

# TRUEtest™ Blood Glucose Test Strips Instructions for Use

## Intended Use

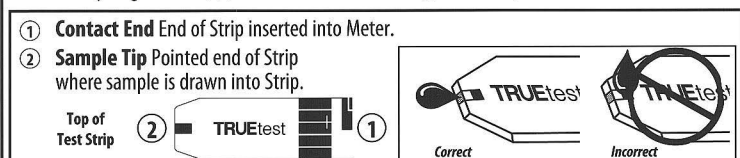
TRUEtest™ Blood Glucose Test Strips are used only with TRUEresult® and TRUE2go® Meters to quantitatively measure whole blood glucose. TRUEtest Strips can be used for self-testing at home or for professional use. TRUEtest is for *in vitro* diagnostic use only.

## Test Principle

The TRUEtest Strip is a plastic strip containing chemicals and electrodes. When inserted into a TRUEresult or TRUE2go Meter, glucose is measured using amperometric technology employing a glucose dehydrogenase-PQQ reaction. When whole blood or Control is drawn into the Sample Tip of the 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-PQQ (*Acinetobacter calcoaceticus*), mediators, buffers and stabilizers.



## Caring for Strips

- Strips must be kept in original vial with vial cap tightly sealed. NEVER transfer Strips from one vial to another.
- Use Strip quickly after removing from vial. Recap vial right away. Strips left outside of vial too long give an error message.
- Write date opened on Strip vial label when removing the first Strip. Discard all unused Strips in vial after date printed on the Strip vial label, or 4 months after date opened, if either date has passed.
- Store Strip vial in a dry place at room temperature below 86°F. 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 Strips in any way.

## Important Information

- Strips are for *in vitro* testing only. Do not consume.
- Use TRUEtest Strips only with TRUEresult and TRUE2go Meters and TRUEtest Glucose Control. Using other meters or Controls may give inaccurate results.

## 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 Strip. Adding more sample gives an error message.
- Do not change treatment plan based on the results from the TRUEtest Strips and TRUEresult/TRUE2go Meters without the advice of a Doctor or Healthcare Professional.
- Discard used Strips and lancets into an appropriate container.
- Using Test Strips either 4 months after date first opened (written date) or printed date on the Strip vial label may cause inaccurate results.
- Discard any Strips or vials that appear damaged.
- NEVER use serum, plasma, or dotted blood for testing. Use fresh, capillary whole blood or venous whole blood drawn into an EDTA (purple top) or heparin (green top) vacutainer tube. Mix well before sampling.
- Lancing device is for self-testing and intended for use by one patient ONLY. Not suitable for use by healthcare or care workers.
- When using the forearm for blood sample:
  - 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. An automatic self-test is performed each time a TRUEtest Strip is inserted into a TRUEresult or TRUE2go Meter. Upon inserting a Strip into the Test Port, if all segments appear and the Drop Symbol appears in the Display, the Meter is working properly and can be used for testing.

**Important Information:** There are three levels of TRUEtest Glucose Control available that contain known amounts of glucose. It is important to perform Control Tests with more than one level of Control to assure your System is working properly and your testing technique is good. For more information on obtaining different levels of Control, call 1-800-803-6025 or 1-954-677-4599. See TRUEtest Glucose Control Instructions for Use or TRUEresult/TRUE2go Owner's Booklet for more information on Quality Control testing.

## Blood Glucose Testing

Note to Healthcare Professionals: Venous whole blood collected in EDTA (purple top) or heparin (green top) vacutainer tubes may be used for testing. Mix blood thoroughly before testing.

