

### Intended Use

Medicare Blood Glucose Test Strips are used with the Medicare Blood Glucose Meters. They are intended for self-testing by people with diabetes at home and health care professionals in a clinical setting to monitor glucose concentrations in capillary and venous whole blood. They are for testing outside the body (*in vitro* diagnostic use only). Do not use them for diagnosis of diabetes or testing on neonates.

### Test Principle

Glucose in the blood samples mixes with a special chemical in the test strip and produces a small electric current. The amount of current produced changes with the amount of glucose in the blood. The glucose meter measures the strength of the current and displays the results as a blood glucose level.


### Characteristics

Each test strip is plasma-calibrated<sup>†</sup>, requiring a sample volume of 0.3 µL and taking just 6 seconds to return a test result. The test range is 1.1-33.3 mmol/L (20-600 mg/dL) with resolution at 1 mg/dL. <sup>†</sup>plasma-calibrated means the following:

- The traceable calibrator used is the YSI 2747 Glucose Standard, which is a NIST traceable glucose standard.
- The reference instrument used is the YSI 2300 Glucose Analyzer, which is calibrated by YSI 2747 Glucose Standard.
- The margin of error of the Calibrated YSI Glucose Analyzer measurement is 0.289 mg/dL when the blood glucose concentration is higher than 100 mg/dL, or 0.029 mg/dL when the blood glucose concentration is lower than 100 mg/dL.
- Test results produced on capillary and venous whole blood samples by the Medicare System are compared with the results of the corresponding plasma samples tested by the calibrated YSI 2300 Glucose Analyzer.

### Limitations of the System

Medicare Blood Glucose Test Strips provide accurate results when the following considerations are observed:

- Use fresh capillary and venous whole blood only. Do not use serum or plasma.
- Do not use for testing on neonates.
-  The test strips are for single use only. Do not reuse.
- Hematocrit levels below 30% or above 55% can cause inaccurate results. Please consult your doctor if you do not know your hematocrit level.
- Dehydration may cause lower test results. If you are severely dehydrated, contact your physician immediately.
- Testing at altitudes up to 3,402 meters (or 11,161 ft) does not significantly affect results.

### Storage and Handling

Please take the followings precautions to ensure your Medicare Blood Glucose Test Strips are effective.

- Prior to first use, ensure that the package is undamaged and closed.
- Keep the test strip package out of sunlight and in a cool, dry place between 4 - 40°C (39 - 104°F). Do not refrigerate or freeze it.
- Store test strips in their original pack only. Do not put the test strips in any other container.

- Use test strips immediately after removing from the package.
- Do not use test strips after the expiration date.
- Avoid getting dirt, food or water on the test strip. Do not handle test strips with wet hands. All parts of the test strip should be touched only with dry and clean fingers.
- Do not perform blood glucose tests at a temperature below +10°C (50°F) or above +40°C (104°F), or above 85% relative humidity.

\* For vial pack test strips:


- Close the vial cap tightly immediately after removing a test strip. This keeps the remaining test strips fully functional right up to the expiration date.
- Make a notation of the date on the vial label when you first open it. Discard remaining test strips 180 days after first opening the vial.

\* For blister pack test strips:

- Do not use the test strip if its blister or foil has a puncture or tear in it.
- Do not cut or separate the blister packet into isolated blisters with any method.
- Do not cut the foil or use sharp instruments to take out the test strip from the blister.
- If the drying agent has turned pink, do not use the test strip because it has been exposed to moisture.

### Warnings

- Discard used test strips and lancets responsibly according to your local regulations.
- Keep test strips away from children. A child could choke on the test strips. The test strips and their packaging contain agents that may be harmful if swallowed. If they are swallowed, promptly see a doctor for immediate assistance.

 Do not change your prescribed medication based on the test results without the advice of your physician or your healthcare professional.

