



Diabetes Screening Urine Glucose Test Strips Package Insert

REF G80501	English
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For the semiquantitative detection of Glucose in human urine.
For self-testing and *in vitro* diagnostic use only.

INTENDED USE

Suresign Diabetes Screening Urine Glucose Test Strips are intended for home use self-testing to provide tests for the semiquantitative determination of Glucose in Urine. Screening test results may provide information regarding the status of carbohydrate metabolism.

TEST PRINCIPLE

This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyses the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyses the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colours ranging from green to brown.

REACTIVE INGREDIENTS

Based on dry weight at time of impregnation; 1.7% w/w glucose oxidase (microbial, 123U); 0.2% w/w peroxidase (horseradish, 203IU); 71.8% w/w buffer; 0.1% w/w potassium iodide; 26.2% w/w nonreactive ingredients.

STORAGE

Strips must be kept in the sealed original foil pouch.
Store at temperatures between 2-30 degrees C (39-86 degrees F).
Keep away from direct sunlight and moisture.
Protect against exposure to light, heat, and ambient moisture to guard against altered reagent reactivity.

PRECAUTIONS

- For self-testing and *in vitro* diagnostic use only.
- Do not open the foil pouch until you are ready to carry out the test.
- Do not touch the reagent area of the strip.
- Do not use a test strip beyond the expiration date.
- If on opening a sealed foil test do not use a test strip if the colour of the reagent area on the strip is darker than the lowest block on the colour reference card, the test strip is unusable, discard the test strip and use a new test strip.
- Each strip must be used only once.
- Large amounts of ascorbic acid may affect the test for glucose.
- Deterioration may result in discoloration or darkening of the reagent area 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.
- User should not take any decision of medical relevance without first consulting his or her medical practitioner.

MATERIALS

Materials Provided

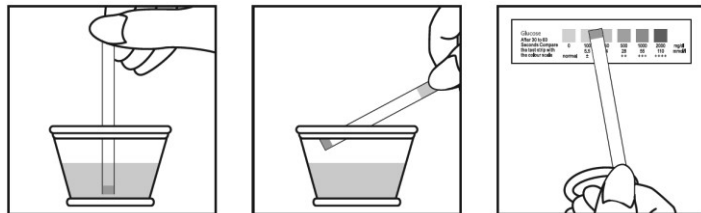
• Test Strips	• Package Insert	• Colour Reference Card
Materials Required but Not Provided		
• Timer	• Dry and clean plastic container	• Paper towel

SPECIMEN COLLECTION AND PREPARATION

- Collect fresh urine in a clean and dry container.
- Do not centrifuge the urine.
- Mix the sample well before testing it.
- The container should allow for complete dipping of the reagent area on the strip.

PROCEDURE

- Remove the test strip from the foil pouch and use immediately.
- Immerse the reagent area of the strip in the urine specimen and remove quickly from the urine, within 1 second. Start timing.
- Run the edge of the strip against the rim of the container to remove excess urine. Lay the strip on a paper towel with the reagent pad area facing upward. Wait for 30 to 60 seconds.
- In good light, hold the strip up vertically and compare the reagent area on the strip to the colour blocks on the colour reference chart. Hold the strips close to the colour blocks and match carefully. **Note:** Do not read the test after 2 minutes, colour changes after this time are of no diagnostic value.
- Dispose of strips in accordance with local regulations. Do not flush down the toilet.



EXPECTED VALUES

Normally, a small amount of glucose may be excreted through the kidneys. The amount is usually below the sensitivity of the reagent test. If your results are consistently in the positive reference level, this may indicate a significant abnormality.

If a positive result is obtained, please consult your healthcare professional as soon as possible for further investigations. When you visit your healthcare professional, please take these instructions with you so that they will be better informed as to the type of test you have performed.

Note: Visual reading results may not exactly match instrumental reading results because of the difference between the perception of human eyes and the optical instrument. Most visual and instrument readings are within one level of true value.

LIMITATIONS

Ascorbic acid concentrations of 4.9mg/dL and/or acetoacetic acid concentrations of 19.4mg/dL or lower will not influence the test.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of the strips are determined both by clinical analysis and study. The results from visual readings and instrumental readings represent an actual range of analyte concentrations. Because of the variety of the specimens and reading methods, the values obtained from the results of tests may have been 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 colour block % Agreement using 967 samples in laboratory comparison studies between Suresign Diabetes Screening Glucose Strips and Bayer Multistix 10 SG Reagent Strips.

Analyte	% Agreement
Glucose	96.9% (937/967)

In 90% of urines tested, glucose concentrations of 80 mg/dL or greater will produce a positive result. Sugars other than glucose will not react with the reagent. If the colour appears somewhat mottled at the higher glucose concentrations, match the darkest colour to the blocks.

The sensitivity of the strips on clinical urine specimens may vary depending upon several factors, such as the variability of colour perception, specific gravity, PH value, and the lighting conditions when the strips are read visually. Test sensitivities and are given in the following table.

Sensitivity of Suresign Diabetes Screening Urine Glucose Test Strips		
Test Pad	Sensitivity	Test Range
Glucose (mg/dL)	100	100-2000

BIBLIOGRAPHY

- "Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline"; NCCLS Document GP16-A (ISBN 1-56238-282-9); 1995. NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA19087, USA.
- "Operating Rules Of Clinical Test" (REV.2), The Ministry of Health of P.R.C. Publishing, Yingwu Ye, Yusan Wang.
- "The Clinical Analysis of Urine Recent Period", The Science and Technology Publishing House, Yu Long Cong, Jun Long Ma, Editors; 1998; pp.37-81, 96-97.
- "Compendium-Urinalysis with Test Strips" Roche Diagnostic, Combur® Reagent Strips.

INDEX OF SYMBOLS

	Consult Instructions for Use		Tests per kit		Authorized Representative		Caution
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse		Do not expose to direct sunshine
	Store between 2-30°C		Lot Number		Catalog #		
	Do not use if package is damaged		Manufacturer		Importer		



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