

PocketScan™

Test Strips For Testing Glucose in Whole Blood



IMPORTANT: Please read this information and your PocketScan™ Owner's Booklet before using PocketScan™ Test Strips.

Intended Use

PocketScan™ Test Strips are used with the PocketScan™ Blood Glucose Meter for quantitatively measuring glucose in whole blood. The PocketScan™ Meter reads the glucose level of a whole blood sample on a PocketScan Test Strip. The PocketScan™ System is calibrated to allow easy comparison of results with laboratory methods. PocketScan Test Strips are for testing outside the body (in vitro diagnostic use).

Storage and Handling

- Store the test strip package in a cool, dry place not above 30°C (86°F). Keep away from direct sunlight and heat. Do not refrigerate.
- Store your test strips in their original vial only; do not transfer them to a new vial or any other container.
- After removing a PocketScan Test Strip from the vial, replace the vial cap and close it tightly.
- Use each test strip immediately after removing it from the vial.
- Write the discard date on the vial label when you open it. Discard PocketScan Test Strips 3 months after first opening the vial.
- Avoid getting dirt or food on the target area.
- Do not use test strips beyond the expiration date printed on the package since they may cause inaccurate results.
- Do not bend, cut, or alter a PocketScan Test Strip in any way.

Original Vial



(Example)

WARNING: Keep the test strip vial away from children; the cap is a choking hazard. The cap contains a pouch filled with drying agents that may be harmful if inhaled or swallowed and may cause skin or eye irritation.

Precautions to Ensure Accurate Results

- Code the PocketScan Blood Glucose Meter to match the code number printed on the PocketScan Test Strip vial.
- Use only PocketScan Test Strips with the PocketScan Meter to obtain accurate and consistent results.
- If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all instructions described in the PocketScan™ Owner's Booklet, call your healthcare professional.
- Never make significant changes to your diabetes control program or ignore physical symptoms without speaking with your healthcare professional.



(Example)

Test Procedure for Blood Glucose Measurement

Materials provided: PocketScan Test Strips.



Materials required but not provided: PocketScan Blood Glucose Meter with Owner's Booklet; Automatic Blood Sampler; new, sterile lancet.

Blood Sample Collection

PocketScan Test Strips are designed to be used with fresh whole blood from a fingerstick. To obtain a drop of blood, follow these steps:

- Step 1: Wash your hands.** Use warm, soapy water. Rinse and dry them thoroughly. Warm water helps you get the blood flowing in your fingertips. Hanging your arm down for about 20 seconds will also help when you have difficulties in obtaining a sufficient blood sample.
- Step 2: Lance your finger.** Use the PenletPlus Automatic Blood Sampler to obtain a drop of blood. Do not squeeze excessively on the puncture site. If you use an alcohol swab, make sure that your finger is completely dry before pricking your finger.

Blood Glucose Testing

- Step 1: Insert test strip.** Remove a test strip from the vial. Recap the vial immediately. With the contact bars end first and facing up, insert the test strip into the test port. The meter will turn on automatically. All segments will appear briefly on the display followed by the date and time. Then "code 12" (example) and the  symbol will appear. Make sure the code number on the display matches the code number on the test strip vial. If the code numbers do not match, code the meter correctly.
- Step 2: Apply sample.** Obtain a drop of blood using the procedure described above. While the  symbol is displayed, apply your sample by touching a small drop of blood to the white target area of the test strip. When enough blood has been drawn into the test strip's reaction cell, the meter will begin counting down. (If the meter does not begin counting down, contact LifeScan Customer Care FreePhone at UK: 0800 121200, Republic of Ireland: 1800 535676.)
- Step 3: Accurate results in just 15 seconds.** Your blood glucose result will appear on the display in just 15 seconds. Blood glucose results are automatically stored in the meter memory. Turn the meter off by removing the test strip.

For detailed information on the test procedure and coding your meter, please refer to the PocketScan Owner's Booklet.

Test Results

- Blood glucose test results are shown on the meter as either millimoles of glucose per liter of blood (mmol/L) or milligrams of glucose per deciliter of blood (mg/dL), depending on which unit of measurement you have selected.
- The PocketScan Meter displays results between 1.1 and 33.3 mmol/L (20-600 mg/dL). If your test result is lower than 1.1 mmol/L (20 mg/dL), "lo" will appear on the meter display. This indicates severe hypoglycemia (low blood glucose). **You should immediately treat hypoglycemia as recommended by your healthcare professional. If your test result is above 33.3 mmol/L (600 mg/dL), "hi" will appear on the meter display. This indicates severe hyperglycemia (high blood glucose). You should seek immediate medical assistance.**
- When your blood glucose result is between 13.3 and 33.3 mmol/L (240-600 mg/dL), "ketones?" will appear on the meter display. This message does not mean that the system detected ketones but that testing with a ketone strip may be advisable.

Range of Expected Values

Blood glucose monitoring requires the help of a healthcare professional. Together you can set your own range of expected blood glucose values, arrange your test times, and discuss the meaning of your blood glucose results.