1. Wash area to be lanced, dry.
2. Allow Meter and Strips to sit at room temperature for 30 minutes. If opening vial for the first time, write date opened on vial label.
3. Check EXP on Strip vial. Do not use if past either 4 months after date first opened (written date) or date printed on the Test Strip vial, whichever comes first. Discard vial and test with new vial.
4. Remove one Strip from vial. Recap vial right away.
5. Insert Contact End of Strip into Test Port of Meter. Meter turns on. Do not remove Strip from Meter until testing is finished.
6. Obtain blood drop.
7. After Drop Symbol appears in Display, **TRUEresult:** With Test Strip still in Meter, touch edge of Sample tip to blood drop and allow blood to be drawn into strip. Remove Test Strip sample tip from sample drop immediately after the meter beeps and dashes appear across meter display. **TRUE2go:** With Test Strip still in Meter, touch edge of Sample tip to blood drop and allow blood to be drawn into strip. Remove Test Strip sample tip from sample drop immediately after dashes appear across the meter display. **CAUTION!** Holding the Test Strip Sample Tip to the blood sample too long after the Meter begins testing may cause inaccurate results. If Meter does not begin testing 5 seconds after touching Strip to blood drop, see Troubleshooting in the TRUEresult/TRUE2go Owner's Booklet.
8. Result is displayed. Record result.
9. Hold Meter with Strip pointing down. Press Strip Release button to discard Strip into appropriate container.

## Expected Results for people without diabetes:<sup>2</sup>

	Plasma Blood Glucose Result
Before eating	< 110 mg/dL
Two hours after meals	< 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 TRUEtest strips to laboratory test results, perform a fingerstick blood test within 30 minutes of the laboratory test. Diabetes experts have suggested that glucose meters should agree within 15 mg/dL of a laboratory method when the glucose concentration is less than 75 mg/dL, and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher.<sup>3</sup> If you have eaten recently, results using TRUEtest Strips can be up to 70 mg/dL higher than laboratory results.<sup>4</sup>

## 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 TRUEtest Strip.
- If the results still do not match the way you feel, check with your Doctor or Healthcare Professional before changing your treatment program.
- If the results are not within range:
- Check the Expiration Dates. Do not use if past either written date or date printed on Test Strip vial or Control bottle. Test with new Strips/Control.
  - Check for error messages. If an error message appears, follow the Actions in the Display Message Section of the Owner's Booklet.
  - Check your testing technique. Perform another Control Test.
  - Check the temperature. Allow System to reach room temperature 68-77°F before testing.

## Limitations

- WARNING!**
- **Peritoneal dialysis patients receiving dialysis solutions containing Icodextrin (e.g., Extraneal®, Icodial®) should not use the TRUEresult or TRUE2go System. The dialysis solution may falsely raise glucose results.<sup>5</sup>**
  - **Injection or infusion of solutions containing galactose or maltose (includes some human immunoglobulin preparations) may falsely raise glucose results.<sup>5</sup>**
  - **Blood concentrations of galactose > 10 mg/dL, maltose > 12.5 mg/dL, maltotriose > 20 mg/dL and maltotetraose > 10 mg/dL may falsely raise glucose results.<sup>6</sup>**
  - **Do not use TRUEresult or TRUE2go Systems during a xylose absorption test. This may falsely raise glucose results.<sup>6</sup>**
  - Blood samples containing high uric acid concentration (≥ 9 mg/dL) at glucose levels < 240 mg/dL may be detected as control samples by the TRUEresult Meter, but not the TRUE2go Meter.<sup>6</sup>
- The following will not affect accurate results:<sup>6</sup>
- Testing at altitudes up to and including 10,150 feet.
  - Hematocrit levels between 20% and 60%.

**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):<sup>7</sup>

- shock
- severe hypotension
- severe dehydration
- hyperglycemia with hyperosmolarity, with or without ketosis.

## FOR CONSUMERS • Performance Characteristics<sup>6</sup>

**Accuracy:** Diabetes experts have suggested that glucose meters should agree within 15 mg/dL of a laboratory method when the glucose concentration is less than 75 mg/dL, and within 20% of a laboratory method when the glucose concentration is 75 mg/dL or higher.<sup>3</sup> TRUEresult and TRUE2go were tested by users at diabetes clinics, large urban hospitals, and diabetes care centers. The table below shows how often user TRUEresult and TRUE2go fingertip values can achieve these goals. The fingertip data were compared to parallel results obtained on a Yellow Springs Instrument (YSI) Model 2300.

