

Gluco Spark Test Strips

For use in Whole Blood

Please read these instructions in your Glucospark User Manual before using Glucospark Test Strips

Intended Use

Gluco Spark Test Strips are used to measure glucose in Capillary whole blood outside of the body (in vitro diagnostic use). Use Gluco Spark Test Strips only with the Gluco Spark Blood Glucose Test System. Gluco Spark Test Strips are plasma calibrated to allow easy comparison of results with laboratory methods.

Storage and Handling

- Store the strips in their original vial in a cool, dry place between 10°-30° C (50° and 86° F). Keep away from sunlight and heat.
- Do not refrigerate or freeze.
- When you take a strip from the vial, close the cap immediately. Use the strip immediately.
- Check the expiry date on the vial. If the expiry date has passed do not use the strips.

Test Materials

Provided in this package:

- **Gluco Spark** Test Strips
- **Gluco Spark** Test Strips Instructions

You will also need:

- **Gluco Spark** Blood Glucose Meter
- **Gluco Spark** User Manual
- Lancing Device
- Sterile Lancet

How to do the Test

Use **Gluco Spark** Test Strips only with fresh capillary whole blood.

1. Preparing to Test

- Take a strip from the vial and put it into the meter. Close the vial immediately.
- Push the strip in firmly until it stops. You will see the meter turn on automatically. The meter then checks each item of information on its display.
- After the meter turn on appears, the drop of blood symbol will appear and begin flashing. You can now apply the blood sample.

2. Getting a Blood Sample

To get a sample from your finger proceed as follows:

- Wash your hands in warm, soapy water and dry well.
- Lance your skin with the lancing device.
- Squeeze gently until you get a rounded drop of blood. The blood sample must be at least 0.5micro liters to get an accurate result.

3. Testing

- While the drop of blood symbol is flashing, touch and hold the top EDGE of the strip to the rounded drop of blood so it meets the test zone. The strip draws the blood into the test zone. Only apply blood while the drop of blood symbol is flashing.
- Do not use a smear or scrape blood into the strip.
- Hold the blood drop to the top EDGE of the test strip until blood has completely filled the test zone and the meter beeps. The meter will then count down in seconds 4, 3, 2, 1 on the display.
- If the test zone does not fill up, stop the test and retest with a new strip.

4. Your Result

- After 5 seconds the meter will beep, your glucose result will be displayed on the meter display and then automatically stored in the meter memory.
- Turn the meter off by removing the strip by hand.

What Do Your Results Mean?

Your blood glucose values will vary due to such things as diet, time of day and what you are doing. Your healthcare professional will help you to understand these variations. You should set your own range of expected blood glucose values, testing times, and discuss your blood glucose results with your healthcare professional.

Expected blood glucose levels for people without diabetes:

Time	Range, mg/dL
Before meals	70-110
1 hour after meals	Less than 160
2 hours after meals	Less than 120
Between 2 and 4 Hrs.	Greater than 70

The normal fasting adult blood glucose range for a non diabetic is 70-110 mg/dL.

Test Units

Blood glucose test results are shown on the meter as milligrams of glucose per deciliter of blood (mg/dL)

Unexpected Results

Very high or very low blood glucose readings can indicate a serious medical condition. Repeat the test if you see an unusual reading. If these results are still unusual, or do not match your symptoms, contact your health care professional for advice. Hi or Lo readings may indicate hyper or hypoglycemia and should be treated immediately.

Some of the reasons for unusually high or low results:

- Poor technique
- Strip was used after expiry date.
- Vial cap was not replaced and sealed.
- Storage in too high or too low temperatures.
- Strip was not used immediately after removing from vial.

Whenever your blood glucose value is inconsistent with your previous results, glucose trends or your symptoms, contact your doctor. Follow the advice of your doctor before you change your therapy.

Limitations

Gluco Spark Test Strips give accurate results when the following limitations are observed:

- Use fresh whole capillary blood. Do not use plasma or serum.
- Use each test strip once. Do not reuse.
- Do not bend, cut or damage the test strip.
- Do not use for the testing of newborns.
- Very high haematocrit levels (above 55%) may cause falsely low readings. Very low levels (below 25%) may produce falsely high readings. Consult your healthcare professional if you do not know your haematocrit level.
- Vitamin C (ascorbic acid) does not significantly affect results at normal levels or normal therapeutic levels. Abnormally high vitamin C levels may produce falsely high results.
- **Gluco Spark** Test Strips may be used at altitudes up to 10,000 feet without an effect on test results.
- **Gluco Spark** Test Strips are designed for use at temperatures between 10° C to 30° C and relative humidity between 10% and 90%.
- Do not test critically ill patients with blood glucose meters. The readings may be misleadingly low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without Ketosis).

Test Principle

When blood is added to the Gluco Spark strip, the chemicals within the strip react to create a tiny electrical current. Your meter reads the current and displays your level of blood glucose.

Chemical Composition

Each Gluco Spark strip contains the enzyme glucose Oxidase (*Aspergillus Sp.*) \geq 1IU and other ingredients (mediator, Surfactant, Stabilizing agents etc.) \geq 200 μ g.

CALL Gluco Spark CUSTOMER SERVICE



SEE USER MANUAL

Packaging Symbols



Lot Number



Expiry Date



For in vitro diagnostic use



Caution symbol: See Instructions for use



Manufactured by



Storage Temperature

Sensa Core Medical Instrumentation Pvt.Ltd.

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