

TRUEresult Blood Glucose Test Strips Instructions for Use

Intended Use: TRUEresult Blood Glucose Test Strips are used only with TRUEresult and TRUEresult twist Meters to quantitatively measure whole blood glucose. TRUEresult Strips may be used for self-testing at home or for professional use.

Test Principle: The TRUEresult Strip is a plastic strip containing chemicals and electrodes. When inserted into a TRUEresult or TRUEresult twist Meter, glucose is measured using amperometric technology employing a glucose dehydrogenase-FAD 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-FAD (*Aspergillus sp.*), mediators, buffers and stabilisers.

①

Contact End

End of Strip inserted into Meter.

②

Sample Tip

Pointed end of Strip where sample is drawn into Strip.

Top of Test Strip

②

①

Correct

Incorrect

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 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 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 Strips in any way.

Important Information

- Strips are for *in vitro* testing only. Do not consume.
- Use TRUEresult Strips only with TRUEresult and TRUEresult twist Meters and TRUEresult Control Solution. Using other meters or Controls 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 Strip. Adding more sample gives an error message.
- Do not change treatment plan based on the results from the TRUEresult Strips and TRUEresult/TRUEresult twist Meters without the advice of a Doctor or Health-care Professional.
- Discard used Strips and lancets into an appropriate container.
- Using Strips past written or printed dates on the Strip vial label may cause inaccurate results.
- Discard any 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 vacutainer tubes may be used for testing by healthcare professionals. Use of EDTA vacutainer tubes (purple top) 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 health-care or care workers.
- When using the forearm for blood sample:
 - Check with your Doctor or Health-care 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 TRUEresult Strip is inserted into a TRUEresult or TRUEresult twist Meter. Upon inserting a Strip into the Test Port, if all segments appear and the Drop Symbol appear in the Display, the Meter is working properly and may be used for testing.


Important Information: *There are three levels of TRUEresult 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, call the number on the front cover of the Owner's Booklets.*

See TRUEresult Control Solution Instructions for Use or TRUEresult/TRUEresult twist Owner's Booklet for more information on Quality Control testing.

Blood Glucose Testing

Note to Health-care Professionals: Venous whole blood collected into sodium or lithium heparin vacutainer tubes may be used for testing by healthcare professionals. Use of EDTA vacutainer tubes (purple top) is not recommended and may cause low results. Mix tube well before sampling.

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 written date and printed date on Strip vial label. Do not use if either date has passed. 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.
TRUEresult twist: 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.

 *Holding the Test Strip Sample Tip to the blood sample too long after the Meter begins testing may cause inaccurate results.*

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:²

	<i>Plasma Blood Glucose Result</i>	<i>Plasma Blood Glucose Result</i>
Before eating < 6.1 mmol/L (110 mg/dL)		Two hours after meals < 7.8 mmol/L (140 mg/dL)

A Doctor or Diabetes Health-care 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 Health-care Professional right away.

If comparing results using TRUEresult 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 (15 mg/dL) of a laboratory method when the glucose concentration is less than 4.2 mmol/L (75 mg/dL), and within 20% of a laboratory method when the glucose concentration is 4.2 mmol/L (75 mg/dL) or higher.³ If you have eaten recently, results using TRUEresult Strips may be up to 3.9 mmol/L (70 mg/dL) 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 TRUEresult Strip.

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

If the results are not within range:

- Check the . 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 between 10°C-40°C before testing.

Limitations⁵

- Do not use the TRUEresult or TRUEresult twist Systems during a xylose absorption test. This may falsely raise glucose results. Please check with your Doctor before using the TRUEresult or TRUEresult twist Systems.
- Ascorbic acid concentrations at or above 0.28 mmol/L (5 mg/dL) may cause elevated meter glucose results.

The following will not affect accurate results:⁵

- Testing at altitudes up to and including 3094 metres.
- Haematocrit levels between 25% 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):⁶

- shock • severe hypotension • severe dehydration • hyperglycemia with hyperosmolality, 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 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.

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.

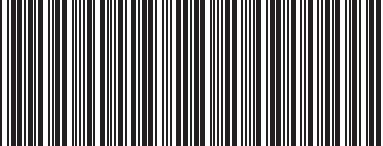
6. Atkins, S.H., et al. Fingertick Blood Glucose Determination in Shock. Annals of Internal Medicine, 114:1020-1024 (1991).

