

TRUEbalance® Blood Glucose Test Strips

Instructions for Use

Intended Use

TRUEbalance Blood Glucose Test Strips are used with TRUEbalance Meters to quantitatively measure whole blood glucose. TRUEbalance can be used for self-testing at home or for professional use. TRUEbalance is for *in vitro* diagnostic use only.

Test Principle

The TRUEbalance Test Strip is a plastic Strip containing chemistries and electrodes. TRUEbalance measures glucose by using amperometric technology employing a glucose oxidase reaction. When whole blood or Control is drawn into the tip of a Test Strip, glucose in the sample reacts with chemicals and produces an electrical current. The Meter measures electrical current and calculates amount of glucose. The glucose result is displayed as a plasma value.

Chemical Composition

Glucose oxidase (*Aspergillus sp.*) 2.5 units, mediators, buffers and stabilizers.

① **Contact End** End of Strip inserted into Meter.
 ② **Sample Tip** Pointed end of Strip where sample is drawn into Strip.

Top of Test Strip

Correct Incorrect

WARNING!

Upon opening the test strip carton, examine the product for missing, damaged or broken parts. Ensure the test strip vial cap is securely closed. If the product is damaged or the vial cap is not closed, DO NOT use the test strips for testing; product may give inaccurate results. Contact Trividia Health Customer Care at 1-800-803-6025 for replacement and assistance.

Caring for Test Strips

- Use Strip quickly after removing from vial. Recap vial right away. Strips left outside of vial too long may give an error message.
- Strips **must** be kept in original vial, with vial cap tightly sealed. NEVER transfer Strips from one vial to another.
- Write date opened on Strip vial label when removing first Strip. Discard all unused Strips in vial after date printed on the Strip vial label, or 120 days after date opened, if either date has passed.
- Store Strip vials in a dry place at room temperature below 86°F (30°C). **DO NOT REFRIGERATE OR FREEZE.** DO NOT store in bathroom or kitchen. DO NOT expose to extreme heat or cold, direct sunlight, or high humidity for any length of time.
- DO NOT reuse Test Strips.
- DO NOT bend, cut or alter Test Strips in any way.

Important Information

- Test Strips are for *in vitro* testing only. **DO NOT consume.**
- ONLY** use TRUEbalance Test Strips with TRUEbalance Meters and TRUEcontrol® Control. Using other Meters or Control may give inaccurate results.
- WARNING!** NEVER reuse Test Strips. NEVER wipe Test Strips with water, alcohol, or any cleaner. **DO NOT** attempt to remove blood or control sample from Test Strips or clean Test Strips and re-use. Reuse of Test Strips will cause inaccurate results.
- NEVER** add a second drop of sample to Strip. Adding more sample gives an error message.
- Do not change your medication or treatment plan based on results from the TRUEbalance Strips and TRUEbalance Meter without advice of Doctor or Diabetes Healthcare Professional.
- Discard used Test Strips and Lancets into an appropriate container (biohazard/ for sharp objects).
- Using Test Strips past written or printed dates on the Strip vial label may cause inaccurate results.
- Discard any Strips or vials that appear damaged.
- NEVER** use serum, plasma, or clotted blood when testing with TRUEbalance. **ONLY** use fresh capillary whole blood from the finger or forearm.
- TRUEbalance is not recommended for use with venous samples.**
- Lancing device is for self-testing and intended for use by one patient **ONLY**. Not suitable for use by healthcare or care workers.
- When using the forearm for blood sample:¹
 - Check with your Doctor or Diabetes Healthcare Professional to see if forearm testing is right for you.
 - Results from forearm are not always the same as results from finger.
- Use finger instead of forearm for more accurate results:
 - Within 2 hours of eating, exercise, or taking insulin,
 - If your blood sugar may be rising or falling rapidly or your routine results are often fluctuating,
 - If you are ill or under stress,
 - If your forearm test results do not match how you feel,
 - If your blood sugar may be low or high,
 - If you do not notice symptoms when blood sugar is high or low.

Quality Control (QC) Testing

There are two quality control tests to let you know that the System is working properly.

Quality Control Test: Automatic Self-Test

An automatic self-test is performed each time a TRUEbalance Test Strip is inserted into a TRUEbalance Meter. Upon inserting a Strip into the Test Port, if all segments appear and the Drop Symbol appears in the Display, the Meter is working properly.

Quality Control Test: Control

TRUEcontrol Glucose Control is used to check testing technique and System performance. When Control results fall within ranges found on Test Strip vial label of Test Strips being used, System is working properly and testing technique is good. See Owner's Booklet or TRUEcontrol Glucose Control Instructions for Use for more information on Control Testing.

Important Information

There are three levels of TRUEcontrol Glucose Control available that contain known amounts of glucose. It is important to perform Control Tests with more than one level of Control to assure your System is working properly and your testing technique is good. For more information on obtaining different levels of Control, call 1-800-803-6025 or 1-954-677-4599.

Blood Glucose Testing

- Wash area to be lanced. Dry thoroughly.
- Allow Meter and Test Strips to sit at room temperature for 30 minutes before using. If opening vial for the first time, write date opened on vial label.
- Check EXP on Strip vial. Do not use if past either 120 days after date first opened (written date) or date printed on the Test Strip vial, whichever comes first. Discard vial and test with new vial.
- Remove one Strip from vial. Recap vial right away.
- Insert Contact End of Strip, contacts facing up, into Test Port of Meter. Meter turns on. Do not remove Strip from Meter until testing is finished.
- Obtain blood drop.
- After Drop Symbol appears in Display, place Sample Tip of Strip gently against blood drop and allow blood to be drawn into Strip. Remove Strip Sample Tip from sample drop immediately after Meter beeps and starts to countdown on Meter display.

