Dear Colleagues,

Re: Introduction of an Equivocal zone for the Voltage-gated potassium channel (VGKC) assay.

As part of the preparation for our pending UKAS accreditation, in-house assays such as the VGKC assay are required to be validated formally. Part of this process involves determining and understanding the limitations of the assay, including the inter-assay variation of the VGKC assay.

Validation of the VGKC assay has been carried by the laboratory according to the standards outlined in ISO 15189 for diagnostic laboratories. This has included validating all quality controls, levels of uncertainty, precision and reproducibility.

To control for the possibility that repeating any one sample on two different assays may lead to a sample changing its overall result from positive to negative or vice versa, we have introduced an equivocal zone to the results of the VGKC assay. This zone is shown below.

**Voltage Gated Potassium Channel Results**

<table>
<thead>
<tr>
<th>Results</th>
<th>69 pM/l⁻¹ and below</th>
<th>131 pM/l⁻¹ and above</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>are negative</td>
<td>are positive</td>
</tr>
</tbody>
</table>

Results between 70 – 130 pM/l⁻¹ are equivocal.

Results will continue to be reported as positive (≥131 pM/l⁻¹) and negative (≤69 pM/l⁻¹). However from November 27th, 2015 we will be using the above equivocal zone (70 – 130 pM/l⁻¹) with the VGKC assay. Previously we did not utilise an equivocal zone with the results of this assay.

**Definition of equivocal zone**

The equivocal zone of the VGKC assay, falls between the negative (≤69 pM/l⁻¹) and positive range of values (≥131 pM/l⁻¹). Results within this range have insufficient statistical power to determine them as either negative or positive, they are therefore termed equivocal (neither negative nor positive) and therefore add no scientific merit to a diagnosis: Please rely on the clinical picture to inform patient diagnosis and management.

We hope that this change will cause minimum disruption to your clinical work. Please do not hesitate to contact me if you have any queries

Yours sincerely

[Signature]

Professor BL Ferry