

For the Semi-quantitative detection of Glucose and Protein

#### INTENDED USE

Urine Test Strips contains solid phase reagent areas affixed to a plastic stick. They are provided as a dry reagent. Urine Test Strips provide test for the semi-quantitative determinations of Glucose and Protein. The test results may provide information regarding the status of carbohydrate metabolism, Kidney function, liver function, acid base and urinary tract infection.

#### SUMMARY AND EXPLANATION

The urinalysis test strips are ready to use upon removal from the bottle. The entire reagent strips are disposable, No additional laboratory equipment is necessary for testing. The directions must be followed exactly. Accurate timing is essential to provide optional results. The strips are packaged in a plastic bottle, containing desiccant. The bottle must be capped tightly to maintain reagent activity.

#### TEST PRINCIPLE

**Glucose** : The test is based on a double sequential enzyme reaction One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide with Potassium iodide to oxidize the chromogen to color ranging from blue to dark brown

**Protein:** The 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 green to green-blue for "Positive reaction".

#### REAGENT COMPOSITON

Glucose: 10.54% w/w glucose oxidase (aspergillus, 250 IU), 0.2% w/w Peroxidase (horseradish, 2,500 IU), 0.07% w/w, Potassium iodide and 84.3% non reactive ingredients.

Protein: 1.5% w/w tetrabromophenol blue and 98.5% w/w non reactive ingredients.

#### Materials Provided

Urine test strips  
Color label chart  
Instructions for use.

#### PRECAUTIONS

For in vitro diagnostic use only.  
Do not touch areas of strips.  
After removing a test strip, replace cap on bottle promptly.  
Working area should be free of detergents and other contaminants.

#### STORAGE

Storage at room temperature between 15 – 30° C (59-89 F) and out of direct sunlight.  
Do not use after expiry date  
Do not refrigerate or freeze.  
Store all test strips in the original bottle. Do not remove the desiccant from bottle.  
Close the bottle cap tightly after each use.

#### SPECIMEN COLLECTION

Urine should be collected in a clean container, either plastic or glass.  
Do not centrifuge.

If testing cannot be done within an hour after voiding, refrigerate the specimen immediately.

It is especially important to use fresh urine to obtain optimal test results for bilirubin and urobilinogen.

#### RECOMMENDED HANDLING PROCEDURE

All unused strips must remain in the original bottle. Transfer to another container may cause reagents strips to deteriorate and become unreactive. Do not remove strips from the bottle until immediately before it is used for testing. Replace cap immediately and tightly after removing reagents strips.

#### TEST PROCEDURE

Bring specimens to room temperature before use.  
Remove Accucare strip from the bottle. Replace cap immediately.  
Inspect the strip. (Discoloration or darkening of reagent test areas may indicate deterioration. Do not use the strip.)  
Immerse test areas of the strip completely in urine and remove immediately to avoid dissolving of reagents.  
To remove excess urine, run the edge of the strip against rim of the urine container. Hold the strip in horizontal position to prevent possible mixing of chemicals from adjacent reagent areas. Excess urine may also be removed by gently blotting the lengthwise edge on absorbent paper.  
Compare the optimal results carefully with the color chart on the bottle label in a good light.  
Note: The optimal reading time of each test parameter varies from 30 to 60 seconds. Changes in color that appear only in the edges of the test areas or after more than 60 secs are of no clinical significance.

#### RESULTS

The results are obtained by dipping the strips in urine and direct comparison of the test strip with the color blocks printed on the bottle label.

#### LIMITATIONS

Glucose: Large amounts of ketone bodies (50 mg/dl or greater) may decrease color development.  
Protein: False positive results may be obtained with alkaline urine.  
Expected values:  
Glucose: The kidney normally excretes small amounts of glucose. Concentrations of as little as 0.1 gm/dl glucose, read either at 10-30 seconds may be scientifically abnormal if found consistently.  
Protein: Normally urine specimens contain some protein, (0.4 mg/dl) therefore; only persistent levels of urine protein indicate kidney or urinary tract disease.

#### PERFORMANCE CHARACTERSTICS

Studies comparing the Accucare Urinalysis Strip and other commercially available strips resulted in greater than 99% agreement with 60 urine samples.

#### BIBLIOGRAPHY

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3. J.M. Wilson and G.Hunger "Principles and practice of screening for disease "Public Health Papers Bo. 34, World Health Organization, Geneva, 1986.