**Intended Use**

Accutest® URS-10 Urine Reagent Strips for Urinalysis are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis. Accutest® URS-10 Urine Reagent Strips are for single use in professional near patient (point-of-care) facilities, and certified laboratory locations by medical technologists who read visually and on the Accutest 50 and Accutest 500 urine analyzers and the Bayer Clinitek® 50, 100, 200, and 500 analyzers.

**Summary and Explanation of Tests**

Accutest® URS-10 Urine Reagent Strips provide tests for Glucose, Bilirubin, Ketone (acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in Urine.

**Test Principles**

**Urobilinogen:** this test is based on the Ehrlich reaction in which p-diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

**Bilirubin:** The direct bilirubin and dichlorobenzene diazonium produce fuchsia azo dyes in a strongly acid medium.

**Ketone:** The reaction in the alkaline medium, which produces a violet color.

**Blood:** Hemoglobin acts as a peroxidase. It can cause peroxidase to release neo-ecotypes oxide [O]. [O] oxidizes the indicator and causes the color change.

**Nitrite:** The test is based on the protein-error-of-indicators principle. An ion in the specific pH indicator attracted by a cation on the protein molecule makes the indicator further ionized, which changes its color.

**Nitrile:** Nitrile in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h)quinolin 3-phenol causes the color change.

**Leukocytes:** Granulocyte leukocytes in urine contain esterase that catalyzes the hydrolysis of the pyrrole amino acid ester to liberate 3-hydroxy-5-pyrrrole. This pyrrrole reacting with diazonium form a purple color.

**Glucose:** The glucose oxidized by glucose oxidase catalyzes the formation of gluconic acid and peroxide hydrogen. Peroxide hydrogen releases neo-ecotypes oxide [O] under the function of peroxidase. [O] oxidizes iodide potassium, which causes the color change.

**Specific Gravity:** Electrolyte (M’X) in the form of salt in urine reacts with poly vinyl ether and maleic acid (–COOH), which is a weak acid ionic exchanger. The reaction produces hydrogenous ionogen, which reacts with a pH indicator that causes the color change.

**pH:** This test is based on a double indicator principle that gives a broad range of colors covering the entire urine pH range.

**Reactive Ingredients**

- **Urobilinogen:** 0.2% w/w fast blue B salt; 98.0% w/w buffer; 1.8% w/w nonreactive ingredients.
- **Bilirubin:** 0.6% w/w 2,4-dichlorobenzene amines diazonium salt; 57.3% w/w buffer; 42.1% w/w nonreactive ingredients.
- **Ketone:** 5.7% w/w sodium nitroprusside; 64.4% w/w buffer; 29.9% w/w nonreactive ingredients.
- **Blood:** 26.0% w/w disopropylbenzenedi hydro peroxide; 1.5% w/w tetramethyl-benzidine; 35.3% w/w buffer; 37.2% w/w nonreactive ingredients.
- **Nitrite:** 9.0% w/w sodium nitroprusside; 97.4% w/w buffer; 2.0% w/w nonreactive ingredients.
- **Nitrile:** Nitrile in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h)quinolin 3-phenol causes the color change.
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**Quality Control**

Test positive and negative commercial quality controls with each new lot, new shipment of reagent strips, and when you open a new bottle of reagent strips. Test reagent strips monthly that are stored for more than 30 days. Run positive and negative commercial QC to ensure reagent strip storage integrity; train new users; confirm test performance; and when patients’ clinical conditions or symptoms do not match the results on the test strip. Also, run QC tests per your laboratory procedures. Do not use water as a negative control. For recommendations of control materials and technical questions, call (800) 676-5565, Monday-Friday 8:00am-5:00pm (PST) Compare your QC results to the acceptable results list in the QC manufacturer’s labeling. If the QC results are not acceptable, do not test the patient samples until you solve the problem. Repeat QC tests once. If results are still unacceptable, call (800) 676-5565

**Important Notes**

1. Do not take the strips from the bottle unless they are for immediate use.
2. Do not touch reagent areas of strips.
3. Do not use strips beyond the expiration date.
4. Each strip can be used only once.
5. Large amounts of ascorbic acid may effect the test for glucose, bilirubin, nitrite, and blood [2,4].
6. Deterioration may result in discoloration or darkening of the reagent areas of the strip. If this happens, or the test results are questionable or inconsistent with expected results, check and make sure the strips are within the expiration date, and also check results with the control urine.

