Analytical Claim

Hemoglobin was analyzed by methods Reference Method and New Method to determine whether the methods are equivalent within Allowable Total Error of 0.67 g/dL or 7%. 20 specimens were compared over a range of 5.6 to 18.2 g/dL. The test PASSED. The difference between the two methods was within allowable error for 19 of 20 specimens (95.0%). The average Error Index (Y-X)/TEa was 0.09, with a range of -0.55 to 1.17. The largest Error Index occurred at a concentration of 12.2 g/dL.

Key Statistics:
- Average Error Index: 0.09
- Error Index Range: -0.55 to 1.17
- Coverage Ratio: --

Evaluation Criteria:
- Allowable Total Error: 0.67 g/dL or 7%
- Reportable Range: --

Deming Regression Statistics:
- Y = Slope * X + Intercept
- Correlation Coeff (R): 0.9951
- Slope: 1.009 (0.960 to 1.059)
- Intercept: -0.03 (-0.67 to 0.60)
- Std. Err of Estimate: 0.40
- N: 20 of 20

Experiment Description

<table>
<thead>
<tr>
<th></th>
<th>X Method</th>
<th>Y Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expt Date</td>
<td>02 Mar 2009</td>
<td>02 Mar 2009</td>
</tr>
<tr>
<td>Result Ranges</td>
<td>5.6 to 18.2</td>
<td>5.4 to 18.9</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>12.24 ± 3.84</td>
<td>12.32 ± 3.88</td>
</tr>
<tr>
<td>Units</td>
<td>g/dL</td>
<td>g/dL</td>
</tr>
<tr>
<td>Analyst</td>
<td>XYZ Lab</td>
<td>QRS Lab</td>
</tr>
<tr>
<td>Comment</td>
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</table>

Accepted by: ___________________________  ___________________________
Signature                      Date
## Two Instrument Comparison

### Experimental Results

<table>
<thead>
<tr>
<th>Specimen</th>
<th>X</th>
<th>Y</th>
<th>Error Index</th>
<th>Specimen</th>
<th>X</th>
<th>Y</th>
<th>Error Index</th>
<th>Specimen</th>
<th>X</th>
<th>Y</th>
<th>Error Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>S00001</td>
<td>10.2</td>
<td>10.1</td>
<td>-0.14</td>
<td>S00008</td>
<td>7.8</td>
<td>7.6</td>
<td>-0.30</td>
<td>S00015</td>
<td>9.2</td>
<td>9.5</td>
<td>0.45</td>
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<tr>
<td>S00002</td>
<td>11.2</td>
<td>11.5</td>
<td>0.38</td>
<td>S00009</td>
<td>8.2</td>
<td>8.6</td>
<td>0.60</td>
<td>S00016</td>
<td>17.8</td>
<td>18.0</td>
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<td>S00003</td>
<td>5.6</td>
<td>5.4</td>
<td>-0.30</td>
<td>S00010</td>
<td>16.7</td>
<td>16.9</td>
<td>0.17</td>
<td>S00017</td>
<td>17.2</td>
<td>16.9</td>
<td>-0.25</td>
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<tr>
<td>S00004</td>
<td>13.5</td>
<td>13.8</td>
<td>0.32</td>
<td>S00011</td>
<td>18.2</td>
<td>18.9</td>
<td>0.55</td>
<td>S00018</td>
<td>11.6</td>
<td>11.8</td>
<td>0.25</td>
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<tr>
<td>S00005</td>
<td>14.2</td>
<td>14.3</td>
<td>0.10</td>
<td>S00012</td>
<td>15.7</td>
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<td>-0.45</td>
<td>S00019</td>
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<td>0.11</td>
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<tr>
<td><strong>S00006</strong></td>
<td><strong>12.2</strong></td>
<td><strong>13.2</strong></td>
<td><strong>1.17</strong></td>
<td><strong>S00007</strong></td>
<td><strong>6.5</strong></td>
<td><strong>6.6</strong></td>
<td><strong>0.15</strong></td>
<td><strong>S00013</strong></td>
<td><strong>12.1</strong></td>
<td><strong>11.9</strong></td>
<td><strong>-0.24</strong></td>
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<tr>
<td>S00007</td>
<td>6.5</td>
<td>6.6</td>
<td>0.15</td>
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<td>-0.30</td>
<td>S00020</td>
<td>15.5</td>
<td>14.9</td>
<td>-0.55</td>
</tr>
</tbody>
</table>

Values with an "X" were excluded from the calculations.
Two Instrument Comparison (2IC) is a simple, straight-forward procedure for comparing two methods without using linear regression. The pass-fail rule is easy to understand: two methods X and Y are the same within allowable error if the difference between them does not exceed Allowable Total Error (TEa).

