GlucoSure STAR Blood Glucose Test Strips

⚠IMPORTANT

PLEASE READ THIS INFORMATION AND YOUR GLUCOSURE STAR USER'S GUIDE BEFORE USING THE GLUCOSURE STAR TEST STRIPS TO TEST YOUR BLOOD SUGAR.

For questions and assistance, please contact the authorized representative found at the end of this insert.

Intended Use

The GlucoSure STAR Blood Glucose Test Strips are to be used with the GlucoSure STAR Blood Glucose Meter to quantitatively measure glucose in capillary whole blood. The GlucoSure STAR Meter reads the glucose level of a whole blood sample on a GlucoSure STAR Blood Glucose Test Strip. The GlucoSure STAR System is plasma-calibrated for easy comparison to lab result. The GlucoSure STAR Blood Glucose Monitoring System is intended for self-testing by persons with diabetes and by health care professionals.

Introduction

The biosensor-based GlucoSure STAR Blood Glucose Test Strips employs the enzyme Glucose Oxidase that is specific for blood glucose measurement from 20 to 600 mg/dL (1.1 to 33.3 mmol/L). The arrow printed on the Test Strip indicates the direction of insertion. When blood from a puncture site touches the tip of the Test Strip; capillary action leads the blood into the reaction zone. The enzyme reacts with glucose in blood and produces an electrical signal. This signal is measured by the GlucoSure STAR Meter and test result is displayed in 6 seconds.

Reagent Composition

Each cm² of test strip contains the following ingredients in the approximate concentrations listed below:

- Glucose oxidase (A. niger) 7.6%
- Electron shuttle 53.3%
- Non-reactive ingredients 39.1%

Warnings and Precautions

The GlucoSure STAR Blood Glucose test strips are for use outside the body (IVD *IN VITRO* diagnostic use).

- Do not use Test Strips after expiration date. The ⌛ expiration date is printed on the carton and on the label of the test strip bottle.
- Do not use strips that are wet or damaged.
- ⊗ Do not re-use the strips.
- Make sure the code number displayed on the Meter matches the code number printed on the test strip bottle every time you test.
- **⚠If your test result is below 50 mg/dL (2.8mmol/L) or above 250 mg/dL (13.9mmol/L), perform the Control Solution Test to make sure your system is working properly and then repeat your blood glucose test once more. If the result is still the same; contact your healthcare professional immediately.**
- If you have symptoms that are inconsistent with your test results and you have eliminated common errors as described in the user's guide; contact your healthcare professional immediately.
- Never make significant changes in your diabetes treatment program or ignore symptoms without consulting your physician.
- Use the GlucoSure STAR Blood Glucose Monitoring System within temperature range of 🌡 10°C to 40°C (50°F to 104°F).

Storage and Handling

1. Always close the vial cap tightly after removing a test strip to avoid moisture and direct sunlight.
2. Store the test strips at temperatures between 🌡 4°C to 30°C (39.2°F to 86°F).
3. Store 🌴 out of direct sunlight; do not refrigerate or freeze.
4. Unopened test strips are stable until ⌛ the expiration date printed on the bottle when stored properly.
5. The month printed refers to the END of that month.
6. Use within 3 months after first opening.
7. Do not handle the test strips with wet or dirty hands.

Sample Collection and Preparation

Fresh finger stick capillary whole blood may be collected into heparin or sodium EDTA test tubes and should be used within 15 minutes. Do not test on plasma or serum samples. Do not use fluoride-based preservatives.

Test Procedures

📖 Refer to "Testing Your Blood" section in the User's Guide of the GlucoSure STAR Blood Glucose Meter.

Alternate Site Testing

The GlucoSure STAR Blood Glucose Monitoring System can test for blood glucose from sites other then your fingertip such as palm and forearm (alternate site testing, or AST). Physiological differences between the finger or palm and forearm may result in different blood glucose readings[1]. You should not test on alternate site and use fingertip testing instead when:

- You have hypoglycemic unawareness
- You suspect you blood glucose level is changing rapidly because of exercise or after rapid-acting insulin injection or it has been less then two hours after a meal.
- You will be driving a car or participating in risky activities such as operating machinery.
- You are sick

If results from alternate site testing do not agree with how you feel, use fingertip testing instead

Consult your doctor or healthcare professional to decide if alternate site testing is right for you.

Expected Values

Consult with your physician or healthcare professional to determine an appropriate blood glucose target range for you.

Quality Control

Run a control solution test by following the instructions detailed in User's Guide when:

- Your test results do not agree with how you feel.
- At least once per week to verify that the meter and test strips are working properly together.
- Your test strips were stored at temperatures and humidity outside the specified storage conditions.
- Every time you open a new bottle of test strips.
- Practice your testing technique.
- You drop your meter.

