STANDARD™ GlucoNavii® GDH

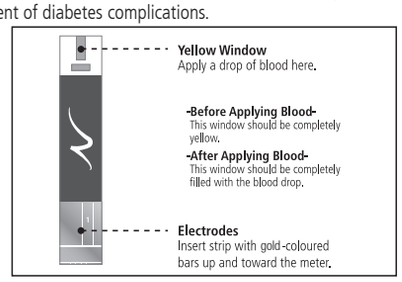
BLOOD GLUCOSE MONITORING SYSTEM

NOTE :

1. Please read this information before using STANDARD™ GlucoNavii® GDH Blood Glucose Test Strip.
2. Your STANDARD™ GlucoNavii® GDH Blood Glucose Test Strip must be used with Analyzer STANDARD™ GlucoNavii® GDH Blood Glucose meter. Do not use with other blood glucose meters.
3. For more information on performing a blood glucose test, carefully read the STANDARD™ GlucoNavii® GDH Blood glucose meter user instruction guide.

INTRODUCTION

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



Intended use

STANDARD™ GlucoNavii® GDH blood glucose test strip is designed for self testing blood glucose using fresh capillary whole blood from finger prick, palm, forearm or upper arm or fresh venous blood. This can only be used to test neonates by medical professionals. This strip is intended to use outside the body (in vitro diagnostic use) and only with the STANDARD™ GlucoNavii® GDH blood glucose meter.

Product Description and the Principle of use

STANDARD™ GlucoNavii® GDH 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.

STANDARD™ GlucoNavii® GDH 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 STANDARD™ GlucoNavii® GDH test strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full, the STANDARD™ GlucoNavii® GDH 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 dehydrogenase (GDH) 39.2 units
Potassium ferricyanide (mediator) 1.9 mg

PRECAUTION

1. Test strips are for in vitro diagnostic use (outside the body) only.
2. The test strips are for single use only. Never reuse a test strip that has had either blood or control solution applied to it.
3. STANDARD™ GlucoNavii® GDH blood glucose test strip should be used with STANDARD™ GlucoNavii® GDH blood glucose meter only.
4. Discard the used test strip and lancet carefully.
5. Insert a test strip into the test strip slot, with gold-coloured bars facing up and toward the meter.
6. Store test strip containers in a cool, dry place at 2-32°C (36-90°F). Keep away from direct sunlight and heat. Do Not refrigerate test strips.
7. Do not expose strips to heat, moisture or humidity. Temperatures outside the required range, as well as moisture and humidity (e.g. bathroom, kitchen, laundry room, car, or garage) can damage your test strips and lead to inaccurate results.
8. Store test strips in their original container only to avoid damage or contamination.
9. After removing a test strip from the container, replace the container cap immediately and close it tightly. Do Not use test strips from any container that is damaged or left open to air.
10. Write the opening date on the container label when you first open it. Discard remaining test strips after the discard date (6 months after first opening the container).
11. Do Not use test strips beyond the expiration (printed on package) or discard date, whichever comes first, because they may cause inaccurate results.
12. Be careful not to use too much force when inserting a test strip into the meter, as you may damage the test strip. You need to gently insert a test strip in the meter until it will go no further.
13. The volume of blood required for testing is 0.5µl. If you do not apply a sufficient amount, then you may get an error message or an inaccurate reading.
14. Do not apply blood to any area of the test strip other than the yellow window.
15. Do not touch the yellow window of a test strip.
16. Avoid getting dirt, food or liquids on the test strip. With clean, dry hands, you may touch the test strip anywhere on its surface.
17. Do Not bend, cut, or alter a test strip in any way. Use only fresh capillary whole blood and venous whole blood. Do not use serum, plasma or arterial blood.
18. Not following these precautions can lead to inaccurate results.
19. Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional right away.
20. Extremes in hematocrit may affect test results. Hematocrit levels greater than 70% may cause falsely low readings.

