INTENDED USE:
Urine Reagent Strips (URS-5U) for Urinalysis are firm plastic strips to which are affixed several separate reagent areas. Urine Reagent Strips provide tests for the semi-quantitative determination of occult blood, urobilinogen, glucose, protein and pH in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney function, liver function, acid-base balance, and bacteriuria.

SUMMARY:
The reagent test areas of urine reagent strips are ready to use upon removal from the bottle. The entire strip is disposable. No additional laboratory equipment is necessary for testing. The directions must be followed exactly. Accurate timing is essential to provide optimal results. The reagent strips must be kept in the original bottle with the cap tightly closed to maintain reagent reactivity. To obtain optimal results, it is necessary to use fresh, well-mixed, uncentrifuged urine.

CHEMICAL PRINCIPLES OF THE PROCEDURE:

Blood: This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of cumene hydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green to dark blue.

Urobilinogen: This test is based on the Ehrlich reaction in which p-dimethylanilinobenzaldehyde reacts with urobilinogen in a strong acid medium to produce a brown-orange color.

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 a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.

Protein: This test is based on the protein error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.

pH: This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.

Blood: 5.0% w/w cumene hydroperoxide; 4.0% w/w 3,3',5,5'-tetramethylbenzidine; 48.0% w/w buffer; 43.0% w/w nonreactive ingredients.

Urobilinogen: 2.9% w/w p-dimethylanilinobenzaldehyde; 97.1% with buffer and nonreactive ingredients.

Glucose: 16.3% w/w glucose oxidase (Aspergillus niger) (1.3 IU); 0.6% w/w peroxidase (Horseradish) (3300 IU); 7.0% w/w potassium iodide; 60.7% w/w buffer and 15.4% nonreactive ingredients.

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

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

WARNINGS AND PRECAUTIONS:
Urine reagent strips are for in vitro diagnostic use.

STORAGE: Store opened and unopened bottles at temperature between 15°-30°C(59°-86°F) and out of direct sunlight. Do not use after expiration date. Deterioration rate will be affected by mishandling of device.

RECOMMENDED PROCEDURE FOR HANDLING URINE REAGENT STRIPS: All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive. Do not remove desiccant(s) from bottle. Replace cap immediately and tightly after removing reagent strip. Do not touch test areas of the reagent strip. Work areas and specimen containers should be free of detergents and other contamination substances.

Dip test areas in urine completely, but briefly, to avoid dissolving out the reagents. Read test results carefully at the times specified in a good light and with the test area held near the appropriate Color Chart on the bottle label.

IMPORTANT: Protection against ambient moisture, light and heat is essential to guard against altered reagent reactivity. Discoloration or darkening of reagent areas may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected finding, the following steps are recommended: (1) confirm that the product is within the expiration date shown on the label. (2) check performance against known positive control materials. (3) retest with fresh product.

SPECIMEN COLLECTION AND PREPARATION: Collect urine in a clean container according to NCCLS GP16-T and test as soon as possible. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing.

Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose.

Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent specific gravity) test results. The user should determine whether the use of such skin cleansers is warranted.

MATERIALS PROVIDED:
1. 1 bottle containing 100 strips of URS-5U.
2. A visual comparison Color Chart for reading test results is printed on the bottle.

MATERIALS REQUIRED BUT NOT PROVIDED:
1. Clean, dry container for urine sample.
2. Commercial urine controls
3. Timer or watch capable of measuring accurately in seconds.

PROCEDURE: MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE TEST RESULTS.
1. Collect FRESH urine specimen in a clean dry container. Mix well immediately before testing.
2. Remove one strip from bottle and close the cap immediately. Completely immerse reagent areas of the strip in FRESH urine and remove immediately to avoid dissolving out reagents.
3. While removing, run the edge of the strip against the rim of the urine container to remove excess urine. Alternatively, run the edge of the strip against a paper towel to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas and/or soiling of hands with urine.
4. Compare reagent areas to corresponding color chart on the bottle label at the time specified. HOLD STRIP CLOSE TO COLOR BLOCKS AND MATCH CAREFULLY.
5. Do not use the same urine sample more than once, as the urine may have been contaminated with the dissolving of the different reagent areas. Always use fresh urine sample with each test.

Proper read time is critical for optimal results. Generally, all reagent areas may be read between 1 and 2 minutes for screening positive from negative specimens.

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. Negative and positive specimens or controls may also be randomly hidden in each batch of specimens tested.
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 with URS-5U are obtained in clinically meaningful units directly from the Color Chart comparison. The color blocks represent nominal values; actual values will vary around the nominal values.

LIMITATIONS OF PROCEDURE:
As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method. These tests are only for screening; all positive results should be confirmed by a quantitative method where accuracy and sensitivity are greater.

