Omnitest® plus

ACCURACY TEST

INTERNATIONAL STANDARD ISO 15197:2013
Omnitest® plus
System Accuracy Evaluation

In accordance with the ISO 15197:2013 standard, new criteria for blood glucose meters have been published.
The aim of this document is to present how Omnitest® plus meets these new requirements.

TEST INFORMATION
SYSTEM ACCURACY

The accuracy of Omnitest® plus blood glucose monitoring system was assessed by comparing patients’ blood glucose results obtained with Omnitest® plus with those of a standard laboratory instrument, the YSI 2300 auto analyzer.

1) Test date
   November 26th, 2012 - December 12th, 2012

2) Test meter serial number
   GKRBMCO0034 - GKRBMCO0039

3) Test strip lot numbers
   B4MK07 (Lot #1), B4MK08 (Lot #2), B4MK09 (Lot #3)

4) Sample numbers
   • 6 x Omnitest® plus meter
   • 600 x Omnitest® plus test strips (three lots)
   • 1 x YSI 2300 auto analyzer

5) Standard/guidance documents referenced
   • ISO/DIS 15197:2010 In vitro diagnostic test systems Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus (during clinical trial)
   • ISO 15197:2013 In vitro diagnostic test systems Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus (for data analysis)
   • CLSI EP09-A2:2004 Method comparison and bias estimating using patient samples

SAMPLE DISTRIBUTION
SYSTEM ACCURACY

Distribution of glucose concentrations in samples for system accuracy evaluation

<table>
<thead>
<tr>
<th>Glucose concentration mmol/L</th>
<th>Percentage of sample</th>
<th>Sample numbers</th>
<th>Preparation of sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 2.77</td>
<td>5%</td>
<td>5</td>
<td>glycolyzed</td>
</tr>
<tr>
<td>&gt; 2.77 – 4.44</td>
<td>15%</td>
<td>15</td>
<td>unaltered</td>
</tr>
<tr>
<td>&gt; 4.44 – 6.66</td>
<td>20%</td>
<td>20</td>
<td>unaltered</td>
</tr>
<tr>
<td>&gt; 6.66 – 11.10</td>
<td>30%</td>
<td>30</td>
<td>unaltered</td>
</tr>
<tr>
<td>&gt; 11.10 – 16.65</td>
<td>15%</td>
<td>15</td>
<td>unaltered</td>
</tr>
<tr>
<td>&gt; 16.65 – 22.20</td>
<td>10%</td>
<td>10</td>
<td>unaltered</td>
</tr>
<tr>
<td>&gt; 22.20</td>
<td>5%</td>
<td>5</td>
<td>supplemented with glucose</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>
System Accuracy Evaluation

Difference Plot

**ACCEPTANCE CRITERIA**

**ACCURACY PLOT – PART 1**

**TEST RESULTS**

**SYSTEM ACCURACY PLOT**

**DATA ANALYSIS**

**BIAS DISTRIBUTION ANALYSIS COMPARED WITH YSI 2300**

**RESULT**

97.3% of results are within ±0.83 mmol/L or ±15% for combined lots.

**CONCLUSION**

Omnitest® plus exceeds the minimum requirement of 95% system accuracy.
System Accuracy Evaluation
Consensus Error Grid

Acceptance Criteria
Accuracy Plot – Part 2

Test Criteria | Tolerance Range
---|---
Consensus Error Grid | 99% of results within zones A and B of the consensus error grid for type 1 diabetes

| Zone | Classification |
---|---|
A | No effect on clinical action. |
B | Altered clinical action – little or no effect on clinical outcome. |
C | Altered clinical action – likely to affect clinical outcome. |
D | Altered clinical action – could have significant medical risk. |
E | Altered clinical action – could have dangerous consequences. |

Test Results
Consensus Error Grid

Data Analysis
Consensus Error Grid

| Strip Lot | Zone A | Zone B | Zone C | Zone D | Zone E | Total |
---|---|---|---|---|---|---|
Lot 1 | 99.5% [199/200] | 0.5% [1/200] | 0% [0/200] | 0% [0/200] | 0% [0/200] | 100% [200/200] |
Lot 2 | 100% [200/200] | 0.0% [0/200] | 0% [0/200] | 0% [0/200] | 0% [0/200] | 100% [200/200] |
Lot 3 | 99.5% [199/200] | 0.5% [1/200] | 0% [0/200] | 0% [0/200] | 0% [0/200] | 100% [200/200] |
Combined | 99.7% [598/600] | 0.3% [2/600] | 0% [0/600] | 0% [0/600] | 0% [0/600] | 100% [600/600] |

Result
Conclusion
100% of results are within zones A and B of the consensus error grid.
Omnistest® plus exceeds the system accuracy requirement that 99% of results are within zones A and B.