SUMMARY
Urine Reagent Strips (URS) for Urinalysis are firm plastic strips to which several different reactant areas are affixed. Depending on the product being used, Urine Reagent Strips provide tests for Glucose, Bilirubin, Ketone (Acetooxidizable acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes, and Ascorbic Acid in urine.

TEST PRINCIPLE
Glucose: This test is based on a double sequential enzymatic reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide to oxidize the chromogen to colors ranging from blue-green to greenish-brown through brown and dark brown.

Ketone: This test is based on the reaction of acetocetic acid with potassium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a “Positive” reading to pink and pink-purple for a “Negative” reading.

Specific Gravity: This test is based on the apparent pka-change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low tonic concentration to pink-purple for a “Positive” reading.

Blood: This test is based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction of 3,3',5,5'-tetramethylbenzidine diazonium salt with hydrogen peroxide from the oxidation of glucose. The resulting colors range from orange to yellow-green and dark green.

pH: This test is based on the well known double indicator method, where bromoindigotriol blue and bromoindigo red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.

Protein: This test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein substrates range from yellow for a “Negative” reaction to yellow-green and blue-green for a “Positive” reaction.

Urobilinogen: This test is based on a modified Ehrlich reaction in which p-diphenylbenzaldehyde reacts with urobilinogen in a strongly acid medium. The colors range from light pink to bright magenta.

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrate reacts with p-arsanilic acid to form a diazotization compound in an acid medium. The diazonium compound in turn coupled with 1,2,3,4-tetrahydrobenzoi(h)quinolin to produce a pink color.

Leukocytes: This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.

Ascorbic Acid: This test is based on the action of a complex clotting agent with a polyanion metal ion in its higher state and an indicator dye that can react with the metal ion in its lower state to produce a color change from blue-green to yellow.

REAGENTS (Basis on dried weight at time of impregnation)
Glucose: 16.3%/w glucose oxidase (Aspergillus niger, 1.3U); 0.6%/w peroxidase (horseradish, 3300 IU); 7.7%/w sodium nitroprusside; 97.1%/w buffer and non-reactive ingredients.

Bilirubin: 0.4%/w 2,4-dichloroaniline diazotium salt, balanced with buffer and non-reactive ingredients.

Ketone: 7.7%/w sodium nitroprusside balanced with buffer and non-reactive ingredients.

Specific Gravity: 2.8%/w bromomylotol blue, 69.0%; poly (methyl vinyl ether/maleic anhydride), 29.2%; sodium hydroxide

Blood: 6.6%/w cumene hydroperoxide; 4.0%/w 3', 5', tetramethylbenzidine; 89.4%/w buffer and non-reactive ingredients.

pH: 0.2%/w methyl red; 2.8%/w bromomylotol blue; 97%/w non-reactive ingredients.

Protein: 0.3%/w tetrabromophenol blue; 99.7%/w buffer and non-reactive ingredients.

Urobilinogen: 2.9%/w p-diphenylbenzaldehyde balanced with buffer and non-reactive ingredients.

Nitrite: 1.4%/w p-arsanic acid, balanced with buffer and non-reactive ingredients.

Leukocytes: 0.4%/w indoxyl ester derivative; 0.2%/w diazonium salt; 99.4%/w buffer and non-reactive ingredients.

Ascorbic Acid: 5.8%/w ferric chloride; 9.4%/w DTPA; 1.2%/ w/dipryridyl; 89.1%/w buffer and non-reactive ingredients.

WARRANTS AND PRECAUTIONS
Urine Reagent Strips are for in vitro diagnostic use. Do not touch test areas of Urine Reagent Strips.

STORAGE
Store at room temperature between 15°-30°C (59°-86°F) and out of direct sunlight. Do not use after expiration date.

RECOMMENDED HANDLING PROCEDURES
All unused strips must remain in the original bottle. Transfer to any test area of Urine Reagent Strips after removing the strip from the plastic bottle with a twist-off cap. 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.

TEST PROCEDURE
1. Remove from the bottle only enough strips for immediate use and replace cap tightly.

2. Completely immerse the reagent area of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid drying. Do not remove from the package.

3. While removing, touch the side of the strip against the rim of the test area of Urine Reagent Strips.

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.

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 of are of no diagnostic value.

QUALITY CONTROL
For best results, performance of reagent strips should be confirmed by testing known positive and negative 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 an 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. Glucose: Moderate amounts of ketone bodies (400mg/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 reaction of the glucose test decreases as the SG and/or ascorbic acid of the urine increases. Reactivity may also vary with temperature.

Bilirubin: Reactions may occur with urine containing large doses of chlorpromazine or rifampin that might be mistaken for positive bilirubin. Indoxyl (indoxyl sulfate) and metabolites of Lodine® may cause false positive or atypical color; ascorbic acid (25mg/dL or greater) may cause false negative results.
**SPECIFIC PERFORMANCE CHARACTERISTICS**

The performance characteristics of Urine Reagent Strips (URS) have been determined both in the laboratory and in clinical settings. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, Urine Reagent Strips (URS) 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 or read on a fresh sample from the same patient. *Post-test sample should be considered as positive if no glucose is detected.* The reagent area does not react with lactose, galactose, fructose, or reducing metabolites of drugs; e.g. salicylates and naldixic acid. This test may be used to determine whether the reducing substances found in urine is glucose. Approximately 100 mg/dl glucose in urine is detectable. Bilirubin: The test has a sensitivity of 0-0.8 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 diacetoacetate or with beta-hydroxybutyrate. This test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

**Ph:** The pH test area permits qualitative differentiation of pH value to within the range of 5.6. pH variation is not affected by variation in the urinary buffer concentration.

**Blood:** The test reaction area is positive for more than 10 mg/dl ascorbic acid in the sample. This test can detect ascorbic acid in concentrations as low as 10 mg/dl in urine.

**BIBLIOGRAPHY**


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

**Nitrite:** Nitrite is a registered trademark of Vychet-Ayurved Laboratories. *Post-test sample should be considered as positive if no nitrite is detected.*

**Bilirubin:** Bilirubin is a registered trademark of Roche Laboratories. *Post-test sample should be considered as positive if no bilirubin is detected.*