BETACHEK G5

BETACHEK® G5 BLOOD GLUCOSE TEST STRIPS

Device for self-testing

ENGLISH **Instructions for use**

Intended Use: Betachek® G5 Test Strips are to be used together with Betachek G5 meters for quantitatively measuring glucose in fresh capillary whole blood. Betachek® G5 Test Strips are intended for self-testing of blood glucose as an aid to monitor the effectiveness of diabetes control.

General: Self-testing helps both you and your doctor check your blood glucose management, however self-testing should not be seen as a substitute for regular visits to your doctor. Please remember that testing should only be undertaken after you have received a thorough course of instruction from a qualified healthcare professional. You should only adapt your treatment if you have been trained to do so.

Contents of the pack: Container with test strips (check labels for quantity), 1 label on the test strip container with colour chart, table of concentrations and code number, 1 memory card, 1 package insert.

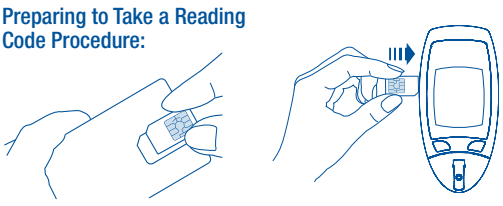
Materials required but not provided: Betachek G5 meter, meter instruction manual, lancing device and lancet.

Storage and Handling

- Store Betachek® G5 Test Strips in their original container in a cool, dry place at 2-30ºC (35-86ºF). Do not freeze. If stored in a refrigerator, remove and warm to room temperature before opening.
- Testing should be performed between 10-40ºC (50-104°F).
- Do not use test strips past the expiration date.
- Use the test strip immediately after it is removed from the container; replace the container cap immediately and close it tightly. The cap contains a drying agent that can become exhausted if exposed to humidity.
- Do not use any test strips from a container that has been left open or is damaged.
- Do not bend the test strip. If a strip is bent when being inserted into the meter it should be discarded. Hold the strip close to the black tape when inserting to avoid bending.
- Do not store used test strips or anything else in the test strip container as this will cause deterioration of the test strips.
- All items in the pack may be discarded with your regular household waste.

Preparing to Take a Reading

Code Procedure:



After opening a new pack of G5 test strips, you must remove the old memory card from the meter and replace it with the new one from the new pack. When you have inserted the new memory card check that the 3-digit code number displayed by the meter matches the code number printed on the label of new test strips. This card remains in the meter until a new pack of strips is used. Please read your G5 meter instruction manual for details.

WARNING: The memory card programs the meter with information about the lot of test strips. Failure to replace a memory card will result in false readings.

Test Procedure

Wash hands: Select the puncture site. The best place to obtain blood is from the fingertip. Wash your hands with warm, soapy water. Dry them thoroughly.

Check the test strip: Remove a test strip from the container. Recap the container immediately. Before using a strip turn it over and compare the colour of the round control window with the zone labeled '0' on the colour chart. The colours should approximately match. If the colours do not match, the strip is unusable and should be discarded.

Step 1 Insert strip: At one end of the strip there is a cut out in the shape of a key hole. Insert this end into the meter, with the gauze facing up and the circle facing down. When inserting the test strip hold it close to the black tape rather than at the end, to avoid bending it. Push the strip into the meter completely until it will go no further. Ensure the strip is lying flat and straight. Turn the meter on. (Alternatively the meter may be turned on before inserting the test strip). Note: Later models turn on automatically when the strip is inserted - there is no need to press the on button in this case. Check the code number printed on the test strip container matches the code number displayed by the meter. If they do not match, see your meter instruction manual for information on coding the meter correctly.

Step 2 Obtain a drop of blood: Obtain a drop of blood by pressing the lancing device firmly against the side of your finger. Press the release button. Gently squeeze and/or massage your fingertip until a hanging drop of blood forms on your fingertip. Do not squeeze the puncture site excessively. The blood sample must be at least 1-2 µL in volume or you may get an inaccurate result.

Step 3 Apply blood, await result: When the flashing apply blood symbol appears on the display, touch and hold the drop of blood to the centre of the white square test zone. The result will be displayed in approximately 5 seconds. Results are automatically stored in the meter and card memory.

Test Results

If your test result is lower than 10 mg/dL (0.6 mmol/L), a 'Lo' message will appear indicating a low glucose level. This may indicate severe hypoglycemia (low blood glucose). You should treat this immediately and repeat the test. If the result is higher than 500mg/dL (27.7mmol/L) a 'Hi' message will be displayed. This may indicate severe hyperglycemia. You should repeat the test and if the 'Hi' message appears again you should contact your healthcare professional.

Range of Expected Values

Blood glucose management requires the assistance of a healthcare professional.

Together you can set your own range of expected blood glucose values, ideal testing times, and discuss your blood glucose results. Expected blood glucose levels for people without diabetes - related to plasma (divide table values by 1.11 to obtain whole blood values):

Time	Range, mg/dL	Range, mmol/L
Before breakfast[1]	70–110	3.9–6.1
2 hours after meals[2]	Less than 140	Less than 7.8
Between 2 and 4 am	Greater than 70	Greater than 3.9

If You Get Unexpected Results

If your blood glucose result is less than 70 mg/dL (3.9 mmol/L) indicating low blood glucose or higher than 180 mg/dL (10.0 mmol/L) indicating high blood glucose, you should contact your healthcare professional and follow their treatment advice.

If you continue to get unexpected results, check your system with Control Solution. If you are experiencing symptoms that are not consistent with your blood glucose test results AND you have followed all steps described in your meter instruction manual, call your healthcare professional. Never ignore symptoms.