SYMBOLS:	<div>① Control Level</div> <div>② Serial Number</div> <div>③ Single Use Only</div>	<div> Use By Date</div> <div> Keep Dry</div>
<div> For Assistance Call</div> <div> Attention! Read Instructions for Use.</div> <div><div><div>°C</div><div>°F</div></div><div>Storage Temperature Range</div></div> <div><div>STERILE</div><div>R</div><div>Sterile</div></div>		
<div><div>LOT</div><div>Lot Number</div></div> <div><div>IVD</div><div>For in vitro Diagnostic Testing Only</div></div> <div><div>EC REP</div><div>Authorised Representative</div></div> <div><div> Manufactured By</div></div>		

Additional Information: See the Owner's Booklets for more detailed instructions. Call the number on the front cover of the Owner's Booklets for assistance. For medical assistance, call your Doctor or Diabetes Health-care Professional.


If you are calling from:	Use the number listed below:
Australia	1 800 451 737
India	1 800 209 5200
All other countries	US: 1 954 677 4599

TRUEresult



E31NP03FDR22

TRUEresult



FOR CONSUMERS • Performance Characteristics⁵

Accuracy: Diabetes experts have suggested that glucose meters should agree within 0.83 mmol/L (15 mg/dL) of a laboratory method when the glucose concentration is less than 4.2 mmol/L (75 mg/dL), and within 20% of a laboratory method when the glucose concentration is 4.2 mmol/L (75 mg/dL) or higher.³ TRUEresult and TRUEresult twist were tested by users at diabetes clinics, large urban hospitals, and diabetes care centers. The table below shows how often user TRUEresult and TRUEresult twist 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 - <4.2 mmol/L (75 mg/dL) (user finger vs. YSI)

±0.3 mmol/L (5 mg/dL)	±0.6 mmol/L (10 mg/dL)	±0.8 mmol/L (15 mg/dL)
10/17 = 59%	15/17 = 88%	17/17 = 100%

TRUEresult Finger Sample - ≥4.2 mmol/L (75 mg/dL) (user finger vs. YSI)

±5%	±10%	±15%	±20%
155/359 = 43%	281/359 = 78%	330/359 = 92%	354/359 = 99%

TRUEresult twist Finger Sample - <4.2 mmol/L (75 mg/dL) (user finger vs. YSI)

±0.3 mmol/L (5 mg/dL)	±0.6 mmol/L (10 mg/dL)	±0.8 mmol/L (15 mg/dL)
7/14 = 50%	11/14 = 79%	14/14 = 100%

TRUEresult twist Finger Sample - ≥4.2 mmol/L (75 mg/dL) (user finger vs. YSI)

±5%	±10%	±15%	±20%
119/327 = 36%	232/327 = 71%	286/327 = 87%	315/327 = 96%

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

TRUEresult Forearm Sample - <4.2 mmol/L (75 mg/dL) (user forearm vs. user finger)

±0.3 mmol/L (5 mg/dL)	±0.6 mmol/L (10 mg/dL)	±0.8 mmol/L (15 mg/dL)
3/6 = 50%	6/6 = 100%	6/6 = 100%

TRUEresult Forearm Sample - ≥4.2 mmol/L (75 mg/dL) (user forearm vs. user finger)

±5%	±10%	±15%	±20%
180/370 = 49%	291/370 = 79%	335/370 = 91%	358/370 = 97%

TRUEresult twist Forearm Sample - <4.2 mmol/L (75 mg/dL) (user forearm vs. user finger)

±0.3 mmol/L (5 mg/dL)	±0.6 mmol/L (10 mg/dL)	±0.8 mmol/L (15 mg/dL)
10/12 = 83%	11/12 = 92%	12/12 = 100%

TRUEresult twist Forearm Sample - ≥4.2 mmol/L (75 mg/dL) (user forearm vs. user finger)

±5%	±10%	±15%	±20%
142/318 = 45%	243/318 = 76%	290/318 = 91%	310/318 = 97%

FOR HEALTH-CARE PROFESSIONALS⁵

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 Health-care Professionals.