### Additional Information for Healthcare Professionals

1. Follow the infection control procedures appropriate for your facility.
2. A venous whole blood sample may also be used. Venous whole blood results are usually about 7% lower than a capillary sample from the same person with normal glucose levels. Use venous blood within 30 minutes after drawing. Common anticoagulants (heparin or EDTA) may be used. Do not use other anticoagulants or preservatives.
3. Avoid air bubbles when using pipettes.
4. Cholesterol concentrations up to 500 mg/dL or triglycerides up to 2000 mg/dL do not significantly affect test results. However, glucose values in specimens beyond these levels should be interpreted with caution.
5. Inaccurate results may occur on severely hypotensive individuals or patients in shock. Inaccurate results may also occur when individuals are in hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with glucose meters.
6. Interference: Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect results. The limiting concentration of several compounds are listed in the following chart:

Compounds	Concentrations higher than the following values may cause inaccurate results
Acetaminophen	8.0 mg/dL (0.53 mmol/L)
Ascorbic Acid	5.0 mg/dL (0.28 mmol/L)
Aspirin	60 mg/dL (3.33mmol/L)
Bilirubin	90 mg/dL (1.54 mmol/L)
Cholesterol	500mg/dL (12.9mmol/L)
Creatinine	5.0 mg/dL (0.44 mmol/L)
Dopamine	2.0 mg/dL (0.11 mmol/L)
Galactose	900 mg/dL (50 mmol/L)
Gentisic Acid	5.0 mg/dL(0.32 mmol/L)
Hydroxyurea	3.0 mg/dL (0.39 mmol/L)
L-dopa	10 mg/dL (0.51 mmol/L)
Maltose	900 mg/dL (26.3 mmol/L)
Methyldopa	3.0 mg/dL (0.13 mmol/L)
Tolbutamide	400 mg/dL (14.8 mmol/L)
Triglycerides	2,000 mg/dL (22.6 mmol/L)
Uric Acid	8.0 mg/dL (0.48 mmol/L)

### Blood Glucose Testing Procedure

See your Medicare User Manual and accompanying insert for detailed illustrations for all test procedures.

### Test Results

Test results are shown in milligrams of glucose per deciliter of blood (mg/dL). The meter is capable of displaying test results in the range of 20 to 600 mg/dL.

Glucose levels below 50 mg/dL or above 250 mg/dL may indicate a potentially serious medical condition. If your test result is below 50 mg/dL or above 250 mg/dL, please consult your healthcare professional immediately.

### Inconsistent Results

If you are getting test results which are inconsistent with your state of wellness or how you feel, please do the following:

- Make sure the blood sample applied completely fills the test strip channel.
- Check that the test strips have not expired.
- Verify the performance of the meter and the test strips using the control solution.

Consult your doctor if you continue getting the same high or low results.

### Quality Control (QC) Testing

Run a control test anytime you want to check the performance of the meter, the test strip or your testing technique. Only use Medicare Glucose Control Solution. These control solutions are designed specifically for use with the Medicare System. The control results should fall within the control ranges printed on the test strip packaging.

**Important:** the control solution range may vary with each new box of test strips. Always use the control range stated on package of the test strips.

### Test Strip Chemical Components











Each blood glucose test strip contains

- Glucose dehydrogenase (FAD-dependent) .....0.4%
- Mediators.....3.8%
- Buffer.....94.4%
- Non-reactive ingredients.....1.4%

### Performance Characteristics

Accuracy: > 95% in A zone of EGA vs YSI 2300 glucose analyzer : Within  $\pm 15$  mg/dL(0.83 mmol/L) at glucose concentration < 75 mg/dL(or 4.2 mmol/L) and within 20% at glucose concentration >75 mg/dL(or 4.2 mmol/L).

Precision: CVs(%) of intermediate precision and repeatability were less than 5%.

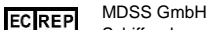
Symbol	Description
	For <i>in vitro</i> diagnostic use.
	Please consult instructions for use
	Do not re-use
	Lot Number
	Caution, consult accompanying document
	Temperature limitation / Store at
	Use by /Expiry date
	Manufacturer
	EU representative
	This product fulfils the requirements of Directive 98/79/EC on <i>in vitro</i> diagnostic medical device.

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