



Test-Point

TEST-POINT DIABETES TEST Manual

Important

Read the manual completely. You need a stopwatch or clock which you can use by hand. This test includes a step with time measurement, which needs to be executed right for correct results.

Step 1

Wash your hands and make them dry. Use the alcohol swab to wipe over the tip of your finger. Dry off before you are to use the test.



Step 2

Turn off the cap from the lancet.



Step 3

Firmly push the lancet to your finger until you hear a "click".



Step 4

Squeeze your finger until a drop of blood is shaped. Prepare to start the time measurement.



Step 5

Put down the drop of blood on the testing surface and start the time measurement.



Step 6

Wipe off the blood after 30 seconds with a tissue. Do not use the alcohol swab for this purpose.



Step 7

After another 30 seconds you can read the result by comparing the test surface with the result chart. After 5 minutes the result starts to fade away.



What is this Test for?

Test-Point Diabetes Test is intended as a screening test for the early detection of abnormal fasting plasma glucose (FPG) levels.

Abnormal fasting glucose levels can be a sign of diabetes or other health problems.

The test uses a drop of capillary blood to provide a preliminary semi-quantitative result.

Any abnormal result should be confirmed by a doctor using a quantitative laboratory based method.

The test is not intended to provide a formal diagnosis of diabetes.

A formal diagnosis can only be made by a doctor.

Background

Type 2 Diabetes:

Studies have found that 30% - 50% of people with diabetes are unaware that

they have it. This is because when a person first develops diabetes it is common for them to have no signs of illness. They do however have high levels of glucose in their blood, which over time badly damages many parts of the body.

Diagnosis often occurs after the onset of symptoms, by which time preventable, severe and irreversible damage has already occurred.

This damage can be prevented if high glucose levels are reduced by early treatment.

Test-Point Diabetes Test is a convenient and effective way to measure glucose levels in just 60 seconds.

Individuals who obtain an abnormal result should see their doctor for further testing.

How Does the Test Work?

The test zone consists of two test pads containing sensitive chemicals.

When blood is applied to this zone, the chemicals react with the glucose in the blood.

The reaction produces a colour change that varies with the amount of glucose in the blood.

The test uses the enzymes Glucose Oxidase and Peroxidase which along with color forming chemicals and non-reactive ingredients is contained in the test zone.

Chemical Composition

Each Test-Point GT test strip contains (Quantity/cm²): Glucose Oxidase 0.08 U, Peroxidase 9.4 U, TMB 77 µg, DCP 20 µg, Stabiliser 0.12 mg, Inert ingredients 2.20 mg (w/w).

Failure to fast will produce invalid high results.

For *in vitro* diagnostic use only.

Use the test strips only between 18 and 35°C (64 and 95°F).

Performing a test below 18°C (64°F) will give low results and performing a test above 35°C (95°F) will produce high results.

There is no need to refrigerate this product, however if refrigerated, do not use the test until it has warmed to room temperature.

Failure to do so could lead to low results.

Use only fresh capillary whole blood from a finger stick.

The test strips are for single use only.

Incorrect timing – leaving the blood on too long will increase the result and wiping the blood too early will decrease the result.

Blood drop must cover the test zone – see inset picture with tick.

Smearing too little blood will lead to uneven color development that will not be readable.

Blood cannot be added after timing has started – repeat with new test.

The test is not intended for use by individuals who are pregnant.

As the reading range is 1.0 – 35 mmol/L (18 – 630 mg/dL), the test should not be used by people with diabetes to monitor their glucose levels or adjust any treatment.

Storage and Handling

Store Test-Point Test Strips in their original foil packing in a cool, dry place between 4-30°C (39-86°F).

Do not freeze.

Use the test strip **immediately** after opening the foil packaging.

If the test strip packaging has been tampered with or opened it should not be used.

Quality Checks

The test strips can be checked against the '0' (unreacted) colour block on the result chart to see they are in good condition.

If any sign of blue is visible, the strip should not be used.

What is Included?

Test-Point tests*, single use lancets*, alcohol swabs*, result chart, package insert. * See outer pack for quantity.

Measurement Range

The measurement range is 1.0 – 35mmol/L (18 – 630 mg/dL).

When Should I Test?

An ideal time to test is before breakfast. Do not eat or drink for 8 hours before testing (you may drink water only).



