

STANDARD[®] GlucoNavii GDH

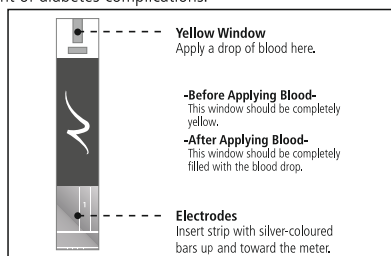
BLOOD GLUCOSE TEST STRIP

NOTE :

- Please read this information before using STANDARD[®] GlucoNavii GDH Blood Glucose Test Strip.
- 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 meter.
- 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 be used to test neonates for professional use. This strip is intended to use outside the Body (in vitro diagnostic use) and only with the STANDARD[®] GlucoNavii GDH blood glucose meter. This system should not be used for the diagnosis of diabetes or for testing newborns.



The measurement using the venous or neonatal blood should be done by healthcare professionals.

Product Description and the Principle of the 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 start 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

- A test strip should be used for in vitro diagnostic use.
- A test strip is for single use only. Do not reuse.
- STANDARD[®] GlucoNavii GDH blood glucose test strip should be Used with STANDARD[®] GlucoNavii GDH blood glucose meter only.
- Discard the used test strip and lancet carefully.
- Insert a test strip into 'test strip slot' of the meter with bars printed 'N' facing up and toward the meter.

- A test strip is sensitive of humidity. Therefore, you should keep a test strip in the specified container, and after pulling out the test strip from its container, close a container cap of the test strip immediately.
- After pulling out a test strip from its container, you should use it within 3 minutes.
- Use the test strips till the expiration date printed on strips box and vial label.
- If you insert a test strip by a strong power, it is easily to bend. Therefore, insert a test strip in the meter gently until it will go no further.
- The blood specimen for a test strip must be 0.5µl in volume. If the blood does not apply enough amounts, it will be an inaccurate test result, so discard the used test strip.
- Do not apply other site except the yellow window of a test strip.
- Do not touch the yellow window of a test strip as possible.
- STANDARD[®] Glucose check strip should not intend to measure blood glucose.
- Do not bend, cut or modify a test strip and check strip.
- This system has been tested at altitudes ranging from sea level to 3,520 meters.

INFORMATION ABOUT ALTERNATIVE SITE TESTING

Sites other than your fingertip may have fewer nerve endings so obtaining a blood specimen 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, as fingertip test is usually the preferred method of testing under these circumstances. If bruising occurs, you may choose to lance a fingertip instead.

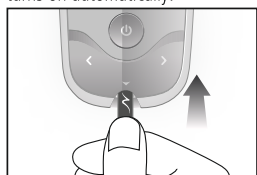


If the repeated Alternative site result is still not consistent with how you feel, confirm your blood glucose level with fingertip testing.

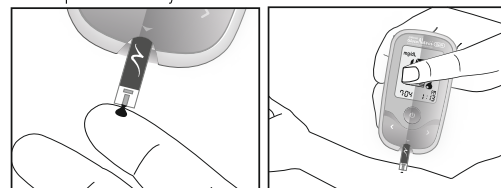
PERFORMING A TEST

Testing Procedure Testing Blood Glucose

- Remove a new test strip from container. Be sure to tightly replace container cap after removing test strip.
- Insert the test strip into test strip slot until it will go no further with bars printed 'N' facing up and toward the meter. Then, the meter turns on automatically.



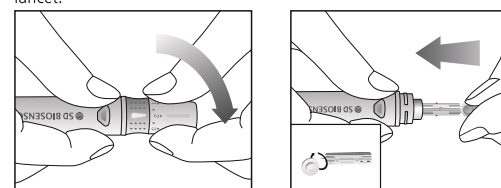
- Obtain a drop of blood specimen using the lancet and lancing device.
- Touch and hold drop of blood to the edge of the strip until the yellow window is completely filled with blood. The blood will be drawn into the strip automatically.



