Prepare the Lancing Device

1) Pull off the depth adjustable cap.
2) Insert a new disposable lancet firmly into lancet carrier.
3) Twist off and set aside the protective cover of the disposable lancet.
4) Choose a depth of penetration by rotating the top portion of the depth adjustable cap until the setting matches the window. Settings are based on skin type: "soft" for soft skin or thin fingers; "firm" for average skin; "hard" for thick or calloused skin.
5) Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger. It will automatically move back to its original position near the hub.
6) Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger. It will automatically move back to its original position near the hub.

Please take a minimum of 1.4 µL to do the test on this sample. An incorrect test strip or an incorrect amount of blood sample size might contaminate the Smart Code Key.

Sample Size Example

<table>
<thead>
<tr>
<th>Amount (µL)</th>
<th>Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>1.4</td>
</tr>
<tr>
<td>2.0</td>
<td>3.0</td>
</tr>
<tr>
<td>3.0</td>
<td>6.0</td>
</tr>
<tr>
<td>4.0</td>
<td>8.0</td>
</tr>
</tbody>
</table>

Precautions

Check the expiration date printed on the package every time you use the device. Do not reuse test strips. Close the vial cap immediately after testing strip out from the vial. Do not store or transport test strips within expired control solutions. Do not bend or tear the test strip. Damage of test strip may cause wrong result. Do not reuse lancets. Discard used lancets properly. Wash at least 20 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 Bionime representative.

Warning

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

Limitations

Grossly lipemic (fatty) samples may interfere with some methodologies. To be aware of such interferences, please ensure the test strips are tested with extreme caution.

Expected values

- Normal fasting glucose: 3.9 to 5.5 mmol/L (70 to 99 mg/dL)
- From 70 to 99 mg/dL (3.9 to 5.5 mmol/L)
- From 100 to 125 mg/dL (5.6 to 6.9 mmol/L)
- 126 mg/dL (7.0 mmol/L) and above on more than one testing occasion
- If your blood glucose result is unusually high or low, or if you question your results, repeat the test with a new test strip. If the test result still remains unusually high or low, contact your doctor immediately.
- Do not reuse test strips.
- Do not perform quality control test with expired control solution.
- Blood glucose test results are shown on the meter as mg/dL.
- If your blood glucose result is above 33.3 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.
- If your blood glucose result is below 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 33.3 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.
- Do not perform quality control test with expired control solution.
- Blood glucose test results are shown on the meter as mg/dL.
Non-reactive Ingredients: 43.0%

- Potassium Ferricyanide: 8.5%
- Glucose Oxidase (GOD): 6,000 mg/dL (0.94 mmol/L)

Uric acid is within ±15 mg/dL (0.83 mmol/L)

1.8 mg/dL (0.10 mmol/L) of L-Dopa
15 mg/dL (0.48 mmol/L) of Tolazamide

- Use test strips within 3 months after first opening.

Within ± 5%

Within ± 10 mg/dL (0.56 mmol/L)

Within ± 5 mg/dL (0.28 mmol/L)

- The use of cellular phones and other radio transmitting devices should be prohibited in areas where testing occurs. - Hands and fingers contaminated with sugar from foods or beverages may cause falsely elevated results.
- Fluoride should not be used as a preservation for venous specimens when using blood glucose monitors.
- Suggest not to use this meter close to source of strong electromagnetic radiation, to avoid interference with proper operation.

NOTE:

- Severe dehydration and excessive water loss may cause inaccurately low results.
- Do not keep test strips in an environment with high altitude more than about 3.400 meters (10.000 feet) above sea level.
- Hematocrit should be between 35% – 48%. If you do not know your hematocrit, ask your healthcare professional.

Severe dehydration and excessive water loss may cause inaccurately low results.

- Use test strips within 3 months after first opening.

Storage and Handling:

- Store the strips in the original capped vials at temperatures between 4 °C to 30 °C (39 °F to 86 °F), and relative humidity.
- Replace the vial cap immediately and close tightly after taking test strip out from the vial. Do not leave the cap of vial opened. Store the vials in the cap exposed to the light, it will affect the moisture and cause wrong result.

Use test strips within 3 months after first opening.

Measurement Range:

The accuracy of the test study of the Blood Glucose Meter was demonstrated by comparing whole blood (plasma equivalent) glucose values on the

100 % of 154/154
85.1 % (135/154)
87.7 % (135/154)

Laboratory instrument - YSI 2300. 100 % of

The results and differences between the two methods, Rightest™ System and YSI 2300 (as the reference method) are proved in the tables below.

<table>
<thead>
<tr>
<th>Reference number</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>Glucose levels</td>
<td>CS/LS</td>
<td>CS/LS</td>
<td>CS/LS</td>
<td>CS/LS</td>
<td>CS/LS</td>
</tr>
<tr>
<td>(1) Total test numbers (n)</td>
<td>300</td>
<td>300</td>
<td>300</td>
<td>300</td>
<td>300</td>
</tr>
<tr>
<td>(3) SD mg/dL (mmol/L)</td>
<td>1.2 (0.02)</td>
<td>1.8 (0.03)</td>
<td>2.5 (0.04)</td>
<td>2.6 (0.04)</td>
<td>2.9 (0.05)</td>
</tr>
<tr>
<td>(2) Mean mg/dL (mmol/L)</td>
<td>147.1 (2.65)</td>
<td>139.6 (2.48)</td>
<td>137.4 (2.04)</td>
<td>127.5 (2.88)</td>
<td>134.2 (2.44)</td>
</tr>
</tbody>
</table>

8.5 %

- Within ± 5%
- Within ± 10 mg/dL (0.56 mmol/L)
- Within ± 5 mg/dL (0.28 mmol/L)
- Within ± 10 mg/dL (0.56 mmol/L)
- Within ± 10 mg/dL (0.56 mmol/L)