Clinical Equivalence vs. Statistical Equivalence
Traditional method comparison protocols test whether two methods are statistically equivalent. In contrast, 2IC tests whether the two methods are clinically equivalent. What's the difference?

Statistical Equivalence. Two methods are statistically equivalent if the difference between them is random. It does not matter how large the difference is.

The CLIA limit for Calcium is 1 mg/dL. However, two Calcium tests could differ by 3 mg/dL and still test as statistically identical -- if no bias is present. Suppose you constructed an experiment by arranging the specimens in increasing order by X, with a +3 mg/dL error at the even-numbered points and a -3 mg/dL error at the odd-numbered points. On average, the bias is zero. A regression-based comparison considers these methods "identical", even though the error is far greater than TEa.

Clinical Equivalence. Two methods are clinically equivalent if the difference between them is less than allowable error. It does not matter if there is a bias, as long as that bias is within allowable error.

For example, suppose Calcium for the Y method is, in every case, 0.2 mg/dL higher than for the X method. These methods are not statistically identical, because the difference is not random. However, they are clinically identical, since the difference is less than allowable error.

Data Quality
2IC gives a meaningful comparison with fewer data points than are required for traditional, regression-based procedures -- perhaps 5 to 10 specimens. However, it is important that the specimens cover the reportable range of the method, and include points near the Medical Decision Points.

Key Statistics and Evaluation Criteria
Allowable Total Error (TEa). TEa states the laboratory's policy for how much error is medically (or administratively) acceptable. Regulatory requirements represent an upper limit.

Examples: the CLIA limit for Sodium is 4 mmol/L; the CLIA limit for Glucose is 6 mg/dL or 10%, whichever is greater.

Error Index. The ratio of the difference Y-X to Allowable Total Error. The Error Index is measured for each X-Y pair. An index greater than 1.00 or less than -1.00 is unacceptable -- it means the difference between the methods exceeds TEa. If more than 5% of the specimens have an unacceptable Error Index, the experiment fails.

Reportable Range. The maximum range of values that can be measured accurately without diluting the specimen. Synonyms: Analytical Measurement Range, Assay Range, Analytical Range.

Coverage Ratio. The percent of the Reportable Range covered by the analysis. The ideal is 100%.

Coverage is computed as 100 x (Xhi - Xlo) / (Rhi - Rlo). Rlo and Rhi are the lower and upper limits of the Reportable Range. Xhi is the smaller of maximum X and the upper limit of the range. Xlo is the larger of minimum X and the lower limit of the range.

Example: Suppose the Reportable Range is 100 to 300, and the range of X values measured is 200 to 350. There is a 50% overlap between the X-range and the Reportable Range. The coverage ratio is 100 x (300 - 200) / (300 - 100) = 50%.

Deming Regression Statistics. The report shows the slope, intercept, standard error of estimate, and correlation coefficient for reference only. They are not used to determine whether the experiment passes or fails. Note that the slope and intercept are computed from Deming regression, assuming that the two methods have comparable precision (i.e., the same representative SD).

Plots
Scatter Plot. The Scatter plot shows the data points, together with the 1:1 (Y=X) line with Allowable Error bounds around it. Vertical lines mark the Reportable Range and Medical Decision Points (if these values were input). The plot does NOT show the regression line.

Error Index Plot. The Error Index plot shows the Error Index. Points that fall in the shaded area have an unacceptable Error Index (> 1.00 or < -1.00).

Logarithmic Scale. When the data covers a wide range and has a tight cluster of points at the low end, the scatter plot may be shown on a logarithmic scale instead of a linear scale. Using a log scale gives better visual separation of the points at the low end.

When the plots are shown on a log scale, the regression fit is computed for the logs of the data points, and the Standard Error of Estimate (SEE) represents percent variation around the regression line. (SEE of 0.10 means 10% variation.)
Two Instrument Comparison
Report Interpretation Guide

Pass or Fail?
The objective is to determine whether the two methods are clinically equivalent. The experiment passes if the Y-X is less than TEa at for at least 95% of the specimens.

Preliminary Report
The word PRELIMINARY printed diagonally across the report indicates that the data is incomplete, and the report is not acceptable as a final report. Some or all of the statistics may be missing.

The 2IC report is preliminary if there are less than 5 unexcluded data points.