GlucoTeq

microlife®

IB BGM 200 GlucoTeq Test Strips EN 2620
Revision Date: 2020-06-23

Blood Glucose Test Strips

Model No.: BGM 200

IVD

Instructions for use

Intended use:

Microlife GlucoTeq Glucose Test Strips are used with the Microlife GlucoTeq 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 whole blood drawn from the fingertips, forearm, upper arm, palm, calf or thigh. They are for testing outside the body (*in vitro* diagnostic use only). Do not use them for diagnosis of diabetes or testing on neonates.

Warning:

- Discard used test strips and lancets responsibly according to your local regulations.
- Keep test strips vial away from children. A child could choke on the test strips. The test strips and their vial contain agents that may be harmful if swallowed. If they are swallowed, promptly see a doctor for immediate assistance.
- For self-testing.
- For single use only.
- Measured values are plasma-equivalent.

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

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†, requiring a sample volume of 0.5 µL and taking just 5 seconds to return a test result. The test range is 20 to 600 mg/dL (or 1.1 to 33.3 mmol/L) with resolution at 1 mg/dL (0.1 mmol/L). †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. (1 mmol/L= 18 mg/dL).

† Test results produced on capillary whole blood samples by Microlife GlucoTeq System are compared with the results of the corresponding plasma samples tested by the calibrated YSI 2300 Glucose Analyzer.

Limitations of the System:

Microlife GlucoTeq Glucose Test Strips provide accurate results when the following considerations are observed:

- Use fresh capillary whole blood only. Do not use serum or plasma.
- The test strips are for single use only. Do not reuse.
- Hematocrit levels below 20% or above 60% 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) may affect the test results.

Storage and Handling:

Please take the following precautions to ensure your Microlife GlucoTeq Glucose Test Strips are effective:

- Prior to first use, ensure that the package is undamaged and closed.
- Keep the test strip vial away from sunlight and in a cool, dry place between 4 - 40°C (39 - 104°F). Do not 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.

Storage and Handling:

- 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.
- 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.

Additional Information for Healthcare Professionals:

1. Follow the infection control procedures appropriate for your facility.
2. Microlife GlucoTeq Glucose Test Strips are not validated for and should not be used for testing venous blood specimens.
3. Cholesterol concentrations up to 500 mg/dL (12.9 mmol/L) or triglycerides up to 2000 mg/dL (22.6 mmol/L) do not significantly affect test results. However, glucose values in specimens beyond these levels should be interpreted with caution.
4. 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.
5. 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 below 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 (3.33 mmol/L)
Bilirubin	90 mg/dL (1.54 mmol/L)
Cholesterol	500 mg/dL (12.9 mmol/L)
Creatinine	5.0 mg/dL (0.44 mmol/L)
Dopamine	2.0 mg/dL (0.11 mmol/L)
EDTA	360 mg/dL (12.3 mmol/L)
Galactose	900 mg/dL (50 mmol/L)
Gentisic Acid	5.0 mg/dL (0.32 mmol/L)
Glutathione	53 mg/dL (1.72 mmol/L)
Haemoglobin	500 mg/dL (0.08 mmol/L)
Heparin	8,000 U/dL
Hydroxyurea	3.0 mg/dL (0.39 mmol/L)
Ibuprofen	50 mg/dL (2.42 mmol/L)
Icodextrin	13 mg/dL (0.01 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)
Pralidoxime Iodide	25 mg/dL (0.94 mmol/L)
Salicylate	60 mg/dL (4.34 mmol/L)
Tolazamide	100 mg/dL (3.21 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)
Xylose	100 mg/dL (6.66 mmol/L)

Blood Glucose Testing Procedure:

See your Microlife GlucoTeq User Guide 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) or in millimoles of glucose per liter (mmol/L).

The meter is capable of displaying test results in the range of 20 to 600 mg/dL (or 1.1 to 33.3 mmol/L).

Glucose levels below 50 mg/dL (or 2.8 mmol/L) or above 250 mg/dL (or 13.9 mmol/L) may indicate a potentially serious medical condition. If your test result is below 50 mg/dL (or 2.8 mmol/L) or above 250 mg/dL (or 13.9 mmol/L), please consult your healthcare professional immediately.

