



## Blood Glucose Test Strips (Glucose Dehydrogenase Method) Instructions

### Important Note:

Users should read all information in this instructions and instructions for the blood glucose meter carefully when using the Yuwell blood glucose test strip for testing.

### [ Product name ]

● General name: blood glucose test strips (glucose dehydrogenase method)

### [ Package specifications ]

Blood glucose test strips (Model: Y350): 50-piece package.

### [ Intended use ]

Blood glucose test strips (hereinafter referred to as test strips) are mainly used for *in vitro* quantitative detection of glucose concentration in fingertip fresh capillary whole blood and vein whole blood.

● Test strips can be used for blood glucose monitoring by a professional or a diabetic user at home or in a medical unit.

● Test strips are only used to monitor the effect on blood glucose control of diabetics, but can not be used for the diagnosis and screening of diabetes, nor used as the basis for the adjustment of therapeutic drugs.

### [ Testing principle ]

The test paper absorbs the sample by capillary action. The sample quickly dissolves flavin adenine dinucleotide-dependent glucose dehydrogenase (FAD-GDH), hexaammineruthenium (III) chloride, and some non-reactive substances (malic acid, polyvinylpyrrolidone) in the reaction zone. The glucose in the sample reacts to produce a micro current that is detected by the blood glucose meter. The current intensity is directly proportional to the blood glucose concentration in the blood sample, and the blood glucose meter detects the micro-current and converts it into blood glucose concentration.

### [ Main ingredients ]

● The main ingredients of the test strip: 10% flavin adenine dinucleotide-dependent glucose dehydrogenase (FAD-GDH), 35% hexaammineruthenium (III) chloride, 55% non-reactive substance (2% malic acid, 2% polyvinylpyrrolidone).

● It can be used together with any lancet that has obtained a CE medical device registration certificate.

### [ Storage conditions and shelf life ]

● Unopened test strips shall be sealed and stored in a dark, dry place away from direct sunlight, and it is forbidden to place it into a refrigerator.

● Storage environment restrictions: ambient temperature range: 4 °C–30 °C, relative humidity range: 10%–85%.

● Each time the test strip is removed from the tube, the cover should be tightly closed to prevent the test strip from moisture in the air.

● Unopened test strips are valid for 24 months from the date of production.

● The validity period of the test strip after opening is 3 months (not exceeding the expiration date on the test strip label). After the test strip is opened, please mark the opening date in time to avoid forgetting or exceeding the expiration date.

● Single-piece packaged test strips can be opened for direct use.

● Do not use test strips that are expired.

● Improper storage of test strips will affect the test results.

● The blood glucose control solution should be stored at a temperature of 4°C to 30°C for a period of 12 months. After opening for 3 months (not exceeding the expiration date on the label of the control solution bottle), please dispose of all unused solution. Please note the expiration date on the label of the control solution bottle.

### [ Instruments applied ]

This product is suitable for yuwell blood glucose meter: 660.

### [ Sample requirements ]

● When sampling, fingertips should be gently rubbed to form blood droplets, and blood samples should be tested immediately.

● When using a sample of fresh capillary whole blood, the first droplet should be wiped off and the second drop of whole blood sample should be used for detection.

● A sample of venous whole blood must be taken by medical personnel. Anticoagulant tube with sodium heparin, lithium heparin, sodium citrate can be used to take blood samples. Do not use test tubes with other anticoagulant. In order to avoid glycolysis, test must be performed within 20 minutes after blood collection.

● Sample size: 0.8 μL

● Blood glucose testing should be performed immediately after blood collection. If the blood sample for testing is squeezed too much that contaminates test strips or the blood sample is insufficient to fill the reaction area, please take a piece of test strip again for testing.

● The detection results of the selective detection site may differ from the detection results on fingers when the glucose level changes rapidly such as after a meal, taking a hypoglycemic agent, during an insulin injection, or after exercise.

### [ Testing method ]

The frequency and time of blood glucose monitoring should follow the guidance of medical profession-als.

### Required items for testing

● Prepare blood glucose meter, test strips, lancet.

● The test strip can only be used with a matching blood glucose meter.

● At least 2 levels of blood glucose control solution are available.

### Environmental requirements required for testing

● Excessive changes in the ambient temperature affecting the test results should be avoided when testing blood glucose

● Ambient temperature range: 10°C–40°C

● Relative humidity range: 10%–85%

● Exceeding the detection temperature or humidity may result in wrong test results.

### Specific steps for blood glucose testing

● Check the use by date on the test strip container. Do not use test strips past the use by date.

● Prepare the lancing device.

● Wash hands with soapy and warm water, wipe dry, or use alcohol swabs for cleaning.

### Blood sampling

● Step 1: Select the sampling site, usually fingertip capillary whole blood.

Note: It is not appropriate to collect blood in the area of edema or infection.

