

TRUE METRIX[®] Self Monitoring Blood Glucose Test Strips

Instructions for Use

Intended Use

TRUE METRIX[®] Self Monitoring Blood Glucose Test Strips are to be used with TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO Self Monitoring Blood Glucose Meters to quantitatively measure whole blood glucose in fresh, human capillary whole blood taken from the fingertip. **The TRUE METRIX and TRUE METRIX AIR meters are indicated for forearm testing. TRUE METRIX GO meter is not indicated for forearm testing.** TRUE METRIX Self Monitoring Blood Glucose Test Strips, used with the TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO Self Monitoring Blood Glucose Meters, are intended to be used by a single person and not shared. The TRUE METRIX Self Monitoring Blood Glucose Test Strips are intended to be used with the TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO Self Monitoring Blood Glucose Meters for self-testing at home (over-the-counter). Testing is performed outside the body (*in vitro* diagnostic use) by a single person with diabetes as an aid for monitoring the effectiveness of diabetes control. TRUE METRIX Self Monitoring Blood Glucose Test Strips, with the TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO Self Monitoring Blood Glucose Meters, should not be used on neonates or for the diagnosis or screening of diabetes mellitus. Alternative site testing can only be performed during steady-state blood glucose conditions (when glucose is not changing rapidly).

Test Principle

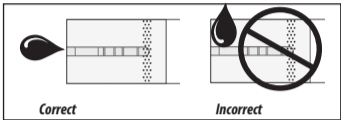
The TRUE METRIX Self Monitoring Blood Glucose Test Strip is a plastic strip containing chemicals and electrodes. When inserted into a TRUE METRIX, TRUE METRIX AIR or a TRUE METRIX GO Self Monitoring Blood Glucose Meter, glucose is measured using amperometric technology employing a glucose dehydrogenase-FAD reaction. When whole blood or TRUE METRIX Control Solution is drawn into the Sample Tip of the test strip, glucose in the sample reacts with the chemicals and produces an electrical current. The meter measures the current, detects and corrects for hematocrit and temperature, and calculates the glucose result. The result is displayed as a plasma value.

Chemical Composition

Glucose dehydrogenase-FAD (*Aspergillus species*), mediators, buffers and stabilizers.

① **Contact End** - End inserted into meter.

② **Sample Tip** - End where sample is drawn into test strip.



Top of Test Strip

Caring for Test Strips

- Test strips must be kept in original vial with vial cap tightly sealed. NEVER transfer test strips from one vial to another.
- Write date opened on test strip vial label when removing the first test strip. Discard all unused test strips in vial after either date printed next to **EXP** on the test strip vial label or 4 months after date opened, whichever comes first. Using test strips past these dates may cause inaccurate results.
- Store test strip vial in a dry place at a temperature between 40°F-86°F at 10%-80% relative humidity. **DO NOT 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.
- Discard any test strips or vials that appear damaged.
- Do not bend, cut, or alter test strips in any way.

Important Information

- Use TRUE METRIX Self Monitoring Blood Glucose Test Strips only with TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO Self Monitoring Blood Glucose Meters and TRUE METRIX Control Solution. Using other meters or controls may give inaccurate results.
- Test strips are for *in vitro* diagnostic use only. Do not consume.
- Meter and lancing device is for self-testing and intended for use on one person ONLY. Do not share your meter or lancing device.
- Use fresh, capillary whole blood from fingertip or forearm.* Do not use venous blood for testing.
- 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.
- Alternative site testing* should not be used to calibrate continuous blood glucose monitors (CGMs). Alternative site testing* should not be used for insulin dose calculations.
- Use finger instead of forearm* for more accurate results:¹
 - 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 low or high.
- NEVER use serum, plasma, or clotted blood for testing.

* **The TRUE METRIX and TRUE METRIX AIR meters are indicated for forearm testing. TRUE METRIX GO meter is not indicated for forearm testing.**

WARNING!

- NEVER reuse test strips. NEVER wipe test strips with water, alcohol or any cleaner. DO NOT attempt to remove blood or control solution from test strips or clean test strips and re-use. Reuse of test strips will cause inaccurate results.
- Use test strip quickly after removing from vial. Recap vial right away. Test strips left outside of vial too long give an error message.
- NEVER add a second drop of sample to test strip. Adding more sample gives an error message.
- Discard used test strips and lancets into an appropriate container. Contact with blood presents an infection risk.
- Do not change treatment plan based on the results from the System without the advice of your Doctor or Diabetes Healthcare Professional.
- Do not use on neonates.

