

TRUE METRIX Blood Glucose Test Strips Instructions for Use

Intended Use

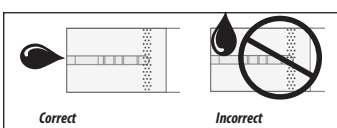
TRUE METRIX Blood Glucose Test Strips are used only with the TRUE METRIX Family of Meters (TRUE METRIX, TRUE METRIX GO and the TRUE METRIX AIR Meters) to quantitatively determine glucose in human whole blood taken from the fingertip or forearm (capillary) or from the vein (venous). The System is intended 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.

- Contact End** - End inserted into meter.
- 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 if either date printed next to on the test strip vial label or 4 months after date first opened has passed, whichever comes first. 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 (Non-condensing). **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. 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 thoroughly cleaned and disinfected 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 and disinfect the meter and lancing device, see *Meter Care, Cleaning/Disinfecting* and *Lancing Device Cleaning and Disinfecting* Sections in the Owner's Booklets/System Instructions for Use.

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 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 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 in the Owner's Booklets/ System Instructions for Use.*

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

Blood Glucose Testing

- Check opened date and printed date next to on test strip vial label. Do not use if either date printed next to on the test strip vial label or 4 months after date first opened has passed, whichever comes first. Discard vial and test strip 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 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/ System Instructions for Use.
- Result is displayed. Record result.
- 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 (100 mg/dL)	Two hours after meals < 7.8 mmol/L (140 mg/dL)

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 (70 mg/dL) 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 either 4 months past written date or date printed next to on test strip vial or control solution bottle label has passed, 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 Owner's Booklets/ System Instructions for Use.
- 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.

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 a Doctor before using the System.
- Ascorbic acid (Vitamin C) greater than 0.11 mmol/L (2 mg/dL) 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 (5 mg/dL). 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.
- Testing at altitudes greater than 3109 metres 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.

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

Performance Characteristics - TRUE METRIX and TRUE METRIX AIR⁶

The performance characteristics presented below are for the TRUE METRIX and TRUE METRIX AIR Systems. For TRUE METRIX GO System please see the *Performance Characteristics* Section in the TRUE METRIX GO Owner's Booklet/ System Instructions for Use.

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
Mean (mg/dL)	44	86	144	203	321
SD (mmol/L)	0.09	0.16	0.24	0.39	0.49
SD (mg/dL)	1.7	2.9	4.4	7.0	8.8
%CV	3.9	3.3	3.0	3.4	2.7

Intermediate Precision: N=100

Mean (mmol/L)	2.1	6.4	18.4
Mean (mg/dL)	37	116	332
SD (mmol/L)	0.1	0.2	0.6
SD (mg/dL)	1.6	3.8	11.2
%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 (15 mg/dL) of the medical laboratory values at glucose concentrations below 5.55 mmol/L (100 mg/dL) and within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L (100 mg/dL).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 (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels ≥ 5.55 mmol/L (100 mg/dL).

Fingertip Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83 mmol/L (15 mg/dL)
99/156 (63.5%)	135/156 (86.5%)	155/156 (99.4%)

Fingertip Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L (100 mg/dL)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
207/444 (46.6%)	364/444 (82%)	441/444 (99.3%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within ± 0.83 mmol/L (15 mg/dL) and $\pm 15\%$
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 (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels ≥ 5.55 mmol/L (100 mg/dL).

Forearm Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83 mmol/L (15 mg/dL)
13/41 (31.7%)	26/41 (63.4%)	41/41 (100%)

Forearm Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L (100 mg/dL)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
17/59 (28.8%)	38/59 (64.4%)	59/59 (100%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within ± 0.83 mmol/L (15 mg/dL) and $\pm 15\%$
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 (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels ≥ 5.55 mmol/L (100 mg/dL).

