

BG1000 Blood Glucose Test Strips

For in vitro diagnostic use.
IMPORTANT: Read these instructions for use and the User's manual supplied with your meter before you monitor your blood glucose.
 Failure to follow instructions will cause inaccurate results.

Product Name

Clarity BG1000 Blood Glucose Test Strip

Product Application

For blood glucose testing with Clarity BG1000 Blood Glucose Meter.

Intended Use

The Clarity BG1000 Blood Glucose Test Strips are to be used for monitoring glucose concentration of fresh capillary whole blood with Clarity BG1000 Blood Glucose Meters. The test strips and associated meters are for use with fingertip, forearm, and palm testing. The system is intended for use for multiple patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system to prevent transferring disease by blood. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

Testing Principles

The test strip shows glucose concentration in a blood sample. Glucose in the blood sample reacts with glucose oxidase on the test strip and a harmless electrical current is produced. The strength of these currents change with the amount of glucose in the blood sample and the Clarity BG1000 Blood Glucose Meter automatically interprets this reaction. The Clarity BG1000 Blood Glucose Monitoring System is plasma-calibrated to compare results with laboratory methods. Blood glucose results from plasma-equivalent test strips are approximately 11% higher than whole-blood equivalent test strips.

Major Components

Each Clarity BG1000 Test Strip contains:

- Glucose oxidase (A.Niger) 2.5 unit
- Redox mediator 32.3 μg
- Buffer & Non-reactant 50.5 μg

Storage Condition

Test strips should be stored in the original test strip vial and should be stored in an indoor area between 39.2-86°F. Do Not Freeze.

Expiration Date

Clarity BG1000 Test Strips have a shelf life of 24 months from the date of manufacturing as long as they are stored in the original sealed packaging. Discard any remaining test strips 3 months after first opening the test strip vial. The expiration date is printed on the test strip box and the test strip vial.

Sample Requirements

Fresh capillary whole blood.

Testing Procedure

- Step 1. Prepare for your test by making sure you have your Clarity BG1000 Meter, Clarity BG1000 Test Strips, and Single use Auto-disabling Lancing Devices.
- Step 2. Open your test strip vial and remove one test strip, make sure you close your test strip vial lid tightly.
- Step 3. Make sure that the black side of the test strip is facing upward. Insert the test strip with three (3) black lines facing towards the meter.
- Step 4. Once the test strip is inserted, the meter turns on and will automatically identify the test strip code. If the code displayed on the meter is different from the code displayed on your test strip vial, contact Clarity Diagnostics Customer Service at 1-877-722-6339.
- Step 5. Get the blood sample. Make sure single use, auto-disabling lancing devices are used.
- Step 6. Touch the test strip slit to the drop of blood and the blood will be drawn into the test strip. After five seconds your test result will be displayed on the screen.
- Step 7. Remove the used test strip and your meter will turn off automatically.
- Step 8. Dispose off your used test strip and lancets according to your local medical waste treatment regulation.

Control Solution Check

Generally, quality checks with Control Solution should be performed in the following situation.

- When you feel that the meter and test strips are not functioning properly.
- When you feel the test result is not correct.
- When you open and begin using a new vial of test strips.

Use Clarity BG1000 Glucose Control Solution. If the Control Solution result is in the range marked on the test strip vial, your test strips are functioning correctly. If a patient's results are out of range, re-test. If after re-testing the Control Solution result is still out of range, contact Clarity Diagnostics Customer Service at 1-877-722-6339.

Non-Diabetics Reference Value

Normal blood glucose reference value for non-diabetics are as follow:

- Before eating: < 100mg/dL
- 2 hours after meal: < 140mg/dL

The values shown above are for reference only, patients should always follow the recommendations of their Healthcare Professional.

