Surpasses ISO 15197:2013 Accuracy and Haematocrit Interference Criteria

Requirement A: Accuracy

At glucose levels < 5.55 mmol/L, 95% of results should be within ± 0.83 mmol/L of laboratory results.

At glucose levels ≥ 5.55 mmol/L, 95% of results should be within ± 1.5% of laboratory results.

**Accuracy results for glucose < 5.5 mmol/L, n=198**

<table>
<thead>
<tr>
<th>Range</th>
<th>Within ± 0.28 mmol/L</th>
<th>Within ± 0.56 mmol/L</th>
<th>Within ± 0.83 mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>146 (198) 74%</td>
<td>198 (198) 99%</td>
<td>198 (198) 100%</td>
</tr>
</tbody>
</table>

**Accuracy results for glucose ≥ 5.55 mmol/L, n=402**

<table>
<thead>
<tr>
<th>Range</th>
<th>Within ± 5%</th>
<th>Within ± 10%</th>
<th>Within ± 15%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>317 (402) 78.9%</td>
<td>393 (402) 97.8%</td>
<td>401 (402) 99.8%</td>
</tr>
</tbody>
</table>

**Results:** 100% of results are within 0.83 mmol/L and 99.8% are within ± 15% at respective glucose levels.

**Conclusion:** GlucoMen Areo exceeds ISO 15197:2013 requirement of 95%.

Requirement B: Accuracy

99% of results should fall within Zones A and B of the Consensus Error Grid.

**Results:** 100% of results are within Zone A.

**Conclusion:** GlucoMen Areo exceeds ISO 15197:2013 requirement.

Requirement C: Haematocrit Interference Evaluation

For glucose levels < 5.55 mmol/L.

Results must be within 0.55 mmol/L of results obtained at reference haematocrit of 42%.

For glucose levels ≥ 5.55 mmol/L.

Bias must be less than 10% compared to results obtained at reference haematocrit of 42%.

The GlucoMen Areo sensor has a second electrode position which allows the system to measure haematocrit. The meter then removes the effect of varying haematocrit automatically.

**Haematocrit Range**

10%-70%

**Results:** GlucoMen Areo exhibits an haematocrit interference effect of less than 10% at all levels.

**Conclusion:** GlucoMen Areo exceeds ISO 15197:2013 requirement.