Checking the System

To ensure that your meter and strips are functioning properly and that you are carrying out the test correctly, you may check the performance of the system with Betachek® G5 Control Solution.

When to do a Control Solution Test:

- At least once a week
- When you begin using a new container of test strips
- Whenever you suspect that the meter or test strips are not working properly
- If you have had repeated unexpected blood glucose results
- If you drop the meter

A control test is performed by using a drop of Control Solution in place of blood. The result obtained should fall within the acceptable range printed on the memory card. If Control Solution Test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:

- Error in performing the test.
- Expired or contaminated Control Solution – never touch the strip with the control solution dropper tip.
- Meter, test strip, or Control Solution that is too warm or too cool.
- Failure to discard the first drop of Control Solution and wipe the dispense tip clean.
- Incorrect memory card installed.
- Test strip deterioration.
- Meter malfunction.

CAUTION: If you continue to get Betachek G5® Control Solution Test results that fall outside the range, your meter may not be functioning properly. **DO NOT** use the meter to test your blood until you get a Control Solution Test result that falls within the range. For complete instructions refer to your meter instruction manual.

Limitations of the Test

- For *in vitro* diagnostic use only.
- Test strips should be used once only.
- Do not carry out the test in direct sunlight.
- Not for neonatal use.
- Use fresh capillary blood only. Do not use plasma, venous blood or serum.
- Abnormally low hematocrit (<35%) may produce falsely high readings and abnormally high hematocrit (>55%) may produce falsely low readings.
- Strong electromagnetic fields (e.g. mobile phones, microwave ovens) may affect performance. Betachek G5® will detect this and an error message will be displayed.

Infection control: Never share a lancet or the lancing device with anyone. Keep your meter and lancing device clean. Always wash the puncture site with soap and water before testing.

How the system works: Betachek G5® uses photochemical technology commonly used in clinical laboratories. Sensitive chemicals in the test zone (see below) react with the glucose in the blood to produce a colour change. The G5 meter measures this change with the aid of the lot specific information held in the memory card and converts the signal to a displayed reading.

Healthcare Professionals Please Note

- Fresh capillary blood may be collected into heparin-containing test tubes if the blood is used within 10 minutes. Do not use other anticoagulants or preservatives.
- Interferences: Acetaminophen, salicylates, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may lead to false results.
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
- Critically ill patients should not be tested by blood glucose meters.
- Lipemic samples: Cholesterol levels up to 700 mg/dL (18.1 mmol/L) and triglycerides up to 5000 mg/dL (57.1 mmol/L) do not affect the results.

Test principle: The test employs glucose oxidase, peroxidase and the chromagen 3,3',5,5'-Tetramethylbenzidine along with non reactive ingredients to produce a colour change that is directly proportional to the amount of D-glucose in the blood sample.

Chemical composition: Each Betachek G5 test strip contains: Glucose Oxidase (*Aspergillus niger*) 0.12%, Peroxidase (*Horseradish*) 0.09%, 3,3',5,5'-Tetramethylbenzidine 0.31%, Stabiliser 1.2%, Inert ingredients 98.28%. The cap contains a silica based drying agent.

Measurement range: The Betachek G5 system is linear and displays results between 10 and 500mg/dL or 0.6 and 27.7 mmol/L. The units of measure are factory set and cannot be changed.

Calibration: The system is calibrated using multiple blood samples containing a range of blood glucose concentrations. The reference values are obtained using the hexokinase method. This method is traceable to an NIST standard. The meter will display results that are equivalent to those found in plasma.

Performance Characteristics

Accuracy: Comparison against capillary whole blood by hexokinase method produced the following regression:
$Y(mg/dL) = 1.0307x - 6.4114$ $R^2 = 0.9815$

Precision: The repeatability obtained with the blood samples is shown in the following Table. The table gives the pooled standard deviation and pooled CV% with 95% confidence intervals for the five levels of glucose tested (n=100). No outliers were detected and excluded from data analysis.

At glucose concentrations of 44.7, 96.1, 132, 170 and 276 mg/dL coefficients of variation (CVs) of 3.7, 3.5, 2.3, 2.8 and 2.1% were obtained respectively, indicating a high degree of precision. At all glucose levels tested the coefficient of variation was below 4%.

Grand mean (mg/dL)	44.7	96.1	132	170	276
Pooled SD (mg/dL)	1.7	3.4	3.0	4.8	5.8
95% CI (mg/dL)	1.5-3.0	3.0-6.2	2.6-5.4	4.2-8.7	5.1-10.7
Pooled CV%	3.7	3.5	2.3	2.8	2.1
95% CI	3.2-6.7	3.1-6.4	2.0-4.1	2.5-5.2	1.9-3.9

Reference

1 Stedmans medical dictionary, 27th edition, 1999, p.755

2 American Diabetes Association Clinical Practice Recommendations 2003, Diabetes Care, Vol.26, Supplement , p.S22.

Key to symbols: On the box, label and instructions for use you may encounter the following symbols:

Do not reuse

+30°C +85°F / +2°C +35°F Temperature limitation

LOT Batch code

REF Catalogue number

Caution

Manufacturer

Consult instructions for use

Use by (unopened or opened test strip container)

EC REP Authorised Representative in the European Community

IVD In vitro diagnostic medical device

CE 0123 This product fulfils the requirements of European Directive 98/79/EC on in vitro diagnostic medical devices

NDP National Diagnostic Products
7-9 Merriwa Street, Gordon
Sydney NSW 2072 Australia
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Date issued: 2014-05, version 4

BG5TSI.V4-ENG-MAY14