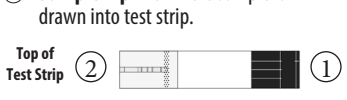
TRUE METRIX® PRO Professional Monitoring Blood Glucose Test Strips Instructions for Use

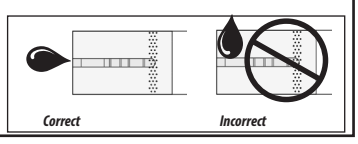
Intended Use
TRUE METRIX® PRO Blood Glucose Test Strips are used only with TRUE METRIX PRO Meter for the quantitative measurement of glucose in fresh, human capillary whole blood taken from the fingertip, forearm or venous blood. The system is intended for multiple-patient use in professional healthcare settings.
Testing is performed outside the body (*in vitro* diagnostic use) as an aid for monitoring the effectiveness of diabetes control. The system is used only with auto-disabling single-use lancing devices. The TRUE METRIX PRO System is not to 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.

Test Principle
The TRUE METRIX PRO Test Strip is a plastic strip containing chemicals and electrodes. When inserted into a TRUE METRIX PRO 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.





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
- Test strips must be kept in original vial with vial cap tightly sealed. NEVER transfer test strips from one vial to another.
- Use test strip quickly after removing from vial. Recap vial right away. Test strips left outside of vial too long give an error message.
- 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 PRO Test Strips only with TRUE METRIX PRO Meter and TRUE METRIX Control Solution. Using other meters or controls may give inaccurate results.
- Test strips are for *in vitro* testing only. Do not consume.
- Use only auto-disabling single use lancing devices.
- Use fresh, capillary whole blood from the fingertip or forearm. Venous whole blood drawn into only a sodium heparin blood collection tube may also be used for testing. Mix well before sampling. DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing, as this may cause false low results.
- NEVER use serum, plasma, or clotted blood for testing.
- If using the forearm for blood sample:[1]
  - Check with the patient's Doctor or Diabetes Healthcare Professional to see if forearm testing is appropriate.
  - 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:
  - Within 2 hours of eating, exercise, or taking insulin,
  - If the patient's blood sugar may be rising or falling rapidly or routine results are often fluctuating,
  - If the patient is ill or under stress,
  - If the patient's forearm test results do not match how the patient feels,
  - If the patient's blood sugar may be low or high.

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 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 patient's treatment plan based on the results from the TRUE METRIX PRO System without the advice of a Doctor or Diabetes Healthcare Professional.
- Not for use on neonates (newborns).

Cleaning and Disinfecting
- **ALL** parts of the System (meter, test strips, auto-disabling single use lancets) could carry blood-borne pathogens after use, even after cleaning and disinfecting.[2,3]
- Cleaning and disinfecting the meter destroys most, but not necessarily all, blood-borne pathogens.
- A new pair of clean gloves must be worn before testing a new patient.
- It is important to keep the meter clean and disinfected. For instructions on how to clean and disinfect the meter, see Meter Cleaning and Disinfecting in the Owner's Booklet.
- Users should 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 manufacter's disinfection procedures are followed.

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 PRO Test Strip is inserted into a TRUE METRIX PRO 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 the 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, Monday - Friday, 8AM-8PM EST.*

See TRUE METRIX Control Solution Instructions for Use or TRUE METRIX PRO Owner's Booklet for more information on the frequency of Quality Control testing.

Blood Glucose Testing
CAUTION! *Healthcare Professionals should wash hands and wear a new pair of gloves before testing each patient. Contact with blood presents an infection risk.*
1. 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.
2. 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.
3. Wash area to be lanced, dry.
4. Remove one test strip from vial. Recap vial right away.
5. 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.
6. Obtain blood drop.
7. 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 PRO Owner's Booklet.
8. Result is displayed. Record result as required by your facility.
9. Hold meter with test strip pointing down. Press Strip Release Button to discard test strip into approved biohazard container. Wash hands after taking off gloves.

Expected Results for people without diabetes:[4]

	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 comparing results using TRUE METRIX PRO Test Strips to laboratory test results, perform a fingerstick blood test within 30 minutes of the laboratory test. If the patient has recently eaten, fingerstick results using TRUE METRIX PRO Test Strips can be up to 70 mg/dL higher than venous laboratory results.[5]

Troubleshooting
If the patient's result is unusually high or low or doesn't match the way they feel, perform a Control Test (see **Quality Control Testing**).
If the Control Test is within range:
- Read **Blood Glucose Testing** again.
- Recheck the results with a new TRUE METRIX PRO Test Strip.

If the results still do not match the way the patient feels, check with the Doctor or Diabetes Healthcare Professional before changing the patient's treatment program.
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 bottle, whichever comes first. Test with new test strips/control.
- Check for error messages. If an error message appears, follow the Actions in the Message Section of the Owner's Booklet.
- Check testing technique. Perform another Control Test.

Limitations[6]
- 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 the patient's Doctor or Diabetes Healthcare Professional before using the TRUE METRIX PRO 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 the blood level of uric acid to rise. These conditions include gout or kidney disease, this means there may be significant interference resulting in inaccurate glucose results and the blood glucose results may be not reliable. Please check with the patient's Doctor or Diabetes Healthcare Professional before using the TRUE METRIX PRO System.
- DO NOT use venous whole blood collected in sodium fluoride blood collection tubes for testing, as this may cause false low results.
- Testing at altitudes greater than 10,200 feet may cause inaccurate results.[6]
- Hematocrit levels below 20% or above 70% may cause inaccurate results.[6]
- **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.

Operating Conditions: 41°-104°F, relative humidity (rH) 10%-90%.

Performance Characteristics[6]
Accuracy: TRUE METRIX PRO System was tested by users at a research center. Studies were conducted at 2 sites. The data was compared to parallel results obtained on the Yellow Springs Instrument (YSI).

The table below shows how often TRUE METRIX PRO Blood Glucose System fingertip values obtained by lay users 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 PRO 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%)

TRUE METRIX PRO System was also tested by healthcare professionals at a research center. The data was compared to parallel results obtained on a Yellow Springs Instrument (YSI). The table below shows how often TRUE METRIX PRO Blood Glucose System venous values obtained by healthcare professionals achieve the accuracy goals.
Venous samples drawn into sodium heparin anticoagulant tubes.

Venous Blood Results vs. YSI < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
5/6 (83.3%)	6/6 (100%)	6/6 (100%)

Venous Blood Results vs. YSI ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
20/106 (18.9%)	60/106 (56.6%)	101/106 (95.3%)	106/106 (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	3.6	3.4		

Additional Information: See the Owner's Booklet for more detailed instructions. Call Trividia Health, Inc. at 1-800-803-6025 (USA) or 1-954-677-4599 for assistance, Monday - Friday, 8AM-8PM EST. For medical assistance, contact the Doctor or Diabetes Healthcare Professional.

References
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 Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication.* Available at https://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.
3. *Infection Prevention during Blood Glucose Monitoring and Insulin Administration.* Available at http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html.
4. American Diabetes Association. *Diagnosis and Classification of Diabetes Mellitus.* Diabetes Care, Volume 39, Supplement 1, January 2016.
5. Larson-Cohn U: *Difference between capillary and venous blood glucose during oral glucose tolerance tests.* Scand J Clin Lab Invest 36:805-808, 1976.
6. Data on file.

TRUE METRIX® PRO

R3TVHP03R53

TRUE METRIX® PRO

Manufactured by:
TRIVIDIA HEALTH™
FORT LAUDERDALE, FL 33309 U.S.A.

R3TVH**P**03 Rev. 53