

## 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 has come into contact with human blood carefully to prevent transmitting infectious diseases, including sanitised objects.
- ▶ Please read this sheet and your Blood Glucose Monitoring System Owner's Manual before you use these test strips. Use only GlucorX Vivid Test Strips with GlucorX Vivid Blood Glucose 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 their physiological blood glucose level. It may apply in 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, seek medical assistance immediately.
- ▶ Patients undergoing oxygen therapy may yield falsely low results.

### Intended Use

GlucorX Vivid test strips, when used together with GlucorX Vivid Blood Glucose Monitoring System, allows your blood glucose levels to be measured by yourself at home or by healthcare professionals.

They can use fresh whole blood samples from the finger, palm, upper arm or forearm. This system is not intended for use in the diagnosis or screening of diabetes mellitus.

Professionals may use these test strips to test capillary and venous whole blood; home use is limited to capillary whole blood testing.

### About Alternative Site Testing (AST)

**IMPORTANT:** There are limitations for performing AST. Please read your GlucorX Vivid Blood Glucose Monitoring System Owner's Manual and consult your doctor before you perform AST.

Alternative site testing (AST) is when individuals check their blood glucose levels using areas of the body other than the fingertip. The GlucorX Vivid Test Strips allow AST to be performed on sites other than the fingertip. We strongly recommend that you perform AST **ONLY** at the following times:

- During a pre-meal or fasting state (more than 2 hours since your last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do **NOT** use AST if:

- You think your blood glucose is low (you may not notice if you are hypoglycaemic).
- Your AST results are inconsistent with the way you feel.
- You are testing for hyperglycaemia.
- Your routine blood glucose results often fluctuate.

To obtain a blood sample from the alternative sites, please **rub the puncture site for approximately 20 seconds before following** the procedures of "Testing Your Blood Glucose".

### Limitations

- ▶ Haematocrit: The Haematocrit level is limited to between 35% and 60%. Please ask your healthcare professional if you do not know your Haematocrit level.
  - ▶ Neonatal Use: **These test strips must not be used for testing on newborns.**
  - ▶ Metabolites: Dopamine, L-Dopa, methyldopa, uric acid, ascorbic acid, and acetaminophen at normal blood concentration do not significantly affect blood glucose test results.
  - ▶ No significant interference in the presence of xylose, maltose or fructose has been observed in blood glucose tests.
  - ▶ Lipemic Effects: Blood triglycerides up to 33.9 mmol/L do not affect results significantly, but may affect results at higher levels.
  - ▶ Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.
- The following compounds, when determined to be in excess of their limitation and tested with the GlucorX Vivid Blood Glucose Meter, may produce elevated glucose results:

### Summary of substances and concentrations in excess of limitation with interference

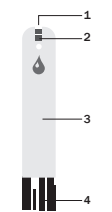
Substance	Limiting Concentration (mmol/L)	Therapeutic / Physiologic Concentration Range (or Upper Limit) (mmol/L)
Acetaminophen (Paracetamol)	> 0.41	0.03 – 0.20
Ascorbic Acid	> 0.28	0.11
Pralidoxime Iodide	> 0.19	~ 0.38 (i.v. Dose 500 mg)

### 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°F) and 10% to 85% 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 container.
- ▶ Do not touch the test strips with wet hands.
- ▶ Close the vial immediately after taking out a strip. Use each test strip immediately after taking it out of the vial.
- ▶ Keep the vial closed at all times.
- ▶ Do not bend, cut, or alter the test strips.

### Strip Appearance



#### 1. Absorbent Hole

Apply a drop of blood here. The blood will automatically be absorbed.

#### 2. Confirmation Window

This shows if enough blood has been drawn into the absorbent hole of the strip.

#### 3. Test Strip Handle

Hold this part to insert your test strip into the slot.

#### 4. Contact Bars

Insert this end of your test strip into the meter. Push it in firmly until it will go no further.

