CareTouch®
Blood Glucose Test Strips

Suitable for self testing.
For in vitro diagnostic use.
For over-the-counter 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
CareTouch® Blood Glucose Strip

Product Application
For blood glucose testing with CareTouch® Glucose Meter.

Intended Use
The CareTouch® Blood Glucose Test Strip is to be used with CareTouch® Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. CareTouch® test strips and associated meter are for use in fingertip, forearm, and palm testing. The strips are intended for self-testing by persons at home, are for single-patient use only, and should not be shared. 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 meter automatically interprets this reaction. The test results are 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 CareTouch® Test strip contains:
- Glucose oxidase (A.Niger) ..... 2.5 unit
- Redox mediator ..... 32.3 ㎍
- Buffer & Non-reactant ..... 50.5 ㎍

Storage Condition
Test strips should be stored in the original strip vial between 39~86ºF, 10~90%RH and must not be frozen.

Expiration Date
CareTouch® 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 whole blood from a capillary vessel.

Testing Procedure
Step 1. Prepare for your test by making sure you have either your CareTouch® meter, CareTouch® test strips, Lancing Device and Lancets.
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 it into the strip slot of the meter to the stop.
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 Customer Service at 1866.890.8500
Step 5. Insert a lancet into the lancing device; use the lancing device to prick your skin to draw blood. (Refer to the meter manual for details)
Step 6. Touch the front edge of the test strip 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. Remember to record your test result in your log book.
Step 8. Dispose of your used test strip accordingly.

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 CareTouch® 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 your results are out of range, re-test. If after re-testing the Control Solution result is still out of range, contact Customer Service at 1866.890.8500

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, you should always follow the recommendations of your 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㎕
- Operating Temperature : 50 ~ 104ºF
- Operating Humidity : 10 ~ 90%RH
- Permissible Hematocrit Range : 30 ~ 55%

Limitations
- This product is only for in-vitro diagnostic use and for self-testing.
- Interferences: Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C) and other interferent substances in normal blood or normal therapeutic concentrations, do not significantly affect results however, abnormally high concentrations in blood may cause inaccurate results.
- Patients undergoing oxygen therapy may yield falsely low results.
- Test results may be falsely 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 this blood glucose meter.
- Lipemic samples (triglycerides) in excess of 1,500 mg/dL may produce elevated results.
- 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. If you do not know your hematocrit level, consult your healthcare professional.
- This test strip is not designed for use with arterial, venous, neonatal, serum or plasma samples.
- Testing on blood samples out of the Hematocrit level range specification (30~55%) may cause inaccurate results.
- The CareTouch test strip may be used at altitude up to 10,000 feet.

Performance Characteristics
1. Accuracy :
Comparisons with the CareTouch® 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 ±15mg/dL at glucose concentrations < 75mg/dL
- 95% of individual glucose results must fall within ±20% at glucose concentrations ≥ 75mg/dL

1-2. Result
- No. of samples: 108
- Regression Equation:
  y = 1.005x + 0.6506 (mg/dL)
  r(corr.coef.) = 0.9777

System Accuracy Results for Glucose Concentration < 75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
9/20 (45%)	17/20 (85%)	20/20 (100%)

System Accuracy Results for Glucose Concentration ≥ 75mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 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, CareTouch® 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 ±15mg/dL at glucose concentrations < 75mg/dL
- 95% of individual glucose results must fall within ±20% at glucose concentrations ≥ 75mg/dL

2-2. Result (Professional result vs. YSI reference result)
- No. of samples: 156
- Regression Equation
  y = 0.9694 x + 5.1823 (mg/dL)
  r(corr.coef.) = 0.9762

System Accuracy Results for Glucose Concentration < 75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
5/16 (31.3%)	12/16 (75%)	16/16 (100%)

System Accuracy Results for Glucose Concentration ≥ 75mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 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 = 0.966 x + 4.8475 (mg/dL)
  r(corr.coef.) = 0.9749

System Accuracy Results for Glucose Concentration < 75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
3/16 (18.8%)	9/16 (56.3%)	16/16 (100%)

System Accuracy Results for Glucose Concentration ≥ 75mg/dL

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

3. Alternate Site Testing (AST):
Compare with CareTouch® and YSI2300 Biochemical Analyzer.

3-1. Acceptance Criteria
ISO 15197 Minimum Acceptable Accuracy Requirement:
- 95% of individual glucose results must fall within ±15mg/dL at glucose concentrations < 75mg/dL
- 95% of individual glucose results must fall within ±20% at glucose concentrations ≥ 75mg/dL

3-2. Result
- No. of samples: 104

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

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

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

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

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

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
51/92 (55.4%)	83/92 (90.2%)	92/92 (100%)	92/92 (100%)

Information for AST
- Contact your Healthcare Professional before you begin using alternative sites to test your 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 you have hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose), or at times when you think your blood glucose may be rising or falling rapidly.
- Do not use AST if your AST results do not match the way you feel.
- AST measurements should never be used to calibrate continuous glucose monitors (CGMSs).
- 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 your blood glucose is low.
  - you are not aware of symptoms when you become hypoglycemic.
  - the site results do not agree with the way you feel.
  - after a meal.
  - after exercise.
  - during illness.
  - during times of stress.

Storage and Handling
- Always close the vial cap tightly after removing a test strip.
- Store the test strips in the original vial between 39.2°F and 86°F at indoor area. Do not freeze.
- Test strip may be stored in a refrigerator at 39.2~46°F. But must be brought to room temperature before using.
- Do not test if there is condensation (water build-up) on your meter or test strip vial. Move your meter or a test strip vial to a cool, dry spot and wait for the meter or a test strip vial surface to dry before testing.
- Keep away from the heat and direct sunlight.
- When properly stored, unopened test strips are stable until the expiration date printed on the Vial.
- Test strips are good three months after opening date or until the last day of the month of expiration, whichever comes first. Discard any unused test strip three months after opening. Write the first opening date of the new test strip vial to prevent using any expired products.
- Do not handle the test strips with wet or dirty hands.
- Dispose of used test strips and lancets according to instructions from your healthcare professional.

WARNING:
- This test strip is only for in-vitro diagnostic use and for self-testing.
- This products should be used with the CareTouch® meter only.
- Before using please check the expiration date on the package.
- Do not touch the test strip slit.
- Do not force the test strip when inserting it into the meter.
- This test strip could support your healthcare program but never make major changes in your diabetes treatment program without consulting your physician.
- The results of this test strip should not be used for diabetic treatment or medications without consulting your 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.
- Never ignore symptoms of high or low blood glucose.
- If your blood glucose does not match how you feel, perform a fingertip test to confirm the result. If the fingertip test result still does not match how you feel, call your physician or healthcare professional.
- Keep the test strip away from all children and pets; test strips may be a choking hazard.

Cleaning and Disinfection
Blood glucose meters are at a high risk of becoming contaminated with blood-borne pathogens such as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Refer to the User Manual of CareTouch® Blood Glucose Monitoring System for cleaning and disinfection.

References

1. National Committee for Clinical Laboratory Standards. Point-Care Blood Glucose Testing in Acute and Chronic care Facilities; Approved Guidline, 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
Call Customer Service toll-free 24 hours a day, 7days a week in US at 1866.890.8500
If you have questions or need assistance outside the operational days and time, please contact your healthcare provider.
*** NOT FOR EMERGENCY OR MEDICAL INFORMATION.**

Manufactured for:
Future Diagnostics LLC
Brooklyn, NY 11220

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