

TysonBio® AC500 PRO *Test Strip Package Insert*

For Testing Glucose in Capillary Whole Blood

IMPORTANT: Please read this information and your TysonBio AC500 PRO user's manual before using TysonBio AC500 PRO Test Strips. Call TysonBio Customer Service immediately if these instructional materials or your meter results seem unclear.

Intended Use

The TysonBio AC500 PRO Blood Glucose Test Strips are used with the TysonBio AC500 PRO Blood Glucose Meter for quantitatively measuring glucose (sugar) in whole blood obtained from the fingertip, palm and forearm. The TysonBio AC500 PRO Blood Glucose Monitoring System is intended for use by multiple patients in a professional healthcare setting to monitor blood glucose levels. The TysonBio AC500 PRO Test Strips are for testing outside the body (in vitro diagnostic use).

Test Principle

On each test strip there is a test area containing reaction chemicals. When blood is applied to this area, a chemical reaction takes place, then a transient electrical current is formed. The blood glucose concentration is calculated based on the electrical current detected by the meter, then the result is showed on the display. The test measures glucose from 20 mg/dL (1.1mmol/L) to 600 mg/dL (33.3 mmol/L). The TysonBio AC500 PRO Test Strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

Precautions

- For in vitro diagnostic use (outside the body) only.
- Do not reuse test strips.
- Do not use test strips beyond the expiration date printed on the package since this may cause inaccurate results.
- Discard the vial and any unused test strips 3 months after you first open it. Constant exposure test strips to air may destroy chemicals in the test strip. This damage can cause incorrect readings.
- The sample must only be applied to the tip of the test strip. Do not apply blood or control solution to the top, left or right sides of the test strip. This may cause inaccurate test results.
- Keep the test strip vial away from children. The cap is a choking hazard. The cap or vial contains drying agents to protect the test strips. Drying agents may be harmful if inhaled or swallowed and may cause skin or eye irritation.
- **Any change in medication based on the TysonBio AC500 PRO blood glucose test results without the consent and advice of a physician or healthcare professional is not recommended. Consult your physician or healthcare professional before making changes in your treatment plan based on your blood glucose test results.**
- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
- All devices contaminated with blood should be disposed of properly.
- If you get TysonBio AC500 PRO Control Solution test results that fall outside the range printed on the test strip vial, repeat the test with a new test strip. If the test result is still outside the range printed on the test strip vial, the TysonBio AC500 PRO may not be working properly. DO NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip vial label.

Storage and Handling

- Store between 39-86°F (4-30°C). Do not refrigerate or freeze. Avoid exposing test strips to extreme temperatures.
- Store away from direct sunlight and heat.
- Use each strip immediately after removing it from the vial.
- Store your test strips in their original vial only. The cap or vial contains drying agents to protect the test strips. Do not transfer test strips to a new vial or any other container.
- **After removing a test strip from the vial, replace the vial cap immediately and close it tightly.**
- Do not bend, cut, or alter the Test Strip in any way.
- With clean, dry hands you may gently touch the test strip anywhere when removing it from the vial or inserting it into the meter.

Warning

Alternate site testing (AST) should ONLY be used in the following intervals:

- In a pre-meal or fasting state.
(more than 2 hours since the 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 are unaware of hypoglycemia.
- Your AST results do not match the way you feel.
- You are testing for hyperglycemia.
- Your routine glucose results are often fluctuating.
- If you are pregnant.

Limitations:

- (a) AST measurements should never be used to calibrate continuous glucose monitors (CGMs).
- (b) AST measurements should never be used in insulin dosing calculations.

- Users need to adhere to Standard Precautions when handling or using this device. All parts of the glucose monitoring system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of infectious Agents in Healthcare Settings 2007".
<http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>
- The meter should be cleaned and disinfected after use on each patient. This Blood Glucose Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.
- Only auto-disabling, single use lancing devices may be used with this device.
- A new pair of clean gloves should be worn by the user before testing each patient.
- Refer to your user's manual for how to clean and disinfect your meter.

