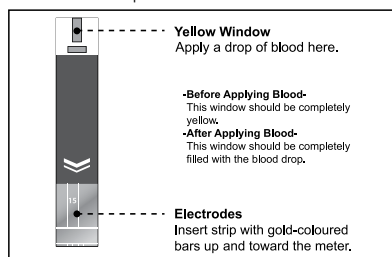


NOTE :

- Please read all this information carefully before using SD CodeFree™ Blood Glucose Test Strip.
- Your SD CodeFree™ Blood Glucose Test Strip must only be used with the SD CodeFree™ meter. Do not use with any other blood glucose meter.
- For more information on performing a blood glucose test, carefully read the SD CodeFree™ Blood glucose meter user instruction guide.

INTRODUCTION

Testing your blood glucose regularly helps you to better manage your diabetes. Medical studies show that, with your doctor's care, you may be able to maintain your glucose at near normal levels. This can prevent or slow the development of medical complications associated with diabetes.



Intended use

SD CodeFree™ blood glucose test strip is designed for self testing blood glucose using fresh capillary whole blood from finger prick, palm, forearm or upper arm. This strip is intended for home use outside the body (in-vitro diagnostic use) and only with the SD CodeFree™ blood glucose meter.

Product Description and the Principle of use

The SD CodeFree™ test strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that cause a small electric current. The amount of current that is created depends on how much glucose is in the blood.

The SD CodeFree™ meter measures the current that is created and converts the measurement to the amount of glucose that is in the blood. The blood glucose result is displayed on the meter's LCD display.

By touching a drop of blood to the tip of the SD CodeFree™ test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, the SD CodeFree™ meter starts to measure the blood glucose level. It is a simple and practical system for the daily monitoring of your blood glucose level.

Reagent Composition : Active Ingredient (per 100 strips)

Glucose oxidase (GOD) 300 units
Potassium ferricyanide (mediator) 9.0 mg

PRECAUTIONS

- Use only fresh capillary whole blood by finger prick or alternative sites (palm, forearm and upper arm) for blood glucose testing.
- A test strip should only be used in accordance with the specified intended use.
- A test strip is for single use only. Do not reuse.
- The SD CodeFree™ blood glucose test strip should only be used with the SD CodeFree™ blood glucose meter.
- Dispose of the used test strip and lancet carefully.
- Insert a test strip into 'test strip slot' of the meter with gold-coloured bars and printed arrow symbol facing up and toward the meter.
- The test strip is sensitive of humidity. Therefore, you should keep the test strips in the specified container. After removing a test strip from its container, close the container cap of the test strip immediately.
- After removing a test strip from its container, you should use the test strip within 3 minutes.
- Do not use the test strip 3 months after opening the container. After this time all remaining test strips should be discarded.

- You should insert a test strip in the meter gently until it will go no further. If you insert the test strip too firmly you can easily damage the test strip.
- The blood sample for a test strip must be at least 0.9µl in volume. If there is insufficient blood you will get an inaccurate test result and the test strip should be discarded.
- Only apply blood to the yellow window of a test strip.
- Try to avoid touching the yellow window of a test strip.
- The 'check strip' should only be used to check the meter is operating correctly.
- Do not bend, cut or modify a test strip or 'check strip'.

INFORMATION ABOUT ALTERNATIVE SITE TESTING (AST)

Sites other than your fingertip may have fewer nerve endings so obtaining a blood sample from these sites may be less painful. The technique for alternative site testing is different from fingertip testing. Blood glucose results from sites other than your fingertip could be significantly different due to blood glucose levels changing rapidly after a meal, insulin, or exercise. Consult with your diabetes healthcare professional prior to testing from a site other than your fingertips.

Consider Alternative Site Testing(AST) When;

- Testing before a meal
- You are in a fasting state
- Two hours have passed since a meal
- Two hours have passed since insulin dosing
- Two hours have passed since physical activity

Use Fingertip Testing ;

- Within two hours after a meal
- Within two hours after insulin dosing
- Within two hours after physical activity
- If you have a history of hypoglycemia, are experiencing low blood glucose, or suffer from hypoglycemic unawareness (you cannot tell when you have low blood glucose)
- During times of stress or illness

Ask your diabetes healthcare professional about recommended testing procedures. If bruising occurs when using AST you may prefer to lance a fingertip instead. When operating machinery or driving a car, fingertip testing is recommended in these circumstances.



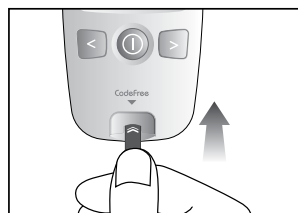
If the repeated alternative site result is still not consistent with how you feel, confirm your blood glucose level with fingertip testing.

