Rightest™ GS300 BLOOD GLUCOSE TEST STRIP INSERT

Intended Use
This Rightest™ Blood Glucose Monitoring System is used by individuals with diabetes. It's for checking on glucose levels of whole blood from capillary blood. Capillary blood can be sampled from the fingertip, palm or forearm. It's an aid in management of diabetes at home and clinical sites.

Rightest™ Blood Glucose Test Strips are intended for testing outside the body (in vitro diagnostic use) (for self-testing).

The Rightest™ System holds the capillary blood and provides results equivalent to a laboratory instrument (please equalize).
The Rightest™ System includes a Smart Code Key. It is designed for use only with the Rightest™ Blood Glucose Meter GM300.

The Rightest™ Blood Glucose Monitoring System includes Meter, Test Strips, Smart Code Key, Check Key, Control Solutions, Lancing Device and Lancets.

Test Procedure
Refer to the User’s MANUAL for MORE DETAILED INFORMATION.

Preparations
1. Wash and dry your hands. Take one strip from the vial. Close the vial cap immediately.

2. Insert the strip into the strip port on meter with the indication symbol facing up. Push the strip in until it snaps and stays in place. The meter will turn on automatically.

3. Make sure the code number on the meter screen matches the code number on the test strip vial.

4. Gently squeeze your fingertip to get a drop of blood.

5. Hold the release button in one hand and pull on the plunger in the other hand will safely eject the used disposable lancet.

6. Hold the release button and pull on the plunger in the other hand to eject the used disposable lancet.

7. Hold the release button in one hand and pull on the plunger in the other hand to safely eject the used disposable lancet.

8. Pull off the depth adjustable cap. Without touching the used disposable lancet, stick the lancet tip into the protective cover.

9. Hold the release button and pull on the plunger in the other hand to eject the used disposable lancet.

10. Discard the used disposable lancet into an appropriate puncture-proof or biohazard container.

11. Replace the depth adjustable cap after finishing the test.

12. Store the test strip or vial cap away from children. They may cause a choking hazard. If a test strip or vial cap is swallowed, contact your doctor immediately.

Warning
- Do not reuse lancets. Discard used lancets properly.
- Do not reuse test strips.
- Do not perform quality control test with expired control solution.
- If your test result is above 600 mg/dL (33.3 mmol/L), “Hi” will appear on the screen. Please repeat your test using a new test strip and repeat the test with a new test strip. If you still get a “Hi” result, you should immediately contact your doctor.
- If your test result is below 10 mg/dL (0.6 mmol/L), “Lo” will appear on the screen. Please repeat your test again with another strip. If you still get a “Lo” result, you should immediately contact your doctor.
- If your test result is above 400 mg/dL (22.2 mmol/L), “Hi” will appear on the screen. Please repeat your test again with another strip. If you still get a “Hi” result, you should immediately contact your doctor.

Expected values
Blood Glucose test results are shown on the meter as mg/dL or mmol/L, depending on which unit of measurement you have chosen. Consult your doctor before making any changes to your diabetes medication program.
- If your blood glucose test result is below 70 mg/dL (3.9 mmol/L), your result is low. You should ingest carbohydrates immediately.
- Your blood glucose test result is 70 to 99 mg/dL (3.9 to 5.5 mmol/L). It's in the normal range.
- If your blood glucose test result is between 100 and 125 mg/dL (5.6 to 6.9 mmol/L), you have diabetes or are pre-diabetic (Impaired fasting glucose).
- If your blood glucose test result is between 126 mg/dL (7.0 mmol/L) and above on more than one testing occasion, you have diabetes.

GLUCOSE LEVEL INDICATION
From 70 to 99 mg/dL (3.9 to 5.5 mmol/L) Normal fasting glucose
From 100 to 125 mg/dL (5.6 to 6.9 mmol/L) Pre-diabetes (Impaired fasting glucose)
126 mg/dL (7.0 mmol/L) and above Diabetes

Precautions

- Check the expiration date on the package before every use you take the strip. Do not use expired test strips.
- Close the vial cap immediately after testing lest test strip out from the vial.
- Do not partially control test with used strip.
- Do not bend or twist the test strip. Damage of test strip may cause wrong result.
- Do not touch the test strip. Damage of test strip may cause wrong result.
- Do not reuse lancets. Discard used lancets properly.
- Wait at least 5 minutes to perform a test if you have moved the meter to an area of different temperature.
- If you want to purchase a new control solution, please contact your authorized Biomine representative.

Starting
- 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 doctor immediately.

Limitations
Generally, blood samples may interfere with some methodologies. To be aware of such interferences, patients undergoing the extension of their doctor should have baseline glucose values established by a clinical laboratory method prior to starting glucose monitoring at home. These baseline values should be checked periodically thereafter.
**Rightest™ Blood Glucose Monitoring System**

The accuracy of the Rightest™ Blood Glucose Monitoring System was demonstrated by comparing whole blood glucose levels of a total of 106 patients. Each patient collected and tested their own blood samples (from the finger, palm, forearm, and forearm). The blood samples were centrifuged immediately after collection to obtain plasma.

Analyze the plasma by the lab instrument – YSI 2300. 99.7 % of the results were within ± 15 % at glucose concentrations < 100 mg/dL (0.59 mmol/L) and within ± 5 % at glucose concentrations ≥ 100 mg/dL (0.59 mmol/L). The differences and results between the two methods, Rightest™ and YSI 2300 (as the reference method) are provided in the tables below.

### Additional Information for Healthcare Professionals

**Detection Principle**

The following compounds may interfere with the glucose measurement at the concentrations listed:

- GABA (200 mg/dL) ≥ 14.3 mmol/L
- L-Dopa (200 mg/dL) ≥ 11.5 mmol/L
- Dopamine HCl (200 mg/dL) ≥ 11.5 mmol/L
- Ascorbic acid (200 mg/dL) ≥ 11.5 mmol/L
- Uric acid (200 mg/dL) ≥ 10 mg/dL (0.59 mmol/L)
- Glutathione reduced (40 mg/dL) ≥ 2.28 mmol/L

**References**


### Table 1: Difference in results between the Fingertip, Palm and Forearm Rightest™ blood samples

<table>
<thead>
<tr>
<th>Rightest™ sample type</th>
<th>Fingertip</th>
<th>Palm</th>
<th>Forearm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within ± 5 mg/dL (0.28 mmol/L)</td>
<td>82 % (123/150)</td>
<td>64.5 % (62/96)</td>
<td>100 % (96/96)</td>
</tr>
<tr>
<td>Within ± 10 mg/dL (0.59 mmol/L)</td>
<td>69.3 % (101/146)</td>
<td>95.8 % (92/96)</td>
<td>100 % (96/96)</td>
</tr>
<tr>
<td>Within ± 15 mg/dL (0.94 mmol/L)</td>
<td>51.3 % (75/146)</td>
<td>90.0 % (86/96)</td>
<td>100 % (96/96)</td>
</tr>
</tbody>
</table>

**Accuracy**

The accuracy of the Rightest™ Blood Glucose Monitoring System was demonstrated by comparing whole blood plasma equivalent glucose values on the Rightest™ meter with plasma glucose values on a lab instrument. A total of 106 patients enrolled in the study and each patient collected and tested their own blood samples. The results do not vary significantly due to patient technique.

The percent (and number) of samples of alternative site were the same blood sample. A well characterized clinical laboratory method employing hexokinase or glucose oxidase should be the gold standard for the measurement of the same blood sample. A well characterized clinical laboratory method employing hexokinase or glucose oxidase should be the gold standard for the measurement of the same blood sample.