Substances that cause abnormal urine color, such as Serenium®, drugs containing Azo dyes (e.g., Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Macrobid®, Furadantin®), and riboflavin, may affect the readability of reagent areas on urinalysis reagent strips. The color development on the reagent pad may be masked or a color reaction may be produced on the pad that could be interpreted as a false positive.

High blood concentration in sample may mask color development or cause atypical color formation. Turbid urine may be used, however reaction must be observed carefully.

Interpretation of results will depend upon several factors: the variability of color perception; the presence or absence of inhibitory factors; the presence or absence of inhibitory factors typically found in urine, the specific gravity or the pH; and the lighting conditions under which the product is used.

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 a false positive reaction. Certain oxidizing contaminants such as hypochlorite may 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-aminosalicylic acid. This test is not a reliable method for the detection of porphobilinogen. Drugs containing Azo-dyes (e.g., Azo Gantrisin) may give a masking golden color. The absence of urobilinogen cannot be determined with this test.

Glucose: Ascorbic acid concentrations of 50 mg/dl or greater may cause false negatives for specimens containing small amounts of glucose (100 mg/dl). Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dl) may cause false negatives for specimens containing small amounts of glucose (100 mg/dl), but the combination of such ketone levels and low glucose levels is metabolically improbable in screening. The reactivity of the glucose test increases as the SG of the urine decreases. In dilute urine containing less than 5 mg/dl ascorbic acid, as little as 40 mg/dl glucose may produce a color change that might be interpreted as positive. Reactivity may also vary with temperature.

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

pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing a false lowering in the pH result.

EXPECTED VALUES:
Blood: The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Development of green spots (free intact erythrocytes) or green color (free hemoglobin/myoglobin) on the reagent area within 60 seconds indicate the need for further investigation. Blood is often but not always found in the urine of menstruating females.

Urobilinogen: In a healthy population, the normal urine urobilinogen range obtained with this test is 0.1 to 1.0 Ehrlich unit per dl. A result of 2.0 EU/dl represents the transition from normal to abnormal, and the urine specimen should be evaluated further.

Glucose: Small amounts of glucose are normally excreted by the kidney. These amounts are usually below the sensitivity of this test but on occasion may produce a color between the negative and the 100 mg/dl color blocks. Results of 100 mg/dl may be significantly abnormal if found consistently.

Protein: Normal secretion of protein in the urine is less than 15 mg/dl. A color matching any block greater than Trace may indicate significant proteinuria. For urine of high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of trace results.

pH: Normal: 4.5-8
Average: 6

PERFORMANCE CHARACTERISTICS:
Sensitivity:
The following table list the generally detectable levels of analytes in contrived urine; however, because of the inherent variability of clinical urine, lesser concentrations may be detected under certain conditions. Sensitivity will vary depending on the limitation factors of each test. (see LIMITATIONS OF PROCEDURE)

<table>
<thead>
<tr>
<th>Reagent Area</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td>0.015 mg/dl hemoglobin</td>
</tr>
<tr>
<td>Urobilinogen</td>
<td>0.1 mg/dl (0.1 Ehrlich Unit)</td>
</tr>
<tr>
<td>Glucose</td>
<td>100 mg/dl glucose</td>
</tr>
<tr>
<td>Protein</td>
<td>15 mg/dl albumin</td>
</tr>
</tbody>
</table>

Specificity:
Blood: At the time of reagent manufactured, the test when read as instructed has a sensitivity to free hemoglobin of 0.015 mg/dl or 5 intact red blood cells/µl in urine. The test is equally sensitive to myoglobin as to hemoglobin. The sensitivity of this test may be reduced in urine with high specific gravity.

Urobilinogen: This test area will detect urobilinogen in concentrations as low as 0.1 mg/dl (approximately 0.1 EU/dl) in urine. The absence of urobilinogen in the specimen being tested cannot be determined.

Glucose: The test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose nor reducing metabolites of drugs (e.g., salicylates and nalidixic acid). This test may be used to determine whether the reducing substance found in urine is glucose.

Protein: The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones Protein and mucoprotein; negative result does not rule out the presence of these other proteins.

pH: The pH test area permits quantitative differentiation of pH values to one unit within the range of 5-9. pH readings are not affected by variation in urine concentration.

BIBLIOGRAPHY:

*Serenium® is a registered trademark of E.R. Squibb & Sons.
**Pyridium® is a registered trademark of Warner-Chilcott Laboratories.
***Azo Gantrisin® and Azo Gantanol® are registered trade marks of Roche Laboratories, Division of Hoffman-LaRoche, Inc.
†Macrodantin® and Furadantin® are registered trade marks of Norwich-Eaton Pharmaceuticals

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