

Sein Test Strips

IMPORTANT

Please read this information and the Sein User Manual before using Sein Test Strips.

INTENDED USE AND TEST PRINCIPLE

Sein Test Strips work with the Sein Blood Glucose & Pressure Monitor to quantitatively measure glucose in whole blood. The Sein Test Strips are for in vitro (i.e., outside the body) diagnostic use only and for self testing. Glucose in a blood sample mixes with special test strip chemicals where a small electrical current is produced. The Sein Monitor then detects the electrical current. The amount of currents produced corresponds with the amount of glucose in the blood sample.

STORAGE AND HANDLING

- Store test strips only in their original bottle.
- Store bottle in cool and dry place between 8-30°C (46-86°F).
- Keep the bottle away from direct sunlight and heat.
- Do not refrigerate or freeze test strips or bottle.
- Close bottle cap tightly immediately after removing a test strip.
- Use test strip immediately after taking it out of the bottle.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter the test strips in any way.
- Do not force a test strip in to the monitor. Gently push it in a monitor port.
- Apply only fresh whole capillary blood to the test strip.
- Do not use test strips past expiration or discard date. Use test strips within three(3) months of opening the bottle. Record the discard date (the date the bottle was opened plus three(3) months) on the bottle label.

WARNINGS AND PRECAUTIONS

Keep test strips and the test strip bottle away from children. The test strips and bottle cap may be choking hazards. Drying agents in the bottle cap may be harmful if inhaled or swallowed or may cause skin or eye irritation.

Test strips are for single use only. Do not reuse.

If code numbers on the monitor screen and test strip bottle do not match, test results may not be accurate. Please refer to the Sein User Manual.

If test strip will not receive a blood sample, please contact your authorized Sein representative.

BLOOD SAMPLE COLLECTION PROCEDURE

Wash hands and sample site with soap and warm water. Rinse and dry thoroughly before beginning blood sample collecting with general or CareLance lancing device.

Fingertip Site Blood Sampling

Unscrew lancing device tip. Place cocked lancing device against fingertip side. Press release button. Massage fingertip to obtain round drop (at least 0.5µl, actual size: ●) of blood. Apply test strip tip to blood sample.

TEST PROCEDURE

- 1) Wash hands and puncture site with soap and warm water. Rinse and dry thoroughly.
- 2) Insert test strip with contact bars facing up into a port. Push strip gently until monitor beeps.
- 3) A code number will appear for three (3) seconds. The ▽ symbol will appear. Display code number should match one on test strip bottle. If not, see the Coding Monitor to Match Test Strips on pages 12-13 of the Sein User Manual.
- 4) Use lancing device to get blood sample. Sample must be at least 0.5µl (actual size: ●) to fill the test strip reaction cell. When the ▽ symbol appears on display, apply blood sample to narrow top edge of test strip until monitor beeps. If confirmation window hasn't filled in time because of abnormal viscosity or insufficient volume, Er4 message will appear.
- 5) Monitor will count down from five-to-one (5-to-1) on the display. Test results, time, and date will appear and automatically store in monitor memory. Remove used test strip from port. Monitor will turn off.

TEST RESULTS

The Sein Blood Glucose & Pressure Monitor will display results between 20 and 600mg/dL (1.1-33.3 mmol/L).

Normal Blood Glucose Results

The normal fasting blood glucose range for a non-diabetic adult is 70-110 mg/dL (3.9-6.1 mmol/L). One-hour after a meal, normal blood glucose results should be less than 160mg/dL(8.9 mmol/L).

Low Blood Glucose Results

If the test result is below 20mg/dL(1.1 mmol/L), LO will appear on the display indicating hypoglycemia (low blood glucose). You should follow the appropriate treatment recommendations of your healthcare professional.

High Blood Glucose Results

If the test result is above 600mg/dL(33.3 mmol/L), HI will appear on the display to indicate hyperglycemia (high blood glucose). If so, follow hyperglycemia treatment recommendations of your healthcare professional.

Unexpected Results

Low or high blood glucose readings can indicate a potentially serious medical condition. If your results are unusually low or high, or don't match the way you feel, repeat the test with a new test strip. If your reading is inconsistent with your symptoms or your result is less than 60 mg/dL(3.3 mmol/L) or higher than 240mg/dL (13.3 mmol/L), contact your healthcare professional.

