

ONETOUCH® Ultra® Test Strips

For whole blood glucose testing with the OneTouch® Ultra® Family of Meters and InDuo® Systems. The OneTouch® Ultra® Family of Meters have OneTouch® Ultra® as part of their brand name (e.g. OneTouch® UltraSmart®, etc.).

IMPORTANT: Please read this information and your OneTouch® Ultra® Family of Meters and InDuo® Systems Owner's Booklet before using OneTouch® Ultra® Test Strips. Do not use your OneTouch® Ultra® Brand Test Strips if your vial is open or damaged in any way as this could lead to error messages or blood glucose values that read higher than the actual value. Call LifeScan Customer Service at 1 800 227-8862 immediately if the test strip vial is open or damaged or if these instructional materials or your meter results seem unclear.

Intended Use

OneTouch® Ultra® Test Strips are used with the OneTouch® Ultra® Family of Meters and InDuo® Systems for quantitatively measuring glucose in fresh capillary whole blood. The OneTouch® Ultra® Test Strips and the associated meters are intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and health-care professionals in the clinical setting, as an aid to monitor the effectiveness of diabetes control. OneTouch® Ultra® Test Strips and associated meters are for use on the finger, palm, and forearm.

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**. To avoid damage or contamination, do not transfer test strips to any other place.
- After removing a OneTouch® Ultra® 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.
- Do not use test strips from any vial that is damaged or left open to air.
- Write the discard date (3 months after first opening the vial) on the vial label when you first open it. Discard remaining OneTouch® Ultra® Test Strips after the discard date.
- Do not use test strips beyond the expiration (printed on package) or discard date, whichever comes first, because they may cause inaccurate results.
- Avoid getting dirt, food or liquids on the test strip. With clean, dry hands, you may touch the test strip anywhere on its surface.
- Do not bend, cut, or alter a OneTouch® Ultra® Test Strip in any way.
- OneTouch® Ultra® Test Strips are for single use only. **Never reuse a test strip that had either blood or control solution applied to it.**
- Apply only OneTouch® Ultra® Control Solution or a blood sample to the test strip.

Flip Top Vial



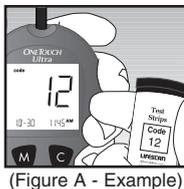
(Example)

WARNING: Keep the test strip vial away from children; test strips are a choking hazard. Do not swallow test strips. The test strip vial 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® Ultra® Family of Meters and InDuo® Systems to match the code number printed on the OneTouch® Ultra® Test Strip vial.

CAUTION: Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check to make sure the code numbers match. (Figure A)
- 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 1 800 227-8862.
- Use only OneTouch® Ultra® Test Strips with the OneTouch® Ultra® Family of Meters and InDuo® Systems to obtain accurate results.
- If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all instructions described in your OneTouch® Ultra® Family of Meters and InDuo® Systems Owner's Booklet, call your healthcare professional.
- Never ignore symptoms or make significant changes to your diabetes control program without speaking to your healthcare professional.
- If your 14- day and 30- day test result averages are not what you expect, you should not rely on them.



(Figure A - Example)

Test Procedure for Blood Glucose Measurement

Materials provided: OneTouch® Ultra® Test Strips.
Materials required but not provided: your meter, owner's booklet, lancing device, optional clear cap, and a new, sterile lancet.

Blood Sample Collection

To obtain a drop of blood, follow these steps:

Step 1: Select the puncture site. You may obtain a blood drop from the fingertip, palm, or forearm. If using the forearm, choose a fleshy area away from bone, visible veins and hair. Sometimes there is less blood flow to the forearm than to the fingertips. If using the palm, choose a fleshy area on the palm below your thumb or pinky finger. Select a spot with no visible veins and away from deep lines, which may cause your blood sample to smear. Wash your hands and the puncture site with warm, soapy water. Dry them thoroughly.

ONETOUCH® Ultra®
Test Strips



Step 2: Lance the puncture site. If lancing the fingertip: Hold the sampler firmly against the side of your finger. Press the release button. Gently squeeze and/or massage your fingertip until a round drop of blood forms on your fingertip. Do not squeeze the puncture site excessively. If lancing the forearm or palm: Replace the regular sampler cap with the clear cap and you may have to adjust the sampler to a deeper setting to get a large enough drop of blood from your forearm or palm. To help you get a large enough drop of blood, you may gently massage or apply warmth to the site to increase blood flow. Press and hold the sampler against your forearm or palm for a few seconds, then press the release button. Keep holding the sampler and cap against your skin until a round drop of blood forms under the cap. Maintain pressure until the drop of blood is of at least one microliter (● actual size).