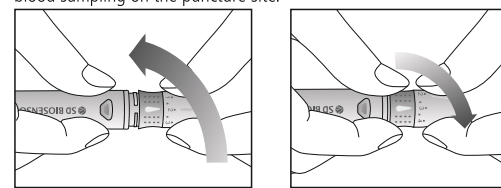
- When blood is applied to strip, the display counts down from 5 to 1 second and your result appears on the display in just 5 seconds.
- Remove and discard the used test strip.

Blood Collection Fingertip

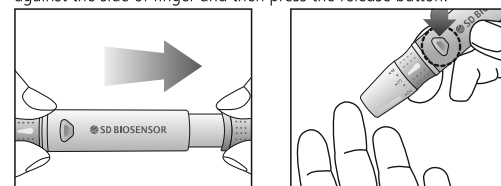
- Wash your hands in warm, soapy water. Rinse well and dry completely. Warming fingers can increase blood flow.
- Turn the lancet insert cap counterclockwise to remove it and insert the lancet into the lancing device holder and push down firmly until it is fully seated. Twist the lancet protective disk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



- Replace the lancet insert cap and turn it clockwise until it is snug. Adjust the puncture depth setting by turning the puncture depth adjust screw that has 1 to 5 step, the higher step has the stronger strength of blood sampling on the puncture site.



- After cocking the lancing device back, hold the lancing device firmly against the side of finger and then press the release button.



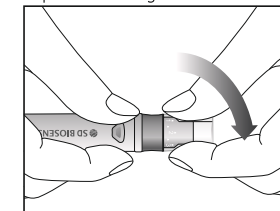
- To reduce the chance of infection for the used lancet, discard it.



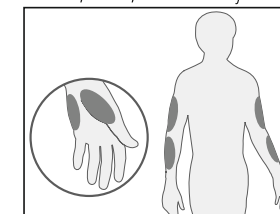
- Lancets are for single use only to reduce the chance of infection.
- It is dangerous for lancing device inserted lancet to apply the eye, tongue or infection site, please be careful.
- Keep the lancet and lancing device away from children.

Alternative sites

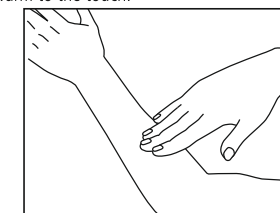
- Insert a lancet and place the AST cap(the one with the clear plastic top) on the top of the lancing device. Arm the lancing device.



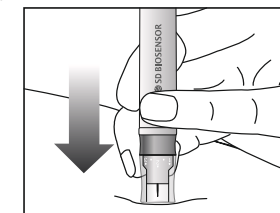
- Select a soft, fleshy area on the palm, forearm, or upper arm that is free of visible veins, moles, hair and away from bone.



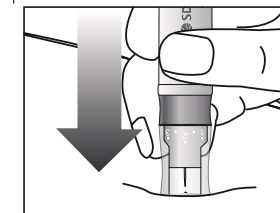
- Press and vigorously rub the selected area for 10 seconds until it starts to feel warm to the touch.



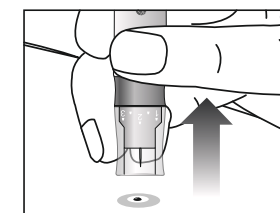
- Wash the area with warm, soapy water. Rinse and dry completely. If you use alcohol wipes to cleanse the site, make sure that the area is dry before lancing the site.
- Firmly hold the armed lancing device against the clean skin for 5-10 seconds.



- 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 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

- 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 result may be higher than 600 mg/dL (33.3 mmol/L). You may have high blood glucose.
2. 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 as prescribed by your healthcare professional and/or contact your healthcare professional immediately.

Control of the 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.

Cause of the 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. Was the test strip container cap tightly sealed?
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 BY A 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.

When you run a control solution test?

