Quality Assessment Scheme for Blood Coagulation  
(UK NEQAS BC) have evaluated the Xprecia Prime Point of care (POC)  
INR device

Evaluation was carried out to assess the possibility of establishing external quality assessment) for this POC device.

Samples used in this evaluation were lyophilised plasma samples obtained from patients being treated with Vitamin K antagonists therapy.

Samples require the addition of a diluent which is added to start the clotting process. We evaluated 3 devices (labelled 1 – 3 in table 1) and 3 different test strip batches (labelled a-c in table 1).

Table 1	1+a	2+b	3+c	1+a	2+b	3+c	mean	CV%
	vial 1			vial 2				
Sample 1	1.6	1.6	1.6	1.7	1.6	1.6	<b>1.62</b>	<b>2.53</b>
Sample 2	1.7	1.6	1.7	1.7	1.7	1.7	<b>1.68</b>	<b>2.43</b>
Sample 3	2.3	2.3	2.3	2.3	2.2	2.3	<b>2.28</b>	<b>1.79</b>
Sample 4	2.6	2.6	2.6	2.6	2.6	2.6	<b>2.60</b>	<b>0.00</b>
Sample 5	2.7	2.7	2.7	2.7	2.7	2.7	<b>2.70</b>	<b>0.00</b>
Sample 6	3.1	3.1	3.1	3.2	3.1	3.1	<b>3.12</b>	<b>1.31</b>
Sample 7	3.6	3.6	3.6	3.7	3.6	3.7	<b>3.63</b>	<b>1.42</b>
Sample 8	3.7	3.6	3.6	3.7	3.5	3.5	<b>3.60</b>	<b>2.48</b>

Further testing was performed on sample 1 and sample 8. Results in table 2 show no variation by test strip or device used. These tests were completed by 4 different operators and no variation was seen by operator.

Table 2	Strip A	Strip B	Strip C	Device 1	Device 2	Device 3
<b>Sample 1</b>						
Mean	1.62	1.61	1.6	1.61	1.62	1.6
Median	1.6	1.6	1.6	1.6	1.6	1.6
%CV	2.3	2.8	2.5	1.9	3	2.5
<b>Sample 8</b>						
Mean	3.56	3.45	3.46	3.49	3.5	3.48
Median	3.5	3.4	3.5	3.5	3.5	3.5
%CV	3	2.2	2.4	2.6	3.6	2.3

Overall 60 tests were completed on each of these 2 samples with mean INR obtained of 1.61 (sample 1) and 3.49 (sample 8). These had % coefficients' of variance of 2.5 and 2.9 respectively.

We conclude that UK NEQAS BC could provide EQA for this device.

Precision on our EQA samples was good with all tests showing CVs of <4%.

For further information please contact [dianne.kitchen@nhs.net](mailto:dianne.kitchen@nhs.net)