Please note that:

- An abnormally high or low red blood cell count (hemato-crit levels over 60% or below 20%) may produce inaccurate results.
- In testing newborns or pregnant women, test results may be affected by the red blood cell count(hematocrit).
- Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
- An abnormally high or low red blood cell count (hematocrit levels over 60% or below 20%) may produce inaccurate results.
- A normal red blood cell count is in the 30-50% range. It may be below or over the normal range in newborns, pregnant women, or those suffering from serious anemia.
- There is no effect from altitude up to 3,000m(10,000 ft) above sea level

Limited

- Blood samples that contain large amounts of ascorbic acid and uric acid may cause a slightly higher result than the actual glucose level.
- High concentrations of Acetaminophen and other reducing substances in the blood may cause inaccurately high results.
- Antiglycolysis and anticoagulants in blood samples may affect the test results.
- As the results the interference effect of the Sein Blood Glucose & Pressure Monitor are all in the applicable range clinically and All levels passed the requirement.

MONITOR AND TEST STRIP PERFORMANCE CHECK

Sein Control Solution contains a known amount of glucose that reacts with a Sein Test Strip in combination with the Sein Monitor to make they are working properly together and the correct testing procedure is being followed. Run a check when you:

- Want to practice the test procedure using the control solution instead of blood.
- Use the monitor form the first time.
- Open a new bottle of test strips.
- Have symptoms that are inconsistent with your blood glucose test results.
- Believe your test results are not accurate.
- Suspect your monitor and test strips are not properly performing.

If your control solution test results do not fall within the range printed on the control solution bottle, repeat the test. Out of range results may be due to one or more of the following factors:

- Error in performing the test.
- Expired or contaminated control solution.
- Expired or damaged test strip.
- Mismatched monitor and test strip bottle code numbers.
- Failure to shake bottle.
- Failure to discard first drop of control solution and wipe bottle tip clean.

If results continue to fall outside the range printed on the bottle, the Sein Test Strip and monitor may not be working properly. If so, do not use your system and contact your authorized Sein representative.

CHEMICAL COMPOSITION

Glucose oxidase: 2.7 units
Hexaamineruthenium(III)chloride: 45.7µg
Other ingredients: 1.6µg

PERFORMANCE CHARACTERISTICS

The performance of Sein Test Strips has been tested in laboratory and clinical studies. The testing range of the Sein System is 20-600 mg/dL (1.1-33.3 mmol/L).

ACCURACY

The accuracy of the Sein System was evaluated by comparing blood glucose results obtained from 310 subjects. Readings obtained with the Sein System were compared to those obtained using a YSI Model 2300 Glucose Analyzer. The results were:

Slope	1.05
y-intercept	4.60 mg/dL (0.26 mmol/L)
Correlation coefficient(r)	0.994
Number of sample	310
Range tested	26-530 mg/dL (1.4-29.4 mmol/L)

PRECISION

The precision of Sein Test Strips was estimated with venous blood samples in the laboratory.

Within Run Precision		
Blood average	42mg/dL (2.3 mmol/L)	CV = 4.6%
Blood average	98mg/dL (5.4 mmol/L)	CV = 3.1%
Blood average	142mg/dL (7.9 mmol/L)	CV = 3.5%
Blood average	208mg/dL (11.6 mmol/L)	CV = 3.4%
Blood average	337mg/dL (18.7 mmol/L)	CV = 3.6%
Control average	42 mg/dL (2.3 mmol/L)	CV = 3.4%
Control average	72 mg/dL (4.1 mmol/L)	CV = 2.5%
Control average	170 mg/dL (9.4 mmol/L)	CV = 2.5%
Control average	354 mg/dL (19.7 mmol/L)	CV = 2.8%

Reference

Source: Krall, L.P., & Beaser, R.S. (1989). Joslin Diabetes Manual. Philadelphia: Lea and Febiger.

- Manufacturer
Company: **SEIN ELECTRONICS CO.,LTD.**
Address: #133-3, Pyungchon-dong, Dongan-gu, Anyang-city, kyungki-do, Korea.
Tel: 82-31-421-0389, 421-3201
Fax: 82-31-421-5639
www.seinbpm.com
- EU Representative
Company: **SEINEX ELECTRONICS CO.,LTD.**
Address: Jennymount Court, North Derby Street, Belfast, BT15 3HN United Kingdom.
Tel: 44-(0)2890-749070
Fax: 44-(0)2890-749081

You can talk to product specialist about the use or performance of this Sein product
Monday to Friday from 9 a.m to 5 p.m Eastern Time
1-877-924-2273 TOLL-FREE INFORMATION LINE