Blood Glucose Test Strip GS550 is designed for use only with the Rightest™ Blood Glucose Meter GM550 to obtain accurate results.

**Test Procedure**

1. Hold the depth adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side. When a gap appears between the cap and hub, pull them in opposite directions.

2. Pull off the depth adjustable cap.

3. Insert a disposable lancet firmly into lancet carrier.

4. Touch and hold the drop to the edge of sample entry until you hear a “beep” (if volume is turned on).

5. Install the vial into the meter with the indication symbol facing up.

6. Press the button to apply the blood onto the test strip.

7. Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked.

8. Release the plunger, it will automatically move back to its original position near the hub.

9. To remove the lancet, pull off the depth adjustable cap of the lancing device. Without touching the used disposable lancet, immediately press the lancing tip into the protective cover. Hold the release button of lancing device in one hand and push on the puncture area in the other hand to safely eject the used disposable lancet.

10. Remove the test strip from the meter. Please follow the local regulation and discard the used strip.

11. You will see the countdown mode on the screen. After 5 seconds, the test result appears.

12. Close the vial cap immediately after taking test strip out from the vial.

13. Check the expiration date printed on the strip vial. Do not use expired test strips.

14. Do not reuse lancets. Discard used lancets properly.

15. Do not bend or twist the test strip. Damage of test strip may cause wrong result.

16. Grossly lipemic (fatty) samples may influence the test results. To be aware of such interferences, alternate testing sites, install the clear cap on the lanceting device (for more information on how to install, see the instructions before use). Increase pressure for a few seconds until the blood sample size is sufficient.

17. If the test does not start, please discard the test strip and repeat the test with a new test strip.

18. If your test result is above 600 mg/dL (33.3 mmol/L), “Hi” will appear on the screen. Please repeat the test with a new test strip. If you still get a “Lo” result, you should immediately contact your healthcare professional.

19. Release the plunger, it will automatically move back to its original position near the hub.

20. Pressing for a few seconds.

21. Touch and hold the drop to the edge of sample entry until you hear a “beep” (if volume is turned on) and the View Window is totally filled with blood. If the View Window is not totally filled with blood or if the View Window is not empty and the View Window is not filled with blood, please repeat the test with a new test strip.

22. If your test result is above 600 mg/dL (33.3 mmol/L), “Hi” will appear on the screen. Please repeat your test with a new test strip. If you still get a “Hi” result, you should immediately contact healthcare professional.

**Sample Size Example**

- 0.75 μL (1.0 μL, 1.5 μL, 2.5 μL, 3.0 μL)

- Please take a minimum of 0.75 μL to do the test on monitoring your blood samples. Blood sample size above 3.0 μL might contaminate the meter.

**Warning**

- If your test result is above 600 mg/dL (33.3 mmol/L). If your test strip or vial cap is swallowed, contact your physician immediately.

- Keep the test strips or vial cap away from children. They may cause a choking hazard. If a test strip or vial cap is swallowed, contact your physician immediately.

- If you are experiencing symptoms that are not consistent with your blood glucose test results and you are experiencing symptoms that are not consistent with your blood glucose test results and you are experiencing symptoms that are not consistent with your blood glucose test results, please contact your healthcare professional immediately.

- Reference the Instructions for the lancing device.

- Do not touch the test strip immediately after the blood sample is applied onto the test strip. Damage of test strip may cause wrong result.

- Do not reuse lancets. Discard used lancets properly.

- If the device is not working properly, please contact your healthcare professional.

- If you are experiencing symptoms that are not consistent with your blood glucose test results and you are experiencing symptoms that are not consistent with your blood glucose test results, please contact your healthcare professional immediately.

- If your test result is above 600 mg/dL (33.3 mmol/L), “Hi” will appear on the screen. Please repeat your test with a new test strip. If you still get a “Hi” result, you should immediately contact healthcare professional.

- Keep the test strips or vial cap away from children. They may cause a choking hazard. If a test strip or vial cap is swallowed, contact your physician immediately.

- For more information on how to use your meter, lanceting device and understand your test results, please refer to the User Manual.

**Expected values**

**Fasting Blood Glucose**

<table>
<thead>
<tr>
<th>Value</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100 mg/dL</td>
<td>Normal fasting glucose</td>
</tr>
<tr>
<td>100-125 mg/dL</td>
<td>Impaired fasting glucose</td>
</tr>
<tr>
<td>126 mg/dL or above</td>
<td>Diabetes</td>
</tr>
</tbody>
</table>

**Precaution**

Check the expiration date printed on the strip vial. Do not use expired test strips.

Close the vial cap immediately after taking test strip out from the vial.

Do not hold patient’s head or body during test.

Do not bend or twist the test strip. Damage of test strip may cause wrong result.

Do not reuse lancets. Discard used lancets properly.

If the Rightest™ Blood Glucose Test Strips are exposed to a high temperature difference, please wait 30 minutes before measurement.

If you want to purchase new control solutions, please contact your authorized Bionime representative.

**Limitations**

Grossly (spicy) fatty samples may influence the test results. To be aware of such interferences, patients under the supervision of their physician should have baseline glucose values established by a clinical laboratory prior to the start of home glucose monitoring.

Baseline glucose values should be checked at least weekly.

The meter readings of the blood glucose may be significantly lower than "true glucose levels" in the hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested by the Rightest™ System, or tested with extreme caution.
Caution is advised in the interpretation of glucose values below 50 mg/dL (2.8 mmol/L) or above 250 mg/dL (13.9 mmol/L). Consult a physician as soon as possible, if values in this range are obtained. Healthcare professionals should evaluate their technique and their patients’ technique at periodic intervals.

