GlucoSure AutoCode Blood Glucose Test Strips

⚠IMPORTANT

PLEASE READ THIS INFORMATION AND YOUR GLUCOSURE AUTOCODE USER'S GUIDE BEFORE USING GLUCOSURE AUTOCODE TEST STRIPS.

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

Intended Use

The GlucoSure AutoCode Blood Glucose Test Strips are to be used with the GlucoSure AutoCode Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. The GlucoSure AutoCode Blood Glucose Monitoring System is plasma-calibrated for easy comparison to lab results. It is intended for self-testing by persons with diabetes and by health care professionals. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

Introduction

The GlucoSure AutoCode Blood Glucose Test Strips use an enzyme to measure blood glucose.

When blood touches the tip of the test strip, it flows into the reaction zone. The enzyme reacts with glucose in blood and produces electrical current. The meter measures the current. The meter shows the test result in 6 seconds.

Reagent Composition

Each cm^2 of test strip contains:

• Glucose Oxidase (A. Niger)	2.3%
• Electron Shuttle	25%
• Non- Reactive Ingredients	72.7%

Warnings and Precautions

The GlucoSure AutoCode Blood Glucose Test Strips are for use outside the body (IN VITRO IVD diagnostic use).

- Do not use test strips after their expiration date. Please check the ⌛ expiration date on the test strip bottle.
- Do not use strips that are wet or damaged.
- ⊗ Do not reuse the strips.
- ⚠If your test result is below 50 mg/dL or above 250 mg/dL (2.8 mmol/L)or above 250 mg/dL (13.9 mmol/L), do Control Solution testing to make sure your system is working properly. Then repeat testing using fingertip blood. If the result is still very high or very low, contact your healthcare professional mimmediately.
- 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 major changes in your diabetes treatment program or ignore symptoms without consulting your physician.
- Operating temperature for the meter and the test strips is between 10°C - 40°C 4°C 40°C(50°F to 104°F).
- Incorrect results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Do not test critically ill patients with blood glucose meters.
- Incorrect result may occur in individuals who are dehydrated.

Storage and Handling

1. Always close the vial cap tightly after removing a test strip. This avoids moisture and direct sunlight.
2. Store the test strips between 4°C~30°C 4°C 40°C(39˚F-86˚F). Do not freeze.
3. Store out of direct sunlight.
4. Unopened test strips are stable until the ⌛ expiration date printed on the bottle when stored properly.
5. Use within 6 months after first opening.
6. Do not handle the test strips with wet or dirty hands.

Sample Collection and Preparation

Fresh finger stick capillary whole blood maybe collected into heparin or sodium EDTA test tubes. Test within 15 minutes. Do not test on plasma or serum samples. Do not use fluoride based preservatives.

Test Procedure

📖See "Testing Your Blood Glucose" in the GlucoSure AutoCode Blood Glucose Meter User's Guide.

Alternate Site Testing

You can also test from palm and forearm. This is called alternate site testing (AST). AST results may differ from fingertip readings(1).

DO AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since last meal).
- 2 hours or more after taking insulin.
- 2 hours or more after exercise.

Alternate Site Testing SHOULD NOT be used when:

- You have Hypoglycemic unawareness (not able to tell if you have low blood sugar).
- Within 2 hours of a meal, exercise, or medication.
- You will be operating machinery or driving a car.
- You are sick.
- You think your blood glucose is low.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- You are pregnant.

Consult your 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 Level 1 and Level 2 control solution tests. Follow the User's Guide instructions.

Do control tests:

- If your test results do not agree with how you feel.
- At least once per week to make sure the meter and test strips are working properly.
- If your test strips were stored at temperatures and humidity outside proper storage conditions.
- When you use your meter for the first time.
- Every time you open a new bottle of test strips.
- To practice your testing technique.
- If you drop your meter.

Use only Contrex™ Plus III Control Solutions. Your test results should fall within the control range printed on the test strip bottle. Repeat control solution testing if results fall out of range.

Results may fall out of range due to:

- Errors in control solution testing.

- Expired or contaminated control solution.
- Test strip damaged.
- Meter malfunction.

If the result continues to fall outside of the printed range; contact the authorized representative found at the end of this insert for assistance.

