Urine Reagent Strips (11 Parameters)

For rapid detection of multiple analytes in human urine.

**For in vitro diagnostic use only**

Store at 15-30°C

**INTENDED USE**

Urine Reagent Strips are firm plastic strips onto which several separate reagent areas are affixed. The test is for the detection of one or more of the following analytes in urine: Leukocytes, Glucose, Ketone (Acetoacet acid), Bilirubin, Blood, Specific Gravity, Protein, Urobilinogen, Nitrile, Ascorbic acid, and pH.

**INTRODUCTION**

Urinary undergoes many changes during states of disease or body dysfunction before blood composition is altered to a significant extent. Urinalysis is a useful procedure as an indicator of health or disease, and as such, is a part of routine health screening. Urine Reagent Strips can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.

**PRINCIPLE AND EXPECTED VALUES**

- **Leukocytes**: This test reveals the presence of granulocyte esterase. The esterase cleaves a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color. Normal urine specimens generally yield negative results. Trace results may be of questionable clinical significance. When trace results occur, it is recommended to retest using a fresh specimen from the same patient. Repeated trace and positive results are of clinical significance.

- **Glucose**: This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose is first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown. Low amounts of glucose are normally exceeded in urine. Glucose concentrations as low as 100 mg/dL, read at either 10 or 30 seconds, may be considered abnormal if results are consistent. At 10 seconds, results should be interpreted qualitatively. For semi-quantitative results, read at 30 seconds only.

- **Ketone**: This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiologic stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentrations before serum ketones are elevated.

- **Bilirubin**: This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acid medium. Varying bilirubin levels will produce a pinkish-tan to brown color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by even the most sensitive methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction.

- **Blood**: This test is based on the peroxidase activity of hemoglobin which catalyzes the reaction of cumene-hydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue. Any green spots or green colors developing in the reagent area within 60 seconds is significant and the urine specimen should be examined further. Blood is often, but not invariably, found in the urine of menstruating females.

- **Specific Gravity**: This test is based on the apparent pH change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration. Randomly collected urine may vary in specific gravity from 1.003-1.040. Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.015-1.022. In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

- **Protein**: This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results. 1-14 mg/dL of protein may be excreted by a normal kidney. A color matching any block greater than trace indicates significant proteinuria. For urine with high specific gravity, the test area may closely match the trace color block even though only normal concentrations of protein are present. Clinical judgment is required to evaluate the significance of trace results.

- **Urobilinogen**: This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobilinogen acid in strongly acid medium to produce a pink color. Urobilinogen is among the major compounds produced in heme synthesis and is a normal substance in urine. The expected range for normal urine with this test is 0.2-1.0 mg/dL (3.5-17 umol/L). A result of 2.0 mg/dL (35 umol/L) may be of clinical significance, and the patient specimen should be further investigated.

- **Nitrile**: This test depends upon the conversion of nitrite to nitrate by the action of Gram negative bacteria in the urine. In an acid medium, nitrite in the urine reacts with p-aminodimethyl amine to form diazomium compounds. The diazonium compounds in turn couple with 1 N-(1-naphthyl)-ethylenediamine to produce a pink color. Nitrite is not detectable in normal urine. The nitrite area will be positive in some cases of infection depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

- **Ascorbic acid**: This test involves decolorization of Tpillmann’s reagent. The presence of ascorbic acid causes the color of the test field to change from blue-green to orange.

- **pH**: This test is based on a double indicator system which gives a broad range of colors covering the entire urine pH range. Colors range from orange to yellow and green to blue. The expected range for normal urine specimens from newborns in pH 5-7. The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.

**MATERIALS**

- **MATERIALS PROVIDED**
  - Strips.
  - Package insert.

- **MATERIALS NEEDED BUT NOT PROVIDED**
  - Specimen collection container.
  - Timer.

**RAEGENTS AND PERFORMANCE CHARACTERISTICS**

- Based on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for each parameter:

