Urinalysis Reagent Strips (Urine) Package Insert

For rapid detection of multiple analytes in human urine. For research use only.

INTENDED USE

The Urinalysis Reagent Strips (Urine) are firm plastic strips onto which several separate reagent areas are screened in which specific concentrations are printed in the urine in order to detect the presence or absence of an analyte. These are used in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine function or disorders of the urinary tract.

SUMMARY

Urine undergoes many changes during states of disease or body dysfunction before being excreted. Urinalysis is the process of examining urine to determine if it contains substances that indicate an indicator of health or disease, and is a part of routine health screening. The Urinalysis Reagent Strips (Urine) are plastic strips containing reagents for the detection of one or more of the following analytes in urine: Ascorbic acid, Glucose, Bilirubin, Ketone, Protein, pH, Specific Gravity, Leukocytes, Nitrite, Urobilinogen, and Blood.

PRINCIPLE AND EXPECTED VALUES

Ascorbic acid: This test involves decoloration of Tollens's reagent. The presence of ascorbic acid forms a complex with Tollens's reagent and causes a pink to red color.

Glucose: This test is based on the enzymatic reaction that occurs between glucose oxidase and peroxidase, which produces gluconic acid and hydrogen peroxide in the reagent. The resulting hydrogen peroxide decomposes and causes a color change.

Bilirubin: This test is based on a colorimetric reaction between the urine bilirubin and diazotized toluidine. The presence of bilirubin in urine turns the toluidine blue to brown.

Ketone: This test is based on ketones reacting with nitroprusside and acetoacetic acid to form colored products. A positive result for ketones is characterized by a pinkish-tan color proportional to its concentration in urine.

Blood: This test is based on the periodate-activity of hemoglobin which catalyzes the oxidation of cumene-hydroperoxide to cumene with concomitant reduction of colorless diazotized toluidine to a pinkish color. The color ranges from orange to green to dark blue. Any green spots or green color development on the protein reagent are indicative of hemoglobin. The negative urine specimen should be examined further. Blood is often, but not invariably, found in the urine of patients with infection, kidney disease, diabetes, and gout.

pH: This test is based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue. The expected range for normal urine specimens is pH 4.5–8, with an average result of pH 6.

Protein: This reaction is based on the phenomenon known as the "protein error" of pH measurement with litmus paper. The presence of proteins may cause an error in pH measurement.

Leukocytes: This test is based on a chemical reaction between leukocytes and a reducing agent that reduces a diazonium compound to a colored product. The concentrations of normal concentrations of protein are present. Clinical judgment is required to evaluate the test results.

Urobilinogen: This test is based on a modified Ehrlich reaction between p-dimethylaminobenzaldehyde and urobilinogen. The urobilinogen is reduced to a yellow color.

Leukocytes: An increase in the number of neutrophils and the presence of red blood cells in the urine are indicative of infection.

For in vitro diagnostic use only. Do not use after the expiration date.

The strip should remain in the closed container until use.

This test strip is intended for use in the diagnosis and treatment of patients only. It is not intended for use in the diagnosis, treatment, or prevention of diseases.

Nitrite: The test strip should be discarded according to local regulations after testing.

For diagnostic and therapeutic tests, all results must be considered with other clinical information available to the physician.

STORAGE AND STABILITY

Store at room temperature (20–25°C). Do not expose to direct sunlight. The strips should be used within 1 year from the date of manufacture. If stored properly, they are stable through the expiration date printed on the canister label. This product may be stored at temperatures as low as 0.5°C (32°F). Thereafter, discard the strip immediately and contact your local distributor.

MATERIALS

Specimen Collection and Preparation

A urine specimen must be collected in a clean and dry container and tested as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. Do not collect urine in a closed container either at room temperature or refrigerated (2–5°C). Keep out of direct sunlight. The strips will exceed the expiration date after exposure to direct sunlight. If this occurs, discard immediately. Do not use for immediate use. Replace cap immediately and tightly. DO NOT FROZE. Do not use any strips that have been frozen for testing.

INTERPRETATION OF RESULTS

Results are obtained by direct comparison of the color blocks printed on the carrier label with the color blocks printed in the reagent areas. Actual values will vary close to the nominal values. In the event of unexpected or questionable results, the following steps are recommended. If the results of the Urinalysis Reagent Strips (Urine) are used in conjunction with other clinical information, the patient should be examined further.

For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed, or whenever the capability of the laboratory should establish its own goals for adequate standards of performance.

Leukocytes: Do not use any strips that may have deteriorated or are not intact. Discard any discarded strips that may have deteriorated or are not intact. Do not use any strips that have been frozen for testing.

Leukocytes: A strip with a pinkish-tan color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by the visual method. The presence of bilirubin in urine turns the toluidine blue to brown.

Bilirubin: A uniform blue color indicates the presence of myoglobin, hemoglobin or β-hemoglobin. Scattered or compacted blue spots indicate false positive reactions. To ensure accuracy, the test strip will run for 10 minutes or until the strip area causes the pH result to appear artificially low. The test is slightly sensitive to false positive and myoglobin or β-hemoglobin. False negative results may be caused by high concentration of ascorbic acid or sulfuric acid. False negative results may be caused by high concentration of ascorbic acid or sulfuric acid. False positive results may be caused by high concentration of ascorbic acid or sulfuric acid. False positive results may be caused by high concentration of ascorbic acid or sulfuric acid. False positive results may be caused by high concentration of ascorbic acid or sulfuric acid. False positive results may be caused by high concentration of ascorbic acid or sulfuric acid.

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For all tests, interpret the test results based on the color chart. Large concentrations of ascorbic acid may decrease sensitivity.