Problem Solving

1. Confirm the test strips are not expired.
2. Make sure the blood fills the reaction zone. “Err 4” will show if there is too little blood. DO NOT add a second drop of blood. Discard the test strip from the meter and retest with a new test strip.
3. Check the system with a control solutions test.
4. Refer to “Solving Problems” in the User’s Guide for more hints.

Limitations

1. DO NOT use plasma or serum samples.
2. DO NOT test on neonatal (newborn) samples.
3. DO NOT test on venous or arterial samples.
4. Altitudes up to 10335 feet will not affect test results.
5. Hematocrit range: 35 - 50%.
6. Methyl-Dopa levels above 3 mg/dL may cause inaccurate results (therapeutic concentration: 1-7.5 mg/dL).
7. Tolazamide levels above 13.3 mg/dL may cause inaccurate results (therapeutic concentration: 23 mg/dL).
8. Ascorbic acid levels above 2.63 mg/dL may cause inaccurate results (therapeutic concentration: 0.4-2 mg/dL).
9. Acetaminophen levels above 6.25 mg/dL may cause inaccurate results (therapeutic concentration: 1-3 mg/dL).
10. Uric acid levels above 11 mg/dL may cause inaccurate results (physiologic concentration: 2.5-8 mg/dL).
11. Cholesterol levels above 210 mg/dL may cause inaccurate results (physiologic concentration: 114-201 mg/dL).

Performance Evaluation Data

Accuracy

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

Accuracy Study - according to EN ISO 15197:2015	
Number of Readings :	600
Sample Range :	35 to 579 mg/dL 1.9 to 32.2 mmol/L

Accuracy for blood glucose level < 100mg/dL (5.56 mmol/L)		
Within ± 5mg/dL ±0.28 mmol/L	Within ± 10mg/dL ±0.56 mmol/L	Within ± 15mg/dL ±0.83 mmol/L
125/180 (69.0%)	174/180 (97.0%)	180/180 (100%)

Accuracy for blood glucose level ≥ 100mg/dL (5.56 mmol/L)		
Within ± 5%	Within ± 10%	Within ± 15%
271/420 (65.0%)	397/420 (95.0%)	419/420 (99.8%)

Total within ± 15mg/dL (0.83 mmol/L) & ± 15%
599/600 (99.8%)

Precision

3 lots GlucoSure AutoCode 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 300 data points for each concentration, as shown in the following tables:

Repeatability Study-According to EN ISO 15197:2015					
Number of Readings:	300	300	300	300	300
Average (mg/dL):	50	70	135	220	330
(mmol/L):	2.8	3.9	7.5	12.2	18.3
S.D. (mg/dL):	3.0	3.2	3.6	6.3	10.6
(mmol/L):	0.2	0.2	0.2	0.4	0.6
CV%:	NA	NA	2.7	2.8	3.2

3 lots of GlucoSure AutoCode Test Strips were used for intermediate precision study. 3 levels of control materials were prepared for glucose test and 300 data points were obtained for each level, as shown in the following tables:

Intermediate Precision Study-According to EN ISO 15197:2015			
Number of Readings:	300	300	300
Average (mg/dL):	40	120	330
(mmol/L):	2.2	6.7	18.3
S.D. (mg/dL):	2.9	17	47
(mmol/L):	0.2	0.9	2.6
CV%:	NA	2.8	2.9

User Performance Study

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results: 100% within ± 15 mg/dL (0.83 mmol/L) of the YSI reference values at glucose concentration < 100 mg/dL (5.56 mmol/L) and 100% within ± 15% of the YSI reference values at glucose concentration ≥ 100 mg/dL (5.56 mmol/L).

Symbols

- Use-by date
- In vitro diagnostic medical device
- Batch code
- Consult instructions for use
- Temperature limit
- Catalogue number
- Do not re -use
- Manufacturer
- Keep away from sunlight
- Caution
- Authorised representative in the European Community
- This product complies with the EC directives and bears the CE mark. 0197 indicates the number of notified body involved in production quality module.

Traceability

The system is calibrated using reference plasma values determined with a YSI analyzer. The YSI analyzer is calibrated using a series of tandards traceable to NIST SRM917C.

Reference

1. Shu M, Osamu F, Kazuhiro H, Yoshihito A: Hypoglycemia Detection Rate Differs Among Blood Glucose Monitoring Sites. Diabetes Care 28(3):708–709, 2005

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