

# ONETOUCH®

Basic  
Profile  
OneTouch II

## Test Strips for Blood Glucose Testing



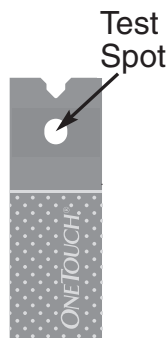
### Patient Information

#### Purpose of Glucose Testing

Blood glucose meters are for use by people with diabetes to check the level of glucose (sugar) in their blood. People with diabetes can use the result of a blood glucose test, with their doctor's advice, to adjust the dose of insulin or other drugs they take and to make changes to diet and exercise. This product is for human use only.

#### Description of the Test Strip

The test strip consists of a blue plastic handle with a test spot attached. The test strips are supplied in a protective vial with a cap containing a drying agent which protects the strips from light, moisture and contamination. When stored and handled properly, the test spot on a strip is cream-colored. Do not use a test strip if the test spot is discolored.



#### Environmental Conditions that Affect Use

Perform the blood glucose test at room temperature whenever possible. NEVER test at a temperature outside the operating range listed in your meter Owner's Booklet.

#### How to Store and Handle the Test Strips

Improper storage and handling may cause inaccurate results.

- ◆ Test Strips are sensitive to moisture and light. The test strips are in a moisture-resistant, light protected vial.
  - The test strips must be stored in the original vial with the cap tightly closed. Never place test strips in another container.
  - Store the test strips in a cool, dry place not above 86° F (30° C) and away from heat and direct sunlight. Do not refrigerate. Improper storage may cause the test strips to give false readings.
- ◆ Do not use the test strips after the expiration date printed on the vial. Expired strips may give false blood glucose readings.
- ◆ Discard test strip vial 4 months after you first open it. Extended exposure to moisture in the air may destroy chemicals on the test strip causing false readings.
- ◆ Do not bend, cut or alter a OneTouch® Test Strip in any way.
- ◆ The test strips are for single use only. Do not reuse.
- ◆ Keep test strip vial away from children. A child could choke on the cap or be harmed if the drying agent in cap is swallowed, inhaled, or contacts skin.

#### How to Perform a Test

This is a summary of the full procedure. Please read the complete instructions in the Owner's Booklet of your OneTouch® System before you start testing your blood glucose. For assistance: please call 1 800 227-8862

*Note: There have been translation errors in some non-English meter displays. If you are not setting your meter to display in English, please call LifeScan or visit the Web site. Information on translations will be given. Customer Service can be reached at 1 800 227-8862 and the LifeScan Web site is found at [www.LifeScan.com](http://www.LifeScan.com)*

#### Before You Begin

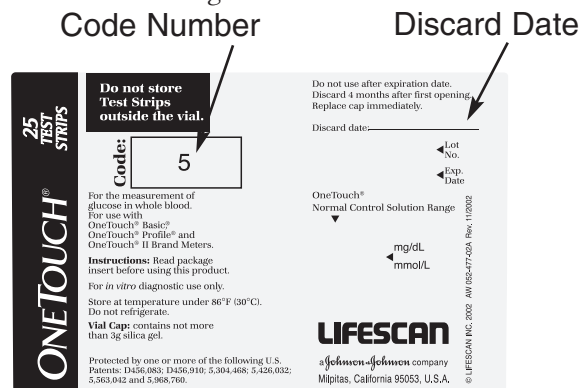
- ◆ Carefully read this entire insert.
- ◆ Use OneTouch® Test Strips with OneTouch® Basic®, OneTouch® Profile® or OneTouch® II Meters.

#### Materials Needed to Test Your Blood Glucose

- ◆ To test your blood glucose, you will need the OneTouch® Test Strips provided in this package and the following materials:
  - OneTouch® Basic®, OneTouch® Profile® or OneTouch® II Meter with Owner's Booklet.
  - Lancing device
  - New, sterile lancet

#### What to Do When you Open a Box of Strips

- ◆ When you open a new box of strips:
  - Enter the "Code" number located on test strip vial label into your meter.
  - Write the date that the vial should be discarded on the vial label (4 months from the day opened).
  - Perform a control solution test and verify result is in control solution range.

