TRUEyou Blood Glucose Test Strips Instructions for Use

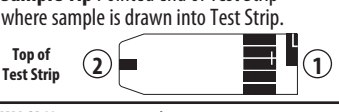
Intended Use: TRUEyou Blood Glucose Test Strips are used only with the TRUEyou Family of Meters (TRUEyou and TRUEyou mini Meters) to quantitatively measure whole blood glucose. TRUEyou Test Strips may be used for self-testing at home or for professional use.

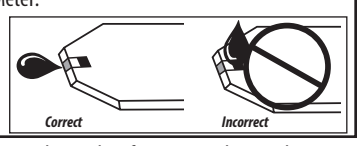
Test Principle: The TRUEyou Test Strip is a plastic strip containing chemicals and electrodes. When inserted into a Meter from the TRUEyou Family, glucose is measured using amperometric technology employing a glucose dehydrogenase-FAD reaction. When whole blood or Control Solution is drawn into the Sample 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. IVD

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

① **Contact End** End of Test Strip inserted into Meter.

② **Sample Tip** Pointed end of Test Strip where sample is drawn into Test Strip.

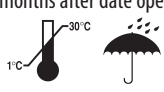




WARNING! Upon opening the test strip carton, examine the product for missing, damaged or broken parts. Ensure the test strip vial cap is securely closed. If the product is damaged or the vial cap is not closed, DO NOT use the test strips for testing; product may give inaccurate results. Contact Trividia 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.
- Use Test Strip quickly after removing from vial. Recap vial right away. Test Strips left outside 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 date printed on the Test Strip vial label, or 4 months after date opened, whichever comes first.
- Store Test Strip vial in a dry place at room temperature below 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 bend, cut, or alter Test Strips in any way.



Important Information

- Test Strips are for *in vitro* testing only. Do not consume. IVD
- Use TRUEyou Test Strips only with the TRUEyou Family of Meters and TRUEyou GDH-FAD Control Solution. Using other Meters or Control Solutions may give inaccurate results.
- 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.
- Do not change treatment plan based on the results from the TRUEyou Test Strips and the TRUEyou Family of Meters without the advice of a Doctor or Healthcare Professional.
- Discard used Test Strips and lancets into an appropriate container.
- Using Test Strips past date printed on the Test Strip vial label or 4 months after date opened may cause inaccurate results.
- Discard any Test Strips or vials that appear damaged.
- NEVER use serum, plasma or clotted blood for testing. Use fresh, capillary whole blood. Venous whole blood collected into sodium or lithium heparin blood collection tubes may be used for testing by Healthcare Professionals. Use of EDTA blood collection tubes is not recommended and may cause low results.
- Lancing device is for self-testing and intended for use by one patient ONLY. Not suitable for use by healthcare or care workers.
- Reuse of devices labeled for single-use may result in product contamination and patient infection.
- To help prevent false high results, wash hands before using the System to test blood, especially after handling fruit or other foods containing sugars.
- When using the forearm for blood sample:[1]
  - Check with your Doctor or 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 low or high.

Quality Control 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 TRUEyou Test Strip is inserted into a Meter from the TRUEyou Family. 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 and may be used for testing.

Quality Control Test: Control Test

TRUEyou GDH-FAD Control Solution is used to check testing technique and System performance. When Control Test result falls within Control Test range printed on Test Strip vial label of Test Strips being used, System is working properly and testing technique is good. See Owner's Booklet or TRUEyou GDH-FAD Control Solution Instructions for Use for more information on Control Testing.

Important Information

There are three levels of TRUEyou Control Solution available which contain known amounts of glucose. It is important to perform Control Tests with more than one level of Control Solution to ensure your System is working properly and your testing technique is good. For more information on obtaining different levels of Control Solution, use contact information on cover of Owner's Booklet.

Blood Glucose Testing

Note to Healthcare Professionals: Venous whole blood collected into sodium or lithium heparin blood collection tubes may be used for testing by Healthcare Professionals. Use of EDTA blood collection tubes is not recommended and may cause low results. Mix tube well before sampling.

1. Allow Meter and Test Strips to sit at room temperature for 30 minutes. If opening vial for the first time, write date opened on vial label.
2. Check written date and printed date on Test Strip vial label. Discard vial and unused Test Strips if either 4 months after opening or date printed next to ⌛ on vial label has passed, whichever comes first. Test with new vial.
3. Wash hands (and forearm for alternate site testing). Rinse well and dry thoroughly.
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. After Drop Symbol appears in Display, with Test Strip still in Meter, touch Test Strip Sample Tip to the top of the blood drop and allow blood to be drawn into Test Strip. Remove Test Strip Sample Tip from sample drop immediately after the Meter begins testing.
8. Result is displayed. Record result.
9. Remove Test Strip from Meter. Meter turns off. Discard used Test Strip and lancet in appropriate container.

