MATERIALS PROVIDED:
1. 1 bottle containing 100 D-Tek ‘ Urine Strips.
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. 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 5. Do not use the same urine sample more than once, as the urine may have been contaminated with the dissolving of sample with each test.

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'-tetrathymethylbenzidine. The resulting color ranges from orange through yellow green to dark green.

Ketone: This test is based on the reaction between acetoacetic acid with nitroprusside. The colors range from buff-pink for a negative reaction to pink to purple for a positive reaction.

Urobilinogen: This test is based on the Ehrlich reaction in which p-dimethylaminobenzaldehyde reacts with urobilinogen in a strong acid medium to produce light pink to bright magenta 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.

pH: This test is based on a double pH indicator principle that gives a broad range of colors covering the entire urinary pH range of 5-9. Colors range from orange through yellow and green to blue.

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 blue-green for “Positive” reactions.

REAGENTS: (Based on dry weight at time of impregnation)
Blood: 6.6% w/w cumene hydroperoxide; 4.0% w/w 3.3',5,5'-tetramethylbenzidine; 88.4% w/w buffer and non-reactive ingredients.
Ketone: 7.1% Sodium nitroprusside; 92.9% w/w buffer and non reactive 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; 76.1% w/w buffer and nonreactive ingredients.
pH: 0.2% w/w methyl red; 2.8% w/w bromthymol blue; 97% w/w nonreactive ingredients.
Protein: 0.3% w/w tetramethylbenzophenol blue; 99.7% w/w buffer and 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 HANDLING PROCEDURES: All unused strips may be read from the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become non-reactive.

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. Opened 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. 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.

QUALITY CONTROL:
Based on dry weight at time of impregnation

Blood:
- 3.3',5,5'-tetramethylbenzidine
- 89.4% w/w buffer and non-reactive ingredients.
- 4.0% w/w cumene hydroperoxide

Ketone:
- 7.1% Sodium nitroprusside
- 92.9% w/w buffer and non-reactive ingredients.

Glucose:
- 16.3% w/w glucose oxidase
- 0.6% w/w peroxidase
- 76.1% w/w buffer and non-reactive ingredients.

pH:
- 0.2% w/w methyl red
- 2.8% w/w bromthymol blue
- 97% w/w non-reactive ingredients.

Protein:
- 0.3% w/w tetramethylbenzophenol blue
- 99.7% w/w buffer and non-reactive ingredients.

WARNINGS AND PRECAUTIONS:
- Urine reagent strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become non-reactive.
- 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. Opened 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. 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.

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.

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 Gantnin) may give a masking golden color. The absence of urobilinogen cannot be determined with this test.

**Ketone:** Red-orange to red color shades can be produced by phenylketone or phthalain compounds which may be administer for liver and kidney function test. 2-Mercaptoethane sulphonate sodium (MESNA) or other sulphydryl containing compounds may cause false positive results.

**Glucose:** 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.

**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.

**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.

**Blood:** The sensitivity 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 0.2 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.

**Ketone:** Normally no ketones are present in urine. Detectable levels of ketone occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine in large amounts before serum ketones are elevated.

**Glucose:** Smal amounts of glucose are normally excreted by the kidneys. 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. At 10 secs, results should be interpreted qualitatively; for semi-quantitative results read at 30 seconds only.

**pH:** New born: 5-7
Normal: 4-5-8
Average: 6

**Protein:** Normal secretion of protein in the urine in 24 hour specimen 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.

**PHYSICAL PARAMETERS:**
- 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)

**Reagent Area**
- Blood: 0.015 mg/dL free hemoglobin
- Urobilinogen: 0.2 mg/dL (0.2 Ehrlich Unit/dL)
- Ketone: 5-10 mg/dL acetocetic acid
- Glucose: 100 mg/dL glucose approximately
- Protein: 15 mg/dL albumin

**Expected Values:**
- 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/L in urine. The test is equally sensitive to myoglobin as to hemoglobin. The sensitivity of this test may be used in urine of high specific gravity.

**Blood:** The test does not react with beta-hydroxybutyric acid or acetone. This test is specific for acetocetic acid.

**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.

**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 urinary buffer concentration.

**Urobilinogen:** This test area will detect urobilinogen in concentrations as low as 0.2 mg/dL (approximately 0.2 EU/dL) in urine. The absence of urobilinogen in the specimen being tested cannot be determined.

**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.

**BIBLIOGRAPHY:**

Azo-Gantnin and Azo-Gantanol are registered trademark of Roche Laboratories

Revised: 07/06