How to do the Test

See the User's Manual for a step-by-step guide on how to do the test.

1. **Select the Puncture Site to Obtain Blood**
You may obtain a blood drop from the fingertip, palm or forearm. When using the fingertip, wash patient's hands and puncture site with warm soapy water. Dry them thoroughly. If using an alcohol swab instead, make sure the skin is dry before lancing. To help get a large enough drop of blood, you may gently massage or apply warmth to the site to increase blood flow. Place and hold the auto-disabling, single use lancing device against patient's fingertip for a few seconds, then press the release button. If using palm or forearm, please see user manual for additional information first.
2. **Blood Glucose Testing**
Insert a test strip into the meter. The arrow should face the front of the meter and be pointed towards the meter when inserted. All segments of the LCD screen will appear, a beep will sound and a clockwise moving dotted line will appear. Discard the first drop of blood to prevent the contamination of body fluid. Touch the tip of the test strip to the drop of blood. Blood is automatically drawn into the test strip. Hold the tip of the test strip touching the blood drop until the meter beeps.
3. **Read Results**
Read the results in an average of 5 seconds. The result will be stored in the meter memory. Results are displayed as mg/dL (milligrams per deciliter of blood). **Wash hands thoroughly with soap and water after landing the meter, lancing devices or test strips.**

What Do Your Results Mean?

Normal Glucose Values

The normal fasting glucose range for a diabetic adult is 70 to 130 mg/dL (3.9 to 7.2 mmol/L). One to two hours after meals, normal glucose values should be less than 180 mg/dL (10.0 mmol/L).¹ For people with diabetes, consult your physician or healthcare professional for the target glucose values that are right for you.

Low Glucose Values

The TysonBio AC500 PRO Meter displays results between 20 and 600 mg/dL (1.1 and 33.3 mmol/L). If your test result is lower than 20, “**Low**” (**LO**) will appear on the meter display. This indicates severe low blood sugar (hypoglycemia). You should immediately treat low blood sugar as recommended by your healthcare professional.

High Glucose Values

If your test result is above 600 mg/dL (33.3 mmol/L), “**High**” (**HI**) will appear on the meter display screen. This indicates severe high blood sugar (hyperglycemia). You should immediately treat high blood sugar as recommended by your healthcare professional.

Unexpected Results

Low or high blood sugar readings can indicate a potentially serious medical condition. If your blood sugar is unusually low or high, or if you do not feel the way your results indicate, repeat the test with a new test strip. **If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), you should contact your healthcare professional and follow his or her treatment advice.**

Limitations

The TysonBio AC500 PRO Blood Glucose Test Strips give accurate results when the following limitations are observed:

- 1. Use only the TysonBio AC500 PRO Test Strip with the TysonBio AC500 PRO Meter.
- 2. **Use only capillary whole blood from finger, palm and forearm. Do not use plasma or serum.**
- 3. **Do not use neonate samples.** TysonBio AC500 PRO Test Strips are not validated for and should not be used for testing neonatal blood specimens.
- 4. The system is tested to accurately read the measurement of glucose in whole blood within the range of 20 to 600mg/dL (1.1-33.3 mmol/L).
- 5. This system can be used up to an altitude of 7545 feet.
- 6. The test strips are for single use only. Do not reuse test strips.
- 7. TysonBio AC500 PRO Test Strip does not interfere with the hematocrit at a normal range (30-55%) of blood glucose.
- 8. Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances when occurring in normal blood or normal therapeutic concentrations do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- 9. Lipemic samples; Cholesterol up to 500 mg/dL or triglycerides up to 1,500 mg/dL do not significantly affect test results. However, glucose values in specimens beyond these levels, should be interpreted with caution.
- 10. Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- 11. Antiglycolysis and anticoagulants in blood samples may affect the test results.
- 12. Severe dehydration, diabetic ketoacidosis, hyperosmolar non-kitotic state, hypotension, shock, or peripheral vascular disease.^{2,3,4} may cause inaccurate results.
- 13. Critically ill patients should not be tested with home use blood glucose monitors as it may lead to inaccurate results.

