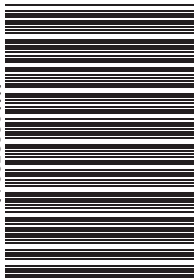


ONE TOUCH Select® Test Strips

AW 06696904



ONE TOUCH Select® Test Strips

Healthcare Professionals: Please contact LifeScan Customer Service for additional instructions on using OneTouch® Meters in a clinical setting (e.g., long term care facilities and physician offices).

In vitro diagnostic. For self-testing.

For whole blood glucose testing with the OneTouch SelectSimple® Meter.

IMPORTANT: Please read this information and your OneTouch SelectSimple® Meter Owner's Guide before using OneTouch Select® Test Strips. Do Not use your OneTouch Select® 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 1800 225544 immediately if the test strip vial is open or damaged or if these instructional materials or your meter results seem unclear.

Intended Use

OneTouch Select® Test Strips are used with the OneTouch SelectSimple® Meter for quantitatively measuring glucose in fresh capillary whole blood. The OneTouch Select® Test Strips and meter are intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and healthcare professionals in the clinical setting, as an aid to monitor the effectiveness of diabetes control. OneTouch Select® Test Strips and meter are for use on the finger, palm, and forearm.

Storage and Handling

- Store the test strip package in a cool dry place not above 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.
- Do Not** open test strip vial until you are ready to test.
- After removing a OneTouch Select® 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 (6 months after first opening the vial) on the vial label when you first open it.
- Do Not** use test strips beyond the expiry (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 Select® Test Strip in any way.
- OneTouch Select® Test Strips are for single use only. **Never reuse a test strip that had either blood or control solution applied to it.**
- Make sure your meter and test strips are about the same temperature before you test.
- Apply only OneTouch Select® Control Solution or a blood sample to the test strip.
- After performing a test, **Do Not** return the used test strip to the 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. Do Not ingest or swallow any items.

Precautions to Obtain Accurate Results

- Check that the meter is showing the correct unit of measure before each test. The unit of measure is either mg/dL or mmol/L. Refer to the Owner's Guide for the correct unit of measure. If the unit of measure is not correct, call the customer service at 1800 225544.
- Use only OneTouch Select® Test Strips with the OneTouch SelectSimple® Meter 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 SelectSimple® Meter Owner's Guide, call your healthcare professional.
- Never ignore symptoms or make significant changes to your diabetes control programme without speaking to your healthcare professional.

Test Procedure for Blood Glucose Measurement

Materials provided: OneTouch Select® Test Strips.

Materials required but not provided: your meter, Owner's Guide, lancing device, optional clear cap, and a new, sterile lancet.

Blood Sample Collection

NOTE: Refer to your system's Owner's Guide for detailed information on preparing the lancing device and 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. Wash your hands and the puncture site with warm, soapy water. Dry them thoroughly.

Step 2: Lance the puncture site.

Obtain a drop of blood. **Do Not** squeeze the puncture site excessively.

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.

NOTE: Confirm if you have the correct cap for alternative site testing.

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 	Fingertip
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 	Fingertip
When you are concerned about the possibility of hypoglycaemia	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 hypoglycaemic (low blood sugar) level sooner than testing 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 hypoglycaemia (insulin reactions), such as when driving a car. This is especially important if you suffer from hypoglycaemia 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

NOTE: For detailed information on the testing procedure including blood sample collection and, for certain meter models, coding your meter, please refer to the Owner's Guide that came with your system.

Step 1: Insert test strip. Remove a test strip and recap the vial immediately. Insert the test strip into the test port. Make sure the three contact bars are facing you and the arrow is pointing down. Push the test strip in as far as it will go. Meter turns on automatically. Use only OneTouch Select® Test Strips (Code 25 only) with your OneTouch SelectSimple® Meter.

Step 2: Apply sample. When the flashing apply sample symbol appears on the display, touch and hold the drop of blood to the narrow channel in the top edge of the test strip. Keep holding the blood drop to the top edge of the test strip until the confirmation window is full.

- Do Not** apply sample to the top of the test strip.
- Do Not** move the test strip in the meter during a test.
- Do Not** press the test strip against your puncture site (fingertip, forearm, or palm).
- Do Not** apply a smeared sample.

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 customer service at 1800 225544 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.

WARNING: Check that the unit of measure is correct (mg/dL). If the unit of measure is not correct, call customer service at 1800 225544.

