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 centralized laboratory locations by medical technologists both read visually and on the Bayer Clin-tek 50, 100, 200, and 500 analyzers.

Accutest® URS-10 Urine Reagent Strips Strips for Urinalysis are intended for use to detect conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

Summary and Explanation of Tests
Accutest® URS-10 Urine Reagent Strips provide test glouces, Bilirubin, Ketone (acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrte and Leukocytes in Urine.

Test Principles
Urobilinogen: this test is based on the Ehrlich reaction in which 2- diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strong acid medium to produce a pink-red color.

Bilirubin: the direct bilirubin and dichlorobenzene diazonium produce fuchsa azo dyes in a strongly acid medium.

Ketone: the acetoacetate and sodium nitroprusside cause a reaction in the alkaline medium, which produces a violet color.

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

Protein: 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.

Nitrite: Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazium compound. The diazium compound reacting with tetrahydro benzeno hydroquinone-3 phenol causes the color change.

Leukocytes: Granulocyte leukocytes in urine contain esterase that catalyze the hydrolysis of the pyrrole acid amino ester to liberate 3-hydroxy-5-pheny pyrole. This pyrole reacting with diazonium forms a purple color.

Glucose: The glucose oxidized by glucose oxidase catalyzes the formation of gluconic acid and peroxide hydrogen. Peroxide hydrogen reacts

Specific Gravity: Electrolyte (M’) in the form of salt in urine reacts with poly methyl vinyl ether and maleic acid (COOH), which is a weak acid isonic exchanger. The reaction produces hydrogenous ionogen, which reacts with the indicator to produce a color change.

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

Reactive Ingredients (based on dry weight at time of impregnation)

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 amine diazonium salt; 57.3% w/w buffer; 42% 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 disopropyl/benzene dihydro peroxide; 1.5% w/w tetramethyl benzone; 35.3% w/w buffer; 37.2% w/w nonreactive ingredients.

Protein: 0.1% w/w p-arsanilicacid-N-(1-Naphthol)-ethylendiamine; 0.9% w/w tetrahydro -quinolone; 89.6% w/w buffer; 8.2% w/w nonreactive ingredients.

Nitrite: 1.3% w/w p-arsanilicacid-N-(1-Naphthol)-ethylendiamine; 0.9% w/w tetrahydro -quinolone; 89.6% w/w buffer; 8.2% w/w nonreactive ingredients.

Leukocytes: 4.3% w/w pyrrole amino acid ester; 0.4% w/w diazonium salt; 92.6% w/w buffer; 2.0% w/w nonreactive ingredients.

Glucose: 1.7% w/w glucose oxidase (microbial, 123U); 0.2% w/w peroxide (boroshardt, 2030U); 71.8% w/w buffer; 0.1% w/w potassium acid; 26.2% w/w nonreactive ingredients.

Specific Gravity: 4.8% w/w bromothymol blue; 90.2% w/w poly (methyl vinyl ether co malic anhydride); 5.0% w/w sodium hydroxide.

pH: 3.3% w/w bromoresol green; 55.0% w/w bromothymol blue; 41.7% w/w nonreactive ingredients.

Storage
Strips must be kept in the original bottle. Transfer to any other container may shorten the expiration date of product. Store at temperatures between 2-30 degrees C (39-86 degrees F). Keep away from direct sunlight and moisture. Do not remove desiccants in the bottles. Replace the cap immediately after removing reagent strips. Protect against exposure to light, heat, and ambient moisture to guard against altered reagent reactivity.

Specimen Collection and Preparation
Collect fresh urine in a clean and dry container. Do not centrifuge the urine. Mix the sample well before testing it [1]. The container should allow for complete dipping of all reagent strip areas. Test the urine within four hours after voiding, sooner if testing for bilirubin or urobilinogen [2].

Expected Results
The sensitivity of Accutest® URS-10 Urine Reagent Strips for Urinalysis in testing clinical urine specimens may vary depending upon several factors, such as the variability of color perception, specific gravity, pH values, and the lighting conditions when strips are read visually. Visual reading results may not exactly match instrumental reading results because of the difference between the perception of human eyes and the optical instrument. Most visual and instrument readings are within one level of the true value.

Procedure
Gather Materials
- Dry and clean plastic container
- Toilet paper
- Stopwatch (if you read the strip visually)

Perform Tests
1. Immers eth reagent area of the strip in the urine specimen and take it up quickly and immediately. Start timing if reading visually.
2. Run the edge of the strip against the rim of the container to remove excess urine. Lay the strips on a paper towel with the reagent areas upward.
3. If reading visually, hold the strip up horizontally and compare the reagent areas on the strip to the corresponding color chart on the bottle label at the exact times specified and in good light. Hold the strips close to the color blocks and match carefully. Make note of the result.

Quality Control
Remove one strip from the bottle and check against the color blocks on the color chart. If the color of the reagent area is darker than the lowest block on the chart (except for specific gravity and pH), the strip is unusable. Discard the strip and check all strips from the bottle before using or discard the bottle. When a new bottle is first opened, use two strips to test known negative and positive specimens or controls. Water should NOT be used as a negative control.