INFORMATION ABOUT ALTERNATIVE SITE TESTING

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 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. When operating machinery or driving a car, a fingertip test is usually the preferred method of testing under these circumstances.

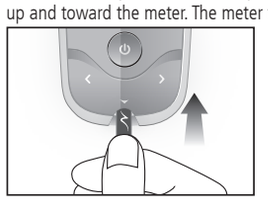
If the repeated Alternative site result is still not consistent with how you feel, confirm your blood glucose level with fingertip testing. If bruising occurs, you may choose to lance a fingertip instead.

PERFORMING A TEST

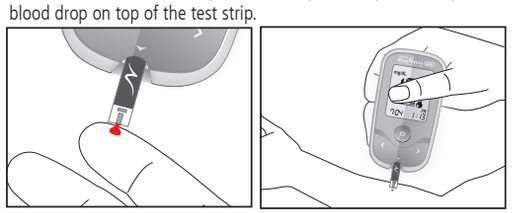
Testing Procedure

Testing Blood Glucose

1. Remove a new test strip from the container. Replace the container cap immediately and close it tightly.
2. Insert a test strip into the test strip slot, with gold-coloured bars facing up and toward the meter. The meter turns on automatically.



3. Obtain a blood sample using the lancet and lancing device. Wipe away the first drop of blood and test using the 2nd drop.
4. Bring the edge of the test strip to the drop of blood at a slight angle. The blood will automatically be drawn up the strip. Do not place the blood drop on top of the test strip.

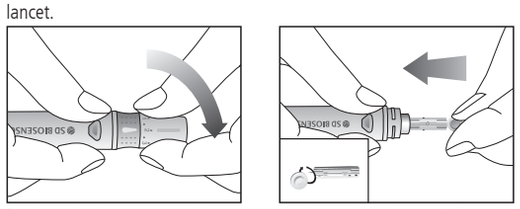


5. When blood is applied to the strip, the display counts down from 5 to 1 second and your result appears on the display.
6. Remove and discard the used test strip.

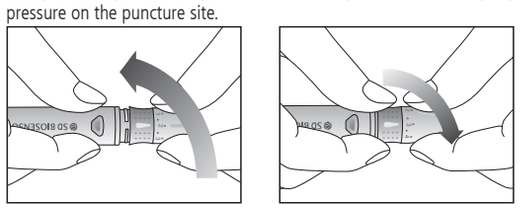
Blood Collection

Fingertip

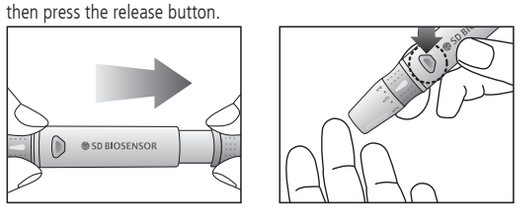
1. Wash your hands in warm, soapy water. Rinse well and dry completely. Warming fingers can increase blood flow.
2. Turn the lancet cap counterclockwise to remove it and insert the lancet into the lancing device holder and push down firmly until it is fully seated. Twist the lancet protective disk until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



3. Replace the lancet cap and turn it clockwise until it is snug. Adjust the puncture depth setting by turning the comfort dial. The dial has 1 to 5 steps; the higher the step number, the stronger the blood sampling pressure on the puncture site.



4. Prime the lancing device as shown below by pulling the arming knob. The release button should now be orange to indicate that the device has been properly armed. Hold the lancing device firmly against the side of your finger (the middle or ring finger are recommended) and then press the release button.

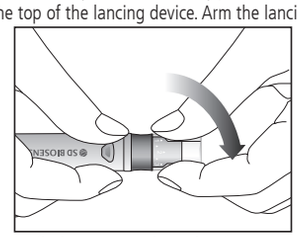


5. To reduce the chance of infection, discard the used lancet.

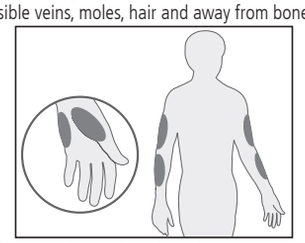
- Lancets are for single use only to reduce the chance of infection.
- Keep the lancet and lancing device away from children.