How do I Perform a Test?

Have a timer ready.

Follow the step by step instructions numbered 1-7.

How do I Read the Result?

Results are obtained by comparing the test zone to the result chart on the label.

Use natural light for best results.

If the test zone colour lies between two colour blocks on the chart e.g. a colour that appears to be between the 4 and the 6mmol/L (72 and the 108mg/dL) colour blocks, then your result is in the range 4 – 6mmol/L (72 - 108mg/dL).

A test zone lighter than 1mmol/L (18mg/dL), is less than 1mmol/L (18mg/dL). A test zone darker than 35mmol/L (630 mg/dL) is greater than 35mmol/L (630mg/dL).

Expected Results

Results ¹	Fasting Plasma Glucose (FPG) - mmol/L (mg/dL)
Abnormally Low	< 4.2mmol/L (75mg/dL)
Normal	4.2 - 6.1mmol/L (75 - 110mg/dL)
Abnormal	> 6.1mmol/L (110mg/dL)

If the test zone colour is *darker* than the 6mmol/L (108 mg/dL) colour block then your result is abnormal.

Abnormal results should be confirmed by re-testing – seek advice from a physician or medical professional.

Do I Need to Test Again?

Annual Testing: Blood glucose should be checked annually by individuals who are any of the following: obese; have a first-degree relative with diabetes; are members of a high-risk ethnic population (African, Aboriginal, Arabian, Asian, Hispanic, Native American, Pacific-Islander).

Also those who have delivered a baby weighing more than 9 pounds; have had gestational diabetes; have high blood pressure; have HDL cholesterol levels \leq 35mg/dL or triglyceride levels \geq 250mg/dL; or who, on previous testing had impaired glucose tolerance or impaired fasting glucose.

Test every 3 years: All adults older than 45 years of age should test every three years.

Performance Characteristics

Accuracy

Diabetes experts have suggested that glucose devices should agree within 0.8mmol/L (15 mg/dL) of a laboratory method when the glucose concentration is lower than 4.2mmol/L (75 mg/dL), and within 20% of a laboratory method when the glucose concentration is 4.2mmol/L (75 mg/dL) or higher.

The table below displays how often the Test-Point Diabetes Test achieves this goal.

The chart is based on a study done on 108 patients to see how well Test-Point Glucose Test compared to laboratory results.

For glucose results lower than 75 mg/dL, the percentage (and number) of Test-Point Diabetes Test results that matched the laboratory method within 15 mg/dL :	(22/22) 100%
For glucose results at 75 mg/dL or higher, the percent (and number) of meter results that match the laboratory method within 20%:	(187/194) 96%

Note: When Test-Point Diabetes Test results are compared to the laboratory results, results below 75 mg/dL are compared in mg/dL.

Classification accuracy

Studies were conducted at three sites with a total of 120 untrained subjects who performed the test unassisted and classified their results as either normal or abnormal. Of the 120 subjects, 119 correctly classified themselves. By computing the 95% confidence interval for the binomial distribution, Test-Point® Diabetes Test exhibited a classification accuracy of greater than 95%.

Precision

Precision was determined using three lots at five different glucose levels.

Repeatability (within-series imprecision):

In a typical series of tests a coefficient of variation of 2.6% was obtained.

Reproducibility (day to day imprecision):

In a typical series of tests a coefficient of variation of 3.3% was obtained.

Specificity:

The test strips react specifically with D glucose and do not react with other sugars that may be present in the blood.

Calibration:

Test-Point is a plasma referenced system. The calibration is traceable to an NIST standard.

Key to symbols:

On the box, label and instructions for use you may encounter the following symbols, shown here with their meaning:

 Manufactured by

 Please read package insert


 Single use


 For in vitro diagnostic use

 Store at

 Use by / Expiry date

 Sterilized using radiation

 Authorised representative in the European Community.

 The Test-Point test strips in this product fulfill the requirements of European Directive 98/79/EC on in vitro diagnostic medical devices.

Lancets

HTL Strefa

Warsaw, Poland

Test-Point Test Strips:

National Diagnostics Products
Sydney, NSW, 2065, Australia

Date Issued: Version BDTINT4 JULY 2008

If you have any questions please contact us at service@test-point.eu