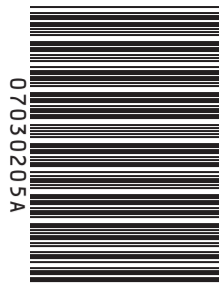


ONE TOUCH
Verio® Test Strips



For India

In vitro diagnostic. For self-testing.

IMPORTANT: Please read this insert and your User Guide or Owner's Booklet that came with your system before using. The User Guide or Owner's Booklet has full instructions for blood glucose and control solution testing. **Do Not** use new test strips if the vial is open or damaged in any way. This could lead to error messages or inaccurate blood glucose results. Contact Customer Care right away if you have questions about your test strips, test results or these instructions. Kindly contact Customer Care at 1800 225544 or visit www.onetouchdiabetes.co.in.

Intended Use

The OneTouch Verio® Test Strips when used with the OneTouch Verio® Family of Blood Glucose Monitoring Systems (OneTouch Verio®, OneTouch Verio Flex™) is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. Venous whole blood samples may be used by healthcare professionals with some systems. Refer to your user guide that came with your meter for sample information. The OneTouch Verio® Family of Blood Glucose Monitoring Systems are intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch Verio® Family of Blood Glucose Monitoring Systems is not to be used for the diagnosis of or screening of diabetes or for neonatal use.

Refer to the User Guide or Owner's Booklet that came with your meter for the full system intended use.

Storage and Handling

- Store the test strip vial in a cool dry place between 5°C and 30°C. **Do Not** refrigerate. Keep away from direct sunlight and heat. Exposure to temperatures and/or humidity outside the storage limits may cause inaccurate readings.
- The expiry date is printed on the vial.
- The discard date is 6 months after you first open a test strip vial. When you open a new vial, write the discard date on the label.
- **Do Not** use after the expiry or discard date, whichever comes first.
- Store your test strips in the **vial only**. To avoid damage or contamination, **Do Not** put test strips in any other container.
- Open the vial **only** when taking out a test strip for use.
- Close the vial lid tightly right away after removing a test strip. Use each test strip **as soon as you take it out** of the vial.
- **Do Not** use test strips from a vial that is damaged or left open to air.
- **Do Not** get dirt, food or liquids on the test strip. You may touch the test strip anywhere on its surface with clean, dry hands.
- **Do Not** bend, cut or alter test strips in any way.
- Test strips are for single use only.
- **Never reuse a test strip that already has blood or control solution on it.**
- Make sure your meter and test strips are about the same temperature before you test.
- Apply only OneTouch Verio® Control Solution or a blood sample to the test strip.
- **Do Not** put the used test strip back in the vial after taking a test.
- Used test strips may be considered biohazardous waste in your area. Be sure to follow your healthcare professional's advice or local laws when throwing them away.

⚠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.

Testing your blood glucose

Read your system User Guide or Owner's Booklet for instructions on running a blood test and getting a blood sample.

Test Results

The OneTouch Verio® Family of Meters shows results between 20 and 600 mg/dL.

Read these cautions when your test results are higher or lower than what you expect.

⚠CAUTION:

Low glucose results

If your blood glucose result is below 70 mg/dL or a low glucose warning is displayed, (meaning the result is less than 20 mg/dL), it may mean hypoglycaemia (low blood glucose). You may need to treat low glucose right away. Follow your healthcare professional's advice. The result could be due to a test error, but it is safer to treat first, then test again.

Dehydration and low glucose results

You may get false low glucose results if you are severely dehydrated. If you think this is the case, contact your healthcare professional right away.

High glucose results

If your test result is above 180 mg/dL, it may mean high blood glucose (hyperglycaemia). You should think about re-testing. Talk to your healthcare professional if you are concerned about high blood glucose.

A high glucose warning is shown when your blood glucose level is over 600 mg/dL. You may have very high blood glucose (severe hyperglycaemia). Re-test your blood glucose. If the result is a high glucose warning again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional right away.

Repeated unexpected glucose results

If you get repeated unexpected results:

- Run a control solution test to check your system.
- Make sure you follow all instructions in your User Guide or Owner's Booklet.
- If your symptoms don't match your blood glucose results, call your healthcare professional.

Never ignore symptoms or make significant changes to your diabetes management programme without speaking to your healthcare professional.

Range of Expected Values

Blood glucose management requires the help of a healthcare professional. Talk to your healthcare professional about:

- The target blood glucose range that is right for you.
- When to test.
- What your blood glucose results mean.

Expected blood glucose levels for non-pregnant people without diabetes¹:

Time	Range, mg/dL
Fasting	Less than 100
2 hours after meals	Less than 140

¹American Diabetes Association, Standards of Medical Care in Diabetes, Diabetes Care Vol. 38, Supplement 1, S1-S94, January 2015.

Checking the System

Use only OneTouch Verio® Control Solution

A control solution test is used to check that:

- The meter and test strips are working together properly.
- You are doing the test correctly.

