



The Business Research Company

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Including: Glucose Oxidase-Based Blood Glucose Test Strips, Glucose Dehydrogenase-Based Blood Glucose Test Strips, Thick Film Electrochemical Blood Glucose Test Strips, Thin Film Electrochemical Blood Glucose Test Strips And Optical Blood Glucose Test Strips

Covering: Roche Holding AG, Abbott Laboratories, Lifescan, Nipro Diagnostics, OK Biotech Co. Ltd., Omron, Ascensia, I-Sens, Agamatrix

Blood Glucose Test Strips Market Global Report

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# Executive Summary

Blood glucose test strips are thin paper or plastic strips that are used to monitor blood glucose levels to help control diabetes. The segments in the blood glucose test strips market are based on the type of the reactive enzyme used in the strips—glucose oxidase and glucose dehydrogenase, and by the type of the electrode used— thick film, thin film, and optical. Glucose dehydrogenase-based test strips are the most accurate and specific of the strips. Major trends shaping the blood glucose test strips market include new FDA guidelines on the accuracy of blood glucose detection, the development of generic blood glucose test strips, low cost alternative silk strips, and innovative blood glucose test methods.

The global blood glucose test strips market was worth $10.6 billion in 2017. The size of the market can be attributed to the prevalence of diabetes, awareness of self-monitoring of blood glucose, and reimbursement of test strips in some countries. This market grew from $9.4 billion in 2013 to $10.64 billion in 2017 at a compound annual growth rate (CAGR) of 3.15% and is estimated to grow to $12.93 billion at a CAGR of 5% by 2021. Major drivers of the blood glucose test strip industry in the historic period include increased diabetes cases**,** increased disposable income, and technological advancement, while major restraints on the market include lack of diabetes awareness, decreased reimbursement price, and investment in new technologies**.**

Major drivers of the blood glucose test strip industry in the forecast period include increasing awareness,government initiatives, rapid industrialization and urbanization, changing life styles. The increasing trend in the prevalence of diabetes in both developed and developing countries will help the diabetes care market to grow which could in turn be a driver for the blood glucose test strips market. Major restraints on the market include alternative testing methods, new technologies and the decreasing price of the product.

North America was the largest market for blood glucose test strips in 2017,with a 47.1% share of market, worth $5.01 billion. This was followed by Western Europe, Asia Pacific, South America, the Middle East, Eastern Europe, and finally Africa. The USA was the largest country in this market followed by Germany and then Brazil. India was the fastest growing market in the historic period and it is estimated to grow at a CAGR of 8.49% between 2017 and2021.

The top four companies in this industry, Roche, Johnson & Johnson, Ascensia (Panasonic Health care), and Abbott account for 50% of the market share. Due to decreasing prices for blood glucose test strips across the world and increasing competition from local players, these companies are losing their market share.

# Blood Glucose Test Strips Market Characteristics

This section provides information on the characteristics and market definitions of the global market for blood glucose test strips. It covers information about the different types of blood glucose test strips, their features, main application areas, the distribution landscape, value chain analysis and end-users.

Diabetes is a chronic condition in which a person’s blood glucose level is excessively high according to medical standards. This is caused by the insufficient production or absence of insulin in the body. Over 422 million people across the world suffer from diabetes and the global prevalence of diabetes was recorded to be 8.5% in 2014.[[1]](#endnote-2) The optimum level of blood glucose is 4-8mmol/L and the blood glucose level of people with diabetes can range from 5-9mmol/L.[[2]](#endnote-3) Diabetes is diagnosed through various tests such as oral glucose tolerance tests (OGTT), random plasma glucose tests, and fasting plasma glucose tests.[[3]](#endnote-4) It is a prerequisite for people suffering from diabetes or individuals with the symptoms of prediabetes to monitor their blood glucose levels at regular intervals to prevent diabetes related complications. Point-of-care devices such as continuous glucose monitoring systems and portable glucose meters help individuals with diabetes to monitor their blood glucose levels by yielding the result in matter of seconds.[[4]](#endnote-5)

The portable glucose meters use test strips to measure blood glucose levels and. Blood glucose test strips are thin paper or plastic strips which help to monitor blood glucose level and control diabetes symptoms. A test strip is composed of several layers. The top layer serves as a mini-sponge to soak up the blood sample. The middle layer acts as a filter to channel the blood sample to the reaction center. The next layer contains the enzyme that reacts with blood glucose. The bottom layer consists of a gold and palladium coated circuit that transfers reaction electrons to the meter for analysis. When blood is placed onto the test strip, it reacts with a chemical called glucose oxidase to produce gluconic acid from the glucose in the blood. The blood glucose meter then uses an algorithm to find the blood glucose level based on the difference in current between the terminals of the blood strip and the level of gluconic acid.

The amount of blood required by a test strip varies between 0.5 microliter to 1 microliter. Blood glucose test strips have to be disposed of after a single use because reusing used strips results in inaccurate measurements.[[5]](#endnote-6) Some blood glucose test strips do not require a meter. When blood is placed on the strip’s active part, the reagents change color and the results are obtained by matching the color to a color chart.

