

# GB-STIX Test for Urinalysis



Genuine Biosystem Pvt Ltd

For the Semi-quantitative and detection of Glucose, Albumin

## INTENDED USE

GB STIX Urine Test Strips contains solid phase reagent areas affixed to a plastic stick. They are provided as a dry reagent. GB STIX Urine Test Strips provide test for the semi-quantitative determinations of Glucose, Albumin. The test results may provide information regarding the status of carbohydrate metabolism. Kindly 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 is 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 O-Touident chromogen to oxidize the chromogen to color s ranging from light green to dark brown.

**Albumin:** The test is based on the Albumin error-of-indicators principle. At a constant Ph, the development of any green color is due to the presence of Albumin. 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 (hoseradish, 2,500 iu), 0.07% w/w, O-Touidene and 84.3% non reactive ingredients.

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

## Materials Provided

1. GB STIX urine test strips
2. Color label chart
3. Instructions for use.

## Materials required but not provided

1. Urine collection cup
2. Clock or timer.

## PRECAUTIONS

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

## STORAGE

1. Storage at room temperature between 2-30°C (35-86 F) and out of direct sunlight.
2. Do not use after expiration date.
3. Do not refrigerate or freeze.
4. store all test strips in the original bottle. Do not remove the desiccant from bottle.
5. Close the bottle cap tightly after each use.

## SPECIMEN COLLECTION

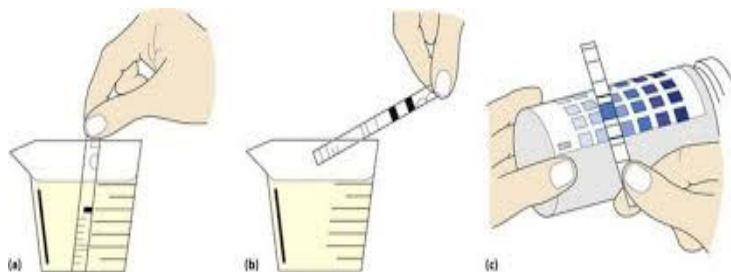
1. Urine should be collected in a clean container, either plastic or glass. Do not centrifuge.
2. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately.

## RECOMMENDED HANDLING PROCEDURE

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

1. Bring specimens to room temperature before use.
2. Remove GB STIX strip from the bottle. Replace cap immediately.
3. Inspect the strip. (Discoloration or darkening of reagent test areas may indicate deterioration. Do not use the strip.)
4. Immerse test areas of the strip completely in urine for 2secs. To remove excess urine, run the edge of the strip against rim of the urine container. Excess urine may also be removed by gently blotting the lengthwise edge on absorbent paper. Hold the strip in horizontal position to prevent possible mixing of chemicals from adjacent reagent areas.
5. Compare the optimal results carefully with the color chart on the bottle label in a good light.
6. Note: The optimal reading time of each test parameter varies from 30 to 60 seconds (Glucose 30secs & Albumin 60secs). 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.

## Expected values:

**Glucose:** The kidney normally excretes small amounts of glucose. Concentrations of as little as 5.0mmol/l glucose, read either at 10-30 seconds may be significantly abnormal if found consistently.

**Albumin:** Normally urine specimens contain some Albumin, (0.3 g/l) therefore, only persistent levels of urine Albumin indicate kidney or urinary tract disease.

#### **NORMAL VALUE REFERENCE**

Glucose	Negative
Albumin	Negative

#### **QUALITY CONTROL**

Check with known negative and positive urine samples or controls

every time a new bottle is opened.

#### **PERFORMANCE CHARACTERISTICS**

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

#### **BIBLIOGRAPHY**

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