

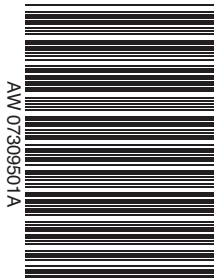
Update to your Owner's Booklet: the discard date for test strips is now 6 months after opening.

ONETOUCH Ultra

Test Strips



Now with the OneTouch® logo!



Health Care Professionals: Please call your authorized LifeScan representative for additional instructions on using OneTouch® Meters in a clinical setting (e.g., long term care facilities and physician offices).

For *in vitro* diagnostic use. For self-testing.

IMPORTANT: Please read this information and your OneTouch Ultra® Family of Meters 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 inaccurate blood glucose values. Call your authorized LifeScan representative 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 for quantitatively measuring glucose in fresh capillary whole blood. The OneTouch Ultra® Test Strips and associated meters are intended for use by people with diabetes at home and health care professionals in the clinical setting. OneTouch Ultra® Test Strips and associated meters are for use in fingertip, palm, and forearm testing.

Storage and Handling

- Store the test strip vial in a cool dry place below 30°C (86°F). **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 container.
- Do Not** open the test strip vial until you are ready to test. **Only open vial when removing strips.**
- After removing a test strip from the vial, immediately close the vial lid 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 (date opened plus 6 months) on the vial label when you first open it.
- Do Not** use test strips beyond the expiration (printed on vial label) or discard date, whichever comes first.
- 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 the test strip in any way.
- Test strips are for single use only. **Never reuse a test strip that had blood or control solution applied to it.**
- Make sure your meter and test strips are about the same temperature before you test.
- Apply only control solution or a blood sample to the test strip.
- After performing a test, **Do Not** return the used test strip to the vial.
- Used test strips may be considered biohazardous waste in your area. Be sure to follow your health care professional's recommendations or your local regulations for proper disposal.

⚠ 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. Do Not ingest or swallow any items.

Blood Glucose Test Procedure

For instructions on performing a blood test (including blood sample collection), refer to the Owner's Booklet that came with your system.

⚠ 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. For instructions on coding the meter, refer to the Owner's Booklet that came with your system.

Test Results

Low Glucose Values

If your test result is below 20 mg/dL or 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 health care professional's recommendations.** Although this message could be due to a test error, it is safer to treat first, and then do another test.

High Glucose Values

If your test result is above 600 mg/dL or 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. If the message appears again, call your health care professional immediately.

If You Get Unexpected Results

If your blood glucose result is below 70 mg/dL or 3.9 mmol/L, indicating low blood glucose, or above 180 mg/dL or 10.0 mmol/L, indicating high blood glucose, you should contact and follow your health care professional's treatment advice.¹ 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 health care professional. Never ignore symptoms or make significant changes to your diabetes control program without speaking to your health care professional.

Range of Expected Values

Blood glucose management 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:⁴

Time	Range, mg/dL	Range, mmol/L
Fasting	Less than 100	Less than 5.6
2 hours after meals	Less than 140	Less than 7.8

Checking the System

Use OneTouch Ultra™ Control Solutions

A control solution test is performed to check that the meter and test strips are working together properly and that you are performing the test correctly. For instructions on how and when to check the system by performing a control solution test, refer to the Owner's Booklet that came with your system.

Limitations of Procedure

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

- Do Not** use for the diagnosis of diabetes or for testing of newborns.
 - 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.² Hematocrit levels below 30% may cause falsely high readings and hematocrit levels over 55% may cause falsely low readings. If you do not know your hematocrit level, consult your health care professional.
 - OneTouch Ultra® Test Strips may be used at altitudes up to 3048 meters or 10,000 feet without an effect on test results. Accurate results were demonstrated in clinical studies performed at altitudes up to 1609 meters or 5,280 feet and in studies simulating altitudes up to 3048 meters or 10,000 feet.
- Health care 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 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 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 or 18.1 mmol/L and triglycerides up to 3000 mg/dL or 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.

Test Principle

The OneTouch Ultra® Family of Meters 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 displayed as your blood glucose result. The strength of this current changes with the amount of glucose in the blood sample.

Reagent Composition

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

Performance Characteristics

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

Measurement Range: The measurement range of the OneTouch Ultra® System is 20–600 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 meters from the OneTouch Ultra® Family of Meters.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 test strip to test strip in blood tests of 3.2% or less.

IMPORTANT: For complete operating instructions and other important technical information, refer to the Owner's Booklet that came with your system. IF YOU HAVE QUESTIONS ABOUT THE USE OF ANY LIFESCAN PRODUCT, PLEASE CONTACT YOUR AUTHORIZED LIFESCAN REPRESENTATIVE.

References

- Beaser, R.S. and Hill, Joan: The Joslin Guide to Diabetes. New York: Simon and Schuster (1995), p. 158.
- Data on file.
- Data on file.
- American Diabetes Association, Position Statement, Diagnosis and Classification of Diabetes Mellitus, Diabetes Care 31:S55-S60, 2008.

OUR COMMITMENT TO YOU:

Our goal is to provide you with quality healthcare products and dedicated customer Care. If you are not fully satisfied with this product, or if you have questions about the use of any LifeScan product, contact Customer Care. Contact Customer Service at 1800 225544 or write to contact.in@onetouch.com.

If you cannot reach Customer Service, contact your health care professional for advice.

Description of Symbols

For a complete description of all symbols used, refer to the Owner's Booklet that came with your system.

Date of Manufacture

Manufactured By:
LifeScan Inc.
20 Valley Stream Parkway,
Malvern, PA 19355, USA

Test strips made in UK.

Patent <https://www.onetouch.com/patents>

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