Alternative sites

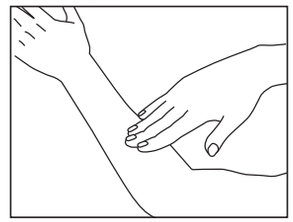
1. Insert a lancet and place the AST cap(the one with the clear plastic top) on the top of the lancing device. Arm the lancing device.



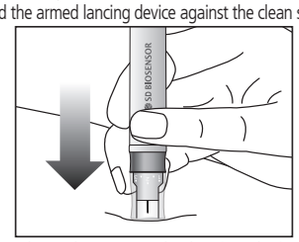
2. Select a soft, fleshy area on the palm, forearm, or upper arm that is free of visible veins, moles, hair and away from bone.



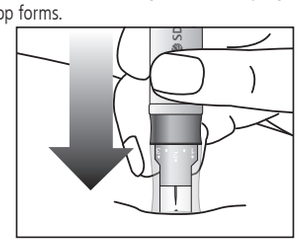
3. Press and vigorously rub the selected area for 10 seconds until it starts to feel warm to the touch.



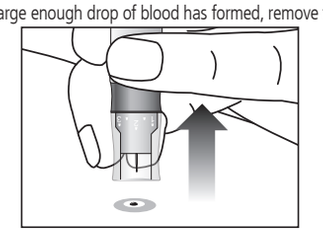
4. Wash the area with warm, soapy water. Rinse and dry completely. If you use alcohol wipes to cleanse the site, make sure that the area is dry before lancing the site.
5. Firmly hold the armed lancing device against the clean skin for 5-10 seconds.



6. 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.



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



- Repeat blood draw 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 TESTING RESULT

Expected blood glucose values for non-diabetic adults are as follows[1]

– Before eating < 100 mg/dL (5.6 mmol/L)
– One to Two hours after meals < 140 mg/dL (7.8 mmol/L)

These test strips deliver results that correspond to blood glucose concentrations in plasma as per the recommendation of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).[5] Therefore, the meter displays blood glucose concentrations that refer to plasma although whole blood is always applied to the test strip. Therefore, there may be a 6 - 7% difference in the glucose levels of fingerstick and venous blood.[4]

Test Result Range

STANDARD™ GlucoNavii® GDH meter reads blood glucose results between 10 - 600 mg/dL (0.6 - 33.3 mmol/L).

1. If 'Hi' is displayed, your blood glucose level may be higher than 600 mg/dL (33.3 mmol/L).
2. If 'Lo' is displayed, your blood glucose level may be lower than 10 mg/dL (0.6 mmol/L).

Unexpected Results

High or low blood glucose results can indicate potentially serious medical conditions. If you get 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 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:

1. Repeat the test with a new strip.
2. Run a control solution test with STANDARD™ GlucoNavii® control solution.
3. 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 causes of Unexpected Results

1. If more than 20 seconds elapsed from sample collection to measurement (evaporation of the blood sample may cause a test result that is higher than the accurate value)
2. Was the blood sample applied to the test strip within 3 minutes of removing it from the container?
3. Was the size of the blood sample sufficient to fill the reaction site?
4. Did you immediately and tightly re-seal the container cap every time you removed a test strip?
5. Was the test strip used before the expiration date?
6. Were the test strips stored at extreme temperatures such as in the car during very cold or hot weather?
7. Were the test strips stored in areas of high humidity such as the kitchen or the bathroom?
8. For AST, did the blood sample appear to be diluted with clear fluid?
9. For AST, did you not vigorously rub the test site?

