# TUP Urine Test Strips

**Visual and Analyzer Reading**

## Comparison Report

**May 2008**

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Visual and Analyzer Reading

I. ulti med TUP Urine Test Strips Visual and Analyzer Reading – Comparison Evaluation

1. Objective
To perform a clinical study including visual and analyzer testing to validate the accuracy of the ulti med TUP Urine Test Strips in comparison to the market leader Siemens Diagnostics (Bayer) Urine Strips.

2. General Procedure
Collect Clinical specimens from a hospital and test the specimens according to the procedures below.

- **Visual Testing**
  Perform Visual Urine Strip comparison tests using the ulti med TUP and Siemens/Bayer Urine Strips. Then calculate the Percent Agreement of the results based on the ± 1 Color Block industry standard.

- **Analyzer Testing**
  Perform Analyzer Urine Strip comparing tests using both the ulti med TUP and Siemens/Bayer Urine Strips on the Clinitek 500, Clinitek 100, and Clinitek Status Analyzers, and then compare the results.

3. Materials
- ulti med TUP Urine Test Strips
- Siemens/Bayer Multistix 10 SG Urine Strips
  - Lot 1: 6L12D; Exp: 2008-05
  - Lot 2: 7B02D; Exp: 2008-08
- 300 Clinical Specimens collected from a Hospital
- Siemens/Bayer Clinitek 100 Analyzer (SN024065)
- Siemens/Bayer Clinitek Status Analyzer (SN10001)
- Siemens/Bayer Clinitek 500 Analyzer (SN6470-1010472)

4. Results
4.1. Visual Test Comparison

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Total No. of Clinical Specimens</th>
<th>% Agreement ± 1 Color Block between Siemens/Bayer Strip Lot 1 &amp; ulti med TUP</th>
<th>% Agreement ± 1 Color Block between Siemens/Bayer Strip Lot 2 &amp; ulti med TUP</th>
<th>Average % Agreement ± 1 Color Block between Siemens/Bayer Strip Lot 1/2 &amp; ulti med TUP</th>
<th>% Agreement ± 1 Color Block between Siemens (Bayer) Lot 1 &amp; Siemens (Bayer) Lot 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukocytes</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Nitrite</td>
<td>300</td>
<td>99.67%</td>
<td>99.67%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Protein</td>
<td>300</td>
<td>100%</td>
<td>99.33%</td>
<td>99%</td>
<td>99.67%</td>
</tr>
<tr>
<td>pH</td>
<td>300</td>
<td>99%</td>
<td>99.33%</td>
<td>99%</td>
<td>99.67%</td>
</tr>
<tr>
<td>Blood</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>300</td>
<td>99.67%</td>
<td>99.67%</td>
<td>99%</td>
<td>99.67%</td>
</tr>
<tr>
<td>Ketone</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Glucose</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

According to the visual results in the above tables, the average percent agreement between the ulti med TUP with both Lots 1 and 2 of the Siemens/Bayer Strips was 99-100% for all parameters.
### 4.2. Reading Comparison on the Clinitek 500 Analyzer

**ulti med TUP and Siemens/Bayer reading on Clinitek 500 Analyzer**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Total No. of Clinical Specimens</th>
<th>% Agreement between Siemens (Bayer) Lot 1 &amp; ulti med TUP</th>
<th>% Agreement between Siemens (Bayer) Lot 2 &amp; ulti med TUP</th>
<th>Average % Agreement ± 1 Color Block between Siemens/Bayer Strip Lot 1/2 &amp; ulti med TUP</th>
<th>% Agreement between Siemens (Bayer) Lot 1 &amp; Siemens (Bayer) Lot 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukocytes</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Nitrite</td>
<td>300</td>
<td>93.33%</td>
<td>92.33%</td>
<td>92.83%</td>
<td>96.33%</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Protein</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>pH</td>
<td>300</td>
<td>97%</td>
<td>99.67%</td>
<td>98.34%</td>
<td>99.33%</td>
</tr>
<tr>
<td>Blood</td>
<td>300</td>
<td>99.67%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>300</td>
<td>99.67%</td>
<td>100%</td>
<td>100%</td>
<td>99.67%</td>
</tr>
<tr>
<td>Ketone</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Glucose</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

According to the Clinitek 500 Analyzer results in the above tables, the average percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 98-100% for all parameters, except Nitrite. The average Nitrite percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 93% which may be due to the lot to lot variation of the Siemens/Bayer Strips which had a 96.33% between lot percent agreement.

### 4.3. Reading Comparison on the Clinitek 100 Analyzer

**ulti med TUP and Siemens/Bayer reading on Clinitek 100 Analyzer**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Total No. of Clinical Specimens</th>
<th>% Agreement between Siemens (Bayer) Lot 1 &amp; ulti med TUP</th>
<th>% Agreement between Siemens (Bayer) Lot 2 &amp; ulti med TUP</th>
<th>Average % Agreement ± 1 Color Block between Siemens/Bayer Strip Lot 1/2 &amp; ulti med TUP</th>
<th>% Agreement between Siemens (Bayer) Lot 1 &amp; Siemens (Bayer) Lot 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukocytes</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Nitrite</td>
<td>300</td>
<td>90.45%</td>
<td>91.36%</td>
<td>90.91%</td>
<td>92.73%</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Protein</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>pH</td>
<td>300</td>
<td>99.09%</td>
<td>99.08%</td>
<td>99.09%</td>
<td>99.54%</td>
</tr>
<tr>
<td>Blood</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>300</td>
<td>99.55%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Ketone</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Glucose</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

