

FREESTYLE LITE BLOOD GLUCOSE TEST STRIPS

FreeStyle Lite Blood Glucose Test Strips- Product Information

Only 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 Monitoring Systems to Test for Glucose in Whole Blood (*Blood Glucose Test Strip with Coulometric Technology*)

IMPORTANT: PLEASE READ THIS INFORMATION AND YOUR OWNER'S BOOKLET BEFORE USING THE FREESTYLE LITE TEST STRIPS TO TEST YOUR BLOOD SUGAR. 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, and FreeStyle Lite 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, calf and thigh and venous whole blood. The FreeStyle Lite blood glucose test strip is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger, hand, forearm, upper arm and venous whole blood for the FreeStyle InsuLinX System. FreeStyle Lite test strips are used for testing outside the body (*in vitro* diagnostic use) and are 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 or screening for diabetes mellitus or for use with neonatal samples or arterial blood.

Warnings

- Do not use during xylose 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 contains 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 the 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.**
- Physiologic differences in the circulation between the finger and other test sites like the forearm, upper arm, thigh, calf 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 unawareness, we recommend that you test on your fingers.**

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, replace 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 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.
- 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 a FreeStyle Lite 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.

Performing a Blood Glucose Test

Test Method

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 it to a glucose value.

See your blood glucose meter Owner’s Booklet for a step-by-step guide on how to do the test.

1. Set Up

- Depending on your blood glucose monitoring system it can be used to test on your finger, hand, forearm, upper arm, calf, and thigh.
- Clean the site you have chosen for the test. Use warm, soapy water. Rinse and thoroughly dry. To bring fresh blood to the surface, rub the test site (except the finger) vigorously for a few seconds until you feel it getting warm.
- Put a strip in the meter. Most meters will turn on automatically. Power on if required.
- For meters that require coding, be sure that the code on the meter display screen matches the code on the test strip vial. If it does not match, see your Owner’s Booklet for how to code the meter.

2. Do the Test

- When the prompt to apply the sample appears on the screen, use your lancing device to obtain a blood sample.
- Gently touch one sample application area of the test strip to the blood sample. If the strip does not fill, reapply the sample to the same area within 60 seconds. Do not apply the sample to both edges of the strip. Do not put the sample on top of the sample application area.
- When the strip is full, the meter will “beep” or you will see the moving lines on the display.

3. Read Results

- Read the test results on the meter display.

What Do Your Results Mean?

- Normal fasting blood glucose range for an adult without diabetes is less than 110 mg/dL (6.1 mmol/L).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
- 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 condition. If your blood glucose reading is unusually low or high, or if 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 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.

Limitations

The FreeStyle Lite blood glucose test strips give accurate results when the following limitations are observed:

- The test strips are for single use only. Do not reuse test strips.
- Use fresh, whole capillary blood from the site you have selected to test.
- Clean the site with warm soapy water and dry thoroughly before testing.
- There is no effect from altitude up to 3,048 meters (10,000 feet) above sea level.
- Haematocrit range: 15% to 65%.

Additional Information for Healthcare Professionals:

- A venous whole blood sample may also be used. Use venous blood within 30 minutes after drawing. Common anticoagulants (heparin, EDTA) may be used.
- Cholesterol up to 500 mg/dL (13 mmol/L) or triglycerides up to 3,000 mg/dL (34 mmol/L) do not significantly affect test results. However, glucose values in specimens beyond these levels should be interpreted with caution.
- In situations of decreased peripheral blood flow, capillary blood testing may not be appropriate as it may not represent the true physiological state. Examples would include but are not limited to: severe dehydration caused by diabetic ketoacidosis or the hyperosmolar non-ketotic state, hypotension, shock, or peripheral vascular disease.^{2,3,4} Critically ill patients should not be tested with home use blood glucose meters.

Checking the System

The control solution is used to check the performance of the meters, test strips, and your testing technique. The system is performing correctly if the control solution test result falls within the specific control solution range listed on your FreeStyle Lite test strip vial.