● Step 2: Get a small drop of blood for testing.

Note: wipe off the first drop and use the second drop of blood. Do not squeeze the sampling site with force.

### Blood glucose test

● Step 1: insert test strip.

After taking out a piece of test strip, immediately close the tube cap, insert the test strip into the meter, the side with yuwell facing up, push the test strip to the end, and the blood glucose meter will start automatically. Make sure that the calibration code displayed on the screen matches that on the label. Please complete the blood glucose test within 3 minutes after starting.

● Step 2: absorb blood samples.

When the blood drop symbol is displayed on the screen, touch the blood sample to the front edge of the window of the test strip and the blood sample will be sucked. Please ensure that the blood sample is filled with the reaction area.

● Step 3: read the result.

● The screen displays the blood glucose test results in 10 seconds. The test result is displayed in mmol/L (or mg/dL)

● If the mg/dL for testing is squeezed too much that contaminates test strips or the blood sample is insufficient to fill the reaction area, please take another piece of test strip again for testing.

### [ Use of control solution ]

● The control solution is used to test whether the self-test blood glucose monitoring system works normally and whether it is used correctly. For accurate results, follow these instructions:

1. Before testing, test strips, blood glucose meter and control solution should be placed at room temperature (20°C–25°C).

2. Shake the control solution before use.

3. After discarding the first drop of control solution, wipe the dropper tip.

4. Drop the control solution in the measurement area of the test strip.

● 50 measurements can be conducted with one bottle of solution.

● It is recommended to conduct control solution test in the following cases: 1. Replace the test paper with new batch; 2. Replace the battery in blood glucose meter; 3. The glucose meter and test strips are not in optimal conditions (impact, falling, high temperature, low temperature, humidity, etc.).

The test result is not within the target value range (target value range: refer to the label on the bottle or on the box), indicating that the self-test blood glucose monitoring system is not stable, please immediately retest with a new test strip. If the result is still not within the target range, stop the blood glucose test immediately and contact the dealer or customer service personnel.

### [ Reference range ]

● The study of non-diabetic patients gives a reference range for normal plasma glucose values in the following cases:

MT	Reference value	Range (mmol/L)	Range (mg/dL)
	Fasting	3.9–6.1	70–110
2 hours after meal	<7.8	<140	

This reference value is derived from the research data of 200 non-diabetic patients. Because of the population differences, climate differences in different regions, etc., the reference range of the blood glucose test strip is also different. To ensure the accuracy and scientificity of the clinical test report, the clinical laboratory is recommended to establish a reference range for blood glucose test strips based on relevant literature and clinical data.

### [ Explanation of test results ]

● The blood glucose test results can be obtained by this product in 10 seconds.

● If your test result exceeds the normal reference value, it is recommended to use a new test strip to retest. If similar results are obtained, please contact a professional medical staff. If the fasting test result is lower than 3.9 mmol/L, indicating hypoglycemia. The fasting test results for

adults without diabetes should be less than 6.1 mmol/L. Consult a professional medical staff to determine if you have diabetes.

● The test sample of this product is whole blood, but the test result is based on the plasma.

● The test result is displayed in mmol/L.(or mg/dL)

● When the test result is lower than 1.1 mmol/L (20 mg/dL), the blood glucose meter screen will display “LO” , and if it is higher than 33.3 mmol/L (600 mg/dL), the blood glucose meter screen will display “HI” .

● When the ambient temperature is lower than 10°C or higher than 40°C, the test results may be significantly affected.

● When the ambient humidity is lower than 10% or higher than 85%, the test results may be significantly affected.

● If the blood sample is insufficient to fill the reaction zone, the test results may be significantly affected. It is recommended to take a new test strip for testing. If the blood sample exceeds the minimum sample volume, there is no effect on the test results.

● When the peripheral circulation is poor and the amount of blood is insufficient, the test results may be affected, and the test results may not reflect the actual physiological conditions. At this time, you should go to the medical unit to ask a professional for testing.

● When the test results do not match your own, it is recommended to repeat the test with a new test strip. If the results are still abnormal, please contact a professional medical staff immediately. Do not adjust your medication according to the test results of yuwell blood glucose test strip before consulting your doctor or medical staff.

● Causes of false test results may be:

● Expiration of test strips.

● Improper storage of test strips, such as dampness.

● Fault of blood glucose meter.

● Not tested under the specified temperature and humidity.

[ Limitation of test method ]

● This product is only used for the monitoring of blood glucose levels in diabetics. It cannot be used for the diagnosis and screening of diabetes, neither can it be used for the glucose test related to glucose metabolism disorders.

● In exceptional cases (such as dehydration, hyperosmolar hyperglycemia, severe hypotension, shock, etc.), deviations may occur in the test results.

● The test is performed immediately during or after the xylose absorption test. Xylose in the blood may interfere with blood glucose test results.