**Limitations**

Urobilinogen: The reagent area may react with interfering substances, such as sulfonamides. Atypical color reactions may be obtained in the presence of high concentrations of p-aminoalicylic acid. False negative results may be obtained if formalin is present and the specimen has been in direct sunlight. The test is not a reliable method for the detection of porphobiligen in [4].

**Bilirubin:** Medicines that dye urine red and anything that shows red in an acid medium (e.g., phenazopyridine) may affect the test result. A high concentration of ascorbic acid (49mg/dL) may cause a false negative result.

**Ketone:** False positive results may occur in highly pigmented urine or those specimens containing a large amount of levodopa metabolites [2].

**Blood:** Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. A high specific gravity in urine may reduce the sensitivity of the test [2]. Protein: False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g., from some antisepsics and detergents) or with cleaners containing chlorhexidine may also produce false positive results [2,4].

**Nitrite:** A negative result does not rule out significant bacteriuria. False negative results may occur (1) when urine does not contain the organism that caused the conversion from nitrate to nitrite, (2) when urine has not remained in the bladder long enough (up to four hours) for the nitrate to convert into nitrite, or (3) when nitrate in foods is absent. A high specific gravity of
Glucose: A high glucose concentration (2000mg/dL) or a high specific gravity in urine may reduce the sensitivity of the test. High concentration of osmotic acid may cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of tetracycline may cause a false negative reaction [2].

Leukocytes: Ascorbic acid concentrations of 10.2mg/dL and/or acetoacetic acid concentrations of 19.4mg/dL or lower will not influence the test [2].

Specific Gravity: Urine nonionic constituents such as glucose or highly buffered alkaline urine may produce low readings compared to other methods. Elevated specific gravity readings may occur in the presence of moderate quantities of protein (750mg/dL). The reagent strip is not suitable for testing newborn because of their low specific gravity (1.002-1.004) [4].

pH: Bacterial growth in a specimen may cause a marked alkaline shift (+8.0), usually because of urea conversion to ammonia.

Expected Values/Reference Ranges
Expected values for a “normal” healthy population and abnormal populations are listed below for each test. Expected values are referenced to European Urinalysis Guidelines, The Clinical Analysis Of Urine Recent Period and Compendium – Urinalysis With Test Strips [2,4,5].

<table>
<thead>
<tr>
<th>Test Pad</th>
<th>Sensitivity</th>
<th>Output Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Instrumental Read</td>
<td>Visual Read</td>
</tr>
<tr>
<td>Urobilogen (mg/dL)</td>
<td>0.2-1.0</td>
<td>—</td>
</tr>
<tr>
<td>Bilirubin (mg/dL)</td>
<td>0.2-0.5</td>
<td>Negative - Large</td>
</tr>
<tr>
<td>Ketone (mg/dL)</td>
<td>5-10</td>
<td>Negative - 80</td>
</tr>
<tr>
<td>Blood (Ery/µL)</td>
<td>5-15</td>
<td>Negative - 200</td>
</tr>
<tr>
<td>Protein (mg/dL)</td>
<td>15-30</td>
<td>Neg - 300</td>
</tr>
<tr>
<td>Nitrite (mg/dL)</td>
<td>0.08-0.1</td>
<td>Negative - Positive</td>
</tr>
<tr>
<td>Leukocytes (Leu/µL)</td>
<td>5-15</td>
<td>Negative - 500</td>
</tr>
<tr>
<td>Glucose (mg/dL)</td>
<td>50-100</td>
<td>Negative - 1000</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>—</td>
<td>1.005 - 1.030</td>
</tr>
<tr>
<td>pH</td>
<td>—</td>
<td>5.0 - 8.5</td>
</tr>
</tbody>
</table>

Performance Characteristics
The performance characteristics of the strips are determined by clinical analysis and study. The results from visual readings and instrumental readings represent an actual range of analyte concentrations. Because of the variety of the specimens and reading methods, the values obtained from the results of tests may have errors compared to the actual values of the specimens. Visual reading results may not exactly match the instrumental reading results because of the inherent difference between the perception of human eyes and the optical instruments.

