PICCOLO®

PERFORMANCE EVALUATION

Oregon Health and Science University

ABAXIS
January 2002
Introduction:

On January of 2002, a comparison study between a Beckman LX-20 analyzer and the Abaxis Piccolo® Point-of-Care Clinical Chemistry Chem 12 disc was performed at the Oregon Health and Science University.

The study consisted of the simultaneous analysis of 60 human samples by both the Beckman LX-20 and the Piccolo analyzers. The samples were analyzed in duplicates.

Results:

The data show an almost perfect correlation between the analyzers. As expected from the use of different methodologies, there are significant differences in the slopes of Albumin, Amylase and total Bilirubin. The differences are exacerbated by the lack of absolute standards for these methods. This is a very common phenomenon in the comparison of different analyzers and the users must take into account these differences in comparing the results.

As is the case here, the high correlation allow the conversion from one analyzer to the other by a simple linear transformation utilizing the slope and intercept calculated from the correlation data.

More commonly, a comparison of the manufacture's package insert for the normal ranges is sufficient to establish the equivalence between methods.

Conclusions:

The study shows a remarkable correlation between the Piccolo analyzer and the Beckman LX-20 analyzer. The lowest correlation coefficient observed was for Total Bilirubin at 96.7%, this is due in part to the granularity of the Beckman data with only one decimal in the reported result and to the very narrow range of values observed for this patient sample. Total bilirubin can go as high as 15 mg/dL, while the observation only cover one fifth of the dynamic range.
ALB comparison between Abaxis disc and Beckman LX-20
All data point

Slope          0.84
Intercept      0.66
Correl          0.971
n                  116
Y Range      1.9 - 4.4
X Range      1.6 - 4.2
ALP comparison between Abaxis disc and Beckman LX-20

All data point

Slope: 0.95
Intercept: 16.8
Correl: 0.991
n: 116
Y Range: 42 - 419
X Range: 35 - 438
ALT comparison between Abaxis disc and Beckman LX-20
All data point

- Slope: 0.95
- Intercept: 1.7
- Correl: 1.000
- n: 116
- Y Range: 7 - 1348
- X Range: 10 - 1383
AMY comparison between Abaxis disc and Beckman LX-20

All data point

<table>
<thead>
<tr>
<th>Slope</th>
<th>0.76</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>3.6</td>
</tr>
<tr>
<td>Correl</td>
<td>0.978</td>
</tr>
<tr>
<td>n</td>
<td>115</td>
</tr>
<tr>
<td>Y Range</td>
<td>21 - 138</td>
</tr>
<tr>
<td>X Range</td>
<td>21 - 138</td>
</tr>
</tbody>
</table>
AST comparison between Abaxis disc and Beckman LX-20

All data point

<table>
<thead>
<tr>
<th>Slope</th>
<th>1.02</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>3.04</td>
</tr>
<tr>
<td>Correl</td>
<td>1.000</td>
</tr>
<tr>
<td>n</td>
<td>116</td>
</tr>
<tr>
<td>Y Range</td>
<td>15 - 644</td>
</tr>
<tr>
<td>X Range</td>
<td>14 - 633</td>
</tr>
</tbody>
</table>
BUN comparison between Abaxis disc and Beckman LX-20

All data point

Beckman LX-20 BUN (n=2) mg/dL

Abaxis disc ALB (n=2) mg/dL

Slope           1.04
Intercept      -1.8
Correl          0.995
n                 116
Y Range      3 - 138
X Range      5 - 129
Ca comparison between Abaxis disc and Beckman LX-20
All data point

Beckman LX-20 Ca (n=2) mg/dL
Abaxis disc Ca (n=2) mg/dL

Slope          1.03
Intercept      -0.06
Correl          0.983
n                 115
Y Range       4.5 - 14.1
X Range       4.6 - 13.2
CHOL comparison between Abaxis disc and Beckman LX-20

All data points

Slope: 0.97
Intercept: 14.67
Correl: 0.972
n: 116
Y Range: 44 - 286
X Range: 49 - 258
CRE comparison between Abaxis disc and Beckman LX-20
All data point

<table>
<thead>
<tr>
<th>Slope</th>
<th>0.99</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>0.12</td>
</tr>
<tr>
<td>Correl</td>
<td>0.999</td>
</tr>
<tr>
<td>n</td>
<td>116</td>
</tr>
<tr>
<td>Y Range</td>
<td>0.4 - 13.7</td>
</tr>
<tr>
<td>X Range</td>
<td>0.3 - 13.5</td>
</tr>
</tbody>
</table>
GLU comparison between Abaxis disc and Beckman LX-20

All data points

Slope: 0.98
Intercept: 10.88
Correlation: 0.997
n: 116
Y Range: 52 - 383
X Range: 40 - 374