CAUTION! Holding the Test Strip Sample Tip to the blood sample too long after the Meter begins testing may cause inaccurate results.

- If Meter does not begin testing 5 seconds after touching Strip to blood drop, see Troubleshooting section in the Owner's Booklet.
- Result is displayed. Record result.
- Remove Strip from Meter. Meter turns off. Discard used Strip and lancet in appropriate container.

Expected Results for people without diabetes:²

Plasma Blood Glucose Result
 Before eating < 100 mg/dL
 Two hours after meals < 140 mg/dL

A Doctor or Diabetes Healthcare Professional determines personal target glucose ranges. Always check with your Doctor or Diabetes Healthcare Professional before changing your treatment program.

If you are having symptoms that your glucose is too low or too high, contact your Doctor or Diabetes Healthcare Professional right away.

The TRUEbalance is optimized for testing with fresh capillary whole blood and calibrated to display a plasma result. Plasma results are estimated to be 10%-15% higher than whole blood results.³

If comparing results using TRUEbalance Strips to laboratory test results, perform a fingerstick blood test within 30 minutes of the laboratory test. Diabetes experts have suggested that glucose meters should agree within 15 mg/dL of a laboratory method when the glucose concentration is less than 75 mg/dL, and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher.⁴ If you have eaten recently, results using TRUEbalance Test Strips can be up to 70 mg/dL higher than laboratory results.⁵ If glucose tests are performed using capillary blood with the TRUEbalance and venous blood with the laboratory system, capillary blood (finger) may be up to 70 mg/dL higher than venous blood (vein), even when each test is performed within 10 minutes after sampling and per manufacturers' instructions.⁶

Troubleshooting (See Owner's Booklet *Display Messages* for more details.)

If your result is unusually high or low or doesn't match the way you feel, perform a Control Test (see *Quality Control Tests*).

If the Control Test is within range:

- Read *Blood Glucose Testing* again.
- Test your blood glucose again using a new TRUEbalance Strip.

If the results still do not match the way you feel, check with your Doctor or Diabetes Healthcare Professional before changing your treatment plan.

If the results are not within range:

- Check the Expiration Dates (Test Strips - 120 days after opening or date printed on vial; Control - 3 months after opening or date printed on bottle). Do not use if Test Strips or Control have expired. Test with a new vial of Test Strips and/or bottle of Control.
- Check for error messages. If an error message appears, follow the Actions in the *Display Message Section* of the Owner's Booklet.
- Check your testing technique. Perform another Control Test.
- Check the temperature. Allow System to reach room temperature 68°-77°F (20°-25°C) before testing.

Limitations

TRUEbalance products cannot be used for testing blood in newborns.

The following **WILL** affect accurate test results:⁶

- Abnormally high doses of acetaminophen.
- Oxygen Therapy.

NOTE: Similar observations have been reported by other blood glucose systems.

The following will **NOT** affect accurate test results:⁶

- Hematocrit levels between 30% and 55%.
- Elevated total blood cholesterol and triglycerides.
- Salicylate occurring in expected blood concentrations.
- Testing at altitudes up to and including 10,150 feet.

DO NOT perform capillary blood glucose testing on critically ill patients.

Capillary blood glucose levels in critically ill patients with reduced peripheral blood flow may not reflect the true physiological state. Reduced peripheral blood flow may result from the following conditions (for example):⁷

- shock
- severe hypotension
- severe dehydration
- hyperglycemia with hyperosmolarity, with or without ketosis.

Performance Characteristics⁶

Accuracy

Accuracy describes how well TRUEbalance results agree with results from an accepted laboratory analyzer. The accuracy of TRUEbalance was assessed against Yellow Springs Instrument Model 23A, (which also uses a glucose oxidase method). Testing was performed by lay users at 4 independent clinical sites. The study demonstrates that TRUEbalance compares well with the laboratory method. A regression analysis of the 229 results is given below:

N	- 229	Slope	- 0.98
Y-intercept	- 5.18	r ²	- 0.96

Precision

Precision describes the variation between TRUEbalance results. Precision studies were performed in a laboratory.

Within Run Precision (whole blood)

	<u>51 mg/dL</u>	<u>82 mg/dL</u>	<u>122 mg/dL</u>	<u>241 mg/dL</u>	<u>500 mg/dL</u>
C.V. (%)	5.1	4.2	3.7	2.7	3.0

Total Precision (Control Solution)

	<u>90 mg/dL</u>	<u>161 mg/dL</u>	<u>286 mg/dL</u>
C.V. (%)	6.3	5.6	4.5

Consumer Study

TRUEbalance was tested at diabetes clinics of a large urban area hospital and diabetes care centers. TRUEbalance results were obtained from 212 patients and were compared to parallel results obtained on Yellow Springs Model 2300 STAT. This study shows that patients, when self-testing, and laboratory professionals are able to obtain accurate results when compared to results obtained from a laboratory system.

A clinical study was performed at an urban area hospital to compare forearm and finger stick blood glucose results using the TRUEbalance. TRUEbalance blood glucose tests were performed by patients self-testing (n=100) and on patients' blood by healthcare professionals (n=108). Results demonstrate substantial equivalence between forearm and finger blood glucose values when patients' blood glucose is in steady state and blood glucose tests are performed by patients or healthcare professionals using the TRUEbalance.

See your TRUEbalance Owner's Booklet for detailed instructions. Call Trividia Health, Inc. at 1-800-803-6025 (USA) or 1-954-677-4599 for assistance, Monday - Friday, 8AM-8PM EST, or visit our website at www.trividiahealth.com for more information.

For medical assistance, contact a Doctor or Diabetes Healthcare Professional.

References

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TRUEbalance



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