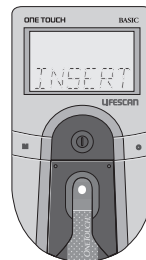


#### How to Test Your Blood Glucose

1. REMOVE A TEST STRIP FROM THE VIAL.
  - ◆ Immediately replace the cap to protect the remaining test strips from moisture in the air.
  - ◆ Check that the test spot is cream-colored; do not use the test strip if it is discolored.
2. PRESS THE ON/OFF BUTTON.

**Make sure all "segments" or parts of the display turn on. (See section titled "Checking the system")**

3. INSERT THE TEST STRIP
  - ◆ Make sure the code number displayed on the meter matches the code number on the test strip vial.
3. INSERT THE TEST STRIP
  - ◆ Be sure to insert the test strip completely and correctly (See the example to the right). The notch in the test strip should not be visible when the strip is inserted completely.
  - ◆ A "NOT OK" error message may indicate that the test strip was inserted upside down. Once the test strip is re-inserted correctly, the error message should no longer be displayed.

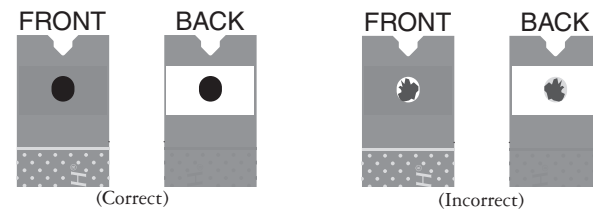


#### 4. OBTAIN A SAMPLE OF BLOOD

- ◆ Wash and dry your hands.
- ◆ Use a lancing device to get a drop of blood from a fingertip.

#### 5. APPLY BLOOD TO THE TEST STRIP

- ◆ Gently apply the sample of blood to the test spot. The blood sample required is 5 microliters in volume. Do not press the finger against the test strip or move the test strip any time during the test.
- ◆ Completely cover the test spot with blood. The following illustration shows examples of proper and improper blood application to the test strip.



- ◆ A "NOT ENOUGH BLOOD" message may indicate too little blood was applied to the test strip or the test spot was not completely covered. Repeat the test if this error occurs.

#### 6. BLOOD TEST RESULTS

- ◆ The blood test result will appear in the meter display window. Your healthcare professional will tell you what your range of blood glucose values should be, how often you should test, and the meaning of your test results.
- ◆ A control solution result ("C" or "CONTRL" and a number) may occur if you test your blood when you have low hematocrit, such as in anemia. It may also occur when you test your blood if the test strip is not inserted completely or if too little blood has been applied. If this error occurs, repeat the test by applying a larger sample of blood to a new test strip.

**WARNING:** A result of "Hi" or "High" on the meter display indicates very high blood glucose levels (severe hyperglycemia); contact your physician immediately.

- If you have symptoms that are not consistent with your test results, consult the Owner's Booklet to check for common testing errors. If the problem persists, contact your healthcare professional immediately.
- If your readings are above or below your prescribed range of blood glucose values, repeat the test. If your results continue to fall outside your prescribed range, follow the treatment advice of your healthcare professional.
- Never make major changes in your diabetes treatment program without asking your doctor and never ignore symptoms.

