

Part no.	312-4216000-XXX
Product name	血糖/單罐(單片包)試片說明書/GlucoRx X6/EN/GlucoRx/
Spec	L250*W288mm/雜誌紙65P/單面/黑/4折(短邊對一折再長邊對三折)完成尺寸L125*W36mm
Designer	JF
Color	 K 100

Blood Glucose Test Strips

Warnings

- ▶ For **in vitro** diagnostic use (for use outside of the body only).
- ▶ For single use only.
- ▶ Healthcare professionals and other users testing multiple patients with this system should handle everything that comes into contact with human blood carefully to prevent transmitting infectious diseases, including sanitised objects.
- ▶ Please read this sheet and your X6 Multi-Functional Monitoring System Owner's Manual before you use this test strip. Use only GlucorX X6 Blood Glucose Test Strips with GlucorX X6 Multi-Functional Monitoring System to obtain accurate results, and be covered by the manufacturer's warranty.
- ▶ Results may be inaccurate when testing on patients with abnormally low blood pressure or those who are in shock.
- ▶ For patients with impaired peripheral circulation, collection of capillary blood from the approved sample sites is not advised as the results may not be a true reflection of the physiological blood glucose level. It may apply under the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to stress hyperglycaemia, hyperosmolar non-ketotic coma, shock, decompensated heart failure NYHA Class IV or peripheral arterial occlusive disease.
- ▶ Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

Intended Use

GlucorX X6 Blood Glucose Test Strips, when used together with GlucorX X6 Multi-Functional Monitoring System, allow your blood glucose levels to be measured by yourself at home or by healthcare professionals. It uses fresh capillary whole blood samples from the fingertip, and from venous, arterial and neonatal whole blood. This system is not intended for use in the diagnosis or screening of diabetes mellitus. It can be used on neonates.

Professionals may use test strips to test capillary, venous, arterial and neonatal blood sample; home use is limited to capillary whole blood testing.

Limitations

- ▶ Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- ▶ Haematocrit: The haematocrit level is limited to between 0% and 70%. Please ask your healthcare professional if you do not know your haematocrit level.
- ▶ Neonatal Use: **This test strip can be used for the testing of newborns.**
- ▶ Metabolites: Dopamine, L-Dopa, methylidopa, uric acid, ascorbic acid and acetaminophen at normal blood concentration do not significantly affect blood glucose test results.
- ▶ There is no significant interference in the presence of galactose, maltose or fructose observed in blood glucose tests.
- ▶ Lipemic Effects: Blood triglycerides up to 3000 mg/dL (33.9 mmol/L) do not affect the results significantly, but may affect results at higher levels.
- ▶ Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.
- ▶ Use only heparin for anticoagulation of fresh capillary or venous whole blood.

The following compounds when determined to be in excess of their limitation and tested with the **GlucorX X6** Multi-Functional Monitoring System may produce elevated glucose results:

Summary of substances and concentrations in excess of limitation with interference

Substance	Limiting Concentration (mg/dL)	Therapeutic / Physiologic Concentration Range (or Upper Limit) (mg/dL)
Acetaminophen (Paracetamol)	> 20	0.45 - 3
Ascorbic Acid (Vitamin C)	> 5.0	2
Uric Acid	> 10	2 - 8
Pralidoxime iodide	> 5.0	~ 10 (i.v. Dose 500 mg)

Storage and Handling

IMPORTANT: Do not use the test strips if they have expired.

- ▶ Store the test strips in a cool, dry place between 2°C and 30°C (35.6°F and 86.0°F), and 10% to 90% relative humidity.
- ▶ Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- ▶ Store the test strips in their original vial ONLY. Do not transfer them to a new vial or any other containers. (For strip vial only)
- ▶ Do not touch the test strips with wet hands.
- ▶ Use each test strip immediately after taking it out of the vial or individual foil packet. Close the vial immediately after taking out a strip. (For strip vial only)
- ▶ Keep the vial closed at all times. (For strip vial only)
- ▶ Do not bend, cut, or alter the test strip.