*Reference: American Diabetes Association, Clinical Practice Recommendations (2015) Diabetes Care, Vol. 38, Supplement 1, p S1 - S93

Specification

- Testing Range : 20 ~ 600mg/dL
- Sample Volume : 0.5 μl
- Operating Temperature : 50 ~ 104°F
- Operating Humidity : 10 ~ 90%RH
- Permissible Hematocrit Range : 30 ~ 55%

Limitations

- Hematocrit is the percentage of red blood cells in the blood. HCT levels of 30-55% were shown not to affect glucose measurements with this device.
- This test strip is not designed for use with arterial, venous, neonatal, serum or plasma samples.
- Testing out of the specification range may cause inaccurate results.
- The Clarity BG1000 Test Strip may be used at altitudes up to 10,000 feet.
- Interferences: Acetaminophen, salicylates, uric acid, ascorbic acid (Vitamin C) and other interfering substances with therapeutic concentration in normal blood, do not significantly affect results however, abnormally high concentrations in blood may cause inaccurate results.
- Patients undergoing oxygen therapy may register a false low result.
- Test results may register a false low if the patient is severely dehydrated, in shock or in a hyperosmolar state (with or without ketosis). Critically ill patients should not be tested using blood glucose meters.
- Lipemic samples (triglycerides) in excess of 1,500 mg/dL may produce elevated results.

Performance Characteristics

1. Accuracy :

Comparisons with the Clarity BG1000 System and YSI2300 Biochemical Analyzer for capillary whole blood samples from 108 subjects at the same time.

1-1. Acceptance Criteria

ISO 15197 Minimum Acceptable Accuracy Requirement:

- 95% of individual glucose results must fall within $\pm 15\text{mg/dL}$ at glucose concentrations < 75mg/dL
- 95% of individual glucose results must fall within $\pm 20\%$ at glucose concentrations $\geq 75\text{mg/dL}$

1-2. Result

- No. of samples: 108
- Regression Equation:
 $y = 1.005x + 0.6506 \text{ (mg/dL)}$
 $r(\text{corr.coef.}) = 0.9777$

System Accuracy Results for Glucose Concentration < 75mg/dL

Within $\pm 5\text{mg/dL}$	Within $\pm 10\text{mg/dL}$	Within $\pm 15\text{mg/dL}$
9/20 (45%)	17/20 (85%)	20/20 (100%)

System Accuracy Results for Glucose Concentration $\geq 75\text{mg/dL}$

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
44/88 (50%)	68/88 (77.3%)	83/88 (94.3%)	87/88 (98.9%)

2. User Performance Test :

Compare results from the user and Healthcare Professional using the same samples, Clarity BG1000 System and YSI2300 Analyzer as the reference method.

2-1. Acceptance Criteria

ISO 15197 Minimum Acceptable Accuracy Requirement:

- 95% of individual glucose results must fall within $\pm 15\text{mg/dL}$ at glucose concentrations < 75mg/dL
- 95% of individual glucose results must fall within $\pm 20\%$ at glucose concentrations $\geq 75\text{mg/dL}$

2-2. Result (Professional result vs. YSI reference result)

- No. of samples: 156
- Regression Equation
 $y = 0.9694x + 5.1823 \text{ (mg/dL)}$
 $r(\text{corr.coef.}) = 0.9762$

System Accuracy Results for Glucose Concentration < 75mg/dL

Within $\pm 5\text{mg/dL}$	Within $\pm 10\text{mg/dL}$	Within $\pm 15\text{mg/dL}$
5/16 (31.3%)	12/16 (75%)	16/16 (100%)

System Accuracy Results for Glucose Concentration $\geq 75\text{mg/dL}$

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
63/140 (45%)	109/140 (77.9%)	134/140 (95.7%)	140/140 (100%)

2-3. Result (User result vs. YSI reference result)

- No. of samples: 156
- Regression Equation
 $y = 0.966x + 4.8475 \text{ (mg/dL)}$
 $r(\text{corr.coef.}) = 0.9749$

System Accuracy Results for Glucose Concentration < 75mg/dL

Within $\pm 5\text{mg/dL}$	Within $\pm 10\text{mg/dL}$	Within $\pm 15\text{mg/dL}$
3/16 (18.8%)	9/16 (56.3%)	16/16 (100%)

System Accuracy Results for Glucose Concentration $\geq 75\text{mg/dL}$

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
63/140 (45%)	118/140 (84.3%)	136/140 (97.1%)	137/140 (97.9%)