### Detection Principle

The glucose oxidase (GOD) reaction takes place in the sample and converts it to the corresponding glucose concentration. The meter produces an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration.

#### Performance Characteristics

- **Sensitivity:** The measurement range of the Rightest™ Blood Glucose Monitoring System GM550 is 15 to 400 mg/dL (0.28 mmol/L to 7.14 mmol/L).
- **Accuracy:**
  - The YSI 2300 was calibrated with NIST (SRM) 917c reference.
  - The YSI 2300 was calibrated with NIST (SRM) 917c reference.

#### Error Terms

- **CV (%):**
- **SD mg/dL (mmol/L):**
- **Mean mg/dL (mmol/L):**
- **Total test numbers (n):**

#### Additional Information for Healthcare Professionals

- **Precautions:**
  - Suggest to keep meter free of dust, water or any liquid.
  - Suggest not to use this meter close to source of strong electromagnetic radiation, to avoid interference with proper operation.

- **Trouble Shooting and Customer Service**
  - Suggest to keep meter clean.
  - Suggest to keep meter away from electrical appliances.
  - Suggest to keep meter away from electrical appliances.
  - Suggest to keep meter away from electrical appliances.

- **References:**
  - Diabetics Information - American Association for Clinical Chemistry (AACC)
  - Electronic Version - Retrieval Service (EVS) Online

### Table 1: Represents samples for glucose results < 100 mg/dL (5.55 mmol/L).

<table>
<thead>
<tr>
<th>Glucose levels</th>
<th>P-01</th>
<th>P-02</th>
<th>P-03</th>
<th>P-04</th>
<th>P-05</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Total test numbers (n)</td>
<td>450</td>
<td>450</td>
<td>450</td>
<td>450</td>
<td>450</td>
</tr>
<tr>
<td>(2) Mean mg/dL (mmol/L)</td>
<td>96.7 (5.3)</td>
<td>98.5 (5.5)</td>
<td>98.9 (5.4)</td>
<td>98.9 (5.4)</td>
<td>98.9 (5.4)</td>
</tr>
<tr>
<td>(3) SD mg/dL (mmol/L)</td>
<td>1.2 (0.06)</td>
<td>2.0 (0.11)</td>
<td>1.1 (0.06)</td>
<td>1.1 (0.06)</td>
<td>1.1 (0.06)</td>
</tr>
<tr>
<td>(4) CV (%)</td>
<td>3.2 %</td>
<td>2.1 %</td>
<td>1.8 %</td>
<td>1.5 %</td>
<td>1.5 %</td>
</tr>
</tbody>
</table>

### Table 2: Represents samples for glucose results ≥ 100 mg/dL (5.55 mmol/L).

<table>
<thead>
<tr>
<th>Glucose levels</th>
<th>P-01</th>
<th>P-02</th>
<th>P-03</th>
<th>P-04</th>
<th>P-05</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Total test numbers (n)</td>
<td>186</td>
<td>186</td>
<td>186</td>
<td>186</td>
<td>186</td>
</tr>
<tr>
<td>(2) Mean mg/dL (mmol/L)</td>
<td>47.3 (2.6)</td>
<td>49.0 (2.7)</td>
<td>47.7 (2.6)</td>
<td>47.7 (2.6)</td>
<td>47.7 (2.6)</td>
</tr>
<tr>
<td>(3) SD mg/dL (mmol/L)</td>
<td>3.2</td>
<td>3.2</td>
<td>3.2</td>
<td>3.2</td>
<td>3.2</td>
</tr>
<tr>
<td>(4) CV (%)</td>
<td>6.5</td>
<td>6.5</td>
<td>6.5</td>
<td>6.5</td>
<td>6.5</td>
</tr>
</tbody>
</table>

### Accuracy

- **Accuracy of the Rightest™ Blood Glucose Monitoring System GM550 was tested by comparing the glucose levels obtained by the Rightest™ Blood Glucose Meter GM550 and plasma glucose values obtained from a YSI 2300 reference instrument.**

### Differences between the Rightest™ Blood Glucose Monitoring System GM550 and the YSI 2300

<table>
<thead>
<tr>
<th>Differences between devices</th>
<th>Rightest™ GM550 and the YSI value within the following intervals.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference in range values</td>
<td>≤ 5 %</td>
</tr>
<tr>
<td>≤ 5 %</td>
<td>≥ 100 mg/dL (5.55 mmol/L)</td>
</tr>
</tbody>
</table>

### Interferences

- **Interferences:**
  - Suggest to keep meter away from electrical appliances.
  - Suggest not to use this meter close to source of strong electromagnetic radiation.

### Lay User Evaluation

Each user tested their Rightest™ fingerprint blood sample with 3 strips of strip GM550 and meter QM550. The Rightest™ Blood Glucose Monitoring System 100 mg/dL (5.55 mmol/L) and 250 mg/dL (13.9 mmol/L) was used and the results of the all volunteers were obtained laboratory measurement on the same blood sample. A well characterized clinical laboratory method employing hexokinase or glucose oxidase should be used as the comparative method.

### References

- **Diabetes Information - American Association for Clinical Chemistry (AACC)**
- **Electronic Version - Retrieval Service (EVS) Online**

**For in vitro diagnostic use**

**Manufacturer**

**Use by**

**Lot number**

**EU/Representative**

**CE mark (with No. of notified body)**

**Do not reuse**