Accuracy requirement
The standard deviation should be < 7.5 mg/dL (0.42 mmol/L), when the blood glucose level is < 100 mg/dL (5.6 mmol/L) and the coefficient of variation should be < 7.5% when the blood glucose level is ≥ 100 mg/dL (5.6 mmol/L).

Caution
- The product is used for monitoring the blood glucose level. It is not used for diagnosis, screen nor for new born baby screen, metabolic disorder tests.
- Expired, damaged or polluted test strips are forbidden to use. Test shall be performed strictly following the rules; otherwise, false result might cause.
- Lancing device can only be used for single person, exclusively; lancet is one time use only.
- Test strip vial should be kept away from child reach.
- To discard the used test strip. Please follow the local environmental affairs regulation.

Specification
- Testing range: Hematocrit (Hct) range: 30%~60%. Hct lower than 30% will cause a faulty high result; while, Hct higher than 60% will cause a faulty low result.
- Operating temperature range: 10°C ~ 40°C, or it may lead to wrong test result.
- RH < 85%, or it may lead to wrong test result.
- When blood volume is lower than 0.8 ul, it may lead to wrong test result. Please test again with a new strip.
- Special circumstances (such as dehydration, oxygen deficit, hyperglycemia state of high permeability, low blood pressure, shock and acidosis, etc.) may lead to wrong test result.
- When receiving oxygen therapy, it may lead to lower blood glucose level.
- When the substances follow are beyond restriction, it may affect the test result: When substances like acetyl aminophenol, vitamin c, dopamine, L-dopa, methyldopa, uric acid, etc. of blood is higher than normal condition, it may lead to higher blood glucose level. When substances like ibuprofen and sulfamoyl in human body is higher than normal condition, it may lead to lower blood glucose level. When cholesterol in blood is higher than 500 mg/dL (27.8 mmol/L) or TG is higher than 3000 mg/dL (166.7 mmol/L), it may lead to abnormal results.

YUWELL Blood Glucose Test Strip Instruction

Product Name
Blood Glucose Test Strip

Packing Type
25 strip/vial x 2 for a box

Intended Use
NOTE: The testing result is for monitoring only; do not change any medication without consulting healthcare professional. This test strip should be used with Yuwell Blood Glucose Monitoring System and to monitor glucose concentration for capillary whole blood.

Testing Principles
The principle of blood glucose measurement is electrochemistry. Start with a blood sample onto the reaction area where reacts with glucose oxidase. Blood glucose is oxidized to gluconic acid and electrons are produced from the reaction. A potential, generated by glucose meter, is provided to measure the electron flow, electrical current. The magnitude of current is then measured, converted and correlated to the glucose concentration level of the blood sample.

Main Components
- Glucose oxidase, 10%
- Potassium ferricyanide, 35%
- Buffer & Non-reactant, 55%
Storage conditions and expiry
- Keep in the vial, away from direct sunshine.
- The test strip should be stored in the original strip vial and at 4~30°C, RH <85%.
- Avoid sun shine and do not freeze.
- The test strip has 24 months shelf-life in sealed condition.
- Discard any remaining test strips when the vial has been used for 3 month. Take one piece of test strip and recap the vial, immediately.
- Tear the single pouch and use it to test.
- Test strip is for one time use only. Please use it to test as soon as possible.

Code
- Change the code chip every time when opens a new test strip vial.
- Confirm the code shown in the meter’s screen with the code shown on the vial’s (or pouch’s) label.
- Leave the code chip in the meter until the new strip test vial and code chip used.

Before testing
- Place the meter, test strip, lancing device and a lancet.
- Wash hands with warm soapy water and dry them well.
- Insert the test strip into the meter. The meter turns on, automatically.

Obtain a blood sample

**Step 1:** Choose a lancing depth. Generally, finger tip is the suitable position.
**NOTE:** Do not lancing in swelling or infected area.

**Step 2:** Shoot and collect a tiny blood drop.
**NOTE:** Do not squeeze the lanced position.

Blood glucose testing

**YUWELL**

**YUWELL**

**Blood inlet**

**Strip end to meter slot**

**Reaction area**

**Step 1:** Insert the test strip. Take a test strip and re-cap it, immediately, to avoid damp. Insert the test strip into the slot with the “YUYUE” side up. The meter turns on, automatically. Confirm the code shown in the meter’s screen with the code shown on the vial’s (or pouch’s) label. Please finish the blood glucose testing in 3 minutes.

**Step 2:** Suck blood sample. When the screen shows flashing "•". Touch the blood sample at the edge of strip tip and the blood will be sucked, automatically.

**Step 3:** The test result will show in 8 seconds.

**Testing result**
- Testing result is displayed in unit of mg/dL(mmol/L).
- Testing result range is between 20 mg/dL(1.1 mmol/L) and 600 mg/dL(33.3 mmol/L) and has been rectified to correspond to the result of biochemical analyzer in central lab.
- If the meter shows "LO", It means that the result is lower than 20 mg/dL(1.1 mmol/L). If the meter shows "HI", It means that the result is higher than 600 mg/dL(33.3 mmol/L). Please test again. If it shows "LO" or "HI" again, consult your doctor’s instruction for a recheck or treatment.

**Diagnostic criteria for diabetes mellitus**

<table>
<thead>
<tr>
<th>Criteria for the Diagnosis of Diabetes mg/dL(mmol/L)</th>
<th>Fasting plasma glucose</th>
<th>2-h plasma glucose during an OGTT</th>
<th>A random plasma glucose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>70<del>100(3.9</del>5.6)</td>
<td>&lt;140(7.8)</td>
<td>-</td>
</tr>
<tr>
<td>Glucose Impaired</td>
<td>101<del>125(5.6</del>6.9)</td>
<td>140<del>199(7.8</del>11.0)</td>
<td>-</td>
</tr>
<tr>
<td>Diabetes</td>
<td>≥126(≥7.0)</td>
<td>≥200(≥11.1)</td>
<td>≥200(≥11.1)</td>
</tr>
</tbody>
</table>


**Product Performance**

When the blood glucose level is <75 mg/dL(4.2 mmol/L), the deviation between monitoring system and lab result should fall within 15 mg/dL(0.83 mmol/L) for the 95% of the testing results.

When the blood glucose level is ≥75 mg/dL(4.2 mmol/L), the deviation between monitoring system and lab result should fall within ±20% for the 95% of the testing results.