PERFORMING A TEST

Testing Procedure (Also see Visual Instructions)

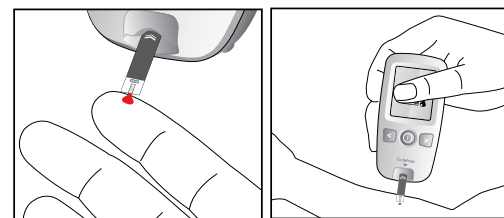
Testing Blood Glucose

- Remove a new test strip from the container. Be sure to reseal the container cap properly after removing test strip.
- Insert the test strip into test strip slot until it will go no further with gold-coloured bars printed arrow symbol facing up and toward the meter. The meter will turn on automatically.



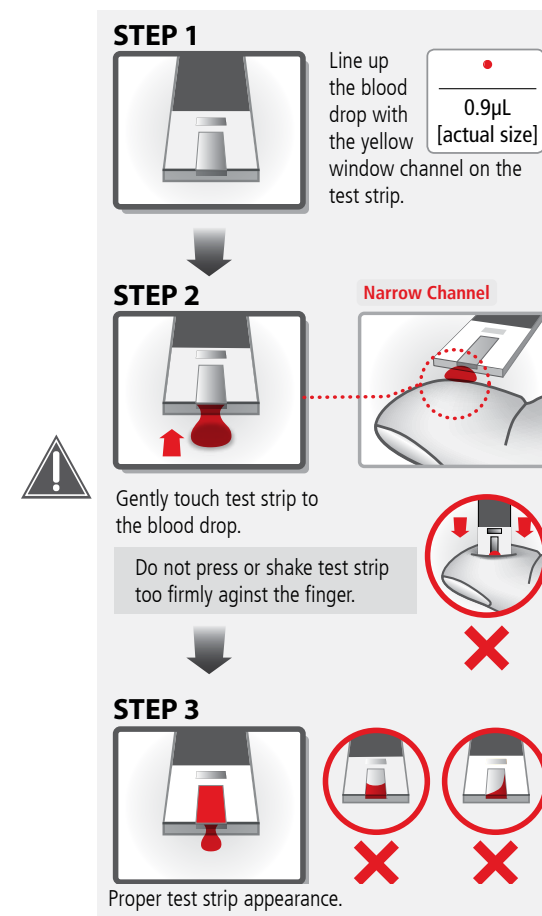
- Obtain a blood drop sample using the lancet and lancing device.
- Touch and hold drop of blood to the edge of the strip until the yellow window is completely filled with blood. The blood will be drawn into the strip automatically.

- When blood is added to the strip, the display counts down from 5 to 1 second and your result appears on the display in just 5 seconds.



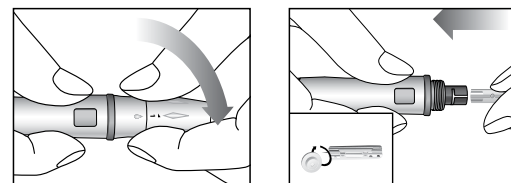
- Remove and discard the used test strip.

Visual Instructions



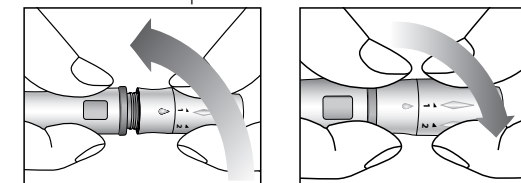
Blood Sampling Fingertip

- Wash your hands in warm, soapy water. Rinse well and dry completely. Warming fingers can increase the blood flow.
- Turn the lancet insert cap counterclockwise to remove the cap. Insert the lancet into the lancing device holder and push down firmly until it is fully seated. Twist the lancet protective disk until it separates from the lancet.

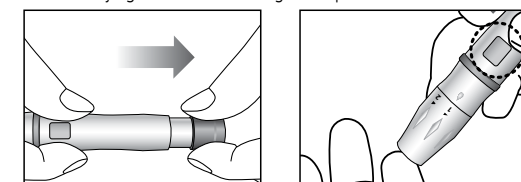


- Replace the lancet insert cap and turn it clockwise until it is snug. Adjust the puncture depth setting by turning the puncture depth adjust

dial that has 1 to 5 steps, the higher the step the higher the impact needle insertion at the puncture site.



- Pull back the priming knob to arm the lancing device. Hold the lancing device firmly against the side of finger and press the release button.



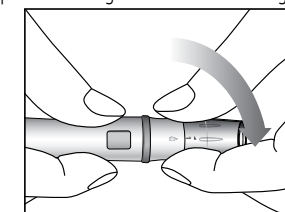
- To eliminate any chance of infection dispose of the lancet properly.



