**Urine Reagent Strips for Urinalysis**

### Test Principle

**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 potassium iodide chromogen to oxidize the former to iodine. The resulting colors range from orange to yellow-green in urine of higher ionic concentration.

**Bilirubin:** This test is based on the coupling of bilirubin with a diazotized dichlorophenol indican to produce a blue-green for a "Positive" reaction. The test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of no diagnostic value, the colors range from dark brown to brown.

**Ketones:** This test is based on the oxidation of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige to buffy-fawn color for a "Negative" reacting to pink and purple for a "Positive" reaction.

**Ketone:** This test is based on the oxidation of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige to buffy-fawn color for a "Negative" reacting to pink and purple for a "Positive" reaction.

**Specific Gravity:** This test is based on the action of esterase present in leukocytes, which couples with 1,2,3,4-tetrahydrobenzo(h)quinolin to produce a pink color. Ascorbic Acid: This test is based on the action of a complex oxidizing agent with polyvinyl alcohol in a higher state and an indicator dye that can react with the metal ion in its lower state to produce a color change from blue-green to yellow.

**Nitrite:** This test is based on the action of an acidified metahemoglobin and an oxidizing agent. The nitrite reacts with p-aminobenzoic acid to form a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,4-trihydroxybenzene (tannic acid) to produce a pink color.

**Protein:** This test is based on the protein error of indicator at a constant pH. The development of any green color is due to the presence of protein. Colors range from yellow for a "Negative" reaction to yellow-green and green-blue for a "Positive" reaction.

**Urobilinogen:** This test is based on a modified Ehrlich reaction in which p-dimethylaminobenzaldehyde reacts with urobilinogen in a strongly acid medium. Colors range from light pink to bright magenta.

**Reagents:** (Based on dried weight at time of impregnation)

- **Glucose:** 16.3% w/w glucose oxidase (Aspergillus niger, 1.3U); 0.6% w/w peroxidase (horseradish, 3300 U); 7.0% w/w potassium iodide; 76.1% w/w buffer and non-reactive ingredients.

- **Bilirubin:** 0.4% w/w 2,4-dihydroxyaniline diazot salt, balanced with buffer and non-reactive ingredients.

- **Ketone:** 7.7% w/w sodium nitroprusside balanced with buffer and non-reactive ingredients.

### Summary

TUP are packaged along with a drying agent in a plastic bottle with a tear-off cap. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. No calculations or laboratory instruments are required. The below color blocks are information only and do not necessarily match perfectly. Refer to color blocks on vial for a perfect match.

### Test Procedure

**Chemical Composition of Reagent Strips:**

- **Acetic Acid:** 28.2% sodium hydroxide; 0.2% w/w methyl red; 2.8% w/w bromothymol blue; 97% w/w non-reactive ingredients.

- **Ascorbic Acid:** 5.8% w/w ferric chloride; 0.4% w/w DTA; 1.2% dipyrone; 89.1% w/w buffer and non-reactive ingredients.

- **Bilirubin:** 2.8% w/w bromothymol blue; 99.7% w/w buffer and non-reactive ingredients.

- **Blood:** 5.8% w/w ferric chloride; 0.2% w/w diazot salt; 93.4% w/w buffer and non-reactive ingredients.

- **Ketone:** 1.4% w/w tetramethylbenzidine; 89.4% w/w buffer and non-reactive ingredients.

### Quality Control

- **Ascorbic Acid:** 11.3% w/w ascorbic acid; 3.5% w/w sodium hydroxide; 68.8% w/w buffer and non-reactive ingredients.

- **Bilirubin:** 5.8% w/w ferric chloride; 4.9% w/w DTPA; 1.2% dipyridyl; 89.1% w/w buffer and non-reactive ingredients.

### Storage

Store at room temperature between 15°-30°C and out of direct sunlight. Do not freeze after expiration date.

### Recommended Handling Procedures

- **Unassembled strips:** Do not handle any strips for immediate use and replace cap tightly.

### Warnings and Precautions

- **Large amounts of blood:** In the presence of an indicator, the colors range from dark blue to blue-green in urine of low ionic concentration. The reagent areas should be used within 3 months after first opening.

- **Negative controls:** Do not use decrescent from bottle. Do not open bottle until ready to use. Open bottles should be used within 3 months after first opening.

### Specimen Collection and Preparation

Collect urine in a clean container and test as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing.