TRUEresult Finger Sample - <75 mg/dL (user finger vs. YSI)				
±5 mg/dL	±10 mg/dL	±15 mg/dL		
16/25 = 64%	23/25 = 92%	25/25 = 100%		
TRUEresult Finger Sample - ≥75 mg/dL (user finger vs. YSI)				
±5%	±10%	±15%	±20%	
169/321 = 53%	271/321 = 84%	310/321 = 97%	319/321 = 99%	

TRUE2go Finger Sample - <75 mg/dL (user finger vs. YSI)				
±5 mg/dL	±10 mg/dL	±15 mg/dL		
15/22 = 68%	22/22 = 100%	22/22 = 100%		

TRUE2go Finger Sample - ≥75 mg/dL (user finger vs. YSI)				
±5%	±10%	±15%	±20%	
171/310 = 55%	255/310 = 82%	299/310 = 96%	309/310 = 99.7%	

The table below shows how often user TRUEresult and TRUE2go forearm values achieve these goals when users' glucose values are not fluctuating.

TRUEresult Forearm Sample - <75 mg/dL (user forearm vs. user finger)				
±5 mg/dL	±10 mg/dL	±15 mg/dL		
17/25 = 68%	23/25 = 92%	25/25 = 100%		

TRUEresult Forearm Sample - ≥75 mg/dL (user forearm vs. user finger)				
±5%	±10%	±15%	±20%	
193/319 = 61%	285/319 = 89%	311/319 = 97%	314/319 = 98%	

TRUE2go Forearm Sample - <75 mg/dL (user forearm vs. user finger)				
±5 mg/dL	±10 mg/dL	±15 mg/dL		
14/19 = 74%	19/19 = 100%	19/19 = 100%		

TRUE2go Forearm Sample - ≥75 mg/dL (user forearm vs. user finger)				
±5%	±10%	±15%	±20%	
203/311 = 65%	269/311 = 86%	299/311 = 96%	306/311 = 98%	

## FOR HEALTHCARE PROFESSIONALS<sup>6</sup>

### Performance Characteristics – TRUEresult System

**Accuracy:** TRUEresult accuracy was assessed against the Yellow Springs Instrument (YSI) Model 2300. Studies were conducted at 4 clinical sites by Healthcare Professionals.

**Fingertip Capillary Blood (mg/dL) (ISO 15197:2003 data finger vs. YSI):<sup>2</sup> N=314**

Slope	y-intercept	r <sup>2</sup>	Range
1.01	-2.19	0.98	24-549

**Venous Blood (mg/dL): N=236**

Slope	y-intercept	r <sup>2</sup>	Range
1.11	-4.40	0.99	34-463

99.4% of Healthcare Professional (HCP) TRUEresult fingertip values fell within 15 mg/dL of the YSI results at glucose levels <75 mg/dL and within 20% at glucose levels ≥75 mg/dL.

**Fingertip Capillary Blood (HCP finger vs. YSI)**

<75 mg/dL				
±5 mg/dL	±10 mg/dL	±15 mg/dL		
28/44 = 64%	42/44 = 95%	44/44 = 100%		
≥75 mg/dL				
±5%	±10%	±15%	±20%	
139/270 = 51%	227/270 = 84%	260/270 = 96%	268/270 = 99%	

98.8% of Healthcare Professional (HCP) TRUEresult forearm values fell within 15 mg/dL of the fingertip results at glucose levels <75 mg/dL and within 20% at glucose levels ≥75 mg/dL when users' glucose values are not fluctuating.

