



## DIABETES SCREENING TEST

FOR IN VITRO SELF-TEST DIAGNOSTIC USE ONLY. FOR USE OUTSIDE THE BODY

Please read the entire insert before performing the test.

### ABOUT THE TEST:

The SURESIGN DIABETES SCREENING TEST detects glucose in urine. It is extremely sensitive and will register small amounts of glucose (100 mg/dl). Glucose in urine is associated with early stages of diabetes and other carbohydrate metabolic diseases. By performing the test yourself at home, you can detect the presence of glucose in your urine. Normally you should have no glucose in your urine. The detection of glucose is based on the glucose oxidase-peroxidase-chromogen reaction. Apart from glucose, no other substance in urine is known to cause a positive reaction. A green to brown colour that develops on the sensor pad indicates a positive reaction and means that you have glucose in your urine. If the test is POSITIVE you should immediately consult your doctor. The clinical symptoms of diabetes include fatigue, excessive thirst and a need to urinate frequently. If you have any of these symptoms you should consult your doctor immediately whether your test result is positive or negative.

### CONTENTS OF THE KIT

3 Glucose Test Strips, Colour Chart, Product Instructions

Test Strips are individually wrapped in foil pouches and are ready to use. The Sensor Pad located on the Test Strip is impregnated with chemicals to detect glucose in urine.

### PROPER USE AND STORAGE

- Do not open the package in a steamy bathroom
- Do not open until ready to use
- Do not touch the Sensor Pad
- Use Test Strip immediately after opening
- Do not let the Test Strip come in contact with any liquid prior to use
- Store kit in a dry place at room temperature (18-27°C). Do not store in the refrigerator.
- Do not use after the expiry date printed on the pack
- Do not re-use the Test Strip
- Discard Test Strip after use in normal household waste

### DIRECTIONS FOR USE

Ideally, you should perform the test about two hours after your last substantial meal.

- Collect fresh urine in a clean dry container and test as soon as possible. If the sample cannot be tested immediately, it can be stored in the refrigerator (2-8°C) for up to 8 hours. If you store your urine, before testing, allow it to warm up by standing at room temperature for 15-20 minutes.
- DO NOT OPEN IN A STEAMY BATHROOM. Remove the Glucose Test Strip from the individual foil package.
- Examine the Test Strip prior to use. The sensor pad should be a pale green colour. Discard if sensor is damaged or discoloured.
- Completely immerse the test area of the Test Strip in fresh urine until sensor pad is wet.
- After wetting the Test Strip with urine drain any excess urine.
- Wait 90 seconds. Compare the colour of the Test Sensor Pad to the Colour chart provided.

WHEN READING, HOLD THE TEST STRIP CLOSE TO COLOUR BLOCKS AND MATCH COLOUR CAREFULLY. IMPORTANT NOTE: IGNORE COLOUR CHANGES THAT OCCUR AFTER THREE MINUTES

### READING THE RESULT

**NORMAL / NEGATIVE:** If after 90 SECONDS of wetting the Test Strip the Sensor Pad is still a very pale green colour (compare to colour chart) the test result is negative. No colour change indicates that there is no detectable glucose (sugar) in your urine.

**ABNORMAL / POSITIVE:** If after 90 SECONDS of wetting the Test Strip, the Sensor Pad becomes a progressively darker colour (compare to colour chart) the test is positive. Any colour change is considered a positive reaction. Call your doctor. A positive result indicates that you have glucose in your urine.

CALL YOUR DOCTOR IF YOU GET ANY COLOUR CHANGE ON THE SENSOR PAD. THIS IS CONSIDERED A POSITIVE TEST FOR GLUCOSE. GLUCOSE IN URINE IS ASSOCIATED WITH DIABETES AND OTHER CARBOHYDRATE METABOLIC DISEASES. IT IS IMPORTANT TO SEE YOUR DOCTOR IF YOU GET A POSITIVE TEST RESULT.

IF THE TEST IS NEGATIVE AND YOU CONTINUE TO EXPERIENCE ANY ABNORMAL SYMPTOMS, CONTACT YOUR DOCTOR.

### GUIDELINES FOR USE

The onset of diabetes can be rapid (within six days), gradual (one week to two months) or indefinite. Diabetes can occur during pregnancy. After the age of 40, when diabetes and other carbohydrate metabolic diseases are most prevalent, testing for sugar (glucose) in the urine several times a year using the SURESIGN DIABETES SCREENING TEST is advisable. Individuals with a family history of diabetes, overweight individuals or pregnant women may consider performing the test more often.

### EXPECTED VALUES

Normally, there is no detectable glucose in urine. Abnormal glucose concentrations are indicated by a colour change from pale green to brown. A pale green test result should be considered negative - normal. Any colour change to darker green-brown should be considered a positive result. After testing, write down your test results so that you can discuss them with your doctor. If you have a negative test result and you continue to have symptoms of diabetes contact your doctor immediately

### LIMITATIONS

- SURESIGN DIABETES SCREENING TEST is not a conclusive test for diabetes. Positive results must be confirmed by your healthcare professional.
- Large amounts of Vitamin C or fruit juices (Ascorbic Acid) and/or antibiotic therapy can lead to lower or false negative results
- False positives can be produced by a residue of peroxide-containing agents (household bleach).
- The test is specific for glucose. No substance excreted in urine other than glucose is known to give a positive result. Other sugars, including Lactose, galactose, fructose or any other metabolic reducing agent (e.g. salicylates), do not interfere with the test reaction.
- Substances that cause abnormal urine colour, such as drugs containing azo dyes (e.g. Pyridium, AZO Gantrisin, AZO Grantanolo), nitrofurantoin and riboflavin, may affect the readability of the SURESIGN DIABETES SCREENING TEST result. The colour development on the reagent pad may be masked or a colour reaction may be produced on the pad that could be misinterpreted. If urine appears to be discoloured, do not perform the test.
- Blood in urine may affect the final colour reaction

### PRODUCT PERFORMANCE

Studies have been done to confirm the performance of the SURESIGN DIABETES SCREENING TEST with another comparable product. The data confirm the sensitivity, specificity and accuracy of the SURESIGN DIABETES SCREENING TEST.

The following is a summary of the performance data.

Sensitivity = >99% Specificity = 98.5% Accuracy = 99%  
The test is specific for glucose. No substance excreted in urine other than glucose is known to give a positive result.

|                 | COMPETITIVE PRODUCT (+) | COMPETITIVE PRODUCT (-) | TOTAL |
|-----------------|-------------------------|-------------------------|-------|
| SURESIGN TEST + | 38                      | 1                       | 39    |
| SURESIGN TEST - | 0                       | 66                      | 66    |
| TOTAL           | 38                      | 67                      | 105   |

### MEANING OF SYMBOLS USED ON PACKAGING

|  |                                     |  |               |  |              |
|--|-------------------------------------|--|---------------|--|--------------|
|  | Attention, see instructions for use |  | Tests per kit |  | Manufacturer |
|  | For in vitro diagnostic use only    |  | Use by        |  | Do not reuse |
|  | Store between 18°C and 27°C         |  | Lot Number    |  | Catalog #    |



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### Diabetes Screening Test

|          |          |
|----------|----------|
| Positive | Negative |
|          | Trace    |
|          | Positive |

If the sensor pad turns any shade of brown you may have glucose (sugar) in your urine and you should consult your healthcare professional

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