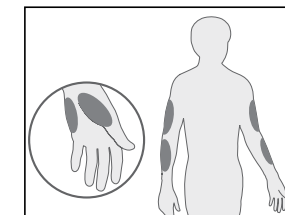
- Lancets are for single use only to reduce the chance of infection.
- It is dangerous for the lancing device with an inserted lancet to be placed anywhere near the eyes, mouth or any infection site.
- Keep the lancing device and lancets well away from children.

Alternative sites

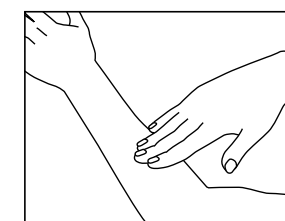
- Insert a lancet and place the AST cap(the one with the clear plastic top) on the top of the lancing device. Arm the lancing device.



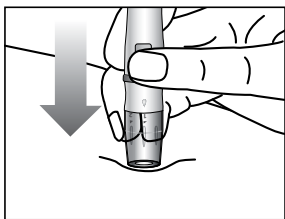
- Select a soft, fleshy area on the palm, forearm, or upper arm that is free of visible veins, moles, hair and away from bone.



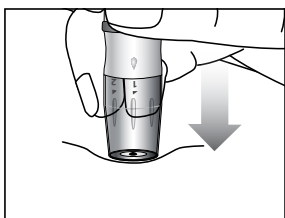
- Press and vigorously rub the selected area for 10 seconds until it starts to feel warm to the touch.



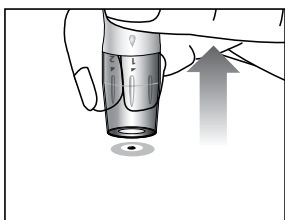
- Wash the area with warm, soapy water. Rinse and dry completely. If you use alcohol wipes to cleanse the site, make sure that the area is dry before lancing the site.
- Firmly hold the armed lancing device against the clean skin for 5-10 seconds.



- Press the release button on the lancing device to lance the skin. Continue to hold the lancing device firmly against the skin until a blood drop forms.



- Once a large enough drop of blood has formed, remove the lancing device.



- Repeat the blood sampling if fluid is clear.
- If it takes longer than 20 seconds to obtain a blood sample and to touch the strip to the blood drop, repeat the blood sampling

UNDERSTANDING YOUR TEST RESULT

Normal blood glucose result

- The fasting adult blood glucose range for a person without diabetes is between 74 and 106 mg/dL (4.1 and 5.9 mmol/L). Two hours after meals, normal blood glucose levels should be less than 140 mg/dL (7.8 mmol/L).
- Consult with your healthcare professional for the blood glucose range that is appropriate for you.

Test Result Range

SD CodeFree™ meter reads blood glucose results between 10 ~ 600 mg/dL (0.6 ~ 33.3 mmol/L).

- If HI is displayed, your blood glucose result may be higher than 600 mg/dL (33.3 mmol/L). You may have high blood glucose.
- If Lo is displayed, your blood glucose result may be lower than 10 mg/dL (0.6 mmol/L). You may have low blood glucose.

Unexpected Results

High or low blood glucose results can indicate potentially serious medical conditions. In case of an unexpected result, you should repeat the test immediately using a new test strip. If your reading is still unexpected or the reading is not consistent with how you feel, you should treat this condition as prescribed by your healthcare professional and/or contact your healthcare professional immediately.

Control of Unexpected Results

If your blood glucose result seems unusually high, low, or inconsistent with your previous results or glucose trends and does not reflect the way you feel, check the following:

- Repeat the test with a new strip.
- If the repeated result is still unexpected run a control solution test with the SD control solution.
- If the control solution test result is within the acceptable range, review proper testing procedure and repeat your blood glucose test with a new test strip. If your blood glucose value is still inconsistent with your previous results, glucose trends, or how you feel, please contact your healthcare professional. Follow the advice of your healthcare professional before you change your therapy.

Possible Cause of Unexpected Results

- If more than 20 seconds has elapsed from sample collection to measurement (evaporation of the blood sample may cause a test result that is higher than the accurate value)
- Was the blood sample applied to the test strip within 3 minutes of removing it from the container?
- Was the size of the blood sample sufficient to fill the reaction site?
- Was the test strip container cap tightly sealed?
- Was the test strip used before the expiration date?
- Were the test strips stored at extreme temperatures such as in the car during very cold or hot weather?
- Were the test strips stored in areas of high humidity such as the kitchen or the bathroom?
- For AST, did the blood sample appear to be diluted with clear fluid?
- For AST, did you vigorously rub the test site?

CHECKING WITH A CONTROL SOLUTION

Control solution test

The Control solution check ensures that you are doing a test correctly and that your meter is working properly. Make sure you use the proper control solution for the test strips you have: SD CodeFree™ blood glucose test strips require SD control solution. This control solution is available from your healthcare professional or the supplier of these test strips.

When should I run a control solution test?

