Blood Glucose Test Strip HGM-STP1A Manual
For Self-Testing

Intended Use

The HGM-STP1A blood glucose test strips are used only with Omron HGM-111 and HGM-112 blood glucose meters. They are designed for users to measure the glucose in fresh capillary whole blood of fingertips and palm. HGM-111 and HGM-112 meters are intended to be used by people with diabetes at home.

- Warning: 1. HGM-111 and HGM-112 system should not be used for screening, diagnosis of diabetes or testing neonates.
- 2. Do not change the therapy according to HGM-111 and HGM-112 meter test result without consulting healthcare professionals. If you have any question about the test results, please discuss with your healthcare professionals.
- 3. For in-vitro diagnostic use only.
- 4. The HGM-STP1A blood glucose test strips must be used with the HGM-111 and HGM-112 blood glucose meter. Do not reuse.
- 5. Please read system user guide and strip manual carefully before using HGM-111 and HGM-112 system.

Storage

- Store strip vials between ambient temperature 4 °C - 30 °C (39 °F - 86 °F) and below 85 % RH.
- Write the first opened date on the vial label. You should discard the strips after 90 days from first opened date.
- Store HGM-STP1A strip vials in a cool, dry place. Keep away from light and excessive heat.
- Store your strips in their original vials only.
- Close the lid of vial immediately after removing a test strip.

Warning: 1. Need to tightly seal the lid of the strip vials to protect test strips from exposure to air.
- 2. Do not use strips if the vial cap is not sealed well, vial is damaged or strips are expired.
- 3. Do not freeze or refrigerate.
- 4. Do not transfer test strips to any other container.

Measuring Principle

The HGM-111 and HGM-112 meter measure the small electrical current and displays the blood glucose result. The current is produced from the blood glucose mixing well with chemicals on the test strips. HGM-STP1A test strips need only 1μL fresh blood for one testing. The test result will be displayed in 5 seconds.

Assure You Get an Accurate Test Result

1. Read system user guide and strip manual before using.
2. Store properly the strips, HGM-STP1A.

Getting Ready to Test

You will need meter, test strips, alcohol prep pad, lancing device, sterile lancet.

Warning: Please place HGM-111, HGM-112 meter and test strips at room temperature before testing. Rapid temperature changes may lead to incorrect results.

Testing Blood Glucose

Step 1: Prepare one test strip

1. Take a test strip from the vial, and press the cap of the vial until hearing "click". Check the expiration date printed on the strip vial before you insert the strip into the meter.
2. Insert the test strip into meter correctly, then the meter will turn on and the symbol flashes.

Step 2: Insert a lancet

3. Insert a new lancet into the lancing device, twist the protective cap and draw out the protective cap from the lancet.
4. Adjust the puncture depth and set up the proper puncture depth.
5. Slide the ejection / cocking control back until hearing "click". The lancing device is ready to use.

Warning: Always use a new lancet to avoid contamination before testing.

Warning: Sterile lancet is single use only, you cannot reuse it.

Step 3: Blood sampling

6. Use soap water or alcohol prep pad to clean your hands and puncture site.
7. Massage the puncture site gently, and obtain a blood sample by your lancing device.

Warning: 1. You can choose a different puncture site each time to decrease the feeling of pain.
- 2. Do not squeeze excessively to obtain blood. HGM-STP1A test strips need only 1μL sample for one testing.
- 3. Keep lancing device away top children, it is harmful if used incorrect.
- 4. Please make sure your hand is dried before taking the blood sample.

Step 4: Apply sample

8. Touch the drop of sample to the top edge of the confirmation window of the test strip. Do not smear sample on the strip.
9. Your blood glucose test result will be displayed after five seconds.

Important information about HGM-111 and HGM-112 system testing:

- Check the confirmation window is full with blood.
- Do not apply more blood to the test strip.
- The blood sample must be 1 μL or more.
- Test immediately when you obtain a fresh blood sample.

Warning: Please follow proper precautions in accordance with local regulations when disposing of all materials.

Test Unit

The unit of HGM-111 and HGM-112 meter was set as mg/dL or mmol/L by the manufacturer. Please be aware of which unit your meter is. The glucose value can be transferred between these two units by the equation. 1 mmol/L = 18.02 mg/dL.

Test Results

The HGM-111 and HGM-112 meter can measure blood glucose within 20~600 mg/dL (1.1~33.3 mmol/L). The meter will display “LO” to indicate a very low glucose level if your test result is lower than 20 mg/dL (1.1 mmol/L). The meter will display “HI” to indicate a very high glucose level if your result is higher than 600 mg/dL (33.3 mmol/L). You should repeat your test when the “LO” or “HI” message appears; if these messages show again, call your healthcare professionals.

Expected Glucose Value

Blood glucose management requires the help of a healthcare professional. Together you can set your own range of expected blood glucose values. Arrange your testing times, and discuss the meaning of your blood glucose results.

<table>
<thead>
<tr>
<th>Time of day</th>
<th>Glucose range for people without diabetes</th>
<th>Your target glucose range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting and before meals</td>
<td>&lt;100 mg/dL (5.6 mmol/L)</td>
<td></td>
</tr>
<tr>
<td>2 hours after a meal</td>
<td>&lt;140 mg/dL (7.8 mmol/L)</td>
<td></td>
</tr>
</tbody>
</table>

- If your reading is usually low or high, or you do not feel the way your reading indicates, repeat the test with a new test strip.
- If your reading is not consistent with your symptoms, or if your blood glucose result is less than 70 mg/dL (3.9 mmol/L) or higher than 180 mg/dL (10.0 mmol/L), you should contact your healthcare professionals and follow his or her advice.

