

SensoLite Nova Test

Blood Glucose Test Strip

IVD

CE 0197

Test strips for quantitative measurement of glucose concentration in whole blood using with the SensoLite Nova and SensoLite Nova Plus blood glucose meter.

Before you begin

Carefully read this entire guide. If you have any question and/or need assistance, please, contact our authorised distributor in your country.

Summary

SensoLite Nova blood glucose test strip was designed to provide an easy, accurate method for the determination of capillary whole blood glucose content. This analysis applies the enzyme glucose oxidase and is based on advanced electromechanical technology that is specific for β -D-glucose measurement. Test strips are designed in such a way that blood sample absorbs into the reaction zone, after blood has been applied to the tip of test strip. In the reagent zone glucose oxidase triggers the oxidation of glucose in blood. Intensity of formed electrons is measured by the meter and correlates well with the concentration of glucose in the blood sample.

Package contents

- 10, 25 or 50 strips in a vial
- Code-card
- Instructions for use

Measuring range

Measurement range of SensoLite Nova Test System is 1.1-33.3 mmol/l (20-600 mg/dl).

Sample volume

One blood drop is enough to determine blood glucose value with SensoLite Nova Test strip. Minimum sample volume is 0.5 μ l.

Reagents

Each test strip contains the following ingredients in the approximate concentrations listed below:

- | | |
|-----------------------------------|--------------|
| • Glucose oxidase | 2.7 I.U. |
| • Hexaamineruthenium(III)chloride | 45.7 μ g |
| • Other ingredients | 1.6 μ g |

Each vial cap contains 2-3 g silica gel.



Warnings and precautions

SensoLite Nova Test blood glucose strips are for IN VITRO diagnostic use only (external use only).

- Do not use test strips after their expiration date.
- Do not use test strips that are wet, bent, scratched, or damaged in any way.
- Do not re-use the strips.
- If you have symptoms which are not consistent with your blood test results always contact your health care professional immediately.
- If your reading result is above or below your expected range of blood glucose values, always repeat the test and prove that the values are consistent.
- Abnormal red blood cell quantity (hematocrit below 30% or above 55%) may cause incorrect results.
- Never make significant changes in your diabetes treatment program or ignore symptoms without consulting your physician.
- You must calibrate (code) the meter before the first use of the system or when a new box of test strips is to be used.

SensoLite Nova and SensoLite Nova Plus systems use internal coding system. A Code-card, being included in the test strip package, holds encoded alphanumeric information that matches the Code value being affixed to the bottle of test strips. Setting the code in the meter means entering the same code value into SensoLite Nova glucose meter that is written on the strips' bottle label whenever you open a new bottle of test strips (either by using the Code-card, or manually). The code value entered into the meter should match the code value indicated on the strip bottle's label and being encoded on Code-card. On how to enter the code number refer to the chapter „Strip code setting“ in the Instructions for Use of SensoLite Nova and SensoLite Nova Plus glucose meters.

Storage and Handling

SensoLite Nova Test blood glucose strips are packaged in bottles. Store test strips at temperature between 8°C and 30°C (47°F and 86°F) and between 30-70% relative humidity and far from direct sunlight. Do not refrigerate or freeze. When stored properly, the unopened test strips are stable until the expiration date, indicated on the bottle. The month indicated, refers to the END of that month. Use the strips within 3 months after first opening of their bottles. Never touch the test strips with wet or contaminated hands.

Sample collection and preparation

Preparation

SensoLite Nova Test blood glucose strips are designed specifically for use with fresh capillary whole blood taken from fingertip or earlobe. Venous blood, plasma, or serum samples cannot be used. Blood testing must be performed immediately after the sample is obtained. Common anticoagulants and preservatives such as heparine and sodium EDTA are allowed to be used, but fluoride preservatives should be avoided.

Testing your blood

Refer to information described in chapter „Measuring with the meter“ of the Instructions for Use of the SensoLite Nova and SensoLite Nova Plus meters.



Used strip and lancet are contaminated with blood. Be careful, follow the relevant, local instructions when you throw the used strip and lancet away.

Quality Control

It is recommended to run the quality control test in (see “SensoLite Nova and SensoLite Nova Plus system checking” chapter in instruction for use) cases:

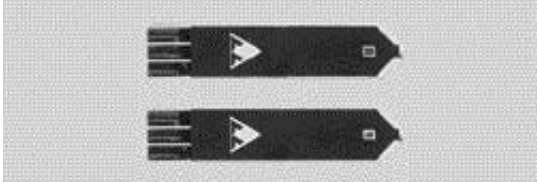
- When your test results do not agree with your expectation based on your actual feeling.
- When the test strips have been exposed to temperature, not conforming to prescribed storage conditions (8°C to 30°C or 47°F to 86°F).
- When you open a new bottle of test strips.
- If the meter has been dropped.
- At least once per week to verify that the meter and test strips are working properly together.