#### Range of Expected Blood Glucose Results

For people without diabetes blood glucose levels are expected to be in the following ranges:<sup>1</sup>

TIME	RANGE MG/DL	RANGE MMOL/L
Before meals	70–110	3.9–6.1
1 hour after meals	Less than 160	Less than 8.9

## What Factors Can Affect the Accuracy of Test Results

- Your meter glucose test result should agree with a laboratory result to within +/- 20% most of the time under normal conditions. A test result within this range is considered accurate when testing with the OneTouch® Profile®, OneTouch® II or OneTouch® Basic® Meters. However, there are factors that cause results to differ by more than 20% in some situations. The system has not been checked under all possible combinations of these factors. When more than one factor is present, the chance of inaccuracy increases.
- The following conditions can affect the accuracy of your test results.
  - Hematocrit:** Factors such as a low or high hematocrit (the percentage volume of red blood cells in your blood) can cause false results. For example, if your hematocrit is too low (below 30%) or too high (above 55%).
  - Neonates:** Do not use the OneTouch® Test Strips to test neonates. The performance of this product has not been validated with neonatal samples.
  - Lipid Effects:** The effect of high lipid (fat) levels in blood samples (i.e. triglycerides greater than 3000 mg/dL) on the accuracy of OneTouch® Test Strips has not been studied.
  - Ascorbic Acid:** The effect of high ascorbic acid (vitamin C) levels in blood samples (i.e. concentrations greater than 3 mg/dL) on the accuracy of OneTouch® Test Strips has not been studied.
  - Hyperglycemic-hyperosmolar state:** This is an acute complication of diabetes that can be life threatening if not treated. This state leads to severe dehydration and an increase in the viscosity of the blood. This can affect the ability of blood to properly penetrate the test spot. As a result, your meter results may be falsely low. Dehydration caused by any other condition may also result in this error.<sup>2,3</sup>
  - High Altitude:** The effect of high altitudes (i.e. greater than 10,000 feet) on the accuracy of OneTouch® Test Strips has not been studied.

## When a Problem Occurs

Error messages or control results that fall outside the range may indicate a procedural error has been made. Errors may also indicate a dirty meter or test strip holder, an expired control solution or a meter malfunction. Refer to the OneTouch® System Owner's Booklet for assistance.

## Cleaning Your Meter

Your OneTouch® Meter must be handled carefully and cleaned regularly to give accurate results. Refer to your Owner's Booklet for detailed instructions.

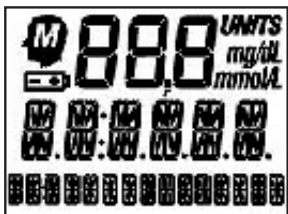
## Checking the System

For OneTouch® Profile® users:

- There have been problems with some OneTouch® Profile® meter displays. Check your meter's display. Press and hold down the on/off button to extend the viewing period. You should carefully observe the display to make sure all "segments" or parts of the display turn on each time you test your blood.

### Display Test

Properly Functioning Display



All segments are active, the display is working properly.

### Display Test

Display with Missing Segments



Some parts of the display are not working. Message will be incomplete.

### Test Result

Recognizable Result, but incorrect



In this example, the 120 mg/dL result is really 420 mg/dL, as indicated by the missing segment shown in gray.

**CAUTION:** If you believe your OneTouch® Profile® meter's display has a problem, or if you need help determining if your display is operating properly, call LifeScan Customer Service at 1 800 227-8862.

For all other OneTouch® meter users:

- Check your meter's display as described in your Owner's Booklet.

## Control Solution System Check

For all OneTouch® meter users:

- Use the OneTouch® Normal Control Solution to check your system:
  - Every time you open a new box of test strips.
  - At least once a week to verify that the meter and the test strips are working properly together.
  - When your results do not agree with how you feel.
  - If you drop your meter.
- The results of a control solution test should fall within the normal control range printed on the test strip vial.
- Repeat the control test if your control solution results fall outside the expected range.

**NOTE:** High (red-capped) and Low (green-capped) control solutions are not intended to be used with this product. If used, your control solution reading may not fall within the appropriate range, as printed on the test strip vial label.

**CAUTION:** If you continue to get OneTouch® Normal Control Solution test results that fall outside the expected range, the OneTouch® System may not be working properly. DO NOT use the system to test your blood. Contact LifeScan Customer Service at 1-800-227-8862.