Strip Appearance

- 1. Absorbent Hole**
Apply a drop of blood here.
The blood will be automatically absorbed.
- 2. Confirmation Window**
This is where you confirm if enough blood has been applied to the absorbent hole in the strip.
- 3. Test Strip Handle**
Hold this part to insert the test strip into the slot.
- 4. Contact Bars**
Insert this end of the test strip into your meter.
Push it in firmly until it will go no further.

ATTENTION

The front side of the test strip should face up when inserting the test strip.

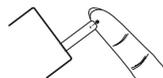
Test results may be wrong if the contact bar is not **fully** inserted into the test slot.

Testing Your Blood Glucose

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.

STEP 1

Insert the test strip fully into the slot of the meter until it will go no further. When the strip is fully inserted, the meter will do several self-checks.



STEP 2

Collect a blood sample of about 0.5 µL with the test strip. Wipe off the first drop of blood with a clean cotton swab. A sufficient quantity of blood is required for the test to provide accurate results. Touch the blood drop with the absorbent hole of the test strip and wait until the confirmation window is fully covered. The meter will start counting down. **Do NOT** apply a smeared blood sample.



STEP 3

After a few seconds, the meter will display your blood glucose level. The last reading will be automatically saved in the meter. Turn it off by removing the test strip and throw away the used test strip.

Example result

Please refer to your Owner's Manual for further information.

The used lancet and test strip are potentially biohazardous. Please dispose of them carefully according to your local regulations.

Reading Your Result

Blood glucose monitoring plays an important role in diabetes control. A long-term study showed that maintaining blood glucose levels close to normal can reduce the risk of diabetes complications by up to 60%.^{*1} The results provided by this system can help you and your healthcare professional monitor and adjust your treatment plan to gain better control of your diabetes. The blood glucose readings deliver plasma equivalent results and are displayed in millimoles of glucose per liter of blood (mmol/L).

Reference values:

Time of day	Normal plasma glucose range for people without diabetes (mmol/L)
Fasting ^{*2} and before meal	Less than 5.5 mmol/L
2 hours after meals	Less than 7.8 mmol/L

*1: American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2020 Jan; 43 (Supplement 1): S14-S31.
<https://doi.org/10.2337/dc20-S002>

*2: Fasting is defined as no caloric intake for at least 8 hours.

Please consult your doctor to determine a target range that works best for you.

Questionable or inconsistent results

If your test results are unusual or inconsistent with how you are feeling:

- Make sure the confirmation window of your test strip is completely filled with blood.
- Check the expiry date of your test strips.
- Check the performance of your meter and test strip with the control solution.

PLEASE NOTE: Unusually high or low blood glucose levels may be symptoms of a serious medical condition. If most of your results are unusually high or low, please contact your healthcare professional.

Quality Control Testing

Our control solution contains a known amount of glucose that can react with test strips. If you suspect your meter or test strips are not working properly, you can check the performance of the meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial or on the package. Please refer to the Owner's Manual for complete testing instructions.

IMPORTANT: The reference range of the control solutions may vary with each new vial or package of test strips. Make sure you check the range on the label of your current vial or on the current package.

Chemical Components

Glucose dehydrogenase (<i>E. coli</i>)	8%
Electron shuttle	55%
Enzyme protector	8%
Non-reactive ingredients	29%

Additional Information for Healthcare Professionals

Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only. Professionals may use test strips to test capillary, venous, arterial and neonatal blood sample.

Sample Size: 0.5 µL

Reaction Time: 5 seconds

System Measurement Range: 0.56 to 44.4 mmol/L

Haematocrit Range: 0% to 70%

Accuracy

Diabetes experts have suggested that glucose meters should be within ±0.83 mmol/L of the reference method when the glucose concentration is lower than 5.55 mmol/L, and be within ±15% of the reference method when the glucose concentration is 5.55 mmol/L or higher. The three tables below display how often GlucorX X6 achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well GlucorX X6 performed compared to Cobas C311 reference method results.