Quality Control

The control solutions are used to check the performance of the TysonBio AC500 PRO meter, Test Strips, and your testing technique. The system is performing correctly if the control solution test result falls within the specific control solution range listed on your Test Strip vial. If control solution test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:

- error in performing the test,
- expired or contaminated control solution,
- test strip deterioration or meter malfunction.

If the problem persists, the system may not be working properly. DO NOT continue to use the system to test your blood glucose level. If you continue to get results that fall outside the specified range, please call Customer Service.

Note: TysonBio AC500 PRO Control Solutions are required but not supplied with Test Strips for checking the system. For order information, please contact Customer Service. There are three TysonBio AC500 PRO Control Solutions at different desired range of aqueous glucose (Level 1, Level 2 or Level 3). Two sets of control solution should be used, a high level and a low level control solution of your choice. For more information about the Control Solution, please read your Control Solution package insert.

Performance Characteristics

Measuring Range

20-600mg/dL (1.1mmol/L to 33.3 mmol/L)

Accuracy

The accuracy of the TysonBio AC500 PRO System was compared with YSI 2300 Stat Plus glucose analyzer with fingertip testing done by persons with diabetes. The linear regression statistics are derived from a plot of the TysonBio AC500 PRO capillary data (y) versus YSI glucose analyzer (x). The linear regression equation for the study was y=1.02x+3.64. The coefficient was 0.9859. The sample numbers were 138. The glucose range of the sample was 59-505mg/dL.

Fingertip results

ISO 15197 requirement: 95% of individual glucose results falling within ±15mg/dL at glucose concentration for samples <75mg/dL and within ±20% at glucose concentrations ≥ 75mg/dL.

Difference distribution for glucose concentration <75mg/dL

within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
5/8 (63%)	5/8 (63%)	8/8 (100%)

Difference distribution for glucose concentration ≥ 75mg/dL

within ±5%	within ±10%	within ±15%	within ±20%
55/130 (42%)	97/130 (75%)	122/130 (94%)	128/130 (99%)

Alternate site testing results

Difference distribution for glucose concentration <75mg/dL

	within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
Palm	3/8 (38%)	7/8 (88%)	8/8 (100%)
Forearm	4/8 (50%)	5/8 (63%)	8/8 (100%)

Difference distribution for glucose concentration ≥ 75mg/dL

	within ±5%	within ±10%	within ±15%	within ±20%
Palm	66/130 (51%)	106/130 (82%)	125/130 (96%)	128/130 (99%)
Forearm	63/129 (49%)	106/129 (82%)	123/129(95%)	127/129(98%)

Precision

Between-run precision of TysonBio AC500 PRO test strips was measured with venous blood samples in the laboratory. The pooled precision data for total three hundred test strips from 3 lots (n=300) is shown in the tables below:

Between-Run Precision

Average Glucose Concentration (mg/dL)	40.6	74.8	132	229	356
SD (mg/dL)	2.3	2.4	3.7	4.5	5.1
CV (%)	5.4	3.2	2.8	2.0	1.4

Chemical Composition

Glucose oxidase (Aspergillus niger)	1.4% w/w
Potassium ferricyanide	2.6% w/w
Non-reactive ingredients	96% w/w

References

- 1. American Diabetes Association Clinical Practice Recommendations, Diabetes Care, 2008:31(supplement 1)S12-S54.
- 2. Atkins SH, Dasmahapatra A, Jaker MA, Chorost MI, Reddy S: Fingertick glucose determination in shock. Ann Int Med 114: 1020-1024. 1991
- 3. Sandler M, Low-Beer T: Misleading capillary glucose measurements. Practical Diabetes 7: 210. 1990
- 4. Wickham NWR, Achar KN, Cove DH: Unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes 3: 100. 1986

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Made in Taiwan

For in vitro diagnostic use