Self-monitoring of blood glucose can be beneficial for patients with all types of diabetes and can help to reduce the risk of developing diabetic complications. Most individuals with type II diabetes are advised to test their blood sugar levels at least once per day. Diabetic patients who use insulin usually test their blood sugar more often, between two and eight times per day, to assess the effectiveness of the insulin dose and to help determine the next insulin dose.[[6]](#endnote-7)

|  |
| --- |
| *“Type IIII diabetic patients should take two readings per day. Fasting blood glucose (FBG) readings should be taken before breakfast or lunch or dinner and post prandial glucose level (PPG) readings should be taken after breakfast or lunch or dinner. For Type I diabetic patients, three readings are required: one in the morning before breakfast, post prandial, and at night (CPG). Apart from this, there are a few patients whose medications have to be altered, and they have to check their blood glucose levels seven times a day*.” *-Area Business Manager, LifeScan (Johnson & Johnson)* |

The utilization of blood glucose strips varies within type I and type II diabetes patients. Regulatory authorities recommend more frequent testing of blood glucose for type I diabetes patients. Generally, the ratio of type I to type II patients globally is 10:90. Type I diabetes patients are recommended to test at least three to four times a day and type II diabetes patients are recommended to self-monitor based on their medication and insulin usage.

|  |
| --- |
| *“Type I and Type II diabetes patients are in the ratio of 10:90.”**Area Business Manager, LifeScan (Johnson & Johnson)* |

Blood glucose test strips usually have an expiry date and are good to use for three to six months once opened. They should meet specific International Organization for Standardization (ISO) accuracy standards when used with meters. According to the US FDA regulations for all blood glucose test glucometers,[[7]](#endnote-8) for results at or above 75 mg/dl, 95% of the meter test outcomes should be within approximately 20 points of the actual blood glucose level, whereas for results below 75 mg/dl, 95% of the meter test results should be within approximately 15 points of the actual blood glucose level.

False blood glucose readings while using a blood glucose test strips can occur when[[8]](#endnote-9)

* insufficient blood is applied to the test strip
* the test strip is not inserted properly into the blood glucose meter
* test strips are stored under extreme temperatures or are exposed to humidity
* damaged test strips or pre-used test strips are used

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| --- |
| *“There are variations in the reading in the blood glucose strips from time to time. So reliability of the results through blood glucose strips is also a challenge.”**-Area Business Manager, LifeScan (Johnson & Johnson)* |

The price of blood glucose strips varies across regions. The price is high in developed countries compared to less developed countries. In USA the price of single blood glucose test strip is around $0.75. In the UK, Germany, France, Italy, and Spain the price of a single blood glucose test strip is in the region of $0.4-$0.6. In less developed economies like India, China and Africa, the price is approximately $0.1-$0.2 per strip.

Blood glucose test strips consist of a porous fabric or material such as polyamide, polyolefin, polysulfone, or cellulose. Chemicals on test strips include enzymes, coenzymes, mediators and indicators. Water, tramethylbenzidine, carboxymethylcellulose, glucose oxidase, horseradish peroxidase, dialyzed carboxylated vinyl acetate ethyl copolymer latex, are other raw materials used. These raw materials are procured from chemical manufacturing companies. The manufactured strips are packaged with absorbent packs of silica gel and dried at 30oC and 25 mm/Hg vacuum, and are then distributed directly to retailers, wholesalers, and other end-users such as medical stores, hospitals, medical professionals, and health care centers.[[9]](#endnote-10)

Blood glucose test strips are available free on prescription or can be bought from pharmacies or online. They are primarily used by hospitals, health clinics and individuals suffering from diabetes, blood disorders, blindness, and kidney disorders. The blood glucose test strips are promoted through various channels including physicians and pharmacy chains.

|  |
| --- |
| *“Companies employ strategies such as promoting blood glucose strips to physicians, endocrinologists, diabetologists, and pharmacy chains. They explain the product to them and give them incentives and discounts to prescribe their product to patients.*”*Area Business Manager, LifeScan (Johnson & Johnson)* |

The segments in the blood glucose test strips market are based on the type of the reactive enzyme used in the strips—glucose oxidase and glucose dehydrogenase, and by the type of the electrode used— thick film, thin film, and optical.

