Intended Use
Clarity® Urocheck 10SG Urine Reagent Strips for Urinalysis are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis. Diagnostic Test Group CLARITY® Urocheck 10SG Urine Reagent Strips are for single use in professional near patient (point-of-care) facilities and centralized laboratory locations by medical technologists both read visually and on the Bayer Clinitek 50, 100, 200, and 500 analyzers.

Clarity® Urocheck 10SG Urine Reagent Strips for Urinalysis 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.

Summary and Explanation of Tests
Clarity® Urocheck 10SG Urine Reagent Strips provide tests for Glucose, Bilirubin, Ketone (acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in Urine.

Test Principles
Urobilinogen: this test is based on the Ehrlich reaction in which p-dihydroxybenzene benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color. Bilirubin: the direct bilirubin and dichlorobenzene diazonium produce fuchsia azo dyes in a strongly acid medium. Ketone: the acetoacetate 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] oxides 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 a cation on the protein molecule makes the indicator further ionized, which changes its color. Nitrite: Nitrite in the urine and amino amino sulphamides are diazotized to form a diazotium compound. The diazotium compound reacting with tetrahydro benzohquinol 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-piperidone. This pyrrole reacting with diazonium forms a purple color. Glucose: The glucose oxidized by glucose oxidase catalyzes the formation of gluconic acid and peroxide hydrogen. Peroxide hydrogen releases neo-ecotypes oxide [O] under the function of peroxidase. [O] oxides 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 ion exchanger. The reaction produces hydrogenous ion, which reacts with a pH indicator that causes the color change. pH: This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range.

Reactive Ingredients (based on dry weight at time of impregnation)
Urobilinogen: 0.2% w/w fast blue B salt; 98.0% w/w buffer; 1.8% w/w nonreactive ingredients. Bilirubin: 0.6% w/w 2,4-dichlorobenzene amine diazotium salt; 57.3% w/w buffer; 42.1% w/w nonreactive ingredients. Ketone: 5.7% w/w sodium nitroprusside; 64.4% w/w buffer; 29.9% w/w nonreactive ingredients. Blood: 26.6% w/w disopyro/benzenes dihydro peroxide; 1.5% w/w tetramethylene-benzidine; 53.5% w/w buffer; 37.2% w/w nonreactive ingredients. Protein: 0.1% w/w tetramethyl blue; 97.4% w/w buffer; 2.5% w/w nonreactive ingredients. Nitrite: 1.3% w/w p-aminoazidoc-1-(N-Naphtho) ethylenediamine; 0.9% w/w tetrahydro -quinoline; 89.6% w/w buffer; 8.2% w/w nonreactive ingredients. Leukocytes: 4.3% w/w pyrrole amino acid ester; 0.4% w/w diazium salt; 92.6% w/w buffer; 2.7% w/w nonreactive ingredients. Specific Gravity: 1.7% w/w glucose oxidase (microbial, 12IU); 0.2% w/w peroxidase (horse-radish, 200IU); 71.8% w/w buffer; 0.1% w/w potassium iodide; 26.2% w/w nonreactive ingredients. Specific Gravity: 4.8% w/w bromothymol blue; 90.2% w/w poly (methyl vinyl ether) co malic anhydride; 5.0% w/w sodium hydroxy. pH: 3.3% w/w bromocresol green; 55.5% w/w bromothymol blue; 41.7% w/w nonreactive ingredients.

Quality Control
Read the test 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 specimens or controls. Water should NOT be used as a negative control.

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 effect the test for glucose, bilirubin, nitrite, and blood [2,4]. 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.

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-aminoanisalicylic 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 [4]. Bilirubin: 1.7% w/w bilirubin that dye red and anything that shows red to brown (e.g., phenazineimidine) may affect the test result. A high concentration of ascorbic acid (49mg/dL) may cause a false negative result. Ketone: False positive results may occur in highly pigmented urine or those specimens containing a large amount of levodopa metabolites [2]. Blood: Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbiol 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 [2]. Protein: False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g., from some antiseptics and detergents) or with cleansers containing chlorhexidine may also produce false positive results [2,4]. Nitrite: A negative result does not rule out significant bacteriuria. False negative results may occur if (1) when urine does not contain the organism that caused the conversion from nitrite to nitrite, (2) when urine has not remained in the bladder long enough (up to four hours) for the nitrate to covert into nitrite, or (3) when nitrate in foods is absent. A 17mg/dL concentration of ascorbic acid or less will not affect the test result [2,4].
Leukocytes: A high glucose concentration (200mg/dL) or a high specific gravity in urine may reduce the sensitivity of the test. High concentration of occlusive acid may decrease test results. Tetracycline may cause decreased reactivity, and high levels of tetracycline may cause a false negative result [2].

Glucose: Ascorbic acid concentrations of 4.9 mg/dL and/or acetoacetic acid concentrations of 19.4mg/dL or lower will not influence the test [2].

Specific Gravity: Urine volume, hydration states 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 (100mg/dL). The reagent strip is not suitable for testing newborn because of their low specific gravity (1.002-1.004) [4].