Cleaning and Disinfecting

- TRUE METRIX Self Monitoring Blood Glucose Test Strips, with the TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO Self Monitoring Blood Glucose Meters, are for one person use **ONLY**. **DO NOT** share your meter or lancing device with anyone, including family members.
- All parts of the System (meter, test strips, control solution, lancing device and lancets) can potentially transmit infectious diseases from bloodborne pathogens, even after cleaning and disinfecting.²
- Cleaning and disinfecting the lancing device and the meter destroys most, but not necessarily all, blood-borne pathogens.
- Wash your hands thoroughly with soap and warm water before and after handling the meter, lancing device, lancets, or test strips as contact with blood presents an infection risk.
- If blood or cleaning solution gets into the test strip vial, discard vial and use a new vial for testing. Using test strips that may have become contaminated may result in incorrect results or error messages if used for testing.
- If you have any liquids on your hands, especially blood, make sure you clean and completely dry your hands before opening the test strip vial.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be cleaned and disinfected prior to use by the second person.
- It is important to keep the meter and the lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see *Meter Cleaning and Disinfecting and Lancing Device Cleaning and Disinfecting* in the TRUE METRIX, TRUE METRIX AIR or TRUE METRIX GO Self Monitoring System Owner's Booklet.

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 TRUE METRIX Self Monitoring Blood Glucose Test Strip is inserted into a TRUE METRIX, TRUE METRIX AIR or TRUE METRIX GO Self Monitoring Blood Glucose Meter. Upon inserting a test 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 Test

TRUE METRIX Control Solution is used to check testing technique and System performance. When Control Test results fall within ranges found on test strip vial label of test strips being used, System is working properly and testing technique is good.

Important Information: *It is important to perform Control Tests with more than one level of control solution to assure your System is working properly and your testing technique is good. There are three levels of TRUE METRIX Control Solution available that contain known amounts of glucose.*

For more information on obtaining different levels of control solution, call 1-800-803-6025 or 1-954-677-4599 for assistance available 24/7.

See TRUE METRIX Control Solution Instructions for Use or TRUE METRIX, TRUE METRIX AIR or TRUE METRIX GO Self Monitoring Blood Glucose System Owner's Booklet for more information on the frequency of Quality Control Testing.

Blood Glucose Testing

- Check opened date and printed date on test strip vial label. Do not use if after either date printed on the test strip vial label or 4 months after date opened, whichever comes first. Discard vial and test with new vial.
- Allow meter and test strips to sit at room temperature for 10 minutes. If opening vial for the first time, write date opened on vial label.
- Wash area to be lanced, dry.
- Remove one test strip from vial. Recap vial right away.
- Insert Contact End of test strip into Test Port of meter. Meter turns on. Do not remove test strip from meter until testing is finished.
- Obtain blood drop.
- With test strip still in meter, touch Sample Tip to top of blood drop and allow blood to be drawn into test strip. Remove Sample Tip from drop immediately after the meter beeps and dashes appear across meter display. If meter does not begin testing 5 seconds after touching test strip to blood drop, see *Troubleshooting* in the TRUE METRIX, TRUE METRIX AIR or TRUE METRIX GO Self Monitoring Blood Glucose System Owner's Booklet.
- Result is displayed. Record result.
- Hold meter with test strip pointing down. Press Strip Release Button to discard test strip into appropriate container.

Expected Results for people without diabetes:³

	Plasma Blood Glucose Result
Before eating	< 100 mg/dL
2 hours after a meal	< 140 mg/dL

A Doctor or Diabetes Healthcare Professional determines personal target glucose ranges.

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

If comparing results using TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO Self Monitoring Blood Glucose Systems to laboratory test results, perform a fingerstick blood test within 30 minutes of the laboratory test. If you have eaten recently, results using TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO Self Monitoring Blood Glucose Systems can be up to 70 mg/dL higher than venous laboratory results.⁴

Troubleshooting

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

If the Control Test is within range:

- Read **Blood Glucose Testing** again.
- Recheck your results with a new TRUE METRIX Self Monitoring Blood Glucose Test Strip.

If the results are not within range:

- Check the Use by Dates. Do not use if past either written date or date printed next to **EXP** on test strip vial or control solution bottle, whichever comes first. Test with new test strips/control solution.
- Check for error messages. If an error message appears, follow the Actions in the Message Section of the TRUE METRIX, TRUE METRIX AIR or TRUE METRIX GO Self Monitoring Blood Glucose System Owner's Booklet.
- Check your testing technique. Perform another Control Test. If the results still do not match the way you feel, check with your Doctor or Diabetes Healthcare Professional before changing your treatment program.