The blood glucose test strips that are based on the type of the reactive enzyme will be referred to as blood glucose test strips by technology hereon forward. Blood glucose test strips by technology include:

**Glucose Oxidase-based Blood Glucose Test Strips –** This segment comprises blood glucose test strips based on glucose oxidase. Glucose oxidase is a chemical used in liquid and powder glucose laboratory reagents, urine test strips, colorimetric blood glucose test strips, and biosensors for blood glucose monitoring. These strips determine glucose levels by a commercially available enzymatic spectrophotometric glucose oxidase method.[[10]](#endnote-11) The sensors on these strips are more substrate specific, hence the probability of a negative result is slightly higher than with other sensor-based test strips.[[11]](#endnote-12)

**Glucose Dehydrogenase-based Blood Glucose Test Strips –** This segment includes blood glucose test strips with glucose dehydrogenase sensors. Glucose dehydrogenase is an enzyme or protein catalyst that is used to accelerate the oxidation of glucose to gluconic acid. Glucose dehydrogenase is less susceptible than glucose oxidase to common interferences.[[12]](#endnote-13) Glucose dehydrogenase-based test strips are the most accurate and specific of the strips as cross-reactivity from other blood sugars such as maltose, galactose or xylose is zero. These strips are also less expensive than glucose oxidase-based test strips.[[13]](#endnote-14)

Glucose dehydrogenase pyroloquinolinequinone (GDH-PQQ) is also used as a sensor on blood glucose test strips. GDH-PQQ-based test strips are not widely used because they do not provide specific results compared to other sensor-based test strips. This is due to the interference of certain products such as peritoneal dialysis solution, immunoglobulin preparations containing maltose and radioimmunotherapy agents.[[14]](#endnote-15)

The blood glucose test strips that are based on the type of electrode used include [[15]](#endnote-16):

**Thick Film Electrochemical Blood Glucose Test Strips –** Thick film electrochemical blood glucose test strips are composed of several layers such as the analytical layer, separating layer, and support layer. Each strip contains printed working and reference electrodes that are coated with reagents and membranes.

**Thin Film Electrochemical Blood Glucose Test Strips –** Thin film electrochemical blood glucose test strips consist of glucose enzyme electrodes on thin layers of enzyme glucose oxidase, entrapped over oxygen electrodes via semi-permeable dialysis membranes.

**Optical Blood Glucose Test Strips –** Optical blood glucose test strips are based on fiber optic and planar devices utilizing the absorption, scattering, polarization, reflection, and interference of light.

Blood glucose test strips find applications in the following types of blood glucose measurement tests –

**Disposable Fasting Blood Sugar Test –** This test is used for determining blood glucose levels before the intake of food or after fasting for eight to ten hours. In this test, a disposable blood lancet is used to obtain a blood sample which is placed on a disposable test strip and then inserted into a glucometer to calculate the glucose level in the blood. A fasting blood glucose level of 7.0 mmol/L or more indicates the presence of diabetes.[[16]](#endnote-17)

**Postprandial Blood Sugar Test –** The postprandial blood sugar test is used for postprandial or post-meal blood glucose measurement, which is commonly taken two hours after the consumption of a meal. A postprandial blood glucose level under 8.5 mmol/L indicates the presence of type IIII diabetes, whereas a level under 9 mmol/L indicates type I diabetes.[[17]](#endnote-18)

**Oral Glucose Tolerance Test –** The oral glucose tolerance test is used to diagnose instances of diabetes mellitus or insulin resistance.[[18]](#endnote-19) It can also be used to determine whether a woman has developed diabetes associated with pregnancy. In this test, a patient is given a dose of 75g of glucose. A glucose level of 11.1 mmol/L or more in the blood sample taken two hours after the intake of glucose by the patient indicates the presence of diabetes.[[19]](#endnote-20)

**Glycohemoglobin A1c Test –** Glycohemoglobin A1c or HbA1c test is a primary test to diagnose type IIII diabetes. The HbA1c test measures the average blood sugar level and is an indicator of how well the diabetes is being controlled. HbA1c, or glycated hemoglobin, occurs when hemoglobin in the red blood cells becomes bonded with glucose in the bloodstream. The higher a person’s blood glucose levels, the higher the number of glycated red blood cells, and therefore the higher their HbA1c level will be. According to the World Health Organization (WHO), the diagnostic guidelines for HbA1c test for diabetes are[[20]](#endnote-21) -

* HbA1c below 42 mmol/mol (6%): Non-diabetic
* HbA1c between 42 and 47 mmol/mol (6-6.4%): Impaired glucose regulation or prediabetes
* HbA1c of 48 mmol/mol (6.5%) or over: Type II diabetes
1. http://www.who.int/mediacentre/factsheets/fs312/en/ [↑](#endnote-ref-2)
2. https://www.diabetes.co.uk/diabetes\_care/blood-sugar-level-ranges.html [↑](#endnote-ref-3)
3. http://www.diabetes.org/diabetes-basics/diagnosis/?referrer=https://www.google.com/ [↑](#endnote-ref-4)
4. https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/monitoring-diabetes/ [↑](#endnote-ref-5)
5. https://www.thediabetescouncil.com/everything-you-need-to-know-about-diabetes-test-strips/ [↑](#endnote-ref-6)
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17. http://www.diabetes.co.uk/features/pre-and-post-meal-testing.html [↑](#endnote-ref-18)
18. https://www.diabetes.co.uk/oral-glucose-tolerance-test.html [↑](#endnote-ref-19)
19. https://patient.info/in/health/tests-for-blood-sugar-glucose-and-HbA1c [↑](#endnote-ref-20)
20. https://www.diabetes.co.uk/HbA1c-test.html [↑](#endnote-ref-21)