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Read Time</th>
<th>Composition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Glucose (GLU)</strong></td>
<td>30 seconds</td>
<td>1.5% w/w glucose oxidase; 0.5% w/w peroxidase; 10.0% w/w potassium iodide; 75.0% w/w buffer; 13.0% w/w non-reactive ingredients</td>
<td>Detects glucose low as 25-50 mg/dL (1.4-2.8 mmol/L). Results may be read at 20 seconds for qualitative results or at 45 seconds for semi-quantitative results.</td>
</tr>
<tr>
<td><strong>Ketone (KET)</strong></td>
<td>40 seconds</td>
<td>5% w/w sodium nitroprusside; 95% w/w buffer and non-reactive ingredients</td>
<td>Detects acetocoll during in vitro assay as low as 2.5-5 mg/dL (0.25-0.5 mmol/L).</td>
</tr>
<tr>
<td><strong>Bilirubin (BIL)</strong></td>
<td>30 seconds</td>
<td>0.5 % w/w 2, 4-dichloroaniline diazonium salt; 99.5% w/w buffer and non-reactive ingredients</td>
<td>Detects bilirubin as low as 0.4-0.8 mg/dL (6.8-13.6 μmol/L).</td>
</tr>
<tr>
<td><strong>Blood (BLO)</strong></td>
<td>60 seconds</td>
<td>4% w/w 3,3',5,5'-tetramethyl benzidine hydrochloride; 6% w/w cumene hydroperoxide; 90% w/w buffer and non-reactive ingredients</td>
<td>Detects free hemoglobin as low as 0.015-0.062 mg/dL or 5-10 Eny/L in urine specimens with ascorbic acid content of &lt;50 mg/dL.</td>
</tr>
<tr>
<td><strong>Specific Gravity (SG)</strong></td>
<td>45 seconds</td>
<td>2.5% w/w bromthymol blue indicator; 17.5% w/w buffer and non-reactive ingredients; 55% poly (methyl vinyl ether/maleic anhydride); 25% sodium hydroxide</td>
<td>Determines urine specific gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within ±0.005.</td>
</tr>
<tr>
<td><strong>Protein (PRO)</strong></td>
<td>60 seconds</td>
<td>0.3% w/w tetrabromophenol blue; 99.7% w/w buffer and non-reactive ingredients</td>
<td>Detects albumin as low as 7.5-20 mg/dL (0.075-0.2 g/L).</td>
</tr>
<tr>
<td><strong>Urobilinogen (URO)</strong></td>
<td>60 seconds</td>
<td>2.5% w/w p-diethylaminobenzaldehyde; 97.5% w/w</td>
<td>Detects urobilinogen as low as 0.2-1.0 mg/dL (3.5-17 μmol/L).</td>
</tr>
<tr>
<td>Nitrite (NIT)</td>
<td>Buffer and non-reactive ingredients</td>
<td>µmol/L</td>
<td>4.5% w/w p-arsanic acid; 95.5% w/w non-reactive ingredients</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>pH</td>
<td>60 seconds</td>
<td>0.5% w/w methyl red sodium salt; 5% w/w bromthymol blue; 94.5% w/w non-reactive ingredients</td>
<td>Permits the quantitative determination of pH values within the range of 5-9.</td>
</tr>
<tr>
<td>Leukocytes (LEU)</td>
<td>120 seconds</td>
<td>0.5% w/w pyrrole amino acid ester; 0.4% w/w diaminois salt; 32% w/w buffer; 67.1% w/w non-reactive ingredients</td>
<td>Detects leukocytes as low as 10-25 white blood cells/µL in clinical urine.</td>
</tr>
<tr>
<td>Ascorbic Acid (ASC)</td>
<td>30 seconds</td>
<td>0.3% w/w 2,6-dichlorophenol indo-phenol; 99.7% w/w buffer and non-reactive ingredients</td>
<td>Detects ascorbic acid as low as 5-10 mg/dL (0.28-0.56 mmol/L).</td>
</tr>
</tbody>
</table>

- **Nitrite (NIT)**
  - Store as packaged in the closed canister either at room temperature (15-30°C).
  - Keep out of direct sunlight.
  - The strip is stable through the expiration date printed on the canister label.
  - Do not remove the desiccant. Remove only enough strips for immediate use.
  - Replace cap immediately and tightly.
  - Do not freeze.
  - Do not use beyond the expiration date.

**STORAGE AND STABILITY**

- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used strip should be discarded according to local regulations after testing.

**INTERPRETATION OF RESULTS**

- Results are obtained by direct comparison of the color blocks printed on the canister label.
- The color blocks represent nominal values; actual values will vary close to the nominal values.
- In the event of unexpected or questionable results, the following steps are recommended:
  - Confirm that the specimens have been tested within the expiration date printed on the canister label.
  - Compare results with known positive and negative controls and repeat the test using a new strip.
  - If the problem persists, discontinue using the strip immediately and contact your local distributor.

**QUALITY CONTROL**

- 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 a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance.

**LIMITATIONS**

- As with all diagnostic and therapeutic tests, all results must be considered with other clinical information available to the physician.
- Glucose: This test is highly 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 ketones, lactose, galactose, fructose or other metabolic substances, nor with reducing metabolites of drugs (e.g. salicylates and nalidixic acid). Sensitivity may be decreased in specimens with high specific gravity (>1.025) and with ascorbic acid concentrations of ≥ 10 mg/dL.
- Ketone: The test does not react with acetone or β-hydroxybutyrate. Urine specimens of high pigment, and other substances containing sulfhydryl groups occasionally give reactions up to and including trace (+).

