URINE REAGENT STRIPS FOR URINALYSIS

This Package Insert to be used with the following products:
- URS-11
- URS-10
- URS-9
- URS-8
- URS-6L
- URS-7
- URS-7L
- URS-6
- URS-6L
- URS-5K
- URS-5N
- URS-5U
- URS-4S
- URS-3K
- URS-2BUL
- URS-2K
- URS-2P
- URS-1B
- URS-1G
- URS-1K
- URS-1N
- URS-1P

For the semi-quantitative and qualitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Ascorbic Acid in urine

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 (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes, and Ascorbic Acid in Urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteriuria. Please refer to the outside box and bottle label for the specific test parameters of the product you are using.

Taco Urine Reagent Strips are packaged along with a drying agent in a plastic bottle with a twist-off cap. Each strip is sterile 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 PRINCIPLE
Glucose: This test is based on a double sequential enzyme 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.

Bilirubin: This test is based on the coupling of bilirubin with a diazotized dianilinamine in a strongly acid medium. The colors range from light tan to reddish-brown.

Ketone: This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" 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 ionic 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'-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green.

pH: This test is based on the well known acidic pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5.5-9. 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. Colors range from yellow to yellow-green to 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. 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 nitrite-reacts with p-arsanilic acid to form a diazouim compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydroxybenzoic acid (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 diazouim salt to produce a beige-pink to purple color.

Ascorbic Acid: This test is based on the action of a complex chelating agent with a polyvalent 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.

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 each 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 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 chloropromazine or rifampin that might be positive for bilirubin. Indian (indoxyl sulfate) and metabolites of Lodine may cause false positive or atypical color: ascorbic acid (250mg/dL or greater) may cause false negative results.
Ketone: Color reaction that could be interpreted as "positive" may be obtained with urine specimens containing MESNA or large amounts of phenylketones or L-dopa metabolites.

Specific Gravity: 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 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.

Blood: 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.

pH: 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 runs onto the pH area, causing a false lowering in the pH result.

Protein: False positive results may be obtained with highly alkaline urine. Contamination of the urine specimen with quartary ammonium compounds may also produce false positive results.

Urobilinogen: The test area will react with interfering substances known to react with Ehrlich’s reagent, such as porphobilinogen and p-aminesulfinic acid. This test is not a reliable method for the detection of porphobilinogen. Drugs containing azo-acyls (e.g., Azo Gantrexin) may give a masking golden color. The absence of urobilinogen cannot be determined with this test.

Nitrite: 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 $10^4$ or more organisms/ml. There are occasional urinary tract infections from organisms, which do not contain reductase to convert nitrate to nitrite.

Leukocytes: Highly colored urine and the presence of the drugs cephalothin (Keflex®) and gentamicin have been found to interfere with this test. High urinary protein of 500 mg/dl or above diminishes the intensity of the reaction color. Elevated glucose concentration or high specific gravity may cause decreased results.

EXPECTED VALUES

Glucose: Small amounts of glucose are normally excreted by the kidney. A trace or 0.1 g/dl glucose read either at 10 or 30 seconds, may be significant if abnormal if found consistently. At 10 seconds, results should be interpreted qualitatively; for semiquantitative results, read at 30 seconds only.

Bilirubin: Normally, no bilirubin is detectable in urine by even the most sensitive method. Even trace amounts of bilirubin are sufficient to alter the reaction 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.

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 1.016-1.022+. In severe renal damage the specific gravity is tied 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. A color matching any color block greater than 0.2 EU/dl in urine. For urine with high specific gravity, the test area may most closely match the 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 urobilinogen concentration or high specific gravity may cause decreased results. A color matching any color block greater than 0.2 EU/dl in urine. For urine with high specific gravity, the test area may most closely match the color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of trace results.

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: it approximately half of the intake. The average urinary output ranges from 20-30 mg/day. If detect ascorbic acid in urine, stop taking ascorbic acid for 24 hours and retest. False negative and weak reaction of blood, glucose 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 Urine Reagent Strips (URS) have been evaluated 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. (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 attain in at 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 give a positive result. The reagent area does not react with lactose, galactose, fructose, or reducing metabolites of drugs; e.g. salicylates and nalidixic 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 0.4-0.8 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 ketones in urine derived from ketosis. Drugs containing azo-dyes (e.g. Azo Gantrexin) may give a masking golden color. The absence of urobilinogen cannot be determined with this test.

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

Blood: At the time of reagent manufacture, this test when read as instructed has a sensitivity to free hemoglobin of 0.015 mg/dl or 5-10 mg/dl of red blood cells/ml. 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 within the range of 5-9. pH testing is not affected by variation in the urinary buffer concentration.

Protein: The test area is more sensitive to albumin than to globulin, hemoglobin, mucoproteins, and mucosubstances; a negative result does not rule out the presence of these proteins. The test area is sensitive to 15 mg/dl albumin.

Urobilinogen: In a healthy population, the normal urine urobilinogen concentration is a minimum of 4 hours incubation.

Nitrite: Nitrite is a test for nitrite reagents which are available in concentrations as low as 0.2 EU/ml. Comparison of the reacted reagent strip to a urine background may aid in the detection of low levels of nitrite in urine which may otherwise be missed.

Ascorbic Acid: This test can detect as low as 15-15 WBC/ml. This test will not be toxic to the urinary epithelium or bacteria cultured in clinical cultures.

Ascorbic Acid: This test can detect as high as 10 mg/dl in urine.

BIBLIOGRAPHY


*Trademark:

Lodine® is a registered trademark of Wyeth-Ayerst Laboratories.

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