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 paminosalicylic 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 phorphobilinogen [4].

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

Ketone: False positive tests 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 cleansers containing chlorhexidine may also produce false positive results [2,4].

Nitrite: A negative test 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 nitrite to nitrite, (2) when urine has not remained in the bladder long enough (up to four hours) for the nitrite to convert into nitrite, or (3) when nitrate in foods is absent. A high specific gravity of urine may reduce the sensitivity of the test. A 17g/dL concentration of ascorbic acid or less will not affect the test result [2,4].
Leukocytes: A high glucose concentration (2000mg/dL) or a high specific gravity in urine may reduce the sensitivity of the test. High concentration of caecal may cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of tetracycline may cause a false negative result [2].

Glucose: Ascorbic acid concentrations of 4.9 mg/dL and/or ascorbate acid concentrations of 19.4mg/dL or lower will not influence the test [2]. Specific Gravity: Urine with high concentrations such as glucose or highly buffered alkaline urine may produce low readings compared to other methods. Elevated specific gravity readings may be present in the presence of moderate quantities of protein (100mg/dL). The reagent strip is not suitable for testing newborn since 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 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].

Urobilinogen: Urobilinogen is normally present in urine at concentrations up to 1.0 mg/dL (1.0 Ehrlich unid). A level of 2mg/dL in urine is the critical value, representing the transition from normal to abnormal, which requires a further check on patients and specimens. Evaluation of both the bilirubin and urobilinogen results helps in the differential diagnosis of jaundice, as well as other liver and biliary disorders.

Bilirubin: Normally, only the most sensitive method cannot detect bilirubin in healthy urine. It is abnormal to have even a little bilirubin in urine, which requires further inspection.

Ketone: Normal urine specimens usually produce negative results in the test. In ketoadiposis, starvation, fasting, pregnancy and frequent strenuous exercise, ketones may appear in urine and may produce positive results [4].

Blood: The ‘trace’ reaction may vary among patients. Clinical judgments are required for individual cases. The presence of green spots (intact erythrocytes) or green color (hemoglobin/myoglobin) on the reagent area within 60 seconds after dipping indicates the need for a further diagnostic check. Erythrocytes are often, but not always, found in the urine of menorrhagia.

Protein: The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones protein, and mucoprotein. Therefore a ‘Negative’ Result is not sufficient to indicate that these proteins do not exist in normal urine. Normally protein is not detectable in urine with conventional methods, although a minute amount of protein is excreted by normal kidney function. Protein in urine is indicated when the color is darker than the plus/minus mark on the chart.

Nitrite: Nitrate-negative bacteria in urine converts nitrate (derived from foods) into nitrite. The reagent is specific to nitrite and will not react with other substances in urine. Any degree of uniform pink color development should be taken as a positive result. The degree of color development and the number of bacteria are not in direct proportion.

Leukocytes: The reagent area of the strip reacts with enzymes in leukocytes (granulocyte leukocytes). Normal urine specimens generally yield negative results. Positive results (+ or greater) are clinically significant. Individual ‘trace’ results are clinically questionable, and it is very important that ‘trace’ results be confirmed in a repeated test.

Ketone: Normally, a small amount of glucose may be excreted through the kidneys. The amount is usually below the sensitivity of the reagent test. Results at the first positive level may be significantly abnormal if found consistently.

Blood: The reagent area is less sensitive to albumin than to globulins, erythrocytes or high levels of bilirubin in urine. The critical value may cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of tetracycline may cause a false negative reaction [2].

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 motled 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 readings represents 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.

Sensitivity and Output Values of Accutest(R) URS-10 Urine Reagent Strips

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<tr>
<th>Test Pad</th>
<th>Sensitivity</th>
<th>Output Value</th>
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<tbody>
<tr>
<td></td>
<td>Instrumental Read</td>
<td>Visual Read</td>
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<tr>
<td>Urobilinogen (mg/dL)</td>
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<td>0.2 - 8.0</td>
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<tr>
<td>Bilirubin (mg/dL)</td>
<td>0.2-0.5</td>
<td>Negative - Large</td>
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<tr>
<td>Ketone (mg/dL)</td>
<td>5-10</td>
<td>Negative - 160</td>
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<tr>
<td>Blood (Gr/L)</td>
<td>5-15</td>
<td>Negative - 200</td>
</tr>
<tr>
<td>Protein (mg/dL)</td>
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<td>Negative - 2000</td>
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<td>Nitrite (mg/dL)</td>
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<td>Leukocytes (Euc/L)</td>
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<td>Glucose (mg/dL)</td>
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<tr>
<td>pH</td>
<td>5.0 - 8.5</td>
<td>5.0 - 8.5</td>
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Notes on Symbols and Marks

4. “Compendium – Urinalysis with Test Strips” Roche Diagnostic, Combur® Reagent Strips.

References:

5. “Compendium – Urinalysis with Test Strips” Roche Diagnostic, Combur® Reagent Strips.