☣ *Treat used Test Strips and lancets as a biological risk. Dispose used Test Strips and lancets in approved container.*

Expected Results for people without diabetes:[2]

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 your glucose is too low or too high, contact your Doctor or Healthcare Professional right away.

If comparing results using TRUEyou Test Strips to laboratory test results, perform a finger-stick blood test within 30 minutes of the laboratory test. Diabetes experts have suggested that glucose meters should agree within 0.83 mmol/L of a laboratory method when the glucose concentration is less than 5.55 mmol/L, and within 15% of a laboratory method when the glucose concentration is 5.55 mmol/L or higher.[3] If you have eaten recently, results using TRUEyou Test Strips may be up to 3.9 mmol/L higher than laboratory results.[4]

Troubleshooting

If your result is unusually high or low or does not 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 TRUEyou Test Strip.

If the Control Test results are not within range:

- Check the ⌛. Do not use Control Solution or Test Strips if Use By Dates have passed (Control Solution - 3 months after opening or date next to ⌛ on bottle label, whichever comes first; Test Strips - 4 months after opening or date next to ⌛ on Test Strip vial label, whichever comes first). Test with new Test Strips/Control Solution.
- Check for error messages. If an error message appears, follow the Actions in the Display Message Section of the Owner's Booklet.
- Perform another Control Test to check your testing technique.
- Check the temperature. Allow System to reach room temperature between 20°C-25°C before testing.

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

Limitations

- Do not use the TRUEyou Family Systems during a xylose absorption test. This may falsely raise glucose results. Please check with your Doctor before using the TRUEyou Family Systems.[5]
- Do not use for diagnosis of diabetes or for testing blood glucose in newborns.

The following will not affect accurate results:[5]

- Testing at altitudes up to and including 3094 metres.
- Haematocrit levels between 20% and 55%.

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):[6]

- shock • severe hypotension • severe dehydration
- hyperglycaemia with hyperosmolarity, with or without ketosis

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. Joslin Diabetes Center. *Goals for Blood Glucose Control* [Electronic Version]. Retrieved June 8, 2015 from http://www.joslin.org/info/Goals-for-Blood-Glucose-Control.html .
3. 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.
4. Larsson-Cohn U: *Differences 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., et. al. *Fingerstick Glucose Determination in Shock.* Annals of Internal Medicine, 114:1020-1024 (1991).

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)	3.4	5.1	8.5	12.1	19.2
SD (mmol/L)	0.11	0.14	0.27	0.37	0.66
%CV	3.2	2.9	3.1	3.0	3.4

Intermediate Precision: N=100

Mean (mmol/L)	3.1	7.6	19.5
SD (mmol/L)	0.09	0.24	0.69
%CV	3.1	3.2	3.5

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. 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 TRUEyou 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 ± 0.83 mmol/L	Within ± 0.83 mmol/L
74/180 (41%)	155/180 (86%)	178/180 (98.8%)

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

Within ± 5%	Within ± 10%	Within ± 15%
272/420 (71%)	395/420 (94%)	418/420 (99.5%)

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

Within ± 0.83 mmol/L and ±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 TRUEyou 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 ± 0.83 mmol/L	Within ± 0.83 mmol/L
18/28 (64%)	26/28 (93%)	28/28 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
50/72 (69%)	64/72 (89%)	72/72 (100%)

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

Within ± 0.83 mmol/L and ±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

99.6% of TRUEyou 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 ± 0.83 mmol/L	Within ± 0.83 mmol/L
10/28 (35.7%)	18/28 (64.3%)	28/28 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
126/214 (58.9%)	191/214 (89.3%)	213/214 (99.5%)

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

Within ± 0.83 mmol/L and ±15%
241/242 (99.6%)

Parkes Error Grid: 99.6% of individual venous glucose measured values performed by healthcare professionals fell within Zone A and 0.4% fell within Zone B of the Parkes Error Grid (PEG).

For Consumers

99% of TRUEyou 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 ± 0.83 mmol/L	Within ± 0.83 mmol/L
11/23 (48%)	21/23 (91%)	23/23 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
38/77 (49%)	66/77 (86%)	76/77 (99%)

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

Within ± 0.83 mmol/L and ±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).

100% of TRUEyou 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 ± 0.83 mmol/L	Within ± 0.83 mmol/L
16/28 (57%)	23/28 (82%)	28/28 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%
42/72 (58%)	61/72 (85%)	72/72 (100%)

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

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

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 99% within ± 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

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

SYMBOLS:

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

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