Do a control solution test

- When you open a new vial of test strips.
- If you think the meter or test strips are not working properly.
- If you get repeated unexpected blood glucose results.
- If you drop or damage the meter.

Read your system User Guide or Owner's Booklet for instructions on how to run a control solution test.

Limitations of Procedure

OneTouch Verio® Test Strips give accurate results under the following conditions:

- 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. Haematocrit levels below 20% may cause false high readings. Haematocrit levels over 60% may cause false low readings. Talk to your healthcare professional if you don't know your haematocrit level.
- OneTouch Verio® Test Strips may be used at altitudes up to 3048 metres with no effect on test results.

Healthcare professionals—please note these additional limitations of procedure:

- Fresh capillary blood or venous blood samples may be collected into sodium heparin, lithium heparin, potassium EDTA and sodium citrate containing test tubes if the blood is used within 10 minutes. **Do Not** use sodium fluoride/oxalate or other anticoagulants or preservatives. Not intended for use with arterial blood samples.
- Interferences: Uric acid and other reducing substances (when occurring in blood at high normal or at high therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately 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 with blood glucose meters.

⚠CAUTION:

- The OneTouch Verio® Family of Blood Glucose Monitoring Systems should not be used for patients within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high results.
- **Do Not** use the OneTouch Verio® Family of Blood Glucose Monitoring Systems when PAM (Pralidoxime) is known or suspected to be in the patient's whole blood sample.

Alternate Site Limitations

Refer to the User Guide or Owner's Booklet that came with your meter for the full system intended use.

Some meter systems are not indicated for Alternate Site Testing (AST).

Results from forearm or palm samples may differ from results using fingertip samples. This is due to normal differences in blood flow. It does not reflect system accuracy. Be sure to talk to your healthcare professional before using your forearm or palm for sampling.

Differences in blood glucose readings between the fingertip and other sites may occur after eating, insulin medication or exercise. This is because blood sugar levels change faster in the fingertip than in other sites.

Alternate site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) or to calculate an insulin dose. AST testing should only be done during steady-state times (when glucose is not changing rapidly).

Test Principle

The OneTouch Verio® Family of Meters is plasma-calibrated for easy comparison of results with lab methods. Glucose in the blood sample mixes with special chemicals on the test strip to produce an electrical current. The strength of the current changes with the amount of glucose in the blood sample. The OneTouch Verio® Family of Meters measures the current, calculates your blood glucose level and shows your result.

Reagent Composition

Each test strip contains: flavin adenine dinucleotide dependent glucose dehydrogenase or FAD-GDH (from *Aspergillus* sp.) - 2 U; potassium ferricyanide 41 µg; and other ingredients (buffer, etc.). The vial contains a drying agent.

Performance Characteristics

See your system User Guide or Owner's Booklet.

IMPORTANT: For instructions, technical data and a list of symbols used, read your system User Guide or Owner's Booklet.

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Read instructions.

Test Strips Made in UK

OneTouch®

For Australia

In vitro diagnostic. For self-testing.

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Storage and Handling

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Testing your blood glucose

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Test Results

The OneTouch Verio® Family of Meters shows results between 1.1 and 33.3 mmol/L.

Read these cautions when your test results are higher or lower than what you expect.

⚠CAUTION:

Low glucose results

If your blood glucose result is below 3.9 mmol/L or a low glucose warning is displayed, (meaning the result is less than 1.1 mmol/L), it may mean hypoglycaemia (low blood glucose). You may need to treat low glucose right away. Follow your healthcare professional's advice. The result could be due to a test error, but it is safer to treat first, then test again.

Dehydration and low glucose results

You may get false low glucose results if you are severely dehydrated. If you think this is the case, contact your healthcare professional right away.

High glucose results

If your test result is above 10.0 mmol/L, it may mean high blood glucose (hyperglycaemia). You should think about re-testing. Talk to your healthcare professional if you are concerned about high blood glucose.

A high glucose warning is shown when your blood glucose level is over 33.3 mmol/L. You may have very high blood glucose (severe hyperglycaemia). Re-test your blood glucose. If the result is a high glucose warning again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your healthcare professional right away.

Repeated unexpected glucose results

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Blood glucose management requires the help of a healthcare professional. Talk to your healthcare professional about:

- The target blood glucose range that is right for you.
- When to test.
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Expected blood glucose levels for non-pregnant people without diabetes¹:

Time	Range, mmol/L
Fasting	Less than 5.6
2 hours after meals	Less than 7.8

¹American Diabetes Association, Standards of Medical Care in Diabetes, Diabetes Care Vol. 38, Supplement 1, S1-S94, January 2015.

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

Read instructions.

Test Strips Made in UK

OneTouch®

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

Manufactured for:
LifeScan Europe GmbH
Gubelstrasse 34
6300 Zug
Switzerland

Australian Sponsor:
Australasian Medical & Scientific Ltd.
2 McCabe Pl, Chatswood
NSW 2067, Australia



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