HighQ Check® Blood Glucose Test Strips User's Manual

IMPORTANT: Please read this information and your HighQ Check® Glucose Monitoring System’s user manual before using HighQ Check® Glucose Test Strips.

Warnings
- For in vitro diagnostic use (for use outside of the body only).
- For single use only.
- Healthcare professionals and other users testing multiple patients with this system should handle everything that has come into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- Please read this sheet and your Blood Glucose Monitoring System Owner’s Manual before you use this test strip. Use only HighQ Check® Blood Glucose Test Strips with HighQ Check® Blood Glucose Monitoring System to obtain accurate results, and be covered by the manufacturer’s warranty.
- Results may be inaccurate when testing on patients with abnormally low blood pressure or those who are in shock.
- Low results may be inaccurate when testing on patients in the hyperglycemic-hyperosmolar state, with or without ketosis.
- Please do not use the Glucose Monitoring System on critically ill patients.
- Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

Intended Use

HighQ Check® Glucose Test Strips are used with the HighQ Check® Blood Glucose Meter for quantitatively measuring glucose (sugar) in whole blood obtained from the fingertip, palm, and forearm. The HighQ Check® Glucose Test Strips are for testing outside the body (in vitro diagnostic use). The HighQ Check® Blood Glucose Meter is intended for use in the home and in professional settings to monitor blood glucose levels.

Limitations

Hematocrit: The hematocrit level is limited to between 10% and 65%. Please ask your healthcare professional if you do not know your hematocrit level.
- Neonatal Use: This test strip must not be used for the testing of newborns.
- Metabolites: Dopamine, L-Dopa, methylcord, uric acid, ascorbic acid, and acetaminophen at normal concentration do not significantly affect blood glucose test results.

Storage and Handling
- Store at room temperature between 4°C and 35°C (39.2°F and 95°F) and below 85% relative humidity. Do not refrigerate or freeze. Avoid exposing test strips to extreme temperatures.
- Store away from direct sunlight and heat.
- Use each strip immediately after removing it from the vial.
- Store your test strips in their original vial only. The cap or vial contains drying agents to protect the test strips. Do not transfer test strips to a new vial or any other container.
- After removing a test strip from the vial, replace the vial cap immediately and close it tightly.

- Do not bend, cut, or alter the Test Strip in any way.
- With clean, dry hands you may gently touch the test strip anywhere when removing it from the vial or inserting it into the meter.

Reference Values

Time of day Normal plasma glucose range for people without diabetes control target.

- Normal Glucose Values
The normal fasting glucose range for a non-diabetic adult is 70 to 110 mg/dL (3.9 to 6.1 mmol/L). One to two hours after meals, normal glucose values should be less than 140 mg/dL (7.8 mmol/L). For people with diabetes, consult your physician or healthcare professional for the target glucose values that are right for you.

- Low Glucose Values
The HighQ Check® Blood Glucose Meter displays results between 20 and 600 mg/dL (1.1 and 33.3 mmol/L). If your test result is lower than 20, “Low” (Lo) will appear on the meter display. This indicates severe low blood sugar (hypoglycemia). You should immediately treat low blood sugar as recommended by your healthcare professional.

- High Glucose Values
If your test result is above 600 mg/dL (33.3 mmol/L), “High” (Hi) will appear on the meter display screen. This indicates severe high blood sugar (hyperglycemia). You should immediately treat high blood sugar as recommended by your healthcare professional.

- Unexpected Results
Low or high blood sugar readings can indicate a potentially serious medical condition. If your blood glucose is unusually low or high, or if you do not feel the way your results indicate, 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 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), you should contact your healthcare professional and follow his or her treatment advice.

Testing Your Blood Glucose

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTS.

1. Insert the test strip fully into the slot of the meter until it will go no further. When the strip is fully inserted, the meter will do several self-checks.

2. Collect a blood sample with the test strip. A sufficient quantity of blood is required for the test to provide accurate results. Touch the blood drop with the absorbent hole of the test strip, and wait until the confirmation window is fully covered. Do NOT apply a smeared blood sample. The meter will start counting down.

3. After a few seconds, the meter will display your blood glucose level. The last reading will be automatically saved in the meter. Turn it off by removing the test strip and throw away the used test strip.
Chemical Components
Non-reactive ingredients: 1.4 % (w/v%)  
Potassium ferricyanide: 5.0 % (w/v)  
Glucose Dehydrogenase: 4 unit per strip

Additional Information for Healthcare Professionals
Always wear gloves and follow your facility’s biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only. Professionals may use test strips to test capillary and venous whole blood.  
Sample Size: 1 μl  
Reaction Time: 7 seconds  
System Measurement Range: 20 mg/dL to 600 mg/dL  
Hematocrit Range: 15 % to 65 %

Repetitive test
In the vein of whole blood, by adding glucose method, get the different glucose concentration of the test results carried out by the same specimen the number of repetitions of 60 times.