**Forearm Capillary Blood (HCP forearm vs. HCP finger)**

<75 mg/dL				
±5 mg/dL	±10 mg/dL	±15 mg/dL		
12/26 = 46%	22/26 = 85%	25/26 = 96%		
≥75 mg/dL				
±5%	±10%	±15%	±20%	
196/318 = 62%	286/318 = 90%	311/318 = 98%	315/318 = 99%	

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

**Blood (Within Lot): N=100**

mg/dL	44	77	130	214	319
CV%	2.5	3.5	3.2	4.6	3.9

**Blood (Within Vial): N=10**

mg/dL	44	78	130	217	319
CV%	2.0	2.2	2.1	3.2	2.4

**Glucose Control: N=100**

mg/dL	45	104	301
CV%	1.7	1.6	4.1

### Performance Characteristics – TRUE2go System

**Accuracy:** The accuracy of TRUE2go was assessed against the Yellow Springs Instrument (YSI) Model 2300. Studies were conducted at 4 clinical sites by healthcare professionals.

**Fingertip Capillary Blood (mg/dL) (ISO 15197:2003 data finger vs. YSI):<sup>2</sup> N=332**

Slope	y-intercept	r <sup>2</sup>	Range
0.95	2.58	0.98	45-498

**Venous Blood (mg/dL): N=236**

Slope	y-intercept	r <sup>2</sup>	Range
1.11	-3.52	0.99	34-463

100% of Healthcare Professional (HCP) TRUE2go Meter fingertip values fell within 15 mg/dL of the YSI results at glucose levels <75 mg/dL and within 20% at glucose levels ≥75 mg/dL.

**Fingertip Capillary Blood (HCP finger vs. YSI)**

<75 mg/dL				
±5 mg/dL	±10 mg/dL	±15 mg/dL		
30/50 = 60%	48/50 = 96%	50/50 = 100%		
≥75 mg/dL				
±5%	±10%	±15%	±20%	
152/289 = 53%	254/289 = 88%	278/289 = 96%	289/289 = 100%	

99.4% of Healthcare Professional (HCP) TRUE2go Meter forearm values fell within 15 mg/dL of the Healthcare Professional finger results at glucose levels <75 mg/dL and within 20% at glucose levels ≥75 mg/dL.

**Forearm Capillary Blood (HCP forearm vs. HCP finger)**

<75 mg/dL				
±5 mg/dL	±10 mg/dL	±15 mg/dL		
18/19 = 95%	19/19 = 100%	19/19 = 100%		
≥75 mg/dL				
±5%	±10%	±15%	±20%	
202/311 = 65%	270/311 = 87%	300/311 = 96%	308/311 = 99%	

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

**Blood (Within Lot): N=100**

mg/dL	47	77	138	211	312
CV%	3.0	2.7	3.1	4.7	4.4

**Blood (Within Vial): N=10**

mg/dL	48	77	139	209	312
CV%	1.7	1.9	2.1	3.1	3.5

**Glucose Control: N=100**

mg/dL	45	102	298
CV%	1.7	1.7	2.8

**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. Joslin Diabetes Center. Goals for Blood Glucose Control [Electronic Version]. Retrieved July 25, 2011 from <http://www.joslin.org/info/Goals-for-Blood-Glucose-Control.html>
3. International Organization for Standardization. In vitro diagnostic test systems. Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus. Reference number ISO 15197:2003 (E). Geneva: International Organization for Standardization; 2003. Data on file.
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. U.S. Food and Drug Administration. Center for Biologics Evaluation and Research. Important Safety Information on Interference With Blood Glucose Measurement Following Use of Parenteral Maltose/Parenteral Galactose/Oral Xylose-Containing Products. [Electronic Version]. Retrieved June 30, 2009. [www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm154213.htm](http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm154213.htm)
6. Data on file.
7. Atkins, 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.

Manufactured by:

**NIPRO**  
DIAGNOSTICS™  
Fort Lauderdale, FL 33309 U.S.A.

**Additional Information:** See the Owner's Booklets for more detailed instructions. Call Nipro Diagnostics, Inc. at 1-800-803-6025 (USA) or 1-954-677-4599 for assistance. For medical assistance, call your Doctor or Diabetes Healthcare Professional.

© 08/2013 Nipro Diagnostics, Inc. TRUEtest, TRUEresult, TRUE2go and the Nipro Diagnostics logo are trademarks of Nipro Diagnostics Inc. E3NPD03 Rev. 23

TRUEtest™



E3NPD03R23

TRUEtest™