Limitations⁵

- Do not use during xylose absorption testing, as xylose may produce falsely elevated glucose results during a xylose absorption test for diagnostic evaluation of malabsorption. Please check with your Doctor before using the TRUE METRIX, TRUE METRIX AIR or the TRUE METRIX GO Self Monitoring Blood Glucose System.
- Ascorbic acid (Vitamin C) greater than normal or therapeutic levels may cause significant interference resulting in inaccurate result.
- It is known that uric acid can interfere with this device at normal and disease levels, when uric acid concentrations are greater than 5 mg/dL. For people with diabetes, certain conditions may cause your blood level of uric acid to rise. These conditions include gout or kidney disease, this means you may have significant interference resulting in inaccurate glucose results and your blood glucose results may be not reliable. Please check with your Doctor or Diabetes Healthcare Professional before using the TRUE METRIX, TRUE METRIX AIR or the TRUE METRIX GO Self Monitoring Blood Glucose System.
- Testing at altitudes greater than 10,200 ft may cause inaccurate results.
- Hematocrit levels below 20% or above 70% may cause inaccurate results.
- Critically ill patients should not be tested with this device.**
- Inaccurate results may occur in severely hypotensive individuals or in dehydrated patients or patients in shock. Inaccurate results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- The TRUE METRIX, TRUE METRIX AIR or TRUE METRIX GO Self Monitoring Blood Glucose Systems have not been tested with animals. Do not use to test blood glucose on pets.

Operating Conditions: 41°-104°F, relative humidity (RH) 10%-80%.

Performance Characteristics - TRUE METRIX and TRUE METRIX AIR⁶

Accuracy: TRUE METRIX Self Monitoring Blood Glucose System was tested by lay users at a research center. The data was compared to parallel results obtained on a Yellow Springs Instrument (YSI).

The table below shows how often lay user TRUE METRIX Self Monitoring Blood Glucose System fingertip values achieve the accuracy goals.

Fingertip Capillary Blood - < 75 mg/dL (user finger vs. YSI)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
2/3 (66.7%)	3/3 (100%)	3/3 (100%)

Fingertip Capillary Blood - ≥ 75 mg/dL (user finger vs. YSI)

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
46/97 (47.4%)	76/97 (78.4%)	95/97 (97.9%)	97/97 (100%)

The table below shows how often TRUE METRIX Self Monitoring Blood Glucose System forearm values obtained by lay users achieve the accuracy goals when users' glucose values are not fluctuating.

Forearm Capillary Blood - < 75 mg/dL (user forearm vs. YSI)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
2/4 (50%)	3/4 (75%)	4/4 (100%)

Forearm Capillary Blood - ≥ 75 mg/dL (user forearm vs. YSI)

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
37/96 (38.5%)	63/96 (65.6%)	91/96 (94.8%)	96/96 (100%)

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

Blood (Within Lot): N=100

Mean (mg/dL)	44	89	150	199	329
SD (mg/dL)	1.8	3.6	4.9	7.3	9.6
CV%	4.1	4.0	3.3	3.7	2.9

Control Solution (Between Day): N=100

Mean (mg/dL)	33	105	306
SD (mg/dL)	1.6	3.8	10.3
CV%	4.8 <td>3.6</td> <td>3.4</td>	3.6	3.4

Performance Characteristics - TRUE METRIX GO⁵

Accuracy: TRUE METRIX GO Self Monitoring Blood Glucose System was tested by lay users at a research center. The data was compared to parallel results obtained on a Yellow Springs Instrument (YSI).

The table below shows how often lay user TRUE METRIX GO Self Monitoring Blood Glucose System fingertip values achieve the accuracy goals.

Fingertip Capillary Blood - < 75 mg/dL (user finger vs. YSI)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
3/4 (75%)	4/4 (100%)	4/4 (100%)

Fingertip Capillary Blood - ≥ 75 mg/dL (user finger vs. YSI)

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
55/96 (57.3%)	86/96 (89.6%)	95/96 (99%)	96/96 (100%)

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

Blood (Within Lot): N=100

Mean (mg/dL)	22	38	74	137	203	294	495
SD (mg/dL)	0.9	1.5	2.4	5.0	6.7	10.1	15.0
CV%	4.3	3.9	3.2	3.6	3.3	3.4	3.0

Control Solution (Between Day): N=100

Mean (mg/dL)	38	115	319
SD (mg/dL)	1.8	4.0	12.6
CV%	4.8	3.5	3.9

Additional Information: See the TRUE METRIX, TRUE METRIX AIR or TRUE METRIX GO Self Monitoring Blood Glucose System Owner's Booklets for more detailed instructions. Call Trividia Health, Inc. toll free 24/7 at 1-800-803-6025 (USA) or 1-954-677-4599 for assistance. For medical assistance, call your Doctor or Diabetes Healthcare Professional.

Manufactured by:



Fort Lauderdale, FL 33309 U.S.A.

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1. U.S. Food and Drug Administration. *Blood Glucose Meters, Getting the Most Out of Your Meter*. [Electronic Version]. Retrieved December 22, 2009 from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.htm>.

2. FDA Public Health Notification: *Use of Fingertip Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens*. Retrieved June 21, 2012 from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.

3. American Diabetes Association. *Classification and Diagnosis of Diabetes*. Diabetes Care. Volume 39, Supplement 1, January 2016.

4. Larson-Cohn U. *Difference between capillary and venous blood glucose during oral glucose tolerance tests*. Scand J Clin Lab Invest 36:805-808, 1976.

5. Data on file.