Table 1 Accuracy results for glucose concentration < 5.55 mmol/L (Capillary)

Within ±0.28 mmol/L	Within ±0.55 mmol/L	Within ± 0.83 mmol/L*
73.4% (185/252)	95.6% (241/252)	100% (252/252)

Table 2 Accuracy results for glucose concentration < 5.55 mmol/L (Capillary)

Within ±5%	Within ±10%	Within ±15%
68.8% (487/708)	96.2% (681/708)	99.7% (706/708)

Table 3 Accuracy results for glucose concentrations between 0.8 mmol/L to 41.1 mmol/L (Capillary)

Within ±0.83 mmol/L or ±15%
99.8% (958/960)

Table 4 Accuracy results for glucose concentration < 5.55 mmol/L (Venous)

Within ±0.28 mmol/L	Within ±0.55 mmol/L	Within ± 0.83 mmol/L*
63.9% (188/294)	93.2% (274/294)	100% (294/294)

Table 5 Accuracy results for glucose concentration < 5.55 mmol/L (Venous)

Within ±5%	Within ±10%	Within ±15%
49.2% (328/666)	89.3% (595/666)	99.1% (660/666)

Table 6 Accuracy results for glucose concentrations between 0.7 mmol/L to 44.3 mmol/L (Venous)

Within ±0.83 mmol/L or ±15%
99.4% (954/960)

*Acceptance criteria in ISO 15197: 2013 and EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., Cobas C311 reference values minus GlucorX X6's glucose values) should be within ±0.83 mmol/L for glucose concentration < 5.55 mmol/L, and within ±15% for glucose concentration ≥ 5.55 mmol/L.

Note: When GlucorX X6 Blood Glucose Test Strips results are compared to the reference values, difference values below 5.55 mmol/L are expressed in mmol/L, while those above 5.55 mmol/L are in percent.

Consensus Error Grid (CEG)

The analysis of the Consensus Error Grid showed 100% of test results were within zone A and zone B compared to the Cobas C311 reference method. (100% of test results were within zone A, while 0% was within zone B, with no results in zones C, D or E).

Figure 1 Error grid analysis of the Consensus Error Grid (mmol/L)

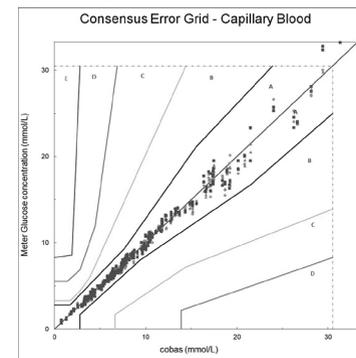


Table 1 Definitions of the Error Grid Zones (CEG)

Risk level (CEG zone)	Percentage	Risk to diabetic patient
100%	A	No effect on clinical action.
0%	B	Altered clinical action – little or no effect on clinical outcome.
0%	C	Altered clinical action – likely to affect clinical outcome.
0%	D	Altered clinical action – could have significant medical risk.
0%	E	Altered clinical action – could have dangerous consequences.

User performance

A study evaluating glucose values from fingertip capillary blood samples obtained by 160 lay persons showed the following results:
97.5% within ±0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 98.3% within ±15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

Precision

The CV (%) is less than 5% both in intermediate precision and repeatability precision.

Symbol Information

Symbol	Referent	Symbol	Referent
	In vitro diagnostic medical device		Manufacturer
	Consult instructions for use		Authorised representative in the European Community
	Temperature limit		Do not re-use
	Use-by date		CE mark
	Batch code		Humidity limitation
	Caution		Catalogue number
	RoHS Compliance		

Distributed by **GlucorX Ltd.**
Unit 1C Henley Business Park,
Pirbright Road, Guildford, Surrey,
GU3 2DX, UK
Customer Careline: 01483-755133
www.glucorx.co.uk

TaiDoc Technology Corporation
Unit 1C Henley Business Park,
B1-7F, No. 127, Wugong 2nd Rd., Wugu Dist.,
24888 New Taipei City, Taiwan
www.taidoc.com
 MedNet EC-REP GmbH
Borkstraße 10, 48163 Münster, Germany

Use only with **GlucorX X6**
Multi-Functional Monitoring System.



For self-testing.
100% 90% 2°C 30°C