Urine Reagent Strips for Urinalysis

**SUMMARY**

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

**TEST PRINCIPLE**

**Glucose:** This test is based on a double 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 and tetrahydrobenzo(h)quinolin to produce a pink color.

**Bilirubin:** This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with a diazonium salt; 99.4% w/w buffer and nonreactive ingredients.

**Ketone:** This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige-pink to purple color.

**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 ionic concentration to green and yellow-green in urine of higher ionic concentration.

**Blood:** This test is based on the pseudoperoxidase action of haemoglobin and erythrocytes which catalyzes the reaction of 3,3',5,5'-tetramethylbenzidine (TMB) and hydrogen peroxide from the oxidation of glucose. The TMB is converted into a blue color.

**pH:** This test is based on the well known double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5.5-6.6. 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. Colors range from yellow for a “Positive” reaction to yellow-green and green to blue-green for a “Negative” reaction.

**Nitrite:** This test is based on the conversion of nitrate to nitrite by the presence of protein. Colors range from yellow for a “Negative” reaction to yellow-green and green to blue-green for a “Positive” reaction.

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

**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.

**REAGENTS** (Based on dried weight at time of impregnation)

**Glucose:** 16.3%w/w glucose oxidase (Aspergillus niger; 13uU); 0.91w/w peroxidase (horsehepate, 3300 IU); 7.0% w/w potassium iodide; 76.1% w/w buffer and non-reactive ingredients.

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

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

**Specific Gravity:** 2.8% w/w bromothymol blue; 69.0%; poly (methyl vinyl ether/maleic anhydride); 28.2% sodium hydroxide.

**Blood:** 6.6% w/w cumene hydroperoxide; 4.0% w/w 3, 5, 1'- tetramethylbenzidine; 89.4% w/w buffer and nonreactive ingredients.

**pH:** 0.2% w/w methyl red; 2.8% w/w bromothymol blue; 97% w/w nonreactive ingredients.

**Protein:** 0.3% w/w tetrabromophenol blue; 99.7% w/w buffer and nonreactive ingredients.

**Urobilinogen:** 2.9% w/w p-dimethylaminobenzaldehyde balanced with buffer and nonreactive ingredients.

**Nitrite:** 1.4% w/w p-arsanilic acid, balanced with buffer and nonreactive ingredients.

**Leukocytes:** 0.4% w/w indoxyl ester derivative; 0.2%/w diazoum 99.4% w/w buffer and nonreactive ingredients.

**Ascorbic Acid:** 5.8% w/w ferri chloride; 4.9% w/w DTPA; 1.2% diprydil; 89.1% w/w buffer and nonreactive ingredients.

**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. Allow refrigerated specimens 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. blot the long edge of the strip on 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.

**RESULTS**

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

**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 their handling and testing procedures if these standards are not met.

**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.

**Glucone:** 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.

**Bilirubin:** Reactions may occur with urine containing large doses of chlorpromazine or rifampen that might be mistaken for positive bilirubin. Indian (indoxyl sulfate) and metabolites of Lodin 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 tests. 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.

**Methods, 16th Ed. Philadelphia: Saunders; (1979).**

**Urinary Occult Blood, Protein, Glucose and pH.**

**Amer. J. Med Tech. 7:314; (1941).**

**3. Lodine.**

**Blood:**

**Ketone:**

**Protein:**

**Acetic Acid:**

This test can detect acetic acid in concentrations as low as 10 mg/dl in urine.

**Urine:**

**Blood:**

**Nitrite:**

**Glucose:**

**Protein:**

**Acetic Acid:**

This test can detect acetic acid in concentrations as low as 10 mg/dl in urine.

**BIBLIOGRAPHY**

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

**Blood:**

**Ketone:**

**Protein:**

**Acetic Acid:**

This test can detect acetic acid in concentrations as low as 10 mg/dl in urine.

**Urine:**

**Blood:**

**Nitrite:**

**Glucose:**

**Protein:**

**Acetic Acid:**

This test can detect acetic acid in concentrations as low as 10 mg/dl in urine.

**BIBLIOGRAPHY**

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

**Blood:**

**Ketone:**

**Protein:**

**Acetic Acid:**

This test can detect acetic acid in concentrations as low as 10 mg/dl in urine.

**Urine:**

**Blood:**

**Nitrite:**

**Glucose:**

**Protein:**

**Acetic Acid:**

This test can detect acetic acid in concentrations as low as 10 mg/dl in urine.

**BIBLIOGRAPHY**

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

**Blood:**

**Ketone:**

**Protein:**

**Acetic Acid:**

This test can detect acetic acid in concentrations as low as 10 mg/dl in urine.

**Urine:**

**Blood:**

**Nitrite:**

**Glucose:**

**Protein:**

**Acetic Acid:**

This test can detect acetic acid in concentrations as low as 10 mg/dl in urine.

**BIBLIOGRAPHY**

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