● The hematocrit is not within the range of 10%~70%, which obviously affects the test results.

● Blood concentrations of ascorbic acid > 3mg/dL will cause overestimation of blood glucose results.

● Blood concentrations of EDTA > 270 mg/dL will cause underestimate of blood glucose results.

● Anticoagulant tube with sodium heparin, lithium heparin, sodium citrate can be used to take blood samples. Do not use test tubes with other anticoagulant.

● The control solution is only suitable for blood glucose test strips (model: Y350) and blood glucose meter (model: 660)

[ Product performance index ]

Yuwell self-test blood glucose monitoring system meets the standard EN ISO 15197-2015 in vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

● Calibration and traceability

The system (blood glucose meters and test strips) is calibrated using venous blood with different blood glucose concentrations. It is traceable to NIST (National Institute of Standards and Technology) SRM (Standard Reference Material) 917c.

● Detection range: 1.1—33.3 mmol/L

● System accuracy

Fingertips: System accuracy when blood glucose concentration is below 5.55 mmol/L (100 mg/dL)		
Within ± 0.28 mmol/L (Within ± 5 mg/dL)	Within ± 0.56 mmol/L (Within ± 10 mg/dL)	Within ± 0.83 mmol/L (Within ± 15 mg/dL)
147/168(87.5%)	166/168 (98.8%)	168/168(100%)
Fingertips: System accuracy when blood glucose concentration is above or equal to 5.55 mmol/L (100 mg/dL)		
Within ± 5%	Within ± 10%	Within ± 15%
261/444 (58.8%)	407/444 (91.7%)	444/444 (100%)
Within ± 15% or Within ± 0.83 mmol/L (Within ± 15 mg/dL)		
612/612 (100%)		

Venous blood: System accuracy when blood glucose concentration is below 5.55 mmol/L (100 mg/dL)		
Within ± 0.28 mmol/L (Within ± 5 mg/dL)	Within ± 0.56 mmol/L (Within ± 10 mg/dL)	Within ± 0.83 mmol/L (Within ± 15 mg/dL)
164/186 (88.2%)	184/186 (98.9%)	186/186(100%)
Venous blood: System accuracy when blood glucose concentration is above or equal to 5.55 mmol/L (100 mg/dL)		
Within ± 5%	Within ± 10%	Within ± 15%
344/426 (80.8%)	423/426 (99.3%)	426/426 (100%)
Within ± 15% or Within ± 0.83 mmol/L (Within ± 15 mg/dL)		
612/612 (100%)		

● Performance assessment by the user: A study evaluating glucose values from fingertip capillary blood samples obtained by 102 lay persons showed the following results:

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

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

● Repeatability

Mean (mg/dL)/(mmol/L)	44.5(2.5)	88.3(4.9)	136.3(7.6)	197.3(11)	348.5(19.4)
Standard deviation (mg/dL)/(mmol/L) Or coefficient of variation	1.51(0.08)	2.60(0.14)	2.8%	2.9%	1.4%

● Intermediate precision

Control solution level	Mean(mg/dL)/(mmol/L)	Standard deviation (mg/dL)/(mmol/L) Or coefficient of variation
Low	66.1(3.7)	1.84(0.10)
Medium	225.6(12.5)	2.6%
High	375.1(20.8)	2.2%

[ Precautions ]

● All packing contents can be disposed of as household waste. Due to the small amount of reactive substances, they are not considered as dangerous substances according to EU regulations. Please dispose of used test strips according to local regulations.

● Notes to users: This product is for in vitro diagnosis only. The blood glucose level measured by the test strip is for reference only. Do not make any treatment changes without the guidance of medical professionals.

● The lancet is only for single use, please do not reuse.

● If your test result exceeds the normal reference value, it is recommended to use a new test strip to retest. If similar results are obtained, please contact a professional medical staff.

● When the test results do not match your own, it is recommended to repeat the test with a new test strip. If the results are still abnormal, please contact a professional medical staff immediately. Do not adjust your medication according to the test results of the test strip.

● This self-test blood glucose monitoring system is used for in vitro diagnosis and monitoring of blood glucose levels in diabetics. It cannot be used for the diagnosis and screening of diabetes.

● Please test your blood glucose according to the standard operating procedures of the instructions, so as not to cause deviations and errors in the test results.

[ Explanation of identification ]

	Refer to instructions for use		Medical device for in vitro diagnosis
	Temperature limit		Batch code
	Validity period		Warning
	Manufacturer		Do not reuse
	Production date		Authorized Representative in the European Community
	Humidity limit		Contains sufficient for <n> tests

[ References ]

1 EN ISO15197-2015 In vitro diagnostic test systems-Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.

2 Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia:report of a WHO/IDF consultation. WHO, Geneva 2006(ISBN 92 4 159493 4,ISBN 978 92 4 159493 6).

[ Basic information ]

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