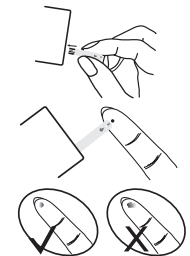
#### ATTENTION

The front side of the test strip should face upwards when inserting it into your meter.

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 your 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 0.7 µL with the test strip. A sufficient quantity of blood is required for the test to provide accurate results. Touch the blood drop with the absorbent hole of your test strip and wait until the confirmation window is fully covered. **Do NOT** apply a smeared blood sample. Your meter will start counting down.

#### 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 and discarding the used test strip.

5.5 mmol/L

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

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

### Reading Your Result

Your blood glucose readings deliver plasma equivalent results and are displayed in millmole of glucose per litre of blood (mmol/L). The measurement range of your meter is 1.1-33.3 mmol/L.

#### Reference values

Time of day	Normal blood glucose range for people with diabetes
Fasting and before meal	4-7 mmol/L
2 hours after meals	Less than 9 mmol/L

Source: Diabetes UK. Blood glucose target. Balance: No.234, 2010 April. P.69

**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 the 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

Taidoc control solution contains a known amount of glucose that can react with test strips. You can check the performance of your meter, test strip and technique by comparing the control solution result with the range printed on the label of your test strip vial. Checking regularly can ensure your test results are accurate. Please refer to your Owner's Manual for complete testing instructions.

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

### Chemical Components of Sensor

- > Glucose dehydrogenase (*E.coli*) 8%
- > Enzyme protector 8%
- > Electron shuttle 55%
- > 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 these test strips to test capillary whole blood.

**Sample Size:** 0.7 µL

**Reaction Time:** 5 seconds

**System Measurement Range:** 1.1 mmol/L to 33.3 mmol/L

**Haematocrit Range:** 35% to 60%

#### 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 5.5 mmol/L, and be within ±15% of the reference method when the glucose concentration is 5.5 mmol/L or higher.

The six tables below display how often GlucorX Vivid meter achieves these targets respectively. The charts are based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well the GlucorX Vivid meter performed compared to YSI-2300 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 *
60.2% (177/294)	89.8% (264/294)	100% (294/294)

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

Within ±5 %	Within ±10 %	Within ±15 %*
49.5% (330/666)	81.2% (541/666)	96.4% (642/666)

Table 3 Accuracy results for glucose concentrations between 1.79 mmol/L to 29.22 mmol/L (Capillary)

Within ±0.83 mmol/L or ±15%
97.5% (936/960)

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 *
58.8% (201/342)	92.1% (315/342)	99.4% (340/342)

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

Within ±5%	Within ±10 %	Within ±15 %*
41.9% (259/618)	78.0% (482/618)	96.4% (596/618)

Table 6 Accuracy results for glucose concentrations between 1.77 mmol/L to 29.89 mmol/L (Venous)

Within ±0.83 mmol/L or ±15%
97.5% (936/960)

\*Acceptance criteria in ISO 15197:2013 and EN ISO 15197:2015, 95% of all differences in glucose values (i.e., YSI-2300 reference values minus GlucorX Vivid meter'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 Vivid 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 Yellow Spring 2300 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 Error grid analysis of the Consensus Error Grid (mmol/L)

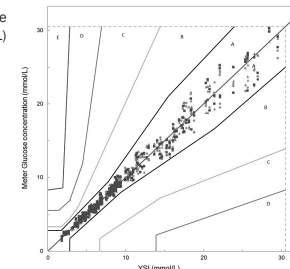


Table Definitions of the Error Grid Zones (CEG)

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 154 lay persons showed the following results:  
100% within ±0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 95.5% within ±15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L. 160 subjects tested on the alternative sites, the palm, the forearm and the upper arm. The tables show how well GlucorX Vivid performed compared to YSI-2300 reference method results.

### 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		Batch code
	Consult instructions for use		Manufacturer
	Temperature limitation		Humidity limitation
	Use by		Authorised representative in the European Community
	Do not reuse		CE mark
	Caution		RoHS compliance
	Catalogue number		

### Use Only With GlucorX Vivid Blood Glucose Monitoring System.

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