CHECKING WITH CONTROL SOLUTION

Control solution test

The control solution test ensures that you are doing a test correctly and that your system is working properly. Make sure you use the proper control solution for the test strips you have: STANDARD™ GlucoNavii® GDH blood glucose test strips require STANDARD™ GlucoNavii® control solution.

You should consider performing a control solution test if:

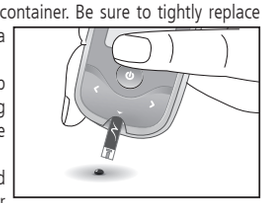
1. You open a new box of test strips.
2. You left the test strip container open or you think your test strips have been damaged.
3. Your test strips were stored in extreme temperatures and/or humidity.
4. You want to check the meter and test strips.
5. You dropped the meter.
6. Your test result does not agree with how you feel.
7. You want to check if you are testing correctly.
8. You want to easily check the performance of the meter.
9. Using your meter for the first time.
10. You have repeated a test and the blood glucose result is still lower or higher than expected.

- Check the expiration date on the control solution container. Record the opening date on the container label. Do Not use after expiration or discard date (date opened plus three months), whichever comes first.
- Control solution, meter, and test strips should be at room temperature 18-30°C (64-86°F) before testing with control solution.

Performing a Control Solution Test

You need the meter, a test strip, and control solution level 2 or 3. The acceptable range of each level is printed on the test strip label.

1. Remove a new test strip from its container. Be sure to tightly replace the container cap after removing a test strip.
2. Insert a test strip into the test strip slot, with gold-coloured bars facing up and toward the meter. The meter turns on automatically.
3. The test strip with flashing blood drop symbol should now appear on the display. Press the left arrow for 3 seconds to test using control solution; if you do not want to test using control solution, press the left button again.
4. 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 second on the display. Tightly replace the cap on control solution.
5. The control solution result appears on the display.



Understanding your control solution result

Compare your control solution result to the range printed on the test strip container. If the results are not within the control range printed on the test strip container, then the meter and strips may not be working properly. Repeat the control solution test. If the results are still outside the range, please contact Home Health UK:
Tel: 01923 711511
email: info@homehealth-uk.com

STORAGE AND HANDLING

1. Store the test strips at room temperature between 2-32°C(36-90°F). Do not refrigerate or freeze. Frozen and thawed reagents may cause incorrect glucose results.
2. Keep the test strip slot free of dust.
3. After removing a test strip from the container, replace the container cap immediately and close it tightly.
4. Store test strips in their original container only to avoid damage or contamination.
5. Store the STANDARD™ GlucoNavii® control solution between 8-30°C (46-86°F).

PERFORMANCE CHARACTERISTICS

All performance characteristics of STANDARD™ GlucoNavii® GDH BGMS shall be evaluated with a series of measurements within a short interval of time in accordance with EN ISO 15197:2015.

Precision

The acceptable criteria are within standard deviation(STD) 4mg/dL at the below 100mg/dL(5.55mmol/L), and coefficient of variation(CV) 5% at the above 100mg/dL(5.55mmol/L).

1) Repeatability Precision

Range	Number of samples	REF. (mg/dL)	AVG (mg/dL)	STD (mg/dL)	CV (%)
30 - 50 mg/dL	300	48.3	52.5	1.8	3.4
51 - 110 mg/dL	300	81.1	85.3	2.1	2.4
111 - 150 mg/dL	300	135.7	140.3	5.1	3.6
151 - 250 mg/dL	300	209.6	224.3	9.4	4.2
251 - 400 mg/dL	300	313.8	324.3	12.9	4

2) Intermediate Precision

	Level 1	Level 2	Level 3
Number of samples	300	300	300
AVG. (mg/dL)	52.1	117.0	328.8
STD	2.2	4.8	12.6
CV (%)	4.2	4.1	3.9

System Accuracy

The accuracy of STANDARD™ GlucoNavii® GDH blood glucose monitoring system was assessed by comparing blood glucose results obtained by patients with results by using YSI Model 2300 STAT Plus glucose analyzer(reference), a laboratory instrument. The results from 600 subjects were evaluated.

