TRUE METRIX Blood Glucose Test Strips Instructions for Use

Intended Use
TRUE METRIX Blood Glucose Test Strips are used only with the TRUE METRIX Family of Meters (TRUE METRIX, TRUE METRIX GO and the TRUE METRIX AIR Meters) to quantitatively determine glucose in human whole blood taken from the fingertip or forearm (capillary) or from the vein (venous). The System is intended for at-home use (self testing) and for use by healthcare professionals in both physicians' offices and in acute and convalescent-care bedside testing facilities in order to assist in the management of diabetes.

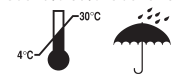
Test Principle
The TRUE METRIX Test Strip is a plastic strip containing chemicals and electrodes. When inserted into one of the TRUE METRIX Family of Meters, glucose is measured using amperometric technology employing a glucose dehydrogenase-FAD reaction. When whole blood or TRUE METRIX Control Solution 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 and calculates the amount of glucose. The result is displayed as a plasma value.

Chemical Composition
Glucose dehydrogenase-FAD *(Aspergillus sp.)*, mediators, buffers and stabilisers.

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 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.
- 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 ⌛ on the test strip vial label or 4 months after date opened. Using test strips past these dates may cause inaccurate results.
- Store test strip vial in a dry place at room temperature between 4°C-30°C 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 Test Strips only with TRUE METRIX Family of Meters and TRUE METRIX Control Solution. Using other meters or controls may give inaccurate results.
- Test strips are for *in vitro* IVD testing only. Do not consume.
- Lancing device is for self-testing and intended for use by one patient only. Not suitable for use by healthcare or care workers. Healthcare or care workers should only use auto-disabling single use lancing devices.
- NEVER use serum, plasma or clotted blood for testing.
- Use fresh, capillary whole blood from fingertip or forearm. Venous whole blood drawn into only a sodium heparin blood collection tube must 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.
- Alternate site testing can only be performed during steady-state blood glucose conditions.
- Alternate site testing should not be used to calibrate continuous blood glucose meters (CGMs).
- Alternate 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 blood sugar may be rising or falling rapidly or routine results are often fluctuating,
  - If ill or under stress,
  - If forearm test results do not match how you feel,
  - If blood sugar may be low or high,
  - If you do not notice symptoms when blood sugar is low or high.

WARNING!
- **NEVER** reuse test strips. ② **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.
- **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. Reuse of devices labeled for single-use only may result in product contamination and patient infection.
- Do not change treatment plan based on the results from the System without the advice of a doctor or healthcare professional.
- Do not use on neonates (newborns) or for the screening of diabetes mellitus.

Cleaning and Disinfecting
- All parts of the System 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.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be throughly cleaned prior to use by the second person.
- It is important to keep the meter and the lancing device clean. For instructions on how to clean the meter and lancing device, see *Meter Care, Cleaning /Disinfecting* and *Lancing Device Care* and *Cleaning* Sections in the 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 Test Strip is inserted into a 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
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 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, use contact information on the cover of the Owner's Booklets.*

See TRUE METRIX Control Solution Instructions for Use or meter's Owner's Booklet for more information on Quality Control Testing.

Blood Glucose Testing
1. Check opened date and printed date next to ⌛ on test strip vial label. Do not use if after either date printed next to ⌛ 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 test strip 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 the *Troubleshooting* Section in the meter's Owner's Booklet.
8. Result is displayed. Record result.
9. Hold meter with test strip pointing down. Press Strip Release Button to discard test strip into appropriate container.

☣ *Treat used test strips and lancets as a biological risk. Dispose used test strips and lancets in appropriate container.*

Expected Results for people without diabetes:[3]

	Plasma Blood Glucose Result	Plasma Blood Glucose Result
Before breakfast	< 5.6 mmol/L	Two hours after meals < 7.8 mmol/L

A doctor or healthcare professional determines personal target glucose ranges. If you are having symptoms that suggest glucose is too low or too high, contact a doctor or healthcare professional right away.
If comparing results using TRUE METRIX Test Strips 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 Test Strips can be up to 3.9 mmol/L higher than venous laboratory results.[4]

Troubleshooting
If a 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 results with a new TRUE METRIX Test Strip.

If the results are not within range:
- Check the Use By Dates. Do not use if past either 4 months past written date or date printed next to ⌛ (whichever comes first) on test strip vial or control solution bottle. 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 Owner's Booklet.
- Check testing technique. Perform another Control Test. If the results still do not match the way you feel, check with doctor or healthcare professional before changing the treatment program.

Limitations[5]
- Do not use the System during a xylose absorption test. This may falsely raise glucose results. Please check with a doctor before using the System.
  - Ascorbic acid (Vitamin C) greater than normal or therapeutic levels may cause significant interference resulting in inaccurate result.
  - Uric acid can interfere with this device at normal and disease levels, when uric acid concentrations are greater than 0.3 mmol/L. For people with diabetes, certain conditions (including gout or kidney disease) may cause the blood level of uric acid to rise. This may cause significant interference resulting in inaccurate glucose results and the blood glucose results may be not reliable. Please check with a Doctor or Healthcare Professional before using the System.

The following will not affect accurate results:[5]
- Testing at altitudes up to and including 3109 metres.
- Hematocrit levels between 20% and 70%.