The blood sample must be at least 1 µL in volume (● actual size) or you may get an inaccurate result.

Choosing the Right Sampling Site at the Right Time

At times, results obtained at the forearm or palm may be different from a fingertip measurement. Talk to your healthcare professional before you begin using your forearm or palm for sampling.

If you are testing:	Use blood sample from your:
Routinely before meals	Fingertip, forearm, or palm
Prior to or more than two hours after:	Fingertip, forearm, or palm
<ul style="list-style-type: none"> • a meal • a rapid-acting insulin injection or insulin pump bolus • exercise 	
When your blood glucose is changing rapidly, such as:	Fingertip
<ul style="list-style-type: none"> • within two hours after a meal • within two hours after a rapid-acting insulin injection or insulin pump bolus, or • during or within two hours after exercise 	
When you are concerned about the possibility of hypoglycemia	Fingertip

CAUTION: Do not test on forearm or palm when:

- You think your blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or insulin pump bolus. Testing with a fingertip sample may identify a hypoglycemic (low blood sugar) level sooner than a test with a forearm or palm sample.
- It has been less than two hours after a meal, a rapid-acting insulin injection or insulin pump bolus, physical exercise, or you think your glucose level is changing rapidly.
- You are concerned about the possibility of hypoglycemia (insulin reactions), such as when driving a car. This is especially important if you suffer from hypoglycemia unawareness (lack of symptoms to indicate an insulin reaction).

Remember: Consult with your healthcare professional before using your forearm or palm for testing.

Blood Glucose Testing

Step 1: Insert test strip. Remove a test strip from the vial. Check the code number on the test strip vial before inserting the strip. Recap the vial immediately. Insert the test strip, contact bars end first and facing up, into the test port. Push it in until it will go no further. The meter will turn on and the display check will appear briefly. Be sure the meter and test strip codes match. If they do not match, see your owner's booklet for instructions on coding the meter correctly.

CAUTION: Matching the code on the meter and the code on the test strip vial is essential to obtain accurate results. Each time you test, check to make sure the code numbers match.

Next, the apply blood symbol will appear.

Step 2: Apply sample. Using the lancing device, obtain a blood sample large enough to fill the confirmation window (● actual size). When the flashing apply blood symbol appears on the display, touch and hold the drop of blood to the narrow channel in the top edge of the test strip.

- DO NOT apply sample to the front or back of the test strip.
- DO NOT press the test strip too firmly against your puncture site (fingertip, forearm, or palm).
- DO NOT apply a smeared sample.

Hold the blood drop to the top edge of the test strip until the confirmation window is full before the meter begins to count down. If the confirmation window does not fill completely before the meter begins to count down, do not add more blood to the test strip; discard the test strip and retest. If the confirmation window is not full, you may get an error message or an inaccurate test result. If you have trouble filling the test strip, contact LifeScan Customer Service for assistance.

Step 3: Accurate results in just 5 seconds. Your blood glucose test result will appear after the meter counts down from 5 to 1. Blood glucose test 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 1 800 227-8862.**

For detailed information on the blood sample collection and coding your meter, please refer to the owner's booklet that came with your system.

Test Results

- The OneTouch® Ultra® Family of Meters and InDuo® Systems display 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), a warning message will appear indicating a low glucose level. This may indicate severe hypoglycemia (low blood glucose).

Treat this condition immediately according to your healthcare professional's recommendations. Although this message could be due to a test error, it is safer to treat first, then do another test. If your test result is above 600 mg/dL (33.3 mmol/L), a warning message will appear indicating a high glucose level. This may indicate severe hyperglycemia (high blood glucose). You should retest your glucose level and if the message appears again, call your healthcare professional immediately.

Range of Expected Values

Blood glucose management requires the help of a healthcare 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:

If your blood glucose result is less than 70 mg/dL (3.9 mmol/L) indicating low blood glucose or higher than 180 mg/dL (10.0 mmol/L) indicating high blood glucose, you should contact your healthcare professional and follow his or her treatment advice.²

If you continue to get unexpected results, check your system with control solution. If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all instructions described in your owner's booklet, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control program without speaking to your healthcare professional.

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 edge of the OneTouch® Ultra® 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 (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 and wipe the dispense tip clean
- Improper coding of the meter
- Test strip deterioration
- Meter malfunction

CAUTION: If you continue to get OneTouch® Ultra® Control Solution test results that fall outside the range printed on the vial, your meter may not be functioning properly. **DO NOT** use the meter to test your blood until you get a control solution test result that falls within the range. If you continue to have problems, call 1 800 227-8862.