Checking the System

When to run the glucose control solution test:

- You think your test strips have been damaged.
- Test result com paring with how you feel is not compatible with how you feel.
- If your glucose reading is usually low or high, or you do not feel the way your reading indicates, repeat the test with a new test strip.

Warning: Please contact your local authorized distributor for more information.

Limitation of Procedure

HGM-STP1A test strips give accurate results when the following limitations are observed:

- Test strips are single use only, do not reuse the strip.
- Do use for testing newborns.
- Use only fresh capillary whole blood.
- Do not test serum or plasma.
- Hematocrit (HCT) is the percentage of the red blood cell in blood. HCT less than 30% may cause falsely high reading. HCT higher than 55% may cause falsely low reading.
- The temperature condition for testing is between 10 °C - 40 °C (50 °F -104 °F).
- The humidity condition for testing is below 90 % RH.
- Do not use the blood sample containing anticoagulation or preservatives.
- HGM-STP1A test strips may be used at altitudes up to 10,000 feet (3048 meters).
- Hemolysis in a whole blood sample was reported to interfere the glucose meter measurement.

Please contact your healthcare professionals if the result does not consist with the...
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way you feel. Please do not change your medication without talking to healthcare professionals.
- Patient undergoing oxygen therapy may yield falsely low results.
- If the patient is severely dehydrated in shock or in a hyperosmolar state, the test results may be incorrect.

Limitation of Interferences
Interfering substances which have been tested:
Exogenous substances: ascorbic acid (Vitamin C), acetaminophen, dopamine, gentamic acid, tamsulosin, levodopa, methyldopa, miltazide, salicylic acid, tetracycline, tolazamide, and tolbutamide.
Endogenous substances: bilirubin, creatinine, cholesterol, triglyceride, uric acid, urea, and glutathione.
These substances will not cause significant interference in blood glucose measurement when their concentrations are normal in human body or below therapeutic level.

Reagent Composition
Each test strip contains:
- Glucose oxidase (Aspergillus niger) ≥ 5%
- Electron shuttle 30%
- Enzyme stabilizer 5%
- Other ingredients 60%

HGM-111 and HGM-112 Performance Characteristics
Traceability:
The test result of HGM-111 and HGM-112 blood glucose meter are plasma calibrated by biochemistry analyzer, and the analyzer was calibrated with a NIST traceable glucose standard solution.

Measurement range:
HGM-111 and HGM-112 meter can measure results between 20 ~ 600 mg/dL (1.1~33.3 mmol/L).

HGM-111
Accuracy:
The accuracy of the HGM-111 meter was assessed by comparing blood glucose results obtained by patients with those obtained using clinical analyzer. The following results were obtained by (200) test numbers.

<table>
<thead>
<tr>
<th>Samples</th>
<th>Mean glucose concentration</th>
<th>measured CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>38.94 mg/dL (2.16 mmol/L)</td>
<td>SD=2.81 mg/dL (0.16 mmol/L)</td>
</tr>
<tr>
<td>Sample 2</td>
<td>84.14 mg/dL (4.67 mmol/L)</td>
<td>4.83%</td>
</tr>
<tr>
<td>Sample 3</td>
<td>121.83 mg/dL (6.76 mmol/L)</td>
<td>4.87%</td>
</tr>
<tr>
<td>Sample 4</td>
<td>178.24 mg/dL (9.89 mmol/L)</td>
<td>4.16%</td>
</tr>
<tr>
<td>Sample 5</td>
<td>338.71 mg/dL (18.80 mmol/L)</td>
<td>3.08%</td>
</tr>
</tbody>
</table>

Within Run Precision

<table>
<thead>
<tr>
<th>Samples</th>
<th>Mean glucose concentration</th>
<th>measured CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control solution 1</td>
<td>43.98 mg/dL (2.44 mmol/L)</td>
<td>4.01 mg/dL (0.22 mmol/L)</td>
</tr>
<tr>
<td>Control solution 2</td>
<td>136.62 mg/dL (7.38 mmol/L)</td>
<td>4.92%</td>
</tr>
<tr>
<td>Control solution 3</td>
<td>338.71 mg/dL (19.80 mmol/L)</td>
<td>4.86%</td>
</tr>
</tbody>
</table>

Between Day Precision

<table>
<thead>
<tr>
<th>Samples</th>
<th>Mean glucose concentration</th>
<th>measured CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control solution 5</td>
<td>70/166 (45.8%)</td>
<td>121/166 (72.9%)</td>
</tr>
</tbody>
</table>

Precision:
This study shows a variability from strip to strip in sample tests. The results are shown in the following table.

<table>
<thead>
<tr>
<th>Samples</th>
<th>Mean glucose concentration</th>
<th>measured CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>41.01 mg/dL (2.28 mmol/L)</td>
<td>SD=0.28 mg/dL (0.02 mmol/L)</td>
</tr>
<tr>
<td>Sample 2</td>
<td>83.49 mg/dL (4.53 mmol/L)</td>
<td>4.26%</td>
</tr>
<tr>
<td>Sample 3</td>
<td>116.82 mg/dL (6.48 mmol/L)</td>
<td>4.85%</td>
</tr>
<tr>
<td>Sample 4</td>
<td>177.52 mg/dL (9.85 mmol/L)</td>
<td>4.66%</td>
</tr>
<tr>
<td>Sample 5</td>
<td>314.61 mg/dL (18.96 mmol/L)</td>
<td>4.05%</td>
</tr>
</tbody>
</table>

Reference: