### REAGENTS

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>16.3mmol/l glucose oxidase (Aspergillus niger, 1.3IU); 0.84mmol/l peroxidase (horseradish, 3200 IU); 7.2% w/w potassium iodide; 76.1% w/w buffer and non-reactive ingredients.</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>0.4% w/w 2,4-dichloronitroaniline diazonium salt, balanced with buffer and non-reactive ingredients.</td>
</tr>
<tr>
<td>Ketone</td>
<td>7.7% w/w sodium nitroprusside balanced with buffer and non-reactive ingredients.</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>2.8% w/w bromothymol blue, 69.0%; poly (methyl vinyl ether/maleic anhydride); 29.2% sodium hydroxide</td>
</tr>
<tr>
<td>Blood</td>
<td>6.6% w/w cumene hydroperoxide; 4.0% w/w 3,3', 5', 5'-tetramethylbenzidine; 89.4% w/w buffer and non-reactive ingredients.</td>
</tr>
<tr>
<td>pH</td>
<td>0.2% w/w methyl red; 2.8% w/w bromothymol blue; 97% w/w buffer and non-reactive ingredients.</td>
</tr>
<tr>
<td>Protein</td>
<td>0.3% w/w tetramethylbenzidine; 99.7% w/w buffer and non-reactive ingredients.</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>2.9% w/w p-dimethylaminobenzaldehyde balanced with buffer and non-reactive ingredients.</td>
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<tr>
<td>Nitrite</td>
<td>1.4% w/w p-aminosalicyclic acid, balanced with buffer and non-reactive ingredients.</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>0.4% w/w indoxyl ester derivative; 0.25%w/w diazomium salt; 99.4% w/w buffer and non-reactive ingredients.</td>
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<tr>
<td>Ascorbic Acid</td>
<td>5.8% w/w ferric chloride; 4.9% w/w DTPA; 1.2% dipyridyl; 89.1% w/w buffer and non-reactive ingredients.</td>
</tr>
</tbody>
</table>

### QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls 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

Results are obtained by direct comparison of the color blocks printed on the bottle label. The color blocks represent nominal values; actual values will vary around the nominal values.

### LIMITATIONS OF PROCEDURE

Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Specific Gravity</th>
<th>Blood</th>
<th>pH</th>
<th>Protein</th>
<th>Urobilinogen</th>
<th>Nitrite</th>
<th>Ketone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>Moderate amounts of ketone bodies (40mg/dl, or greater) may decrease color development in urine containing small amounts of glucose (75-125 mg/dl). However, such concentration of ketone simultaneously with such glucose concentration is metabolically improbable in screening. The reactivity of the glucose test decreases as the SG and/or ascorbic acid of the urine increases. Reactivity may also vary with temperature.</td>
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<tr>
<td>Bilirubin</td>
<td>Reactions may occur with urine containing large doses of chloropromazine or ramafam that might be mistaken for positive bilirubin.</td>
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<tr>
<td>Ketone</td>
<td>Color reaction that could be interpreted as “positive” may be obtained with urine specimens containing MESNA or large amounts of phenyketonuric or L-dopa metabolites.</td>
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<tr>
<td>Specific Gravity</td>
<td>The chemical nature of the specific gravity test may cause slightly different results from those obtained with the specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urine may cause false low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dl) of protein.</td>
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<tr>
<td>Blood</td>
<td>The sensitivity of the blood test is reduced in urine with high specific gravity and/or high ascorbic acid content. Microbial peroxidase, associated with urinary tract infection may cause false positive reactions.</td>
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<tr>
<td>pH</td>
<td>If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as “running over” may occur, in which the acid buffer from the protein reagent area run onto the pH area, causing a false lowering in the pH result.</td>
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<tr>
<td>Protein</td>
<td>False positive results may be obtained with highly alkaline urine. Contamination of the urine specimen with quaternary ammonium compounds may also produce false positive reactions.</td>
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<tr>
<td>Urobilinogen</td>
<td>The test area will react with interfering substances known to react with Ehrlich’s reagent, such as p-hydroxybenzoic and p-aminosalicyclic acid. This test is not a reliable method for the detection of p-hydroxybenzoic. Drugs containing azo-dyes (e.g. Azo Gantrex) may give a masking golden color. The absence of unrobilinogen cannot be determined with this test.</td>
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<tr>
<td>Nitrite</td>
<td>The pink color is not quantitative in relation to the number of bacteria present. Any degree of pink coloration should be interpreted as a positive nitrite test suggestive of 105 or more bacteria present. Any degree of pink coloration should be interpreted as a positive nitrite test suggestive of 105 or more bacteria present.</td>
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</table>

