**INSTRUCTIONS FOR USE**

**Glucoflex-R product improvements** (please review test procedure):

* 60 second test
* Plasma calibrated

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**What is this test for?** Glucoflex-R Test Strips are intended for self-testing of blood glucose. The test uses a small drop of capillary blood (5 microlitres) to provide a semi-quantitative result. The test is not intended for use with neonates.

**What is the purpose of glucose testing?** High blood glucose causes serious harm to the body over time. This damage can be prevented by keeping blood sugar at normal levels. Studies have shown that the better the control of blood glucose, the better the long term health of a person with diabetes. Regular self-testing with Glucoflex-R will provide useful information for both you and your healthcare professional in managing the disease. Repeated testing allows you to see the impact of diet, exercise and your medicine on blood sugar levels. Your healthcare professional will advise you on when you should test and your target glucose range. Please note that blood glucose testing should only be undertaken after you have received a thorough course of instruction from a qualified healthcare professional. Self-testing is not to be seen as a substitute for regular monitoring by your doctor. It can however, allow your doctor to check your blood glucose management. You should only adapt your treatment if you have been trained to do so.

**What is included?** Glucoflex-R Test Strips (see outer packaging for quantity), 1 label with colour chart, instructions for use.

**What is not included but needed?** A watch with a second hand or a timer, a clean white tissue, a lancing pen with lancet.

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**Storing the test strips**

Store Glucoflex-R Test Strips in their original container in a cool, dry place between 2-30˚C (35-85˚F). Keep away from heat and direct sunlight. Do not freeze. If stored in a refrigerator, remove and warm to room temperature before opening. In the original bottle these test strips are stable up to the expiry date. Recap container immediately after removing strips. Use before the expiry date.

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**How to perform a test**

This test has an important timing step. Incorrect timing will give incorrect results.

You need a timer or a watch with a second hand, a clean white tissue and a lancing pen with lancet. Watch a video demonstration at [www.betachek.com/gfx](http://www.betachek.com/gfx)

1. **Preparation** – Wash hands with soap and WARM water and dry them thoroughly. If you use an alcohol wipe, make sure your finger is completely dry before testing. Remove a test strip and immediately recap the container. Check the test zone against the “0 Unused” section of the colour chart on the label. If the test zone shows any sign of blue you should discard the test strip.

2. **Obtain blood sample** – Use your lancing pen according to its instructions to prick your finger. Gently squeeze the selected finger at the base moving toward the tip. This should be repeated several times until you have a large hanging drop of blood (the palm of your hand should be facing down so the drop can hang from the finger).

3. **Apply blood** – Place the strip on a firm level surface or if preferred hold the strip moving it towards the blood drop. Allowing the drop of blood to hang off the finger, press the drop onto the centre of the two pads, moving it around to ensure complete coverage. Avoid touching the pads with your finger. As soon as you have applied the blood to the pads start timing. Blood should completely cover both pads. If you have smeared the blood or not used sufficient blood to completely cover both the pads then you should repeat the test.

4. **Wipe blood off** – Exactly 30 seconds after applying the blood, wipe the blood from the test pads with a tissue. Repeat the wipe using a clean region of the tissue. Ensure the test zone is clean of blood. Excess blood left on the pads will affect the result.

5. **Read results** – After wiping the test zone wait another 30 seconds (1 minute from applying blood), then compare the test zone to the colours on the label chart.

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[www.betachek.com/gfx](http://www.betachek.com/gfx)
Understanding your test results

How do I read the result? Results are obtained by comparing the test zone to the colour chart on the label. Use natural light (e.g. stand near a window) when colour matching for best results. When matching colours always ask the question: is the test zone lighter or darker than the colour standard it is being compared to. After deciding to move to the next colour standard and repeat until you find the closest match. If the test zone colours lie between two values on the label then calculate the average value, e.g. (7 + 9) / 2 = 8. If the colour does not lie exactly between colour blocks you may approximate the value using your judgement. The test zone will remain stable for 10 minutes. The test may be compared to the label at any time during this period.