Use only Contrex™ Plus Control Solution. Your test results should fall within the control range printed on the test strip bottle. If test results fall outside this range; repeat the test. Results that fall outside the range may be caused by:

- Error in performing the control solution test
- Expired or contaminated control solution
- Improper coding of the meter
- Test Strip is damaged
- Meter malfunction

Problem Solving

1. Confirm the Test Strips are within the expiration date.
2. Verify that the Code displayed on the Meter matches the Code printed on the bottle of Test Strips you are using. See 📖 "Coding the Meter" section on the User's Guide for your Meter.
3. Make sure the blood completely fills the reaction zone. "Err" and a flashing test strip icon will display on the GlucoSure STAR Meter if there is insufficient blood. DO NOT add a second drop of blood; discard the test strip from the meter and retest using a new Test Strip.
4. Check the system by performing the Control Solutions Test.
5. Refer to the "Solving Problems" section in the User Guide for additional information.

Limitations

1. Test with fresh capillary whole blood taken from a fingertip. DO NOT use plasma or serum samples.
2. DO NOT test on neonatal samples (new born).
3. DO NOT test on venous or arterial samples.
4. Altitude up to 2,000 meters (6,562 feet)will not affect test results.
5. Hematocrit range: 30% to 55%.
6. Triglycerides: 260 to 360 mg/dL has no significant effect on test results (normal range 36 to 165 mg/dL).
7. Icodextrin and its metabolites (maltose, maltotriose and maltotetraose) do not significantly affect test results.
8. The following will not affect test results in expected blood concentrations: ascorbic acid (Vitamin C), uric acid, or methyldopa.
9. Therapeutic concentration of dopamine or L-dopa may affect results. Individuals taking these drugs should not use this system to test for blood sugar.
10. Higher than therapeutic concentrations of acetaminophen, or glibenclamide may affect test results. Individuals taking these drugs should not use this system to test for blood sugar.

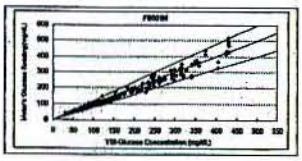
Performance Evaluation Data

Accuracy

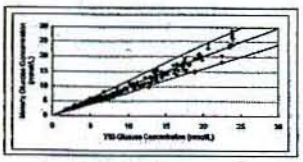
A capillary blood comparison study between the GlucoSure STAR System and YSI 2300 Glucose Analyzer yields the following linear regression data:

Clinical Site Studies	
Number of Samples:	340
Range (mg/dL):	32 to 430
(mmol/L):	1.8 to 23.9
Slope:	1.0131
Intercept (mg/dL):	-3.7106
(mmol/L):	-0.2061
Correlation Coefficient:	0.985

Accuracy Comparison in mg/dL



Accuracy Comparison in mmol/L



Accuracy for blood glucose level < 75 mg/dL (4.2 mmol/L)		
within ± 5 mg/dL	within ± 10mg/dL	within ± 15 mg/dL
± 0.3 mmol/L	± 0.6 mmol/L	± 0.8 mmol/L
25/38 (65.8%)	37/38 (97.4%)	38/38 (100%)

Accuracy for blood glucose level ≥ 75 mg/dL (4.2 mmol/L)			
within ± 5%	within ± 10%	within ± 15%	within ± 20%
146/302	238/302	277/302	294/302
(48.3%)	(78.8%)	(91.7%)	(97.4%)

The result showed the GlucoSure STAR System compares well with the YSI 2300 Glucose Analyzer.

Repeatability

1 lot of GlucoSure STAR Test Strips were used for within-run repeatability study. Venous blood in heparin-tubes was spiked to 5 concentrations. Blood glucose readings were recorded for 1 day resulting in 100 data points for each concentration; as shown in the following tables:

Repeatability Study					
Number of Readings:	100	100	100	100	100
Average(mg/dL):	48	108	148	201	377
(mmol/L):	2.7	6	8.2	11.2	20.9
S.D. (mg/dL):	2.1	3.5	4.2	5.8	10.8
(mmol/L):	0.1	0.2	0.2	0.3	0.6
C.V%:	--	3.2	2.8	2.9	2.9

⌛ (EXP) Expiration date (use by last day of month) — IVD In vitro diagnostic device

(LOT) (LOT) Batch code — 📖 Consult instructions for use

🌡 Temperature limitations — REF Product code number

⊗ Do not re-use — Manufactured by

🌴 Keep away from sunlight/direct light

⚠ Caution/warning, consult accompanying documents

EC REP Authorised Representative in the European Community

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