The following table shows the +/-1 color block % Agreement using 1514 samples in laboratory comparison studies between AccuTec® URS-10 Urine Reagent Strips and Bayer Multistix 10 SG Reagent Strips.

<table>
<thead>
<tr>
<th>% Agreement</th>
<th>Analyte</th>
<th>% Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urobilogen</td>
<td>98.2% (1486/1514)</td>
<td>Bilirubin 97.6 % (1477/1514)</td>
</tr>
<tr>
<td>Ketone</td>
<td>98.6 % (1492/1514)</td>
<td>Blood 96.3 % (1458/1514)</td>
</tr>
<tr>
<td>Protein</td>
<td>99.9 % (1513/1514)</td>
<td>Nitr 98.2 % (1487/1514)</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>98.6 % (1492/1514)</td>
<td>Glucose 96.9 % (1467/1514)</td>
</tr>
<tr>
<td>pH</td>
<td>89.0 % (1348/1514)</td>
<td>Specific Gravity 95.2 % (1441/1514)</td>
</tr>
</tbody>
</table>

Urobilogen: This test can detect urobilinogen in concentrations as low as 0.2mg/dL (approximately 0.2 EU/dL); therefore, most normal urines will give a slightly pink reaction. The absence of urobilogen in the specimen cannot be determined.

Bilirubin: The test has a sensitivity of 0.5mg/dL. Bilirubin in urine indicates liver disease before any clinical signs are usually evident.

Ketone: In 90% of urine tested, acetooacetate acid at 5.0mg/dL will produce a positive reaction. The strip does not react with hydroxybutyric acid and acetone and acetoacetic acid.

Blood: The test is specific for hemoglobin and myoglobin. In 90% of urines tested, hemoglobin or erythrocytes concentrations of 5 Ery/µL will produce a positive result.

Protein: In 90% of urines tested, albumin concentrations of 0.15 µL or greater will produce a color change. The test pad is more sensitive to albumin than globulin, Bence-Jones proteins, and macromolecules.

Nitrite: The test has a sensitivity of 0.08-0.1 mg/dL nitrite ion in urine of normal excreted in urine. Comparison of the reacted area against a white background may aid in the detection of low levels of nitrite. A negative result doesn't mean the existence of bacteria in a large amount. A negative result may occur (1) when urine doesn't contain organisms that cause the conversion from nitrite to nitrate; (2) when urine has not remained in the bladder long enough (four hours or more) to let the nitrate convert into nitrite; or (3) the nitrate in foods is absent.

Leukocytes: Urinary tract infection in up to 90% of all patients can be detected by analysis of random urine specimens. A positive reaction (small or greater) at less than the 2 minutes reading time may be regarded as a positive indication of leukocytes in urine.

Glucose: In 90% of urines tested, glucose concentrations of 80 mg/dL or greater will produce a positive result. Sugars other than glucose will not react with the reagent. If the color appears somewhat mottled at the higher glucose concentrations, match the darkest color to the blocks.

Specific Gravity: The reagent strips test urine specimens for specific gravity between 1.000 and 1.030. In general, the mean error between the results of the strip test and results from the refractive index method is only 0.005. For increased accuracy 0.005 may be added to readings from urine samples with pH equal to or greater than 6.5. Strips read instrumentally are automatically adjusted for pH by the instrument.

pH: Strip test for pH measure test values from pH 5.0-8.5 visually and 5.0-8.5 instrumentally generally to within one level of the expected result.

The sensitivity of the strips on clinical urine specimens may vary depending upon several factors, such as the variability of color perception, specific gravity, pH value, and the lighting conditions when the strips are read visually. Test sensitivities and output values are given in the following table.

Bibliography
5. "Compendium – Urinalysis with Test Strips" Roche Diagnostic, Combur® Reagent Strips.

Notes on Symbols and Marks
- Store At
- Batch Code
- Use By (expiration date)
- In Vitro Diagnostic Use
- Please Read Package Insert
- Rev.: AUG 2012

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