Venous Samples (HCP vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83 mmol/L (15 mg/dL)
16/50 (32%)	39/50 (78%)	50/50 (100%)

Venous Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L (100 mg/dL)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
33/174 (19%)	100/174 (57.5%)	166/174 (95.4%)

Venous Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within ± 0.83 mmol/L (15 mg/dL) and $\pm 15\%$
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 (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels ≥ 5.55 mmol/L (100 mg/dL).

Fingertip Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83 mmol/L (15 mg/dL)
9/18 (50%)	17/18 (94.4%)	18/18 (100%)

Fingertip Samples (User vs. YSI) for glucose concentrations ≥ 5.55 mmol/L (100 mg/dL)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
39/82 (47.6%)	65/82 (79.3%)	81/82 (98.8%)

Fingertip Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within ± 0.83 mmol/L (15 mg/dL) and $\pm 15\%$
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 (15 mg/dL) of the YSI results at glucose levels < 5.55 mmol/L (100 mg/dL) and within 15% at glucose levels ≥ 5.55 mmol/L (100 mg/dL).

Forearm Samples (User vs. YSI) for glucose concentrations < 5.55 mmol/L (100 mg/dL)

Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83 mmol/L (15 mg/dL)
21/41 (51.2%)	32/41 (78%)	41/41 (100%)

Forearm Samples (HCP vs. YSI) for glucose concentrations ≥ 5.55 mmol/L (100 mg/dL)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
21/59 (35.6%)	39/59 (66.1%)	57/59 (96.6%)

Forearm Samples for glucose concentrations between 1.1-33.3 mmol/L (20-600 mg/dL)

Within ± 0.83 mmol/L (15 mg/dL) and $\pm 15\%$
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 (15 mg/dL) of the medical laboratory values at glucose concentrations below 5.55 mmol/L (100 mg/dL) and 98.8% within $\pm 15\%$ of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L (100 mg/dL).

Additional Information: See the Owner's Booklets/ System Instructions for Use for more detailed instructions specific to your system. Use the contact information in the Owner's Booklets/ System Instructions for Use for assistance. For medical assistance, call your Doctor or Healthcare Professional.

References

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- 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.

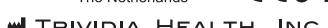
SYMBOLS:

- Biological Risks
- Single Use
- Serial Number
- Caution
- Use-by date
- Keep away from sunlight
- Keep Dry
- Consult Instructions for Use
- Temperature Limit
- Humidity Limitation
- Lot Number
- In vitro* Diagnostic Medical Device
- Authorized Representative in the European Community
- UK Responsible Person
- Manufacturer
- Date of Manufacture
- Single Patient Multiple Use



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URGENT MEDICAL DEVICE CORRECTION

E-5 Error Code Message update

The correction involves the **E-5 Error Code** in the "Messages" section of the Owner's Booklets/System Instructions for Use. The system displays an E-5 error code for a very high blood glucose event (higher than 33.3 mmol/L) or when there is a test strip error. As currently written, the instructions could potentially lead to a delay in treatment if the user does not seek medical attention immediately when they receive an **E-5 error code** and are experiencing symptoms of high glucose. A delay in treatment may result in serious adverse health consequences or death, especially for users with very high blood glucose levels.

Trividia is updating the **E-5 Error Code** actions to emphasize that users must seek medical attention immediately if they receive an E-5 error code and are experiencing symptoms of high glucose.

UPDATED INSTRUCTIONS: FOR TRUE METRIX, TRUE METRIX AIR and TRUE METRIX GO

Display	Reason	Action
	Very high blood glucose result (higher than 33.3 mmol/L) or Test Strip Error	WARNING!! Retest with a new test strip. If the error persists and you have symptoms such as fatigue, excess urination, thirst or blurry vision, seek medical attention immediately. If you are not experiencing symptoms, retest with a new test strip. If the error persists, contact for assistance.

You may continue to use the TRUE METRIX Products.



URGENT MEDICAL DEVICE CORRECTION



URGENT MEDICAL DEVICE CORRECTION

