**SUMMARY**

TUP® for Urinary is firm plastic strips to which several different reagent areas are affixed. Depending on the product being used, TUP® provides tests for protein, leukocytes, nitrite, bilirubin, pH, ketone, glucose, ascorbic acid, and specific gravity. 

**REAGENTS**

<table>
<thead>
<tr>
<th>Test</th>
<th>Normal 1</th>
<th>Trace</th>
<th>Small</th>
<th>Moderate</th>
<th>Large</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrite</td>
<td>0-0.3 mg/dL</td>
<td>≤ 0.3 mg/dL</td>
<td>≤ 0.6 mg/dL</td>
<td>≤ 1.0 mg/dL</td>
<td>&gt; 1.0 mg/dL</td>
<td>≤ 2.0 mg/dL</td>
</tr>
<tr>
<td>Protein</td>
<td>0-1.0 g/dL</td>
<td>≤ 1.0 g/dL</td>
<td>≤ 1.5 g/dL</td>
<td>≤ 2.0 g/dL</td>
<td>&gt; 2.0 g/dL</td>
<td>≤ 4.0 g/dL</td>
</tr>
<tr>
<td>pH</td>
<td>4.5-8.5</td>
<td>≤ 4.5</td>
<td>≤ 5.0</td>
<td>≤ 5.5</td>
<td>&gt; 5.5</td>
<td>≤ 6.0</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.000-1.030</td>
<td>≤ 1.000</td>
<td>≤ 1.005</td>
<td>≤ 1.010</td>
<td>&gt; 1.010</td>
<td>≤ 1.020</td>
</tr>
<tr>
<td>Ketone</td>
<td>0-10 mg/dL</td>
<td>≤ 10 mg/dL</td>
<td>≤ 25 mg/dL</td>
<td>≤ 50 mg/dL</td>
<td>&gt; 50 mg/dL</td>
<td>≤ 100 mg/dL</td>
</tr>
<tr>
<td>Glucose</td>
<td>0-200 mg/dL</td>
<td>≤ 200 mg/dL</td>
<td>≤ 300 mg/dL</td>
<td>≤ 500 mg/dL</td>
<td>&gt; 500 mg/dL</td>
<td>≤ 1000 mg/dL</td>
</tr>
</tbody>
</table>

**TEST PROCEDURE**

1. Collect urine in a clean container and test as soon as possible. Do not centrifuge.
2. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. No calculations or laboratory instruments are required. The values on the bottles are nominal values; actual values will vary around the nominal values.
3. Results are obtained by direct comparison of the color blocks on the bottle label. The color blocks represent nominal values; actual values will vary around the nominal values.

**WARNINGS AND PRECAUTIONS**

- TUP® are for in vitro diagnostic use. Do not touch reactive fields.
- Store at room temperature between 15°-30°C and out of direct sunlight. Do not use after expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

Collect urine in a clean container and test as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately after collection and store at room temperature before testing. 

**TEST PROCEDURE**

1. Remove the bottle only enough strips for immediate use and replace cap tightly.
2. Completely immerse reactive areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagents.
3. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over contamination from adjacent reagent pads.
4. Compare each reactive area to its corresponding color block on the color chart and read at all times specified. Proper reading is critical for optimum results.
5. Obtain results by direct color chart comparison.

**QUALITY CONTROL**

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new test is performed or whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

**RESULTS**

- Note: All reagent areas except leukocytes may be read between 1-2 minutes for screening positive urine from negative urine. Changes in color after 2-3 minutes are indicative of significant results.

**REFERENCES**

For a complete listing of references, see the TUP® package insert.

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**Revision J / 2006-03**
Nitrite: Normally no detectable amount of nitrite is present in urine.

The nitrite test is positive in patients with a history of significant infection, depending on how long the urine specimens were retained in the bladder prior to collection. Collection of the specimen must be prompt. False negative results could be obtained with this test. A trace result may be of questionable clinical significance and it is recommended that the test be repeated using fresh sample from the same patient. Repetitive testing is recommended for clinical significance.

Ascorbic Acid: The daily urinary output of ascorbic acids with the intake will be approximately half of the intake. The average urinary output ranges from 20-30 mg. A falsely ascorbic acid by 24-hour collection and retest.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of TUP have been determined both in the laboratory and in clinical tests. Parameters of importance include sensitivity, specificity, accuracy, and precision. Generally TUP have been developed to be specific for the constituents to be measured with the exception of interference listed above. For visually read strips, accuracy is a function of the manner in which the color block on the bottle label is determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that users are encouraged to develop their own standards of performance.

Glucose: This test is specific for glucose; no substances excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose, or reducing metabolites of drugs; e.g. salicylates and acetoacetic acid.

Bilirubin: This test is sensitive to biliary and mucoprotein; a negative result does not rule out the presence of these other proteins. The test area is sensitive to 15 mg/dl albumin.

Ascorbic Acid: There are no chemicals known in urine that affect the Ascorbic Acid test. Ascorbic acid (25 mg/dl or greater) may cause false negative results. Indican, indoxyl sulfates, and metabolites of Lodine may cause false positive or atypical reaction. Drugs containing aromatic amines (e.g., Azo Gastrointestinal) may cause a masking golden color. The absence of unibolinie cannot be determined with this test.

Leukocytes: This test can detect as low as 10-15 leukocytes/µl. This test will not react with erythrocytes or bacteria common in urine.

Ascorbic Acid: This test can detect acetic acid in concentrations as low as 0.01 mg/dl.


Trademark

Lodine is a registered trademark of Wyeth-Ayerst Laboratories. Keflex is a registered trademark of Dista Products Company. Lodine is a registered trademark of Wyeth-Ayerst Laboratories. Keflex is a registered trademark of Dista Products Company.