BETACHEK® *C50*

Blood glucose test cassette

Instructions for use

These instructions are to be read in conjunction with the Betachek C50 meter instruction manual.

Intended use

The Betachek C50 test cassette with the Betachek C50 meter are intended to quantitatively measure glucose in fresh capillary whole blood. The system is intended for in vitro diagnostic self testing of blood glucose, as an aid in monitoring 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 health care professional. You should only adapt your treatment if you have been trained to do so.

Contents of the pack

Container with 1 or 2 test cassette(s), 1 package insert.

Storage and handling

- Store unopened cassettes in their original container in a cool, dry place at 2-30°C (35-86°F). Do not freeze. If stored in a refrigerator, remove and warm to room temperature before opening the container.
- Testing should be performed between 10-40°C (50-104°F)
- Do not use test cassettes past the expiration date. Test cassettes must be used within three months (90 days) of opening.
- Use the test cassette immediately after it is removed from the container.
- Do not use a test cassette from a container that has been damaged.
- All items in the pack may be discarded with your regular household waste.

Performing a test

See Betachek C50 user manual for instructions. (User manual and instructional videos are also available online.)

Test results

The normal fasting glucose level for a non diabetic adult is below 100mg/dL (5.6mmol/L). Consult your healthcare professional for the glucose range that is appropriate for you. If your test result is lower than 20mg/dL (1.1mmol/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 600mg/dL (33.3mmol/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.

Blood volume and test time

The meter requires at least 0.3µL of blood. The test can take as little time as 5 seconds (time varies with blood glucose concentration).

Checking the system

To ensure that your meter and cassette are functioning properly and that you are carrying out the test correctly, you must regularly check the performance of the system with Betachek control solution. See your meter user manual or control solution instructions for further details.

Limitations of the test

- For in vitro diagnostic use only.
- Test cassettes are for personal use only. They are not suitable for doctor's offices or other health care facilities.
- 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. large magnets, microwave ovens) may affect performance. Move away from electromagnetic fields before testing.

Infection control

Never share your meter, a lancet or the lancing device with anyone. Always wash the puncture site with soap and water before testing.

Test principle

The test employs FAD GDH and a chromagen along with nonreactive ingredients to produce a colour change that is directly proportional to the amount of D-glucose in the blood sample. The meter measures this change and converts it to a blood glucose result.

Interfering substances

- Maltose and Xylose do not affect 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 with blood glucose meters.
- Lipemic samples: Cholesterol levels up to 700mg/dL (18.1mmol/L) and triglycerides up to 5000mg/dL (57.1mmol/L) do not affect the results.

Chemical composition

Betachek C50 test zones contain: FAD GDH 0.12%, chromagen 0.31%, stabiliser 1.2%, inert ingredients 98.28%. The cassette contains a silica based drying agent.

Measurement range

The Betachek C50 system is linear and displays results between 20 and 600mg/dL or 1.1 and 33.3 mmol/L. The units of measure are factory set and cannot be changed.

Calibration

The system is calibrated with whole blood samples adjusted to a range of glucose concentrations. A YSI (Yellow Springs Instruments) 2300 analyser is used to measure the glucose concentrations in the samples. This instrument is traceable to an NIST standard. Control solution results obtained with the cassettes are therefore also traceable to an NIST standard. Results are expressed as plasma equivalents.

Performance characteristics of the Betachek C50 system

The Betachek C50 blood glucose monitoring system complies with the requirements of EN ISO 15197:2013.

Performance characteristics according to EN ISO 15197:2013

System accuracy:

System accuracy results for glucose concentrations <5.55mmol/L (<100mg/dL)

Within ±5mg/dL (Within ± 0.28 mmol/L)	Within ±10mg/dL (Within ± 0.56 mmol/L)	Within ±15mg/dL (Within ± 0.83 mmol/L)
124/198 (62.6%)	189/198 (95.4%)	194/198 (97.9%)

System accuracy results for glucose concentrations ≥5.55mmol/L (≥100mg/dL)

Within ±5%	Within ±10%	Within ±15%
267/402 (66%)	366/402 (91%)	400/402 (99.5%)

System accuracy results for glucose concentration between 37.9mg/dL (2.1mmol/L) and 458.8mg/dL (25.48mmol/L)

Within ±15mg/L (±0.83mmol/L) and within ±15%
594/600 (99%)

Repeatability:

Mean value					
mg/dL	40	92	146	221	288
mmol/L	2.2	5.1	8.1	12.3	16
Standard deviation					
mmol/L	0.1	0.12	0.12	0.2	0.3
Coefficient of variation					
%	-	-	1.4	1.7	1.9

Precision:

Mean value			
mg/dL	50.4	108	288
mmol/L	2.8	6	16
Standard deviation			
mmol/L	0.14	0.16	0.3
Coefficient of variation			
%	4.7	2.6	1.7

Performance assessment by the user:

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 laypersons showed the following results:

- For glucose concentrations less than 5.55mmol/L (100mg/dL), 100% of test results were within ±0.83mmol/L (±15mg/dL) of the results obtained by laboratory testing.
- For glucose concentrations equal to or greater than 5.55mmol/L (100mg/dL), 100% of test results were within ±15% of the results obtained by laboratory testing.

Customer support

National Diagnostic Products
customer.support@betachek.com
Training Videos: www.betachek.com

Explanation of symbols:

The meaning of symbols used in the packaging is as follows:

	Consult the package insert
	Store at
	Use by/Expiry date unopened
	Use cassette within 90 days of opening the container
	Test cassettes can be disposed of in household waste
	Manufacturer
REF	Catalogue number
LOT	Lot number
IVD	For in vitro diagnostic use
CE 0123	This product fulfills the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.
EC REP	Authorised representative in the European Community

Betachek diabetes management app creates graphs and charts. Text, email or print your results. Free to Download.

Download on the App Store

EC REP

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