3. Alternate Site Testing (AST):
Compare with Clarity BG1000 System and YSI2300 Biochemical Analyzer.

3-1. Acceptance Criteria

ISO 15197 Minimum Acceptable Accuracy Requirement:

- 95% of individual glucose results must fall within ± 15 mg/dL at glucose concentrations < 75mg/dL
- 95% of individual glucose results must fall within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL

3-2. Result

- No. of samples: 104

Palm results vs. YSI results for Glucose Concentration < 75mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7/12 (58.3%)	12/12 (100%)	12/12 (100%)

Palm results vs. YSI results for Glucose Concentration ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
48/92 (52.2%)	81/92 (88%)	91/92 (98.9%)	92/92 (100%)

Forearm results vs. YSI results for Glucose Concentration < 75mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
8/12 (66.7%)	12/12 (100%)	12/12 (100%)

Forearm results vs. YSI results for Glucose Concentration ≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
51/92 (55.4%)	83/92 (90.2%)	92/92 (100%)	92/92 (100%)

Information for AST

- Contact patient's Healthcare Professional before you begin using alternative sites to test blood glucose.
- Alternative site results may be different from fingertip results when glucose levels are changing rapidly (e. g. after a meal, after taking insulin, or during or after exercise).
- Use Alternative Site Testing (AST) only two hours or more after taking insulin, two hours or more after a meal, two hours or more after exercise.
- Do not use AST if you are aware that your glucose level is not as stable as usual, or if you think the patient may have hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose), or at times when you think the patient's blood glucose may be rising or falling rapidly.
- Do not use AST if your AST results do not match the way the patient feels.
- AST measurements should never be used to calibrate continuous glucose monitors (CGM).
- AST measurements should never be used in insulin dosing calculations.
- Do not rely on test results at an alternative sampling site if any of the following applies:
 - You think the patient's blood glucose is low.
 - The patient has hypoglycemic unawareness.
 - The site results do not agree with the way the patient feels.
 - After a meal.
 - After exercise.
 - During illness.
 - During times of stress.

WARNING:

- This product is only for in-vitro diagnostic use only.
- Before using please check the expiration date on the package.
- Do not touch test strips with wet or dirty hands.
- Do not touch the test strip slit.
- Do not force the test strip when inserting it into the meter.
- The results of this product should not be used for diabetic treatment or medications without consulting patient's doctor.
- You are handling biologically hazardous material, please handle with care, incorrect test methods may cause serious health problems.
- Use the test strip immediately after retrieving it from the vial and keep the test strip vial closed tightly at all times.
- Do not change patient's treatment without consulting their Physician or Healthcare Professional.
- Never ignore symptoms of high or low blood glucose.
- If the patient's blood glucose does not match how they feel, perform a fingertip test to confirm the result. If the fingertip test result still does not match how patient feels, call their Physician or Healthcare Professional.
- Keep the test strip away from all children and pets; test strips may be a choking hazard.

Cleaning and Disinfection

User need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to 'Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007'.

<http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>

Refer to user manual of Clarity BG1000 Blood Glucose Monitoring System for cleaning and disinfection of blood glucose meter.

References

1. National Committee for Clinical Laboratory Standards. Point-Care Blood Glucose Testing in Acute and Chronic care Facilities; Approved Guideline, 2nd Edition. NCCLS Document C30-A2(ISBN1-56238-471-6)
2. National Committee for Clinical Laboratory Standards. Statistical Quality Control for Quantitative Measurements; Principle and Definitions; Approved Guideline, 2nd Edition. NCCLS Document C24-A2(ISBN1-56238-371-X). 1999
3. National Committee for Clinical Laboratory Standards. User Demonstration of performance for Precision and Accuracy; Approved Guideline. NCCLS Document EP15-A(ISBN1-56238-451-1)
4. National Committee for Clinical Laboratory Standards. Interference Testing in Clinical Chemistry; Approved Guideline. NCCLS Document EP7-A (Vol.22, No.27)

Customer Service: 1-877-722-6339
Monday-Friday 8:30AM-5:30PM EST.
www.claritydiagnostics.com

Not for Emergency or Medical Information.

If you have questions or need assistance outside the operational days and times, please contact your healthcare provider.

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