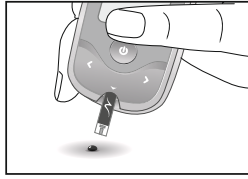
1. If you leave the cap off the container of test strips.
2. Before using your meter for the first time.
3. When you open a new container of test strips.
4. If you drop the meter.
5. Whenever your result does not agree with the way you feel.
6. If you have repeated a test, and the blood glucose result is still lower or higher than expected.
7. When you want to check the performance of the meter and test strip.



- Do not use a control solution expired 3 months from opening. Therefore, please check the date to open first for the accurate review of the meter and the test strip.
- Test control solution at 18-30°C(64-86°F) environment

Checking procedure

1. Press the left button of the meter during 3 seconds to check the testing System using STANDARD® GlucoNavii control solution.
2. 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.
3. 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:

1. Did you use control solution or test strips that were past their expiration date?
2. Did you leave the cap off the container of test strips or control solution?
3. Did you follow the testing steps exactly?
4. Did you use the proper STANDARD® GlucoNavii control solution for the test strips you used?

Repeat the glucose control solution test. If the result still is not acceptable, please contact SD BIOSENSOR HEALTHCARE PVT. LTD. at 1800-10-23105(toll free) or email at care@sdbiosensor.co.in

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 pulling out the test strip from its container, seal the cap of the container tightly to protect test strips.
4. The container of test strip has ability to maintain regular humidity, so you should not change the container of test strip.
5. Keep the STANDARD® GlucoNavii control solution in 8-30°C(46-86°F) environment.

PERFORMANCE CHARACTERISTIC

All performance characteristic 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 following results were evaluated by 600 subjects.

The acceptable criteria for system accuracy is following;

95% of the measured glucose values shall fall within either $\pm 15\text{mg/dL}(\pm 0.83\text{mmol/L})$ of the average measured values of the reference measurement procedure at glucose Concentrations <100mg/dL(5.55mmol/L) or within $\pm 15\%$ at glucose concentrations $\geq 100\text{mg/dL}(\geq 5.55\text{mmol/L})$.

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

Within $\pm 5\text{mg/dL}$ (within $\pm 0.28\text{mmol/L}$)	Within $\pm 10\text{mg/dL}$ (within $\pm 0.56\text{mmol/L}$)	Within $\pm 15\text{mg/dL}$ (within $\pm 0.83\text{mmol/L}$)
49.5%(104/210)	88.6%(186/210)	98.6%(207/210)

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

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
70.8%(276/390)	93.3%(364/390)	98.5%(384/390)

Influence quantities

The acceptable criteria for influence quantities are following;

– 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. Followings interference materials may affect test 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
Glutathione	> 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 is for evaluating glucose values from fingertip capillary blood samples obtained by 165 lay persons showed the following results;

"100% within $\pm 15\text{mg/dL}(0.83\text{mmol/L})$ of the medical laboratory values at glucose concentrations below 100mg/dL(5.55mmol/L), and 100% within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 100mg/dL(5.55mmol/L)."

EXPIRY & DISCARD PROCEDURE

Discard the used test strips and the test strips if they are past the use by date or expiry date following the proper method. The use by date is printed on the test strip box next to expiry icon. The test strip can be used until the printed use by date when they are stored & used as explained in previous section of 'STORAGE & HANDLING'. This applies to the test strips up to the expiry date mentioned on the container.

INFORMATION FOR HEALTHCARE PROFESSIONAL

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.

BIBLIOGRAPHY

1. American Diabetes Association: Standards of Medical Care in Diabetes – 2017. Diabetes Care, January 2017, vol. 40, Supplement 1, S11-S24
2. Stedman, TL. Stedman's Medical Dictionary, 27th Edition, 1999, p.2082
3. 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
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.
5. D'Orazio et al.: "Approved IFCC Recommendation o Reporting Results for Blood Glucose (Abbreviated);" Clinical Chemistry 51:9 1573-1576-(2005)

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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Manufactured by

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