### Test Procedure

1. **Remove the bottle only after strips have dried completely and are ready for immediate use and replace cap tightly.**

2. **Complete immersion of the test strip in fresh, well-mixed urine.**

3. **Remove the strip immediately to avoid dissolving out the reagent areas.**

4. **Comparison is based on the colors in the urine container and the times specified.**

5. **Obtain results by direct color chart comparison.**

### Note:

- **All reagent areas except Leukocytes may be read between 1-2 minutes for screening positive urines for negative urine.** Changes in color after 2 minutes of no diagnostic value.

### Quality Control

- For best results, perform control run strips should be confirmed by testing known negative and positive specimens or controls whenever a new test is performed or whenever a new batch is first opened. Each laboratory should establish its own goals for adequate standards of performance, and should question and handling test procedures if these standards are not met.

### Results

Results are obtained by direct comparison of the color blocks printed on the bottle label. The color blocks represent normal values; actual values will vary around the normal values.
LIMITATIONS OF PROEDURE

Comparison of the color chart is dependent on the interpretation of the individual patient. It is therefore, recommended that all laboratory personnel interpreting the results of these strips are familiar with the chart.

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

Glucose: Moderate amounts of ketones (400 mg/dl or greater) may decrease the color intensity, resulting in the containing small amounts of glucose (75-125 mg/dl). However, such concentration of ketone simultaneously with such glucose concentration is not a diagnostic condition. The negativity of the glucose test decreases as the SG and/or ascorbic acid content of the urine increases. False negative and weak reaction of glucose may be observed if there is more than 5 mg/dl of ascorbic acid in the sample. Reactivity may also be affected with temperature.

Bilirubin: Reactions may occur with urine containing large doses of chloroform, vinchocaine, or substances that may mask the bilirubin reaction. Indian ink, salt, and aminosalicyclic acid (bilirubin) may give a masking golden color. The absence of bilirubin cannot be determined with this test.

Nitrite: The test area will react with nitrites in relative in relation to the number of bacteria present. Any degree of pink color should be interpreted as being positive to nitrite test suggestive of 10 or more organisms/ml. There are occasional urinary tract infections from organisms, which do not contain red blood to convert nitrite to nitric oxide.

Leukocytes: High colored urine and the presence of the drugs cephalaxin (Keflex) or sulfadiazine may generate this abnormality in this test. Low nitrite levels of protein 500 mg/dl or above diminish the intensity of the reaction color. Elevated glucose concentration or high specific gravity may cause decreased reactions.

Blood: There may be slightly different results from those obtained with the specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urine may cause low readings relative to other methods. Elevated specific gravity readings may be obtained from presence of moderate quantities (100-750 mg/dl) of protein.

Bilirubin: The sensitivity of the blood test is reduced in urine with high specific gravity and/or high ascorbic acid content. Microliter peroxide, associated with urine, is obtained from the urine with cephalaxin (Keflex) and sulfadiazine. This test area will show negative or weak results.

Ketone: Color reaction that could be interpreted as "positive" may be obtained with urine specimens containing NSE derivatives in large amounts of phenylketones or lipoic metabolites.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performances characteristics of TUP have been determined both in the laboratory and in clinical trials. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally TUP have been developed to be specific for the constant constituent to the exception of interferences listed above. (See LIMITATIONS OF PROEDURE)

For visual read strips, accuracy is a function of the manner in which the color blocks on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human reader. It is for this reason that they can develop their own standards of performance.

Glucose: This test is specific for glucose; no substances exuded in urine other than glucose is known to give a positive result. The area does not react with lactose, galactose, fructose, or reducing metabolites of drugs; e.g. salicylates and nalidixic acid. This test may be used to determine whether the reducing substances present in the sample are due to reducing sugars or glucose. The area detects a range of 5.0-49 mg/dl of ascorbic acid in the urine. The absence of a negative area detects as little as 5.0 mg/dl ascorbic acid in the urine.

Specific Gravity: The specific gravity test permits determination of urine specific gravity to 500.0/0 or greater. When the Specific Gravity test area will react with interfering substances known to react with the reagent. This test demonstrates the accuracy of the test. The test area will react with interfering substances known to react with the reagent. This test demonstrates the accuracy of the test. The test area will react with interfering substances known to react with the reagent. This test demonstrates the accuracy of the test. The test area will react with interfering substances known to react with the reagent. This test demonstrates the accuracy of the test. The test area will react with interfering substances known to react with the reagent. This test demonstrates the accuracy of the test. The test area will react with interfering substances known to react with the reagent. This test demonstrates the accuracy of the test. The test area will react with interfering substances known to react with the reagent. This test demonstrates the accuracy of the test.