INTENDED USE

Tanner Scientific® 10 Reagent Strips for Urinalysis are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis. The strips are for professional use only. They are intended for use to detect conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed. They can be read visually and instrumentally.

SUMMARY & EXPLANATION OF TESTS

Tanner Scientific® 10 Reagent Strips for Urinalysis provide tests for Glucose, Bilirubin, Ketone (acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in urine.

TEST PRINCIPLES

Urobilinogen: Based on the Ehrlich reaction in which p-diethylamino benzaldehyde, in conjunction with a color enhancer, reacts with urobilinogen in a strong acid medium to produce a pink-red color.

Bilirubin: The direct bilirubin and dichlorobenzene diazonium produce fuchsia azo dyes in a strong acid medium.

Ketone: The acetooacetate and sodium nitroprusside cause a reaction in the alkaline medium, which produces a violet color.

Blood: Hemoglobin acts as a peroxidase. It can cause peroxidase to release neo-ecotypes oxide (O). (O) oxidizes the indicator and causes the color change.

Protein: The test is based on the protein-error-of-indicators principle. An ion in the specific pH indicator, attracted by cations on the protein molecule, makes the indicator further ionized, which changes its color.

Nitrite: Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazouium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the color change.

Leukocytes: Granulocyte leukocytes in urine contain esterase that catalyzes the hydrolysis of the pyrrole amino acid ester to liberate 3-hydroxy-5-pheny pyrrole. This pyrrole reacting with diazonium forms a purple color.

Glucose: The glucose oxidized by glucose oxidase catalyzes the formation of glucuronic acid and peroxide hydrogen. Peroxide hydrogen releases neo-ecotypes oxide (O) under the function of peroxidase. (O) oxidizes iodide potassium, which causes the color change.

Specific Gravity: Electrolyte (M-X) in the form of salt in urine reacts with poly methyl vinyl ether and maleic acid (-COOH), which is a weak acid ionic exchanger. The reaction produces hydrogenous ionogen, which reacts with a pH indicator that causes the color to change.

pH: This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range.

EXPECTED RESULTS

The sensitivity of Tanner Scientific® 10 Reagent Strips for Urinalysis in testing clinical urine specimens may vary depending upon several factors, such as the variability of color perception, specific gravity, pH values, and the lighting conditions when strips are read visually. Visual reading results may not exactly match instrument readings results because of the difference between the perception of human eyes and the optical instrument. Most visual and instrument readings are within one level of the true value. The following table shows expected values for all tests analytes for a normal healthy population based on published literatures.

<table>
<thead>
<tr>
<th>Test</th>
<th>Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urobilinogen</td>
<td>0.2-1mg/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>Neg</td>
</tr>
<tr>
<td>Ketone</td>
<td>Neg</td>
</tr>
<tr>
<td>Blood</td>
<td>Neg</td>
</tr>
<tr>
<td>Protein</td>
<td>Neg or Trace</td>
</tr>
<tr>
<td>Nitrite</td>
<td>Neg</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>Neg</td>
</tr>
<tr>
<td>Glucose</td>
<td>Neg</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.000-1.030</td>
</tr>
<tr>
<td>pH</td>
<td>5.0-8.0</td>
</tr>
</tbody>
</table>
PROCEDURE
Gather Materials
1) Dry and Clean Plastic Container
2) Toilet Paper
3) Watch w/Second Hand or Stopwatch (if reading visually)
4) Urinalysis Reagent Strips
5) Urine Analyzer (if reading instrumentally)

PERFORM TESTS
1) Immerse the reagent area of the strip in the urine specimen and take it up quickly and immediately. Start timing if reading visually.
2) Run the edge of the strip against the rim of the container to remove excess urine. Lay the strips on a paper towel with the reagent areas upward.
3) If reading visually, hold the strip up horizontally in good light and compare the reagent areas on the strip to the corresponding color chart on the bottle label at the exact times specified. Hold strips close to the color blocks and match carefully. Make note of the result. Color changes after 2 minutes are of no diagnostic value. If reading by instrument, carefully follow the directions given in the operating instructions. The instrument will automatically read each reagent area at a specified time.
4) Dispose of strips with laboratory waste. Do NOT flush down toilet.