The acceptable criteria for system accuracy is as follows:
95% of the measured glucose values shall fall within either ±15mg/dL(±0,83mmol/L) of the average measured values of the reference measurement procedure at glucose concentrations <100mg/dL(5,55mmol/L) or within ±15% at glucose concentrations ≥100mg/dL(≥5,55mmol/L).

1) Below 100mg/dL(5.55mmol/L)

Within ± 5mg/dL (within±0.28mmol/L)	Within ± 10mg/dL (within±0.56mmol/L)	Within ± 15mg/dL (within±0.83mmol/L)
49.5%(104/210)	88.6%(186/210)	98.6%(207/210)

2) Above 100mg/dL(5.55mmol/L)

Within ± 5%	Within ± 10%	Within ± 15%
70.8%(276/390)	93.3%(364/390)	98.5%(384/390)

Influence quantities

The acceptable criteria for influence quantities are as follows:
– Below 100mg/dL(5.55 mmol/L), the average difference between the test sample and the control sample is within 10mg/dL(0.55 mmol/L)
– Over 100mg/dL(5.55 mmol/L), the average difference between the test sample and the control sample is within 10%

1. Packed cell volume: STANDARD™ GlucoNavii® GDH BGMS is performed according to EN ISO 15197:2015, 6.4.3 Packed cell volume evaluation. The suitable for STANDARD™ GlucoNavii® GDH BGMS is 0-70%.
2. Interference testing: STANDARD™ GlucoNavii® GDH BGMS is performed according to EN ISO 15197:2015, 6.4.4 Interference testing. Elevated levels of the following compounds may affect results:

Acetaminophen	> 6 mg/dL	Ibuprofen	> 50 mg/dL
Ascorbic acid(Vt.C)	> 4 mg/dL	Levodopa	> 4 mg/dL
Bilirubin	> 40 mg/dL	Maltose	> 60 mg/dL
Total Cholesterol	> 240 mg/dL	Methyl-DOPA	> 2 mg/dL
Creatinine	> 30 mg/dL	Sodium Salicylate	> 20 mg/dL
Dopamine	> 5 mg/dL	Tolazamide	> 9 mg/dL
EDTA	> 0.1 mg/dL	Tolbutamide	> 4 mg/dL
Galactose	> 60 mg/dL	Triglyceride	> 1800 mg/dL
Gentisic Acid	> 1.8 mg/dL	Uric Acid	> 9 mg/dL
Glutatione	> 9.2 mg/dL	Xylose	> 60 mg/dL
Hemoglobin	> 200 mg/dL	Pralidoxime Iodide	> 1.3 mg/dL
Heparin	> 3000 U/L	Icodextrin	> 750mg/dL

User Performance

This study for evaluating glucose values from fingertip capillary blood samples obtained by 165 lay persons showed the following results;
"100% within ±15mg/dL(0.83mmol/L) of the medical laboratory values at glucose concentrations below 100mg/dL(5.55mmol/L), and 100% within ±15% of the medical laboratory values at glucose concentrations at or above 100mg/dL(5.55mmol/L)."

INFORMATION FOR HEALTHCARE PROFESSIONALS

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

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4. Blumenfeld TA, Hertelendy WG, Ford SH. Simultaneously obtained skin-puncture serum, skin-puncture plasma, and venous serum compared, and effects of warming the skin before puncture. Clin Chem 1977;23:1705-10.
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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.

IVD

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REF - Catalogue number (Reference number)
IVD - *In vitro* diagnostic medical device
- Consult instructions for Use
- Contains sufficient for <n> tests
- Temperature limit
CE 0123 - This product fulfills the requirements of Directive 98/79/EC on *in vitro* Diagnostic medical device
- Use-by date
LOT - Batch code
- Manufacturer
- Date of manufacture
6M - Period after opening
EC REP - Authorized representative in the European Community
- Do not re-use