- If the results you are getting are not consistent with previous results.
- If you drop or damage the meter or suspect this has happened.
- Whenever your result does not agree with the way you feel.
- If you have repeated a test, and the blood glucose result is still lower or higher than expected.
- If you want to check the performance of the meter and the test strip.



- Do not use any control solution that has expired or has been opened for longer than 3 months. Please check the date of first opening to ensure an accurate check of the meter and the test strip.
- Test control solution should be stored at 18~30°C (64~86°F) in a dry cool area.

Checking procedure

- Insert a test strip and press the left button of the meter for 3 seconds to check the testing system using a control solution.
- Shake the control solution container and discard the first drop of solution. Gently squeeze the container to form one small drop. Bring the drop to the edge of the strip, and allow the strip to automatically draw the control solution into the yellow window. When control solution is applied to the test strip, the meter counts down from 5 to 1 seconds on the display. Tightly replace the cap on control solution.
- The control solution result appears on the display in just 5 seconds



Understanding your control solution test

- If your glucose control solution test result is within the acceptable range, you can feel confident that your test strips and meter are working correctly.
- If your glucose control solution test result is outside of the acceptable range, your system may not be working properly.

Check the following:

- Did you use control solution or test strips that were past their expiration date?
- Did you leave the cap off the container of test strips or control solution?
- Did you follow the testing steps exactly?
- Did you use the proper control solution for the test strips you used?

Repeat the glucose control solution test. If the result still is not acceptable, please contact your local Standard Diagnostics, Inc. organization or e-mail (sales@sdbiosensor.com)

STORAGE AND HANDLING

- Store the test strips at room temperature between 2°C and 32°C (36°F and 90°F). Do not refrigerate or freeze. Frozen and thawed reagents may cause incorrect glucose results.
- Keep the test strip slot free of dust.
- The test strip is sensitive to humidity, so keep the strips in a location that is dry and cool - do not store in direct sunlight.
- After removing the test strip from its container, seal the cap of the container tightly to protect test strips.
- The container for the test strips has been designed to maintain a regular humidity, so you should not change the container of the test strips.
- Keep the control solution in 8°C~30°C (46°F~86°F) environment.

LIMITATION

SD CodeFree™ test strips provide accurate results within the following limitations;

- This system has been tested at altitudes ranging from sea level to 3,776 metres.
- Extremes of humidity (higher than 90% and lower than 15%) may affect results.
- Extremes in hematocrit may affect test results. Hematocrit levels less than 20% may cause falsely high readings and hematocrit levels greater than 60% may cause falsely low readings. If you do not know your hematocrit level, consult your healthcare professional.
- Interferences : Elevated levels of the following compounds; ascorbic acid, uric acid, acetaminophen, total bilirubin and triglycerides may affect results.

Compound	Limitation
Ascorbic acid	> 4 mg/dL
Uric acid	> 9 mg/dL
Acetaminophen	> 6 mg/dL
Total bilirubin	> 40 mg/dL
Triglycerides	> 1026 mg/dL

PERFORMANCE CHARACTERISTICS

- The performance of SD CodeFree™ test strips has been evaluated both in house and in clinical tests.

Accuracy (Method comparison)

The accuracy of the SD CodeFree™ blood glucose monitoring system was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 STAT Plus glucose analyzer (reference), a laboratory instrument. The following results were obtained from a trial involving 200 patients.

Slope	1.046
y-intercept	4.13
Correlation coefficient (R)	0.995
Number of sample (N)	200
Testing range (mg/dL)	20 ~ 592

< 75 mg/dL (4.2 mmol/L)			
Within ±5mg/dL (Within ±0.28mmol/L)	Within ±10mg/dL (Within ±0.56mmol/L)	Within ±15mg/dL (Within ±0.83mmol/L)	
19/26 (73%)	24/26 (92%)	26/26 (100%)	
≥ 75 mg/dL (4.2 mmol/L)			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
68/174 (39%)	115/174 (66%)	153/174 (88%)	171/174 (98%)

INFORMATION FOR HEALTHCARE PROFESSIONALS

- System measurement range is 10 ~ 600 mg/dL (0.6 ~ 33.3 mmol/L).
- Follow the infectious control procedures appropriate for your facility.
- A drop of fresh capillary whole blood is required to perform a blood glucose test.
- Avoid air bubbles when using pipettes.

BIBLIOGRAPHY

- American Diabetes Association, Clinical Practice Recommendation Guidelines 2003, Diabetes care, Vol. 26. Supplement 1. p.22
- Ellen T. Chen, James H. Nichols, Show-Hong Duh, Glen Hortin, MD: Diabetes Technology & Therapeutics, Performance Evaluation of Blood Glucose Monitoring Devices, Oct 2003, Vol. 5, No. 5 : 749 -768

Disclaimer:

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and / or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning:

The Manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

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