### SPECIMEN COLLECTION AND PREPARATION

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

### TEST PROCEDURE

1. Remove from the bottle only enough strips for immediate use and replace cap tightly.
2. Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
3. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. But 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 reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results.
5. Obtain results by direct color chart comparison.

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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 minutes are of no diagnostic value.
Urine. The nitrite area will be positive in a proportion of cases of
Nitrite. A result of 2.0 EU/dl may be of clinical significance and the same
Urobilinogen. Clinical judgment is needed to evaluate the significance
color block even though only normal concentrations of protein are
specific gravity, the test area may most closely match the trace
than trace indicates significant proteinuria. For urine with high
Ketone. Possibly masking the bilirubin reaction.
Derived bile pigments are present in the urine sample and are
Color Chart) may indicate that bilirubin derived bile pigments are present in the urine sample and are possibly masking the bilirubin reaction.

Any green spots or green color developing on the reagent
area within 40 seconds is significant and the urine should be
examined further. Blood is frequently, but not invariably found in the
urine of menstruating females.

The pH of blood: more than 50 mg/dl ascorbic acid in the sample.
Glucose. A test sensitive to free hemoglobin of 0.015 mg/dl or 5-10
inherent variability in clinical urine lesser concentration may be
result does not rule out the presence of these other proteins. The
specific gravity test area is not affected by variation in the urinary buffer concentration.

Leukocytes: Normal urine specimens generally yield negative
results with this test. A trace result may be of questionable clinical
Ascorbic Acid: The daily urinary output of ascorbic acid varies with
the intake; output is approximately half the intake. The average
urinary output ranges from 20-30 mg/day. If ascorbic acid is
detected in urine, stop taking ascorbic acid for 24 hours and retest.
False negative and weak reaction of glucose, blood and bilirubin may be observed if:

Glucose: more than 50 mg/dl ascorbic acid in the sample.
Bilirubin: more than 50 mg/dl ascorbic acid in the sample.
Blood: more than 10 mg/dl ascorbic acid in the sample.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**The performance characteristics of UreChek™ HealthScreen-10
urine reagent strips have been determined both in the laboratory
and in clinical tests. Parameters of importance to the user
are sensitivity, specificity, accuracy, and precision. Generally,
HealthScreen-10 urine reagent strips have been developed to be
specific for the constituent to be measured with the exception of
interferences listed above.** (See LIMITATIONS OF PROCEDURE)

For visually read strips, accuracy is a function of the manner
in which the color blocks on the bottle label are 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 naltrexone.

**Bilirubin:** The test has a sensitivity of 0.4-0.8 mg/dl bilirubin in urine. The test is considered specific for bilirubin in urine.

**Ketone:** The ketone test area provides semi-quantitative results and reacts with acetoacetic acid in urine. This test does not react with beta-hydroxybutyric acid or acetone. The reagent area detects as little as 5-10 mg/dl acetoacetic acid in urine.

**Specific Gravity:** The specific gravity test permits determination of urine specific gravity between 1.000 and 1.030. In general, the specific gravity test correlates within 0.005 with values obtained with the reflective index method.

**Blood:** At the time of reagent manufacture, this test when read as
instructed has sensitivity to free hemoglobin of 0.015 mg/dl or 5-10
intact red blood cells/µL urine. This test is slightly more sensitive to
free hemoglobin and myoglobin than to intact erythrocytes.

**pH:** The pH test area permits quantitative differentiation of pH
values to one unit within the range of 5-9. pH reading is not
affected by variation in the urinary buffer concentration.