**PRECAUTIONS**

- Ascorbic acid is a reducing agent and may reduce nitrite to Nitrite (NIT). This phenomenon is characterized by color development on the test patch that does not correlate with the colors on the chart. Large concentrations of ascorbic acid may decrease sensitivity.

**LEUKOCYTES (LEU)**

- Leukocytes are a monomeric form of proteins and may remain in the urine after urinary tract infection, including the presence of myoglobin, hemoglobin or hemolyzed erythrocytes. Scattered or compacted blue spots indicate intact erythrocytes. To enhance accuracy, separate color scales are provided for hemoglobin and for erythrocytes. Positive results with this test are often seen with urine from menstruating females. It has been reported that urine of high pH reduces sensitivity, while moderate to high concentration of ascorbic acid may inhibit color formation. Microbial peroxidase, associated with urinary tract infection, may cause a false positive reaction. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

**SPECIFIC GRAVITY**

- Ketone is a reducing compound or protein higher than 100 mg/dL may cause elevated results. Results are not affected by non-ionic urine components such as glucose. If the urine has a pH of 7 or greater, add 0.005 to the specific gravity reading indicated on the chart.

**Protein**

- Any green color indicates the presence of protein in the urine. This test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and mucoprotein. A negative result does not rule out the presence of these other proteins. False positive results may be obtained with highly buffered or alkaline urine. Contamination of urine specimens with quaternary ammonium compounds or skin cleansers containing chlorhexidine may produce false positive results. The urine specimens with high specific gravity may give false negative results.

**Urobilinogen**

- All results lower than 1 mg/dL urobilinogen should be interpreted as normal. A negative result does not at any time preclude the absence of urobilinogen. The reagent area may react with interfering substances known to react with Ehrlich’s reagent, such as P-amino salicylic acid and sulfonamides. False negative results may be obtained if formalin is present. The test cannot be used to detect porphobilinogen.

**Nitrite**

- The test is specific for nitrite and will not react with any other substance normally excreted in urine. Any degree of uniform pink to red color should be interpreted as a positive result, suggesting the presence of nitrite. Color intensity
is not proportional to the number of bacteria present in the urine specimen. Pink spots or pink edges should not be interpreted as a positive result. Comparing the reacted reagent area on a white background may aid in the detection of low nitrite levels, which might otherwise be missed. Ascorbic acid above 30 mg/dL may cause false negatives in urine containing less than 0.05 mg/dL nitrate ions. The sensitivity of this test is reduced for urine specimens with highly buffered alkaline urine. For accurate results, antibiotics should be discontinued for at least 3 days before the test is performed. A negative result does not at any time preclude the possibility of bacteruria. Negative results may occur in urinary tract infections from organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder for a sufficient length of time (at least 4 hours) for reduction of nitrate to nitrite to occur; or when dietary nitrate is absent.

- **pH**: pH readings are not affected by variations in urinary buffer concentration.

- **Leukocytes**: The result should be read between 60-120 seconds to allow for complete color development. The intensity of the color that develops is proportional to the number of leukocytes present in the urine specimen. High specific gravity or elevated glucose concentrations (>500 mg/dL) may cause test results to be artificially low. The presence of cephaloxin, cephalothin, or high concentrations of oxalic acid may also cause test results to be artificially low. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. High urinary protein (>500 mg/dL) may diminish the intensity of the reaction color. This test will not react with erythrocytes or bacteria common in urine.

### REFERENCES


<table>
<thead>
<tr>
<th>REF</th>
<th>Product Reference No.</th>
<th>Store at 15 - 30°C.</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD</td>
<td>For in-vitro diagnostic use.</td>
<td>Caution</td>
</tr>
<tr>
<td>LOT</td>
<td>Number of tests in the pack.</td>
<td>Read product insert before use.</td>
</tr>
<tr>
<td></td>
<td>Lot (batch) number.</td>
<td>Manufacturer.</td>
</tr>
<tr>
<td></td>
<td>Manufacturer telephone number.</td>
<td>Expiry date.</td>
</tr>
<tr>
<td></td>
<td>Manufacturer fax number.</td>
<td></td>
</tr>
</tbody>
</table>

**ATLASS MEDICAL**

William James House, Cowley Rd, Cambridge, CB4 0WX
Tel: ++44 (0) 1223 858 910
Fax: ++44 (0) 1223 858 524

PPSR7A01 Rev C (18.02.2010)