When using Control Solution for system checking apply only CareSens Control Solution, designed specifically for this system. CareSens Control Solution can be obtained from Manufacturer upon user's request for additional charge (see exact address and phone number of manufacturer at the end of this manual). Other control fluids provide incorrect results, therefore cannot be used. When control solutions are used, test results should be within the expected range indicated on test strips bottle (L1, L2). Test results being within the given range, indicate that the system (your meter and test strips) is working properly. If test results obtained with control solution are not within the indicated range, always repeat the control solution test. If the incorrect result still stands, contact your local distributor.

Test results

Blood glucose test results are shown on the meter's LCD display in either mg/dl or mmol/l measurement unit. Units can be set prior the tests (see chapter "Selecting measurement unit" in Instructions for Use of SensoLite Nova or SensoLite Nova Plus). The exchange rate of the units is: 1 mmol/l = 18 mg/dl. If you get an unusual test result, always check the physical circumstances being applied as follows:

1. Check if the drop of blood is completely fills the reaction zone.



2. Check if the expiration date indicated on the test strips bottle is not over yet.
3. Check if the code number of the test strip in use matches the number set in the meter.
4. Check meter ability to function properly with the „Check strip”.
5. Check the system performance with CareSens Control Solution.

When test results are still questionable or inconsistent, and your blood glucose results are less than 50 mg/dl (2.8 mmol/l) or greater than 300 mg/dl (16.7 mmol/l), consult your health care professional before making any changes in your diabetes medication program.

Limitations

- SensoLite Nova Test strip is designed to be used with fresh capillary whole blood samples. NEVER use serum or plasma samples.
- Hematocrit variation in sample: hematocrit between 30% to 55% have no significant effect on test results. Very high (above 55%) and very low (below 30%) hematocrits may cause inaccurate test results.
- Neonates: Do not use SensoLite Nova Test strip to test neonates. The performance of SensoLite Nova and SensoLite Nova Plus system has not been validated with neonatal samples.
- Do not use fluoride as a preservative in blood samples.
- Abnormal blood specimens (i.e., high ascorbic acid, high uric acid) may effect test results. Blood glucose readings in these cases should be interpreted for diagnoses with caution.

- Therapeutic levels of tetracycline may result inaccurate (decreased) glucose readings.
- Therapeutic levels of acetylsalicylic acid(e.g.: Aspirin) may result inaccurate(decreased) glucose readings.

Accuracy

Accuracy of SensoLite Nova Test strip was assessed by comparison of patients with diabetes in one typical clinical evaluation. Reference measurements were done by another approved blood glucose monitor. Specimens ranged from 1.0 mmol/l to 26.4 mmol/l, as measured by the reference method.

The linear regression data from one typical clinical site study is presented in the table below.

Number of Samples:	198
Range (mmol/l):	1.2 - 27.8
Bias (%):	-4.45%
Slope:	1.055
Intercept (mmol/l):	-0.7182
Correlation Coefficient:	0.994

Precision

Test based on Standard EN ISO 15197:2003.

A laboratory study was conducted with SensoLite Nova Test strip using fresh sodium EDTA venous blood with a broad range of glucose levels. Results from a single typical run of this study, shown in the table, exhibit excellent precision characteristics for SensoLite Nova Test strip. From all the studies taken together, estimates of system precision were calculated within-run precision, 3.65% between run precision, 3.42%.

Individual Use Method

Number of Reading	100	100	100	100	100
Average (mmol/l)	2.9	4	6.9	11.4	17.1
SD (mmol/l)	0.12	0.15	0.22	0.35	0.68
CV (%)	4.1	3.75	3.2	3.1	4.0

References:

N.Tietz, Fundamentals of Clinical Chemistry, W.B.Sanders Co., 1987.

A.E.G. Cass, Biosensors: A practical approach, IRL Press, 1990.

D. Schade, „101 Tips for Improving your blood sugar", p 4-5.



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REF

SNT-9901-1 25 pcs. strips/vial
SNT-9907-1 10 pcs. strips/vial
SNT-9908-1 50 pcs. strips/vial

Symbols



In Vitro Diagnosticum



Warning!



Manufacturer



Batch No.



Date of Expiry



Temperature Range



Information inside



Biological risks



Keep away from direct sunlight!



Humidity Range



Catalog Number



98/79/EC IVD directive