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

Expected Values/Reference Ranges

Expected values for the normal urinary population and abnormal populations are listed below for each test. Expected values are referenced to European Urinalysis Guidelines, The Clinical Analysis Of Urine Recent Period and Compendium – Urinalysis With Test Strips [2,4,5].

Urobilinogen: Urobilinogen is normally present in urine concentrations up to 1.0 mg/dL (Ehrlich unit/mL). A level of 2mg/mL in urine is the critical value, representing the transition from normal to abnormal, which requires further check on patients and specimens. Evaluation of both the bilirubin and urobilinogen results helps in determining the differential diagnosis of jaundice, as well as other liver and biliary disorders.

Bladder: Normally, even the most sensitive method cannot detect bilirubin in healthy urine. It is abnormal to have even a little bilirubin in which, requires further inspection.

Ketone: Normal urine specimens usually produce negative results in the test. In ketoadenosis, starvation, fasting, pregnancy and frequent strenuous exercise, ketones may appear in urine and may produce positive results [4].

Blood: The 'trace' reaction may vary among patients. Clinical judgments are required for individual cases. The presence of green spots (intact erythrocytes) or green color (hemoglobin/myoglobin) on the reagent area within 60 seconds after dipping indicates the need for a further diagnostic check. Erythrocytes are often, but not always, present in the urine of menstruation.

Protein: The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones protein, and mucoprotein. Therefore a "Negative" result is not sufficient to indicate that these proteins do not exist in urine. Normally protein is not detectable in urine with conventional methods, although a minute amount of protein is excreted through normal kidney function. Protein in urine is indicated when the color is darker than the plus/minus mark on the chart.

Nitrate: Nitrate-negative bacteria in urine converts nitrate (derived from food) into the reagent strip is specific to nitrite and will not react with other substances in urine. Any degree of uniform pink color development should be taken as a positive result. The degree of color development and the number of bacteria are not in direct proportion.

Leukocytes: Positive reactions of the strip react with esterase in leukocytes (granulocyte leukocytes). Normal urine specimens generally yield negative results. Positive results (or greater) are clinically significant. Individual tests or results are clinically questionable, and it is very important that 'trace' results be confirmed in a repeated test.

Glucose: Normally, a small amount of glucose may be excreted through the kidneys. The amount is usually below the sensitivity of the reagent test. Results at the first positive level may be significantly abnormal if found consistently.

Specific Gravity: The normal specific gravity of urine ranges from 1.003-1.035. If the specific gravity of random urine is 1.023 or greater, the concentrating ability of the kidneys can be considered normal.

pH: The normal pH of urine is range from 4.6 to 8.0. Certain dietary conditions can produce acid or alkaline urine, which can be useful in the treatment, or some cure [4].

Performance Characteristics

The performance characteristics of the strips are determined by clinical analysis and study. The results from visual readings and instrumental readings represent agreement and discordance values. Because of the variations of reading and reproducibility, the values obtained from the results of the strips may have errors compared to the actual values of the specimens. Visual reading results may not exactly match the instrumental reading results because of the inherent difference between the perception of human eyes and the optical instruments.

The following table shows the +/-1 color block % Agreement using 1514 samples in laboratory comparison studies between Clarity® Urocheck 105G Urine Reagent Strips and Bayer Multistix 10 SG Reagent Strips.

<table>
<thead>
<tr>
<th>Test Pad</th>
<th>Sensitivity</th>
<th>Output Value</th>
<th>Instrumental Read</th>
<th>Visual Read</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urobilinogen (mg/dL)</td>
<td>0.2-1.0</td>
<td>0.2 - 8.0</td>
<td>Neg - 300</td>
<td>Neg - 200</td>
</tr>
<tr>
<td>Bilirubin (mg/dL)</td>
<td>0.2-5</td>
<td>Negative - Large</td>
<td>Negative - Large</td>
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<tr>
<td>Ketone (mg/dL)</td>
<td>5-10</td>
<td>Negative</td>
<td>Negative - Large</td>
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<tr>
<td>Blood (Glyc.)/mL</td>
<td>5-15</td>
<td>Negative - Positive</td>
<td>Negative - Positive</td>
<td></td>
</tr>
<tr>
<td>Protein (mg/dL)</td>
<td>15-30</td>
<td>Neg - 300</td>
<td>Neg - 2000</td>
<td></td>
</tr>
<tr>
<td>Nitrite (mg/dL)</td>
<td>0.08-0.1</td>
<td>Negative - Positive</td>
<td>Negative - Positive</td>
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</tr>
<tr>
<td>Leukocytes (Lexa/mL)</td>
<td>5-15</td>
<td>Negative - Large</td>
<td>Negative - Large</td>
<td></td>
</tr>
<tr>
<td>Glucose (mg/dL)</td>
<td>50-100</td>
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<td>Negative - Large</td>
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<tr>
<td>pH</td>
<td>5.0 - 8.5</td>
<td>5.0 - 8.5</td>
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Notes on Symbols and Marks


5. "Compendium – Urinalysis with Test Strips" Roche Diagnostic, Combur® Reagent Strips.

<table>
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<th>Store At</th>
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<td>Rev.: Dec 2006</td>
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| Single Use |

Bibliography


5. "Compendium – Urinalysis with Test Strips" Roche Diagnostic, Combur® Reagent Strips.