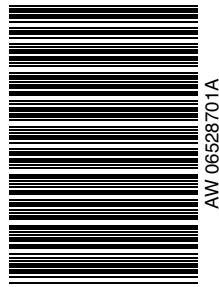


ONE TOUCH[®] VITA[™] Test Strips



ONE TOUCH[®]
VITA[™] Test Strips

IVD For self-testing.

IMPORTANT: Please read this information and your OneTouch[®] Vita[™] User's Handbook before using OneTouch[®] Vita[™] Test Strips. Do not use your OneTouch[®] Vita[™] 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 0800 121 200 (UK) or 1800 535 676 (Ireland) immediately if the test strip vial is open or damaged, or if these instructions or your meter results seem unclear.

Intended Use

OneTouch[®] Vita[™] Test Strips are used with the OneTouch[®] Vita[™] meter for quantitatively measuring glucose in fresh capillary whole blood. OneTouch[®] Vita[™] Test Strips and meter 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 has been left open to air.
- Write the use-by date (date opened plus 6 months) on the vial label when you first open it.
- **Do not** use after the expiry date (printed on vial label) or use-by 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 re-use a test strip that has 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 OneTouch[®] Vita[™] Control Solution or a blood sample to the test strip.
- After performing a test, **do not** return the used test strip to the vial.

⚠ 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) and the range of expected blood glucose values, refer to the User's Handbook that came with your system.

Test Results

The OneTouch[®] Vita[™] Meter displays results between 1.1–33.3 mmol/L (20 and 600 mg/dL). Refer to the User's Handbook for the range of expected blood glucose values.

Low Glucose Values

If your test result is below 1.1 mmol/L (20 mg/dL), a warning message will appear indicating a low glucose level. This may indicate severe hypoglycaemia (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 33.3 mmol/L (600 mg/dL), a warning message will appear indicating a high glucose level. This may indicate severe hyperglycaemia (high blood glucose). You should re-test 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 3.9 mmol/L (70 mg/dL), indicating low blood glucose, or above 10.0 mmol/L (180 mg/dL), indicating high blood glucose, you should contact your health care professional and

follow their advice on treatment.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 User's Handbook, call your health care professional. Never ignore symptoms or make significant changes to your diabetes control programme without speaking to your health care professional.

Checking the System

Use only OneTouch[®] Vita[™] 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 User's Handbook that came with your system.

Limitations of the Procedure

OneTouch[®] Vita[™] Test Strips give accurate results when the following restrictions are observed:

- **Do not** use for the diagnosis of diabetes or for testing newborn babies.
- Test strips are for single use only. **Do not** re-use.
- The test strips are specific to D-glucose and do not react with other sugars that 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.² Haematocrit levels below 30% may cause falsely high readings and haematocrit levels over 55% may cause falsely low readings. If you do not know your haematocrit level, consult your health care professional.
- OneTouch[®] Vita[™] Test Strips may be used at altitudes up to 3048 meters (10,000 feet) without an effect on test results. Accurate results have been 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).

Health care professionals—please note these additional procedural restrictions:

- Fresh capillary blood may be collected in heparin-containing test tubes if the blood is used within 10 minutes. **Do not** use other anticoagulants or preservatives.
- Interferences: Paracetamol, 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 with blood glucose meters.
- Hyperlipidaemic samples: Cholesterol levels up to 18.1 mmol/L (700 mg/dL) and triglycerides up to 33.9 mmol/L (3000 mg/dL) do not affect the results. Grossly hyperlipidaemic patient samples have not been tested and are not recommended for testing with the OneTouch[®] Vita[™] Meter.

Test Principle

The OneTouch[®] Vita[™] system is 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[®] Vita[™] 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 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[®] Vita[™] Test Strips has been evaluated both in laboratory and in clinical tests.²

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

System Accuracy: Diabetes experts have suggested that glucose meters should agree within 0.8 mmol/L (15 mg/dL) of a laboratory method when the glucose concentration is lower than 4.2 mmol/L (75 mg/dL),

and within 20% of a laboratory method when the glucose concentration is 4.2 mmol/L (75 mg/dL) or higher. Samples from 139 patients at 2 clinical centres were tested using both the OneTouch® Vita™ System and the YSI Model 2300 Glucose Analyzer laboratory instrument. The study demonstrates that the accuracy of blood glucose results obtained by the OneTouch® Vita™ System compares well with the laboratory method.²

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|--|-----------------------------|------------------------------|------------------------------|
| For glucose results lower than 4.2 mmol/L (75 mg/dL), the percentage (and number) of meter results that match the laboratory method are: | Within 0.3 mmol/L (5 mg/dL) | Within 0.6 mmol/L (10 mg/dL) | Within 0.8 mmol/L (15 mg/dL) |
| | (26/120) 21.7% | (78/120) 65.0% | (116/120) 96.7% |

| | | | | |
|--|--------------------|--------------------|--------------------|--------------------|
| For glucose results at 4.2 mmol/L (75 mg/dL) or higher, the percentage (and number) of meter results that match the laboratory method are: | Within 5% | Within 10% | Within 15% | Within 20% |
| | (268/714) 37.5% | (500/714) 70.0% | (628/714) 88.0% | (704/714) 98.6% |

Precision:

| | | |
|----------------------|---|-----------|
| Within Run Precision | Blood _{av} 2.4 mmol/L (43 mg/dL) | CV = 3.1% |
| | Blood _{av} 6.1 mmol/L (109 mg/dL) | CV = 2.5% |
| | Blood _{av} 7.6 mmol/L (136 mg/dL) | CV = 1.7% |
| | Blood _{av} 11.8 mmol/L (213 mg/dL) | CV = 1.5% |
| | Blood _{av} 19.5 mmol/L (352 mg/dL) | CV = 1.6% |

| | | |
|-----------------|---------------------------------|-----------|
| Total Precision | Control 2.1 mmol/L (37 mg/dL) | CV = 3.0% |
| | Control 6.2 mmol/L (111 mg/dL) | CV = 2.3% |
| | Control 19.5 mmol/L (351 mg/dL) | CV = 1.7% |

This study shows a variability from test strip to test strip in blood tests of ≤ 3.1%.

IMPORTANT: For complete operating instructions and other important technical information, refer to the User's Handbook that came with your system. IF YOU HAVE QUESTIONS ABOUT THE USE OF ANY LIFESCAN PRODUCT, PLEASE CALL 0800 121 200 (UK) or 1800 535 676 (Ireland).

References


1. Beaser, R.S. and Hill, Joan: The Joslin Guide to Diabetes. New York: Simon and Schuster (1995), p. 158.
2. Data on file.

OUR COMMITMENT TO YOU: Our goal is to provide you with quality health care products and dedicated customer service. If you are not fully satisfied with this product, contact your authorized LifeScan representative on 0800 121 200 (UK) or 1800 535 676 (Ireland).

Description of Symbols

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



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