According to the Clinitek 100 Analyzer results in the above tables, the average percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 98-100% for all parameters, except Nitrite. The average Nitrite percent agreement between the *ulti med TUP* with both Lots 1 and 2 of the Siemens/Bayer Strips was 91% which may be due to the lot to lot variation of the Siemens/Bayer Strips which had a 92.73% between lot percent agreement.
### 4.4. Reading Comparison on the Clinitek Status Analyzer

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Total No. of Clinical Specimens</th>
<th>% Agreement between Siemens (Bayer) Lot 1 &amp; ulti med TUP</th>
<th>% Agreement between Siemens (Bayer) Lot 2 &amp; ulti med TUP</th>
<th>Average % Agreement ± 1 Color Block between Siemens/Bayer Strip Lot 1/2 &amp; ulti med TUP</th>
<th>% Agreement between Siemens (Bayer) Lot 1 &amp; Siemens (Bayer) Lot 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukocytes</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Nitrite</td>
<td>300</td>
<td>95.67%</td>
<td>97%</td>
<td>96%</td>
<td>96%</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Protein</td>
<td>300</td>
<td>98.33%</td>
<td>99%</td>
<td>99%</td>
<td>99.33%</td>
</tr>
<tr>
<td>pH</td>
<td>300</td>
<td>99%</td>
<td>99.67%</td>
<td>99%</td>
<td>99.33%</td>
</tr>
<tr>
<td>Blood</td>
<td>300</td>
<td>99.33%</td>
<td>99.33%</td>
<td>99%</td>
<td>100%</td>
</tr>
<tr>
<td>Specific Gravity</td>
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<td>99.33%</td>
<td>99%</td>
<td>99%</td>
<td>99.67%</td>
</tr>
<tr>
<td>Ketone</td>
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<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Bilirubin</td>
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<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Glucose</td>
<td>300</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

According to the Clinitek Status Analyzer results in the above tables, the average percent agreement between the ulti med TUP with both Lots 1 and 2 of the Siemens/Bayer Strips was 98-100% for all parameters, except Nitrite. The average Nitrite percent agreement between the ulti med TUP with both Lots 1 and 2 of the Siemens/Bayer Strips was 96% which may be due to the lot to lot variation of the Siemens/Bayer Strips which had a 96% between lot percent agreement.

### 5. Conclusion

This study demonstrates that the ulti med TUP Urine Test Strips are substantially equivalent to the Siemens/Bayer Strips when read visually and when read on the Clinitek 500, 100 and Status Analyzers.

### II. Appendix

#### 1. Cleared for US 510(k)
The ulti med TUP Urine Test Strips are cleared for US 510(k). For more information visit the following website:  [www.ultimed.org](http://www.ultimed.org)

#### 2. CE Marked
The ulti med TUP Urine Test Strips and ulti med TUP U120 Urine Analyzer are CE Marked for sale in Europe as of January 17, 2006 and August 10, 2006, respectively. The following table lists the available languages.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Available Languages</th>
</tr>
</thead>
<tbody>
<tr>
<td>ulti med TUP Urinalysis Reagent Strips</td>
<td><strong>Package Insert:</strong> German, English, French, Polish, Netherlands</td>
</tr>
<tr>
<td></td>
<td><strong>Kit Box:</strong> German, English</td>
</tr>
<tr>
<td>ulti med TUP U120 Urine Analyzer</td>
<td><strong>Instruction Manual:</strong> German, English, French, Polish, Netherlands</td>
</tr>
<tr>
<td></td>
<td><strong>Carton Label:</strong> German, English</td>
</tr>
</tbody>
</table>
### 3. Product Catalog Numbers

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>No. of Parameters</th>
<th>Strips per Canister$^*$</th>
<th>Individually Pouched Strips per Kit</th>
<th>Available Strips</th>
<th>Parameters List</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Visual-Read and Analyzer-Read Strips</td>
<td>ASC GLU BIL KET SG BLO pH PRO URO NIT LEU</td>
</tr>
<tr>
<td>U031-111$^*$</td>
<td>11</td>
<td>100</td>
<td>1, 3, 6</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U031-101$^*$</td>
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<td>100</td>
<td>1, 3, 6</td>
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<td>U031-091$^*$</td>
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<td>100</td>
<td>1, 3, 6</td>
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<td>U031-081$^*$</td>
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<td>U031-071$^*$</td>
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<td>1, 3, 6</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>U031-061$^*$</td>
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<td>100</td>
<td>1, 3, 6</td>
<td>√</td>
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<tr>
<td>U031-041$^*$</td>
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<tr>
<td>U031-031$^*$</td>
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<td>100</td>
<td>1, 3, 6</td>
<td>√</td>
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<tr>
<td>U031-021$^*$</td>
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<td>100</td>
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</tr>
<tr>
<td>U031-011$^*$</td>
<td>1</td>
<td>100</td>
<td>1, 3, 6</td>
<td>√</td>
<td></td>
</tr>
</tbody>
</table>

◊ Also available in canisters of 25, 50 and 150 strips
√ CE Marked for Sale in the European Community
† Cleared for US 510 (k) and CLIA Waived

Other combinations available soon!
# TUP Urine Test Strips

## Visual and Analyzer Reading

ulti med TUP U120 Urine Analyzer

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Catalog No.</th>
<th>Components</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>U120 Urine Analyzer</td>
<td>U111-101†</td>
<td>Urine Analyzer</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Strip Holder</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Printer Paper Rolls</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fuses (2.0A)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Power Cord</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Instruction Manual</td>
<td>1</td>
</tr>
<tr>
<td>Printer Paper Rolls</td>
<td>U121-101</td>
<td>Printer Paper Rolls</td>
<td>4</td>
</tr>
</tbody>
</table>

† CE Marked for Sale in the European Community

† Cleared for US 510 (k)