Test Results

The OneTouch SelectSimple® Meter displays results between 20 and 600 mg/dL. If your test result is lower than 20 mg/dL, a warning or error message will appear indicating a low glucose level. This may indicate severe hypoglycaemia (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, a warning or error message will appear indicating a high glucose level. This may indicate severe hyperglycaemia (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 indicating low blood glucose or higher than 180 mg/dL indicating high blood glucose, you should contact and follow your healthcare professional 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 Guide, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control programme without speaking to your healthcare professional.

Checking the System

Use only OneTouch Select® Control Solutions

For complete details about checking the system, refer to your Owner's Guide.

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

If control solution test results fall outside of the range printed on the test strip vial, repeat the test and refer to your Owner's Guide.

CAUTION: If you continue to get OneTouch Select® 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 customer service at 1800 225544.

Limitations of Procedure

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

- Do Not** use for the diagnosis of diabetes or 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.
 - Haematocrit is the percentage of red blood cells in the blood. Extremes in haematocrit may affect test results.³ Haematocrit levels less than 30% may cause falsely high readings and haematocrit levels greater than 55% may cause falsely low readings. If you do not know your haematocrit level, consult your healthcare professional.
 - OneTouch Select® Test Strips may be used at altitudes up to 3048 meters (10,000 feet) without an effect on test results. Accurate results were demonstrated in clinical studies performed at altitudes up to 1609 meters (5,280 feet) and in studies simulating altitudes up to 3048 meters (10,000 feet).
- 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 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 (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 SelectSimple® Meter.

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 SelectSimple® System is plasma-calibrated to allow easy comparison of results with laboratory methods. Glucose in the blood sample mixes with special chemicals in the test strip and a small electrical current is produced. This current is measured by the OneTouch SelectSimple® Meter 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 Select® 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 Select® Test Strips has been evaluated both in laboratory and in clinical tests.³

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

Clinical accuracy: The accuracy of the OneTouch Select® System was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyser, a laboratory instrument. The following results were obtained by 163 diabetic patients at 3 clinical centres:

Slope	0.979
y-intercept	-3.4 mg/dL (-0.2 mmol/L)
Correlation coefficient (r)	0.985
No. of samples	163
Range tested	43–486 mg/dL (2.4–27.0 mmol/L)

This study shows that the OneTouch Select® Meter compares well with a laboratory method.³

Precision:

Within Run Precision	Blood _{av} 42 mg/dL (2.3 mmol/L)	CV = 3.0%
	Blood _{av} 106 mg/dL (5.9 mmol/L)	CV = 1.8%
	Blood _{av} 139 mg/dL (7.7 mmol/L)	CV = 1.5%
	Blood _{av} 224 mg/dL (12.4 mmol/L)	CV = 1.5%
	Blood _{av} 355 mg/dL (19.7 mmol/L)	CV = 1.6%
Total Precision	Control 36 mg/dL (2.0 mmol/L)	CV = 3.2%
	Control 110 mg/dL (6.1 mmol/L)	CV = 2.1%
	Control 337 mg/dL (18.7 mmol/L)	CV = 2.3%

This study shows a variability from test strip to test strip in blood tests of 3.0% or less.

This data was generated using the OneTouch Select® Meter. OneTouch Select® system performance is representative of the OneTouch Select® Family of Meters (OneTouch Select® and OneTouch SelectSimple®).

Please refer to your Owner's Guide for performance information for your OneTouch SelectSimple® Meter.

IMPORTANT: For a complete description of operating instructions and other important technical information, please refer to the Owner's Guide that came with your system. **IF YOU HAVE QUESTIONS ABOUT THE USE OF ANY LIFESCAN PRODUCT, PLEASE CONTACT CUSTOMER SERVICE AT 1800 225544.**

References


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


OUR COMMITMENT TO YOU:

Creating a world without limits for people with diabetes is what OneTouch® is all about. To enjoy the benefits that OneTouch® has to offer, kindly call the customer service at 1800 225544 to enroll on to our OneTouch® Zone programme.


Description of Symbols


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


 Consult instructions for use


 Do not re-use

 Expiry Date

 In Vitro Diagnostic Medical Device

 Lot Number

 Storage temperature limits

 Contains sufficient for <n> tests

 Date of Manufacture

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

AW 06695904A
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IP Holdings, LLC
Rev. date: 08/2023

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

Test Strips Made in UK

Lifescan 