**Protein:** The test area is more sensitive to albumin than to globulin,
hemoglobin, Bence-Jones proteins, and mucoprotein; a negative
result does not rule out the presence of these other proteins. The
area is sensitive to 15 mg/dl albumin. Depending on the
inherent variability in clinical urine lesser concentration may be
detected under certain conditions.

**Urobilinogen:** This test will detect urobilinogen in concentrations
as low as 0.2 EU/dl in urine. The absence of urobilinogen in the
specimen being tested cannot be determined with this test.

**Nitrite:** At the time of reagent manufacture, this test has sensitivity
to sodium nitrite of 0.075 mg/dl. Comparison of the reacted
reagent area on a white background may aid in the detection of
low levels of nitrite ion, which may otherwise be missed. This test
is specific for nitrite and will not react with substances normally
excreted in the urine.

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

**Ascorbic Acid:** This test can detect ascorbic acid in concentrations
as low as 10 mg/dl in urine.

**EXPECTED VALUES**

**Glucose:** Small amounts of glucose are normally excreted by the
kidney.4 Concentrations as little as 0.1 g/l glucose, read
either at 10 or 30 seconds, may be significantly abnormal if
found consistently. At 10 seconds, results should be interpreted
qualitatively; for semi-quantitative results, read at 30 seconds only.

**Bilirubin:** Normally, bilirubin is detectable in urine by even
the most sensitive method. Even trace amounts of bilirubin are
sufficiently abnormal to require further investigation. Atypical colors
(colors produced which are different than the negative or positive
color blocks shown on the Color Chart) may indicate that bilirubin
derived bile pigments are present in the urine sample and are
possibly masking the bilirubin reaction.

**Ketone:** Normally, no ketones are present in urine. Detectable
levels of ketone may occur in urine during physiological stress
conditions such as fasting, pregnancy, and frequent strenuous exercise.6 In starvation diets, or in other abnormal carbohydrate
metabolism situation, ketones appear in the urine in excessively
large amounts before serum ketones are elevated.6

**Specific Gravity:** Random urine may vary in specific gravity from
1.003-1.040+. Twenty-four hour urine from normal adults with
normal diets and normal fluid intake will have a specific gravity of
0.016-1.022. In severe renal damage the specific gravity is fixed
at 1.010, the value of the glomerular filtrate.

**Blood:** Any green spots or green color developing on the reagent
area within 40 seconds is significant and the urine should be
examined further. Blood is frequently, but not invariably found in the
urine of menstruating females.

**pH:** newborn: 5-7 thereafter: 4.5-8 average: 6.3

**Protein:** In 24-hour urine, 1-14 mg/dl of protein may be excreted
by the normal kidney.4 A color matching any color block greater
than trace indicates significant proteinuria. For urine with high
specific gravity, the test area may most closely match the trace
color block even though only normal concentrations of protein are
present. Clinical judgment is needed to evaluate the significance
of trace results.

**Urobilinogen:** In a healthy population, the normal urine
ubrobilinogen range obtained with this test is 0.2-1.0 Enricht Unibit.
A result of 2.0 EU/µl may be of clinical significance and the same
patient sample should be evaluated further.

**Nitrate:** Normally no detectable amount of nitrite is present in urine.7 The nitrite area will be positive in a proportion of cases of
significant infection, depending on how long the urine specimens
were retained in the bladder prior to collection. Retrieval of positive
cases with the nitrite test range from as low as 40%, in instances
where little bladder incubation occurred, to as high as 80% in
instances where a minimum of 4 hours incubation occurred.

**Leukocytes:** Normal urine specimens generally yield negative
results with this test. A trace result may be of questionable clinical
significance and it is recommended that the test be repeated using
a fresh sample from the same patient. Repeated trace and positive
results are of clinical significance.

**Ascorbic Acid:** The daily urinary output of ascorbic acid varies with
the intake; output is approximately half the intake. The average
urinary output ranges from 20-30 mg/day. If ascorbic acid is
detected in urine, stop taking ascorbic acid for 24 hours and retest.
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**Bilirubin:** more than 50 mg/dl ascorbic acid in the sample.

**Blood:** more than 10 mg/dl ascorbic acid in the sample.

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