Expected results – Blood glucose levels normally vary from time to time depending on food intake, medication dosages, health, stress or exercise. Consult your physician or healthcare professional for the target glucose value appropriate for you. Normal glucose values for an adult without diabetes (related to plasma):
- Fasting: 4.1 - 5.9 mmol/l or 74 - 106 mg/dl


⚠️ Warning – Low or high blood glucose readings may indicate a potentially serious medical condition. If you have readings above or below your prescribed range of blood glucose values, repeat the test. If your results continue to fall outside your prescribed range, you should contact your healthcare professional and follow their advice. If you have readings that are not consistent with your symptoms, you should contact your healthcare professional immediately.

Problem solving – Unexpected results.

Contamination – Do not handle the test pads as moisture, oil and dirt from fingers will damage them. Dirty fingers carry traces of glucose from food and will also distort the result. Therefore, it is essential to carry out the entire process with cleanliness.

Expiry date – Check your strips are in date.

Incorrect timing – Leaving blood on too long will cause a falsely high result. Wiping blood off too early will cause a falsely low result.

Inadequate blood – Too little blood will give an incorrect result. A drop sufficient to cover the pads to all corners is required (5µl).

Moisture damage – The reagent pads are extremely absorbent. If the cap is accidentally left off for even a short period of time the test strips will be damaged by moisture.

If you still experience unusual results that are not in agreement with your symptoms then there may be a problem with your test strips (see quality checks).

Record your blood glucose levels – Keeping a daily record of results allows you to see how well you are controlling your blood glucose levels.

Precautions and limitations

Protect the test strips from sunlight and moisture by replacing the cap immediately after use. For in vitro diagnostic use. Use the test strips only between 18 and 35˚C (64 and 95°F). Use only fresh capillary whole blood from a finger stick. Do not use venous blood, plasma or serum. The test strips are for single use only. Incorrect timing – leaving the blood on too long will cause a falsely high result, and wiping the blood off too early will cause a falsely low result. Hematocrit values above 55% can reduce glucose values by as much as 15%. Hematocrit values below 35% can increase glucose values by as much as 10%. Do not touch the test area as it contains chemicals. Wash hands after accidental contact. Do not use test strips if they have expired. Dispose of used test strips in an appropriate container for contaminated waste.

Quality checks – The test strips can be checked against the “0 Unused” colour block to see they are in good condition. If any sign of blue is visible, the strip should not be used.

Performance characteristics

Measurement range – The measurement range is 20-800 mg/dl (1.1-44.4 mmol/l). A test result lighter than the 1 mmol/l colour standard is less than 1.1 mmol/l (20 mg/dl). A test result darker than the 44.4 mmol/l colour standard is greater than 44.4 mmol/l (800 mg/dl).

Calibration and comparing to lab – The results obtained using Glucoflex-R are equivalent to those obtained using plasma. Results may be compared directly to lab results. The calibration is traceable to a method of higher metrological order.

Accuracy – In a study involving 120 patients attending a diabetes clinic, results obtained using Glucoflex-R gave a correlation coefficient of 0.99, indicating good agreement with the laboratory method.

Precision – The within-lot precision of Glucoflex-R Strips was determined for three lots of strips at four different glucose levels. CV’s for all lots were <5%.

How does the test work? The test zone consists of two test pads containing sensitive chemicals. When blood is applied to the test zone, a chemical reaction takes place, causing colour to develop in direct proportion to the amount of glucose in the blood. The test uses the Glucose Oxidase/Peroxidase reaction.

Chemical composition – Each test strip contains:
- Green field: TMB 18.0 µg, APAC 0.59 µg, Glucose Oxidase 2.4 U, Peroxidase 4.6 U
- Blue field: TMB 17.2 µg, Glucose Oxidase 2.4 U, Peroxidase 4.6 U

Key to symbols:
- Do not reuse
- Temperature limitation
- Use by (unopened or opened test strip container)
- LOT Batch code
- REF Catalogue number
- Caution
- Manufacturer
- Manufacturer
- EC REP
- Authorised Representative in the European Community
- IVD In vitro diagnostic medical device
- Consult instructions for use
- This product fulfills the requirements of European Directive 98/79/EC on in vitro diagnostic medical devices

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