## Comparing your Result to the Lab

- You can check the results of your OneTouch® system by comparing your meter result to a clinical lab test. To compare your result you should:
  - Perform the test at least 4 hours after eating.
  - Have blood drawn and tested in the lab within 10 minutes of testing blood from your finger with your meter.
- The meter result should be within 20% of the lab result if your testing system is working correctly.
  - OneTouch® test strips measure glucose in whole blood while most labs measure glucose in plasma or serum (the fluid remaining when red blood cells are removed). Plasma and serum glucose tests will produce results that are about 12% higher than your meter results. To compare your meter result to a plasma or serum test, multiply your meter result by 1.12. This adjusted meter result should be within 20% of the laboratory result.

Example:

OneTouch Brand Meter result	179 mg/dL
Adjusted meter result	179 x 1.12 = 200 mg/dL
Laboratory plasma or serum result	200 mg/dL
Acceptable range	200 mg/dL ±20% 160 mg/dL to 240 mg/dL

## Important Technical and Healthcare Professional Information

### Additional Limitations of Procedure

**WARNING:** Do not use serum or plasma samples. Serum and plasma samples may give false results.

- Venous blood may be used; however, venous blood must be adequately oxygenated (pO<sub>2</sub> greater than 45 mm Hg). Venous and capillary blood glucose concentrations may differ by up to 70 mg/dL depending upon how long after meal samples are taken.<sup>4</sup> Shock and/or administration of vasoactive agents may also cause discrepancies between venous and capillary blood test results.<sup>5,6</sup>
- Perform blood glucose determinations within 10 minutes of sample collection since glycolysis causes continual decreases in the glucose concentration of (unpreserved) whole blood samples.
- When whole blood in a test tube is used, care should be taken that red blood cells are reoxygenated and fully distrib-

uted throughout the test tube of blood before the sample is taken. This may be done by shaking the capped tube gently or by aspirating air through the sample with a transfer pipet until the sample appears bright red.

- Blood samples obtained in containers with common anticoagulants and preservatives (citrate, heparin) may be used. Do not use preservatives that contain sodium fluoride.

## Principles of the Procedure

Glucose and oxygen react in the presence of glucose oxidase yielding gluconic acid and hydrogen peroxide. Hydrogen peroxide subsequently oxidizes the dyes in a reaction mediated by peroxidase producing a blue colored form of the dyes.<sup>7</sup> The intensity of this blue color is proportional to the glucose concentration in the sample.

## Reagent Composition

Each cm<sup>2</sup> of test strips contains the following reactive ingredients in the approximate concentrations listed below:

- Glucose oxidase . . . . .14 IU
- Peroxidase . . . . .11 IU
- 3-Methyl-2-benzothiazolinone  
hydrazone hydrochloride . . . . .0.06 mg
- 3-dimethylaminobenzoic acid . . . . .0.12 mg

Each test strip vial cap contains up to 3-g of silica gel.

## Performance Characteristics

### Precision

Replicate tests (n=192) on OneTouch Brand Meters using heparinized venous blood adjusted to different glucose levels resulted in the following precision estimates (coefficient of variation; CV):

MEAN	CV
51.1 mg/dL . . . . .	2.8%
156.6 mg/dL . . . . .	1.1%
308.7mg/dL . . . . .	1.0%
469.0 mg/dL . . . . .	0.4%

### Clinical Accuracy

The accuracy of the OneTouch System was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2700 Glucose Analyzer, a laboratory instrument. The following results were obtained by 107 diabetic patients at 3 clinical centers:

Slope . . . . .	1.04
y-intercept . . . . .	-0.63 mg/dL
Correlation coefficient (r) . . . . .	0.98
No. of samples . . . . .	107
Range tested . . . . .	55-428 mg/dL

## References

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Covered by one or more of the following U.S. patents: D456,083; 5,304,468; 5,426,032; 5,563,042, 5,968,760 and 6,489,133. Use of these test strips and associated monitoring device is protected under the following U.S. patents: 4,935,346, 5,049,487, and 5,179,005. 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® 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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