



For Testing Glucose in Whole Blood

IMPORTANT: Please read this information and your OneTouch® FastTake® Owner’s Booklet before using OneTouch® FastTake® Test Strips.

Intended Use

OneTouch® FastTake® Test Strips are used with the OneTouch® FastTake® Blood Glucose Meter for quantitatively measuring glucose in whole blood. The OneTouch® FastTake® Meter reads the glucose level of a whole blood sample on a OneTouch® FastTake® Test Strip. The OneTouch® FastTake® System is plasma-calibrated to allow easy comparison of results with laboratory methods. OneTouch® FastTake® Test Strips are for testing outside the body (*in vitro* diagnostic use).

Storage and Handling

- Store the test strip package in a cool, dry place not above 86°F (30°C). **Do Not** refrigerate. Keep away from direct sunlight and heat. Exposure to temperatures and/or humidity outside the required storage conditions may result in inaccurate readings.
- Store your test strips in their original vial only; **Do Not** transfer them to a new vial or any other container.
- After removing a OneTouch® FastTake® Test Strip from the vial, immediately replace the vial cap and close it tightly.
- Use each test strip immediately after removing it from the vial.
- Write the discard date on the vial label when you first open it. Discard remaining OneTouch® FastTake® Test Strips 3 months after first opening the vial.
- Avoid getting dirt or food on the top white edge of the test strip.
- **Do Not** use test strips beyond the expiration date printed on the package since they may cause inaccurate results. Test strips expire on the last day of the month printed on the package.
- **Do Not** bend, cut, or alter a OneTouch® FastTake® Test Strip in any way.

Original Vial



(Example)

WARNING: Keep the test strip vial away from children; the cap is a choking hazard. Also, the cap may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

Precautions to Obtain Accurate Results

- Code the OneTouch® FastTake® Blood Glucose Meter to match the code number printed on the OneTouch® FastTake® Test Strip vial.
- Check that the meter is set to the correct unit of measure before each test. The unit of measure is either mg/dL or mmol/L. Refer to the owner’s booklet for the correct unit of measure. If the unit of measure is not correct, call LifeScan Customer Service.
- Use only OneTouch® FastTake® Test Strips with the OneTouch® FastTake® Meter to obtain accurate and consistent results.
- If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all instructions described in the OneTouch® FastTake® Owner’s Booklet, call your health care professional.
- Never make significant changes to your diabetes control program or ignore physical symptoms without speaking with your health care professional.



(Example)

Test Procedure for Blood Glucose Measurement

Materials provided: OneTouch® FastTake® Test Strips.

Materials required but not provided: OneTouch® FastTake® Blood Glucose Meter with Owner’s Booklet; lancing device; new, sterile lancet.

Blood Sample Collection

OneTouch® FastTake® Test Strips are designed to be used with fresh whole blood. You may obtain a blood drop from either a fingertip or an arm. If you choose to puncture the arm, select a soft, fleshy area (away from bone) that is free of visible veins or excess hair.

Step 1: Wash your hands and the puncture site. Use warm, soapy water. Rinse and dry thoroughly.

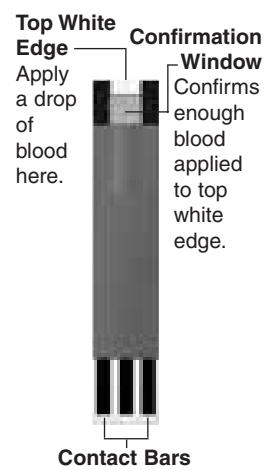
Step 2: Select and lance a puncture site. Use the lancing device to obtain a drop of blood. If puncturing the arm, you may choose to set the lancing device for a greater puncture depth. **Do Not** squeeze excessively on the puncture site. If you use an alcohol swab, make sure that the site is completely dry before lancing it.

