FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS

FreeStyle Lite Blood Glucose Test Strips: Product Information


IMPORTANT: PLEASE READ THIS INFORMATION AND YOUR OWNER’S BOOKLET BEFORE USING THE FREESTYLE LITE TEST STRIPS TO TEST YOUR BLOOD GLUCOSE.

For help call Customer Care.

Intended Use

FreeStyle Lite blood glucose test strips are for use with FreeStyle, FreeStyle Freedom, FreeStyle Mini, FreeStyle Papillon Mini, FreeStyle Navigator, FreeStyle Navigator II, FreeStyle Freedom Lite, FreeStyle Lite and FreeStyle InsuLinx blood glucose meters and are intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, hand, forearm, upper arm and venous whole blood from the body. The FreeStyle Lite test strips are used for testing outside the body (in vitro diagnostics) and for self-testing or care-giver use. FreeStyle, FreeStyle Freedom, FreeStyle Mini, FreeStyle Papillon Mini, FreeStyle Navigator, FreeStyle Navigator II, FreeStyle Freedom Lite, FreeStyle Lite, and FreeStyle InsuLinx blood glucose monitoring systems are intended for use in the home and in professional settings. This product is not intended for the diagnosis of screening for diabetes mellitus or for use with neovascular samples or animal blood.

Warnings

• Do not use during cyanide absorption testing.
• Any change in medication based on your blood glucose test results without the consent and advice of a physician or healthcare professional is not recommended.
• Product contains small components that might be considered a choking hazard.
• The cap or vial contain drying agents to protect the test strips. Drying agents may be harmful if inhaled or swallowed and may cause skin or eye irritation.
• If you get FreeStyle control solution test results that fall outside the range printed on the test strip vial, repeat the test with a new test strip. If the test result is still outside the range printed on the test strip vial, the system may not be working properly. DO NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip vial label.
• Do not fill test strip from both the left and right sample areas during a single test. This may cause inaccurate test results.
• Do not use test strips beyond the expiry date printed on the package since this may cause inaccurate results.
• Physical changes in the environment between the finger and other test sites like the finger, upper arm, thigh, cap and hand may result in differences in blood glucose measurements between the other test sites and your finger.
• Differences in blood glucose measurements between the other test sites and your finger may be observed after eating, insulin medication or exercise. Changes in blood glucose may be observed in finger blood samples sooner than blood samples from the forearm and other alternate sites. Vigorous rubbing of the alternate test sites before lancing will help to minimize the difference between finger and alternate site test results. If you are testing for hypoglycaemia (low blood glucose), or if you suffer from hypoglycaemia awareness, we recommend that you test on your finger.

Precautions

• Ensure that the correct unit of measurement is displayed with each result. See Owner’s Booklet for further details.
• Severe dehydration or excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
• All devices contaminated with blood should be disposed of properly.

Storage and Handling

• Test strips must be discarded after the expiry date printed on the vial.
• After removing a test strip from the vial, seal the vial cap immediately and close it tightly. Use each strip immediately after removing it from the vial.
• Store your test strips in their original sealed vial. 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.
• Store at room temperature between 4°C to 30°C (40°F to 86°F). Use test strips only within the system operating temperature range as outlined in your Owner’s Booklet.
• Avoid exposing test strips to extreme temperatures.
• Do not bend, cut, or alter the FreeStyle Lite test strip in any way.

Performing a Blood Glucose Test

When the blood sample is applied to the test strip, the glucose in the blood reacts with the chemicals on the test strip, producing a small electrical current. The meter measures the current over time, calculates the electrical charge, and converts this a a glucose value.

1. Set Up
• Depending on your blood glucose monitoring system to be used to test on your finger, hand, forearm, upper arm, thigh, and thigh.
• Clean the site you choose for the test. Wash, wash up, wash and thoroughly dry. Bring fresh blood to the surface. Rub the test site with alcohol (propan-2-ol) for a few seconds and let it dry again. skew.

2. Do the Test
• When the menu on the display screen on the system. See your lancing device to obtain a fresh sample.
• Gently touch the sample application area of the test strip to the fresh sample. Do not put the sample on top of the sample application area. You will get a more accurate result.
• When the strip is full, the meter will “beep” you will see the moving lines on the display.

3. Read Results
• Read the test results on the system display.

What Do Your Results Mean?

• Normal fasting blood glucose range for an adult without diabetes is less than 100 mg/dL (5.5 mmol/L),1,1
• Two hours after meals, the blood glucose range for an adult without diabetes is less than 140 mg/dL (7.8 mmol/L),1,1
• Consult your healthcare professional to determine the range that is appropriate for you.
• Low or high blood glucose readings can indicate a potentially serious medical problem. If your blood glucose reading is normally low or high, or if you feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your physiological state, consult your physician immediately.
• Do not use during xylose absorption testing.

Within-lot and within-vial precision of these test strips was measured with venous blood samples in the laboratory. Summary of system accuracy for finger samples with YSI glucose results lower than 75 mg/dL (4.2 mmol/L).

Average Glucose Concentration

<table>
<thead>
<tr>
<th>Range</th>
<th>Mean (µg/dL)</th>
<th>95% CI</th>
<th>99% CI</th>
<th>99.9% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 to 9</td>
<td>6.8 - 7.8</td>
<td>6.3 - 8.3</td>
<td>6.1 - 8.6</td>
<td>6.0 - 8.8</td>
</tr>
<tr>
<td>10 to 20</td>
<td>10.0 - 12.0</td>
<td>9.5 - 12.5</td>
<td>9.2 - 13.0</td>
<td>9.0 - 13.5</td>
</tr>
<tr>
<td>20 to 40</td>
<td>20.0 - 42.0</td>
<td>19.5 - 42.5</td>
<td>19.0 - 43.0</td>
<td>18.5 - 43.5</td>
</tr>
</tbody>
</table>

Within-lot and within-vial precision of these test strips was measured with venous blood samples in the laboratory. Summary of system accuracy for finger samples with YSI glucose results 75 mg/dL or higher.

Average Glucose Concentration

<table>
<thead>
<tr>
<th>Range</th>
<th>Mean (µg/dL)</th>
<th>95% CI</th>
<th>99% CI</th>
<th>99.9% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 to 140</td>
<td>100.0 - 140.0</td>
<td>95.0 - 135.0</td>
<td>90.0 - 130.0</td>
<td>85.0 - 125.0</td>
</tr>
<tr>
<td>150 to 190</td>
<td>150.0 - 190.0</td>
<td>145.0 - 185.0</td>
<td>140.0 - 180.0</td>
<td>135.0 - 175.0</td>
</tr>
<tr>
<td>200 to 240</td>
<td>200.0 - 240.0</td>
<td>195.0 - 235.0</td>
<td>190.0 - 225.0</td>
<td>185.0 - 220.0</td>
</tr>
</tbody>
</table>

Performance Characteristics


Description of Symbols

1. Consult instructions for use
2. Do not reuse
3. In vitro diagnostic device
4. Recycle
5. Expiry date
6. CE Mark
7. Recyclable Polyethylene