When a control solution test is done, you should get results within the expected range printed on the test strip vial. If control solution test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:

- error in performing the test
- expired or contaminated control solution

- improper coding of the meter
- test strip deterioration
- meter malfunction

NOTE: A control solution test should be performed when you question your results and want to confirm that your meter and test strips are working properly. To obtain control solution, call Customer Care.

WARNING: If you continue to get control solution test results that fall outside the range printed on the test strip vial, the system may not be functioning 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. Contact Customer Care.

Performance Characteristics

The performance of these test strips has been tested both in laboratory and clinical studies. The testing range is 20 mg/dL to 500 mg/dL (1.1 mmol/L to 27.8 mmol/L). The FreeStyle Lite test strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

Accuracy

Capillary blood glucose results obtained by lay users were compared with those obtained using the YSI Glucose Analyzer.

Summary of system accuracy for finger samples with YSI glucose results lower than 75 mg/dL (4.2 mmol/L).

Within ± 5 mg/dL (0.3 mmol/L)	Within ± 10 mg/dL (0.6 mmol/L)	Within ± 15 mg/dL (0.8 mmol/L)
73% (8/11)	100% (11/11)	100% (11/11)

Summary of system accuracy for finger samples with YSI glucose results of 75 mg/dL (4.2 mmol/L) or higher.

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
68% (115/168)	95% (160/168)	99% (166/168)	99% (167/168)

The regression statistics are derived from a plot of the lay user finger data versus YSI capillary data.

Slope	0.95	0.95
y-intercept	7.3 mg/dL	0.41 mmol/L
Correlation coefficient (R)	0.99	0.99
Number of samples tested	179	179
Range tested	38-375 mg/dL	2.1-20.8 mmol/L

Precision

Within-lot and within-vial precision of these test strips was measured with venous blood samples in the laboratory.

Average Glucose Concentration	mg/dL (mmol/L)	43.3 (2.4)	94.2 (5.2)	140.7 (7.8)	238.3 (13.2)	345.0 (19.2)
SD	mg/dL (mmol/L)	1.5 (0.1)	2.3 (0.1)	2.9 (0.2)	4.8 (0.3)	6.8 (0.4)
CV	%	3.3	2.4	2.2	2.3	2.4

Average Glucose Concentration	mg/dL (mmol/L)	43.3 (2.4)	94.2 (5.2)	140.7 (7.8)	238.3 (13.2)	345.0 (19.2)
SD	mg/dL (mmol/L)	1.3 (0.1)	2.0 (0.1)	2.4 (0.1)	3.9 (0.2)	6.0 (0.3)
CV	%	2.9	2.2	1.8	1.9	2.1













Variability in blood tests from strip to strip was 3.3% or less.

Chemical Composition

FAD Glucose Dehydrogenase (*Aspergillus Oryzae*) ≥ 1.0 Unit
Other ingredients (buffer, mediator, etc.) ≥ 0.01 mg

Reference

- Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. World Health Organization, Geneva, Switzerland 2006.
- Atkins SH, Dasmahapatra A, Jaker MA, Chorost MI, Reddy S: Fingerstick glucose determination in shock. Ann Int Med 114: 1020-1024. 1991.
- Sandler M, Low-Beer T: Misleading capillary glucose measurements. Practical Diabetes 7: 210. 1990.
- Wickham NWR, Achar KN, Cove DH: Unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes 3: 100. 1986.

	Consult instructions for use		Batch code
	Temperature limitation		Use by
	Manufacturer		Do not reuse
	Recycle		<i>in vitro</i> diagnostic medical device
	Authorised Representative in the European Community		Catalogue number
	CE Mark		Recyclable Polypropylene

This product(s) and/or its use are protected by one or more of the following patents: US6,071,391; US6,120,676; US6,143,164; US6,156,173; US6,299,757; US6,338,790; US6,503,381; US6,591,125; US6,616,819; US6,618,934; US6,676,816; US6,749,740; US6,893,545; US6,942,518; US7,058,437; US7,615,637; US7,713,406; US7,740,581; US7,802,467; US7,866,026; US7,895,740; US7,901,554; USD611,8545; USD613,1905; USD615,8845; EP1119637; EP1145000; EP0958495, CA2346415; CA2358993; CA2351796; CA2423837; CA121137. Additional patents may be issued and/or pending.

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