Important Information About Arm Testing

- Consult your health care professional before you begin using the arm for testing.
- Under certain conditions, blood glucose test results obtained using samples taken from your arm may differ significantly from fingertip samples.
- The conditions in which these differences are more likely to occur are when your blood glucose is changing rapidly such as following a meal, an insulin dose, or associated with physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than arm samples.
- When your blood glucose is falling, testing with a fingertip sample **may** identify a hypoglycemic (low blood sugar) level sooner than a test with an arm sample.
- Use arm samples only for testing prior to, or more than two hours after any of the following: meals, insulin dose, or physical exercise.
- Testing performed within two hours after meals, an insulin dose, or physical exercise, or whenever you feel that your glucose levels may be changing rapidly, should be done from the fingertip.
- You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) such as when driving a car, particularly if you suffer from hypoglycemic unawareness (lack of symptoms to indicate an insulin reaction), as arm testing may fail to detect hypoglycemia.
- Use arm or fingertip samples for testing prior to, or more than two hours after any of the following: meals, insulin dose, or physical exercise. Routine testing before meals can be done either at the fingertip or the arm.

Blood Glucose Testing

Step 1: Insert test strip. Remove a test strip from the vial. Recap the vial immediately. With the contact bars end first and facing up, insert the test strip into the test port. The meter will turn on automatically. All segments will appear briefly on the display followed by the date and time. Next the code number will appear on the display. Make sure the code number on the display matches the code number on the test strip vial. If the code numbers do not match, code the meter correctly. After the code number, the ▲ symbol will appear.



Step 2: Apply sample. Obtain a drop of blood. **The blood sample must be at least 1.5 microliters in volume** or you may get an inaccurately low test result. While the ▲ symbol is displayed, touch and hold the drop of blood to the narrow channel in the TOP WHITE EDGE of the test strip.

- **Do Not** apply sample to the front or back of the test strip.
- **Do Not** press the test strip against the puncture site.
- **Do Not** apply a smeared sample.

Hold the blood drop to the TOP WHITE EDGE of the test strip until blood has completely filled the confirmation window.

Step 3: Accurate results in just 15 seconds. Your blood glucose result will appear on the display in just 15 seconds. Blood glucose results are automatically stored in the meter memory. Turn the meter off by removing the test strip. **WARNING: Check that the unit of measure is set correctly (mg/dL). If the unit of measure is not correct, call LifeScan Customer Service.**

For detailed information on the test procedure and coding your meter, please refer to the OneTouch® FastTake® Owner’s Booklet.

Test Results

- Blood glucose test results are shown on the meter as either milligrams of glucose per deciliter of blood (mg/dL) or millimoles of glucose per liter of blood (mmol/L), depending on which unit of measurement you have selected.
- The OneTouch® FastTake® Meter displays results between 20 and 600 mg/dL (1.1–33.3 mmol/L). If your test result is lower than 20 mg/dL (1.1 mmol/L), “L” will appear on the meter display. This indicates severe hypoglycemia (low blood glucose). **You should immediately treat hypoglycemia as recommended by your health care professional.** If your test result is above 600 mg/dL (33.3 mmol/L), “H” will appear on the meter display. This indicates severe hyperglycemia (high blood glucose). **You should seek immediate medical assistance.**
- When your blood glucose result is between 240 and 600 mg/dL (13.3–33.3 mmol/L), “ketones?” will appear on the meter display. This message does not mean that the system detected ketones but that testing with a ketone strip may be advisable.

Range of Expected Values

Blood glucose monitoring requires the help of a health care professional. Together you can set your own range of expected blood glucose values, arrange your testing times, and discuss the meaning of your blood glucose results.

Expected blood glucose levels for people **without** diabetes:¹

Time	Range, mg/dL	Range, mmol/L
Before breakfast	70–105	3.9–5.8
Before lunch or dinner	70–110	3.9–6.1
1 hour after meals	Less than 160	Less than 8.9
2 hours after meals	Less than 120	Less than 6.7
Between 2 and 4 AM	Greater than 70	Greater than 3.9

If You Get Unexpected Results:

IMPORTANT: Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 70 mg/dL (3.9 mmol/L) or higher than 180 mg/dL³ (10.0 mmol/L), you should contact your health care professional and follow his or her treatment advice.

Quality Control: Checking the System

Use only OneTouch® Ultra® Control Solution.

For complete details about checking the system, refer to your owner's booklet. When to do a Control Solution Test:

- At least once a week
- When you begin using a new vial of test strips
- Whenever you suspect that the meter or test strips are not working properly
- If you have had repeated unexpected blood glucose results
- If you drop the meter

When control solution is applied to the top white edge of the OneTouch® FastTake® Test Strip, **you should get results within the expected range printed on the test strip vial.** If control solution test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:

- Incorrect unit of measure
- Error in performing the test
- Failure to shake the control solution vial well enough (must shake vigorously)
- Expired or contaminated control solution
- Meter, test strip, or control solution that is too warm or too cool
- Failure to discard the first drop of control solution
- Improper coding of the meter
- Test strip deterioration
- Meter malfunction

IMPORTANT: If you continue to get OneTouch® Ultra® Control Solution test results that fall outside the range printed on the OneTouch® FastTake® Test Strips vial, the OneTouch® FastTake® System may not be functioning properly. Do Not use the system to test your blood until you get a control solution test result that falls within the range. If you continue to have problems, call LifeScan at 1 800 227-8862.

Limitations

OneTouch® FastTake® Test Strips give accurate results when the following limitations are observed:

- The test strips are for single use only. **Do Not** reuse.
- The test strips are specific to D-glucose and do not react to other sugars which may be present in blood.
- Use only fresh capillary whole blood. **Do Not** use serum or plasma.
- Extremes in hematocrit may affect test results.² Hematocrit levels less than 30% may cause falsely high readings and hematocrit levels greater than 55% may cause falsely low readings. If you do not know your hematocrit level, consult your health care professional.
- OneTouch® FastTake® Test Strips may be used at altitudes up to 10,000 feet without an effect on test results. Accurate results were demonstrated in clinical studies performed at altitudes up to 1,640 feet and in studies simulating altitudes up to 10,000 feet.

Health care professionals—please note these additional limitations:

- Fresh capillary blood may be collected into heparin-containing test tubes if the blood is used within 10 minutes. **Do Not** use other anticoagulants or preservatives.
- *Interferences:* Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Patients undergoing oxygen therapy may yield falsely lower 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 by blood glucose meters.
- *Lipemic samples:* Cholesterol levels up to 600 mg/dL and triglycerides up to 400 mg/dL do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with the OneTouch® FastTake® System.

Test Principle

Glucose in the blood sample mixes with special chemicals on the test strip and a small electrical current is produced. This current is measured by the OneTouch® FastTake® Meter and displayed as your blood glucose result. The strength of these currents changes with the amount of glucose in the blood sample.

Reagent Composition

Each OneTouch® FastTake® Test Strip contains: Glucose oxidase (*Aspergillus niger*) ≥ 0.08 IU; ferricyanide ≥ 11.19 µg; other ingredients (mediator, buffer, etc.). The vial or vial cap contains approximately 2.8 g of molecular sieve or 1.4 g silica gel.

Performance Characteristics

The performance of OneTouch® FastTake® Test Strips has been evaluated both in laboratory and in clinical tests.²

Measurement range: The measurement range of the OneTouch® FastTake® System is 20 to 600 mg/dL (1.1–33.3 mmol/L).

Accuracy: The accuracy of the OneTouch® FastTake® System was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by 119 diabetic patients at 3 clinical centers:

Slope	1.03
y-intercept	-5 mg/dL
Correlation coefficient (r)	0.982
No. of samples	119
Range tested	46–425 mg/dL

This study shows that the OneTouch® FastTake® System compares well with a laboratory method.

Precision:

Within Run Precision	Blood _{av} 62 mg/dL	CV = 1.7%
	Blood _{av} 87 mg/dL	CV = 4.0%
	Blood _{av} 152 mg/dL	CV = 2.1%
	Blood _{av} 220 mg/dL	CV = 2.9%
	Blood _{av} 378 mg/dL	CV = 2.4%

Total Precision	Control 37 mg/dL	CV = 6.9%
	Control 218 mg/dL	CV = 3.7%
	Control 481 mg/dL	CV = 3.3%

This study shows a variability from strip to strip in blood tests of 4.0% or less.

IMPORTANT: For a complete description of operating instructions and other important technical information, please refer to the OneTouch® FastTake® Owner's Booklet. IF YOU HAVE QUESTIONS ABOUT THE USE OF ANY LIFESCAN PRODUCT, PLEASE CONTACT LIFESCAN CUSTOMER SERVICE AT 1 800 227-8862.

References

1. Krall, L.P., and Beaser, R.S.: *Joslin Diabetes Manual*. Philadelphia: Lea and Febiger (1989), 138.
2. Data on file.
3. Richard S Beaser, MD.: *Joslin Guide to Diabetes*. NY: Simon & Schuster 1995.

OUR COMMITMENT TO YOU:

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