Limitations of Procedure

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

- The test strips should not be used for the testing of newborns.
- 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.
- Hematocrit is the percentage of red blood cells in the blood. Extremes in hematocrit may affect test results.³ 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 healthcare professional.
- OneTouch® Ultra® Test Strips may be used at altitudes up to 10,000 feet (3048 meters) without an effect on test results. Accurate results were demonstrated in clinical studies performed at altitudes up to 5,280 feet (1609 meters) and in studies simulating altitudes up to 10,000 feet (3048 meters).

Healthcare professionals—please note these additional limitations of procedure:

- Fresh capillary blood may be collected into heparin-containing test tubes if the blood is used within 10 minutes. **Do not** use other anti-coagulants 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 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 by blood glucose meters.

- Lipemic samples: Cholesterol levels up to 700 mg/dL (18.1 mmol/L) and triglycerides up to 3000 mg/dL (33.9 mmol/L) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with the OneTouch® Ultra® Family of Meters and InDuo® Systems.

Infection Control

Use universal blood precautions when handling, and disposing of, blood glucose monitoring materials. All patient samples and materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection. Follow proper precautions in accordance with local regulations when disposing of all materials.

CAUTION: To reduce the chance of infection:

Never share a lancet or the lancing device with anyone. Always use a new, sterile lancet. Lancets are for single use only. Keep your meter and lancing device clean. Make sure to wash the puncture site with soap and water before testing.

Test Principle

The OneTouch® Ultra® Family of Meters and InDuo® Systems are plasma-calibrated to allow easy comparison of results with laboratory methods. 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® Ultra® Family of Meters and InDuo® Systems and displayed as your blood glucose result. The strength of this current changes with the amount of glucose in the blood sample.

Reagent Composition

Each OneTouch® Ultra® Test Strip contains: Glucose oxidase (*Aspergillus niger*) ≥ 0.08 IU; ferricyanide ≥ 22 µg; other ingredients (buffer, etc.). The vial contains a drying agent.

Performance Characteristics

The performance of OneTouch® Ultra® Test Strips has been evaluated both in laboratory and in clinical tests.³

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

Clinical Accuracy: The accuracy of the OneTouch® Ultra® 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 117 diabetic patients at 3 clinical centers:

Slope	0.986
y-intercept	-5.5 mg/dL (-0.3 mmol/L)
Correlation coefficient (r)	0.984
No. of samples	117
Range tested	36.4–434 mg/dL (2.0 - 24.1 mmol/L)

This study shows that the OneTouch® Ultra® Meter compares well with a laboratory method. Additional clinical studies were performed using other meters from the OneTouch® Ultra® Family of Meters and the InDuo® System.

Laboratory studies have demonstrated that these meters perform equivalently to the OneTouch® Ultra® Meter.³

Precision:

Within Run Precision	Blood _{av} 45 mg/dL (2.5 mmol/L)	CV = 3.2%
	Blood _{av} 77 mg/dL (4.3 mmol/L)	CV = 2.0%
	Blood _{av} 129 mg/dL (7.2 mmol/L)	CV = 2.1%
	Blood _{av} 220 mg/dL (12.2 mmol/L)	CV = 1.8%
	Blood _{av} 364 mg/dL (20.2 mmol/L)	CV = 1.6%
Total Precision	Control 44 mg/dL (2.4 mmol/L)	CV = 4.4%
	Control 171 mg/dL (9.5 mmol/L)	CV = 2.6%
	Control 366 mg/dL (20.3 mmol/L)	CV = 2.4%

This study shows a variability from strip to strip in blood tests of 3.2% or less.

IMPORTANT: For a complete description of operating instructions and other important technical information, please refer to the owner's booklet that came with your system. **IF YOU HAVE QUESTIONS ABOUT THE USE OF ANY LIFESCAN PRODUCT, PLEASE CONTACT LIFESCAN CUSTOMER SERVICE AT 1 800 227-8862.**

References

- Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), p. 138.
- Beaser, R.S. and Hill, Joan: The Joslin Guide to Diabetes. New York: Simon and Schuster (1995), p. 158.
- Data on file.

OUR COMMITMENT TO YOU:

Our goal is to provide you with quality healthcare products and dedicated customer service. If you are not fully satisfied with this product, contact your authorized LifeScan representative at 1 800 227-8862.

Covered by one or more of the following U.S. patents: 5,708,247, 5,951,836, 6,241,862, and 6,284,125. Use of these test strips and associated monitoring device is protected under the following U.S. patents: 6,413,410, 6,733,655. Purchase of the associated monitoring device does not act to grant a use license under these patents. Such a license is granted only when the associated monitoring device is used with OneTouch® Ultra® Test Strips. No test strip supplier other than LifeScan, Inc. is authorized to grant such a license. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.



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