Reference values: The normal adult fasting blood glucose range for a nondiabetic person is Less than 100 mg/dL and less than 140 mg/dL up to 2 hours after meals*.

These are expected values for people without diabetes. Users are to work with their healthcare professional to determine their target blood glucose values.

**Source: American Diabetes Association Website (http://www.diabetes.org)*

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 Microlife GlucoTeq Solution. This control solution is designed specifically for use with this system. The control results should fall within the control ranges printed on the test strip bottle.

⚠ Important: the control solution range may vary with each new box of test strips. Always use the control range on the label of your current vial of test strips.

Test Strip Chemical Components:

Each blood glucose test strip contains:

- FAD-Dependent Glucose Dehydrogenase *(Aspergillus oryzae)* 20 IU
- Potassium Ferricyanide 0.12 mg
- Non-reactive ingredients 1.8 mg

Performance Characteristics:

Precision

Standard deviation (SD) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and coefficient of variation (CV) for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L) is ≤ 5.0 mg/dL (0.278 mmol/L) and ≤ 5.0%, respectively.

Intermediate precision

Control Solution Level		Low 30-50 mg/dL (1.6~2.7 mmol/L)		Normal 96~144 mg/dL (5.3~8.0mmol/L)		High 280~420 mg/dL (15.5~23.3mmol/L)	
		mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L
Pooled	Mean	44.6	2.48	100.0	5.55	351.8	19.52
	SD	3.0		2.9		8.1	
	CV (%)	6.7%		2.9%		2.3%	

Repeatability

Blood Glucose mg/dL		30-50 mg/dL (1.6~2.7mmol/L)		51-110 mg/dL (2.8-6.1 mmol/L)		111-150 mg/dL (6.1-8.3 mmol/L)	
		mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L
Pooled	Mean	44.7	2.48	101.1	5.61	132	7.33
	SD	3.2		3.2		3.8	
	CV (%)	7.1%		3.2%		2.9%	

Blood Glucose mg/dL		151-250 mg/dL (8.3-13.8 mmol/L)		251-400 mg/dL (13.8-22.2 mmol/L)	
		mg/dL	mmol/L	mg/dL	mmol/L
Pooled	Mean	221.4	12.29	349.1	19.38
	SD	6.8		9.8	
	CV (%)	3.1%		2.8%	

System Accuracy

For glucose concentration <100 mg/dL (5.55 mmol/L)		
Within±5 mg/dL (Within±0.28mmol/L)	Within±10 mg/dL (Within±0.56mmol/L)	Within±15 mg/dL (Within±0.83mmol/L)
109/204 (53.4%)	183/204 (89.7%)	204/204 (100%)
For glucose concentration ≥100 mg/dL (5.55 mmol/L)		
Within±5%	Within±10%	Within±15%
192/396 (48.5%)	310/396 (78.3%)	380/396 (96.0%)
For glucose concentrations between 41.5 mg/dL (2.3 mmol/L) and 525 mg/dL (29.17 mmol/L)		
Within ±15 mg/dL (0.83 mmol/L) or ±15%		
584/600 (97.3%)		

The Microlife GlucoTeq Blood Glucose Monitoring System meets the requirements for System Accuracy as stated in ISO 15197:2013.

User Performance

A study evaluating glucose values from fingertip, palm, forearm, upper arm, calf, and thigh capillary blood samples obtained by 100 lay persons showed the following results:
100% within ± 15 mg/dL (± 0.83 mmol/L) of the medical laboratory values at glucose concentrations below 100 mg/dL (5.55 mmol/L), and ≥ 95% within ±15% of the medical laboratory values at glucose concentrations at or above 100 mg/dL (5.55 mmol/L).

Guarantee

These test strips are part of the accessories of the Microlife GlucoTeq glucose monitor and are excluded from all warranty claims.

Explanation of symbols:

IVD For *In vitro* diagnostic use

Please consult instructions for use

Do not reuse

LOT Lot number

Keep dry

Humidity limitation

Temperature limitation

Use by / Expiry date

Manufacturer

Caution, consult accompanying document

Keep away from sunlight

EC REP EU representative

CE 0123 This product fulfils the requirements of Directive 98/79/EC in vitro diagnostic medical device.

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