<table>
<thead>
<tr>
<th>Avg</th>
<th>mg/dL</th>
<th>53</th>
<th>118</th>
<th>253</th>
<th>403</th>
<th>556</th>
<th>mmol/L</th>
<th>2.9</th>
<th>6.6</th>
<th>14.1</th>
<th>22.4</th>
<th>30.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD</td>
<td>mg/dL</td>
<td>4.32</td>
<td>4.17</td>
<td>7.53</td>
<td>9.52</td>
<td>10.8</td>
<td>mmol/L</td>
<td>0.2</td>
<td>0.2</td>
<td>0.4</td>
<td>0.5</td>
<td>0.6</td>
</tr>
<tr>
<td>CV%</td>
<td></td>
<td>3.53%</td>
<td>2.98%</td>
<td>2.36%</td>
<td>1.94%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Glucose Test Strip Interference Evaluation
Material | Test results |
---|---|
Cholesterol | no interference at ≤345 mg/dL in blood. |
Creatinine | no interference at ≤10.8 mg/dL in blood. |
Triglyceride | no interference at ≤412 mg/dL in blood. |
Uric Acid | interference at > 13.3 mg/dL in blood. |
Sodium Heparin | no interference at ≤79.5 μL/mL in blood. |
EDTA | no interference at ≤90 μL/mL in blood. |
Acetaminophen | interference at > 8.0 mg/dL in blood. |
Ascorbic acid | interference at > 5.0 mg/dL in blood. |
Dopamine | interference at > 3.0 mg/dL in blood. |
Calactose | no interference at ≤500 mg/dL in blood. |
Gemisic acid | interference at > 50 mg/dL in blood. |
Hemoglobin | Plasma free hemoglobin (PFHb) no interference at ≤21.2 mg/dL in blood. |
Bilirubin | Bilirubin no interference at ≤20.3 mg/dL in blood. |
Ibuprofen | no interference at ≤200 mg/dL in blood. |
L-Dopa | interference at > 3.0 mg/dL in blood. |
Maltose | no interference at ≤500 mg/dL in blood. |
Methyl-Dopa | interference at > 2.0 mg/dL in blood. |
Prolidoxime Iodide(PAM) | interference at > 3.0 mg/dL in blood. |
Salicylate | interference at > 100 mg/dL in blood. |
Sulbutamole | no interference at ≤500 mg/dL in blood. |
Tolazamide | interference at > 5.0 mg/dL in blood. |
Xylose | interference at > 20 mg/dL in blood. |
Icodextrin | no interference at ≤0.75 % in blood. |
Glutathione | interference at > 50 mg/dL in blood. |

Accuracy
In non-professional users of 120 cases of test results:
Blood glucose concentration less than 100 mg/dL (5.55 mmol/L) of result:

<table>
<thead>
<tr>
<th>Within ± 5 mg/dL</th>
<th>Within ± 10 mg/dL</th>
<th>Within ± 15 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>(121 / 204) 59.3%</td>
<td>(196 / 204) 96.1%</td>
<td>(204 / 204) 100%</td>
</tr>
</tbody>
</table>

Blood glucose concentration more than 100 mg/dL (5.55 mmol/L) of result:

<table>
<thead>
<tr>
<th>Within ± 5%</th>
<th>Within ± 10%</th>
<th>Within ± 15%</th>
</tr>
</thead>
<tbody>
<tr>
<td>(242 / 438) 55.3%</td>
<td>(389 / 438) 88.8%</td>
<td>(438 / 438) 100%</td>
</tr>
</tbody>
</table>

Lay Person
In non-professional users of 111 cases, each testing twice (The subject background: Age: 18~80, 2 subjects over 81 years old;  
Man: 51, Female: 60; Education: Elementary: 34, High School: 28,  
College: 49; Diabetes: 81, Normal: 30)

System Accuracy For Glucose Concentration < 100 mg/dL
Subject: 68

<table>
<thead>
<tr>
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<th>Within ± 15 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>40/58 69.0%</td>
<td>54/58 93.1%</td>
<td>58/58 100.0%</td>
</tr>
</tbody>
</table>

System Accuracy For Glucose Concentration ≥100 mg/dL
Subject: 134

<table>
<thead>
<tr>
<th>Within ± 5 %</th>
<th>Within ± 10 %</th>
<th>Within ± 15 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>67/142 47.2 %</td>
<td>118/142 83.1 %</td>
<td>139/142 97.9 %</td>
</tr>
</tbody>
</table>

System Accuracy For Glucose Concentration 20-600 mg/dL
Within ± 15 mg/dL or 15% (Within ± 0.28 mmol/L or 15%)
221/222 99.55%

Blood Drop Measure Scope

0.8 μl 1μl 3 μl 5 μl

Symbol Information

IDV | In vitro diagnostic medical device  
LOT | Batch code  
Temperature Limitation | Caution  
No direct sun exposure | Manufacturer  
Use by / Expiry date

AEON DIAGNOSTIC TECHNOLOGY CORPORATION
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