Expected blood glucose levels for people **without** diabetes:¹

Time	Range, mmol/L	Range, mg/dL
Before breakfast	3.9-5.8	70-105
Before lunch or dinner	3.9-6.1	70-110
1 hour after meals	Less than 8.9	Less than 160
2 hours after meals	Less than 6.7	Less than 120
Between 2 and 4 AM	Greater than 3.9	Greater than 70

If You Get Unexpected Results:

IMPORTANT: Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 3.3 mmol/L (60 mg/dL) or higher than 13.3 mmol/L (240 mg/dL), you should contact your healthcare professional and follow his or her treatment advice.

Quality Control: Checking the System

Do a Control Solution Test:

- When you begin using a new vial of test strips
- At least once a week
- Whenever you suspect that the meter or test strips are not working properly
- When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate
- If you drop the meter

When control solution is applied to the target area of the PocketScan™ Test Strip, you should get results within the expected range printed on the test strip vial. If control solution test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:

- Error in performing the test
- Failure to shake the control solution vial well enough (must shake vigorously)
- Expired or contaminated control solution
- Improper coding of the meter
- Test strip deterioration
- Meter malfunction
- Control solution that is too warm or too cool
- Failure to discard the first drop of control solution

IMPORTANT: If you continue to get PocketScan™ Control Solution test results that fall outside the range printed on the vial, the PocketScan™ System may not be functioning properly. DO NOT use the system to test your blood until you get a control solution test result that falls within the range.

Limitations

PocketScan Test Strips give accurate results when the following limitations are observed:

- 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 (from a fingerstick). Do not use serum or plasma.
- Extremes in hematocrit may affect test results.² Hematocrit levels less than 30% may cause falsely high readings and hematocrit levels greater than 55% may cause falsely low readings. If you do not know your hematocrit level, consult your healthcare professional.
- PocketScan Test Strips may be used at altitudes up to 3048 meters without an effect on test results. Accurate results were demonstrated in clinical studies performed at altitudes up to 499 meters and in studies simulating altitudes up to 3048 meters.

Healthcare professionals—please note these additional limitations:

- 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 lower 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 33.3 mmol/L (600 mg/dL) and triglycerides up to 22.2 mmol/L (400 mg/dL) do not affect the results. Grossly lipemic patient samples have not been tested and are not recommended for testing with the PocketScan System.

Test Principle

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 PocketScan™ Meter and displayed as your blood glucose result. The strength of these currents changes with the amount of glucose in the blood sample.

Reagent Composition

Each PocketScan Test Strip contains: Glucose oxidase (*Aspergillus niger*) 3 1.8 IU; other ingredients (mediator, buffer, etc.) 3 0.05 mg. The vial cap contains approximately 1.4 g silica gel.

Performance Characteristics

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

Measurement range: The measurement range of the PocketScan System is 1.1 and 33.3 mmol/L (20-600 mg/dL).

Accuracy: The accuracy of the PocketScan 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 116 diabetic patients at 3 clinical centers:

Slope	0.97
y-intercept	0.1 mmol/L
Correlation coefficient (r)	0.995
No. of samples	116
Range tested	3.2-28.0 mmol/L

This study shows that the PocketScan System compared well with a laboratory method.

Precision:

Within Run Precision	Bloodav 1.8 mmol/L	CV = 6.6%
	Bloodav 4.4 mmol/L	CV = 4.1%
	Bloodav 7.7 mmol/L	CV = 2.8%
	Bloodav 12.0 mmol/L	CV = 2.8%
	Bloodav 18.0 mmol/L	CV = 2.0%

Total Precision	Control 2.2 mmol/L CV = 7.5%
	Control 9.3 mmol/L CV = 3.9%
	Control 20.0 mmol/L CV = 3.1%

This study shows a variability from strip to strip in blood tests of 6.6% or less.

IMPORTANT: For a complete description of operating instructions and other important technical information, please refer to the PocketScan™ Owner's Booklet. IF YOU HAVE QUESTIONS ABOUT THE USE OF ANY LIFESCAN PRODUCT, PLEASE CONTACT LIFESCAN CUSTOMER CARE FREEPHONE AT UK: 0800 121200, REPUBLIC OF IRELAND: 1800 535676.

References

1. Krall, L.P., and Beaster, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 138.
2. Data on file.

OUR COMMITMENT TO YOU:

Our goal is to provide you with quality healthcare products and dedicated customer service. If you are not fully satisfied with this product, we offer a No-Risk, Money-Back Guarantee and will refund your purchase within 30 days. Please contact us regarding a refund or with questions about the use of any LifeScan product. For assistance, please contact LifeScan Customer Care FreePhone at UK: 0800 121200, Republic of Ireland: 1800 535676.

Plasma/Serum: The PocketScan System is Calibrated to Plasma/Serum, which allows you to compare directly PocketScan meter results with your lab results.

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Covered by US Patent 5,708,247 and corresponding foreign patents.
Other patents pending.

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