Critically ill patients should not be tested with this device. 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):[6]
- shock • severe hypotension • severe dehydration
- hyperglycaemia with hyperosmolarity, with or without ketosis.

Operating Conditions: 5-40°C, relative humidity (rH) 10%-90%.

Performance Characteristics[5]
Precision: Precision describes the variation between results. There are two types of precision results measured, repeatability (using blood) and intermediate precision (using control solution).

Repeatability: N=100

Mean (mmol/L)	2.4	4.8	8.0	11.3	17.8
SD (mmol/L)	0.09	0.16	0.24	0.39	0.49
%CV	3.9	3.3	3.0	3.4	2.7

Intermediate Precision: N=100

Mean (mmol/L)	2.1	6.4	18.4
SD (mmol/L)	0.1	0.2	0.6
%CV	4.3	3.2	3.4

System Accuracy: Diabetes experts have suggested that 95% of glucose meter results should agree within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and within ± 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.[7] The tables below show how often healthcare professionals (HCP) and users achieve these goals using capillary fingertip and forearm blood samples when glucose results are not fluctuating. The laboratory reference instrument is the Yellow Springs Instrument (YSI).

For Healthcare Professionals
99.3% of TRUE METRIX fingertip values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Fingertip Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
99/156 (63.5%)	135/156 (86.5%)	155/156 (99.4%)

Fingertip Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
207/444 (46.6%)	364/444 (82%)	441/444 (99.3%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
596/600 (99.3%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

100% of TRUE METRIX forearm values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Forearm Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
13/41 (31.7%)	26/41 (63.4%)	41/41 (100%)

Forearm Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
17/59 (28.8%)	38/59 (64.4%)	59/59 (100%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
100/100 (100%)

Parkes Error Grid: 100% of individual forearm glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

Venous Blood
96.4% of TRUE METRIX venous values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Venous Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
16/50 (32%)	39/50 (78%)	50/50 (100%)

Venous Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
33/174 (19%)	100/174 (57.5%)	166/174 (95.4%)

Venous Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
216/224 (96.4%)

Parkes Error Grid: 100% of individual venous glucose measured values performed by healthcare professionals fell within Zone A of the Parkes Error Grid (PEG).

For Consumers
99% of TRUE METRIX fingertip values performed by users fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Fingertip Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
9/18 (50%)	17/18 (94.4%)	18/18 (100%)

Fingertip Samples (User vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
39/82 (47.6%)	65/82 (79.3%)	81/82 (98.8%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
99/100 (99%)

Parkes Error Grid: 100% of individual fingertip glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

98% of TRUE METRIX forearm values performed by healthcare professionals (HCP) fell within 0.83 mmol/L of the YSI results at glucose levels < 5.55 mmol/L and within 15% at glucose levels ≥ 5.55 mmol/L.

Forearm Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
21/41 (51.2%)	32/41 (78%)	41/41 (100%)

Forearm Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L

Within ± 5%	Within ± 10%	Within ± 15%
21/59 (35.6%)	39/59 (66.1%)	57/59 (96.6%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L

Within ± 0.83 mmol/L or ± 15%
98/100 (98%)

Parkes Error Grid: 100% of individual forearm glucose measured values performed by users fell within Zone A of the Parkes Error Grid (PEG).

User Performance Evaluation: A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:
100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L and 98.8% within ± 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

Additional Information: See the Owner's Booklets for more detailed instructions. The performance characteristics presented above are for the TRUE METRIX System. Please see the Performance Characteristics Section in the Owner's Booklet of the TRUE METRIX GO and TRUE METRIX AIR for the performance data specific to your system. Use the contact information on the cover of the Owner's Booklets for assistance. For medical assistance, call your Doctor or Healthcare Professional.

References
1. U.S. Food and Drug Administration. *Blood Glucose Meters, Getting the Most Out of Your Meter.* [Electronic Version]. Retrieved July 6, 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 Blood Borne Pathogens.* Retrieved February 22, 2012 from http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.
3. Joslin Diabetes Center. *Goals for Blood Control Solution* [Electronic Version]. Retrieved June 8, 2015 from http://www.joslin.org/info/Goals-for-Blood-Glucose-Control.html
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.
6. Atkin, S. H., Dasmahapatra, A., Jaker, M.A., Chorost, M. I., Redd, S., *Fingerstick Glucose Determination in Shock.* Annals of Internal Medicine, 114:1020-1024, 1991.
7. European Committee for Standardization. *In vitro diagnostic test systems. Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus.* Reference number EN ISO 15197:2015 (E). Brussels: European Committee for Standardization; 2015.

SYMBOLS:

Biological Risk	Attention! Read Instructions for Use.
STERILE R Sterile	Regulatory Compliance Mark (RCM)
Do Not Resterilise	Storage Temperature Range
Single Use Only	Storage Humidity Range
CONTROL Control Solution	LOT Lot Number
① ② ③ Control Level	IVD For *in vitro* Diagnostic Testing Only
SN Serial Number	EC REP Authorised Representative
Caution!	Manufactured By
Use By Date	Date of Manufacture
Keep Dry	
Single Patient Use Only	

TRUE METRIX

R3AUT03R51

TRUE METRIX

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