QUALITY CONTROL
Remove one strip from the bottle and check against the color blocks on the color chart. If the color of the reagent area is darker than the lowest block on the chart (except for specific gravity and pH), the strip is unusable. Discard the strip and check all strips from the bottle before using or discard the bottle. When a new bottle is first opened, use two strips to test known negative and positive controls.
+ Test QC per your laboratory policies and follow local, state and federal regulations.
+ Test commercially available positive and negative quality controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips.
+ Note: Water is NOT an appropriate negative control.
+ Test the strips monthly that are stored for more than 30 days.
+ Run QC tests to ensure reagent storage integrity, train new users, confirm test performance, and when patients’ clinical conditions or symptoms don’t match the results obtained on the test strips.

IMPORTANT NOTES
1) Do NOT take the strips from the bottle unless they are for immediate use.
2) Do NOT touch reagent areas of strips.
3) Do NOT use strips beyond the expiration date.
4) Each strip can be used only once.
5) Large amounts of ascorbic acid may affect the test for glucose, bilirubin, nitrite, and blood.29
6) Deterioration may result in discoloration or darkening of the reagent areas of the strip. If this happens, or the test results are questionable or inconsistent with expected results, check and make sure the strips are within the expiration date, and also check results with the control urine.

BIBLIOGRAPHY
(3) “Operating Rules of Clinical Test” (Rev.2), the Ministry of Health of P.R.C. Publishing. Yingwu Ye, Yusan Wang.
(4) “Compendium - Urinalysis With Test Strips” Roche Diagnostic, Combim® Reagent Strips.

LIMITATIONS
Urobilinogen: The reagent area may react with interfering substances such as sulfonamides. Atypical color reactions may be obtained in the presence of high concentrations of p-amino salicylic acid. False negative results may be obtained if formalin is present and the specimen has been in direct sunlight. The test is not a reliable method for the detection of porphobilinogen.

Bilirubin: Medicines that dye urine red and anything that shows red in an acid medium (Example: phenazopyridine) may affect the test result. A high concentration of ascorbic acid (2.8 mmol/L) may cause a false negative result.

Protein: False positive results may occur in highly pigmented urine or those specimens containing a large amount of levodopa metabolites.

Blood: Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. A high specific gravity in urine may reduce the sensitivity of the test.

Leukocytes: A high glucose concentration (20 g/L) or a high specific gravity in urine may reduce the sensitivity of the test. Tetracycline may cause decreased reactivity, and high levels of tetracycline may cause a false negative reaction.

Glucose: Ascorbic acid concentrations of 0.28 mmol/L and/or acetoacetic acid concentrations of 1.1 mmol/L or lower will not influence the test.

Specific Gravity: Urine nonionic constituents such as glucose or highly buffered alkaline urine may produce low readings compared to other methods. Elevated specific gravity readings may occur in the presence of moderate quantities of protein (1.0 g/L). The reagent strip is not suitable for testing newborns because of their low specific gravity (1.002-1.004).

pH: Bacterial growth in a specimen may cause a marked alkaline shift (>8.0), usually because of urea conversion to ammonia.

SENSITIVITY & OUTPUT VALUES OF REAGENT STRIP FOR URINALYSIS

<table>
<thead>
<tr>
<th>ITEM</th>
<th>SENSITIVITY</th>
<th>OUTPUT VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urobilinogen (mg/dL)</td>
<td>1.6</td>
<td>0.2-8</td>
</tr>
<tr>
<td>Bilirubin (mg/dL)</td>
<td>1</td>
<td>0-6</td>
</tr>
<tr>
<td>Ketone (mg/dL)</td>
<td>3</td>
<td>0-160</td>
</tr>
<tr>
<td>Blood (cell/µL)</td>
<td>7</td>
<td>0-200</td>
</tr>
<tr>
<td>Protein (mg/dL)</td>
<td>10</td>
<td>0-2000</td>
</tr>
<tr>
<td>Nitrite (µg/dL)</td>
<td>2</td>
<td>Pos-Neg</td>
</tr>
<tr>
<td>Leukocytes (cell/µL)</td>
<td>12</td>
<td>0-500</td>
</tr>
<tr>
<td>Glucose (mg/dL)</td>
<td>70</td>
<td>0-2000</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>-</td>
<td>1.000-1.030</td>
</tr>
<tr>
<td>pH</td>
<td>-</td>
<td>5.0-8.5</td>
</tr>
</tbody>
</table>

NOTES ON SYMBOLS & MARKS

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TannerScientific
Sarasota, FL 34243
PHONE: 888.708.5233
www.TannerScientific.com
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