Fingertip Capillary Blood (ISO 15197:2003 data finger vs. YSI):² N=376

Slope	y-intercept	r ²	Range
0.98	-0.14 mmol/L (-2.44 mg/dL)	0.97	3.2 - 26.4 mmol/L (57 - 476 mg/dL)

Venous Blood: N=342

Slope	y-intercept	r ²	Range
1.02	0.12 mmol/L (2.07 mg/dL)	0.98	3.0 – 28.1 mmol/L (54 - 506 mg/dL)

98.4% of Health-care Professional (HCP) TRUEresult fingertip values fell within 0.83 mmol/L (15 mg/dL) of the YSI results at glucose levels < 4.2 mmol/L (75 mg/dL) and within 20% at glucose levels ≥ 4.2 mmol/L (75 mg/dL).

Fingertip Capillary Blood (HCP finger vs. YSI)

<4.2 mmol/L (75 mg/dL)

±0.3 mmol/L (5 mg/dL)	±0.6 mmol/L (10 mg/dL)	±0.8 mmol/L (15 mg/dL)
12/18 = 67%	18/18 = 100%	18/18 = 100%

≥4.2 mmol/L (75 mg/dL)

±5%	±10%	±15%	±20%
182/358 = 51%	297/358 = 83%	333/358 = 93%	352/358 = 98%

97.8% of Health-care Professional (HCP) TRUEresult forearm values fell within 0.83 mmol/L (15 mg/dL) of the fingertip results at glucose levels < 4.2 mmol/L (75 mg/dL) and within 20% at glucose levels ≥ 4.2 mmol/L (75 mg/dL) when users' glucose values are not fluctuating.

Forearm Capillary Blood (HCP forearm vs. HCP finger)

<4.2 mmol/L (75 mg/dL)

±0.3 mmol/L (5 mg/dL)	±0.6 mmol/L (10 mg/dL)	±0.8 mmol/L (15 mg/dL)
6/9 = 67%	8/9 = 89%	8/9 = 89%

≥4.2 mmol/L (75 mg/dL)

±5%	±10%	±15%	±20%
176/367 = 48%	293/367 = 80%	345/367 = 94%	360/367 = 98%

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

Blood (Within Lot): N=100

Mean (mmol/L)	2.7	4.8	7.1	12.7	19.0
Mean (mg/dL)	48	86	154	228	342
SD (mmol/L)	0.06	0.11	0.21	0.41	0.74
SD (mg/dL)	1.1	2.0	3.7	7.4	13.3
CV%	2.4	2.3	2.9	3.2	3.9

Blood (Within Vial): N=10

Mean (mmol/L)	2.7	4.8	7.1	12.7	19.0
Mean (mg/dL)	48	86	154	228	342
SD (mmol/L)	0.06	0.10	0.21	0.32	0.68
SD (mg/dL)	1.0	1.8	3.7	5.7	12.3
CV%	2.1	2.1	2.9	2.5	3.6

Glucose Control: N=100

Mean (mmol/L)	2.4	7.2	17.4
Mean (mg/dL)	44	129	314
SD (mmol/L)	0.06	0.20	0.71
SD (mg/dL)	1.1	3.6	12.7
CV%	2.4	2.8	4.0

Performance Characteristics – TRUEresult twist System

Accuracy: The accuracy of TRUEresult twist was assessed against the Yellow Springs Instrument (YSI) Model 2300. Studies were conducted at 4 clinical sites by health-care professionals.

Fingertip Capillary Blood (ISO 15197:2003 data finger vs. YSI):² N=200

Slope	y-intercept	r ²	Range
0.97	-0.009 mmol/L (-0.16 mg/dL)	0.97	1.3 - 32.2 mmol/L (24 - 579 mg/dL)

Venous Blood: N=290

Slope	y-intercept	r ²	Range
0.97	0.48 mmol/L (8.62 mg/dL)	0.98	2.0 - 29.2 mmol/L (36 - 525 mg/dL)

99.5% of Health-care Professional (HCP) TRUEresult twist Meter fingertip values fell within 0.83 mmol/L (15 mg/dL) of the YSI results at glucose levels < 4.2 mmol/L (75 mg/dL) and within 20% at glucose levels ≥ 4.2 mmol/L (75 mg/dL).

Fingertip Capillary Blood (HCP finger vs. YSI)

<4.2 mmol/L (75 mg/dL)

±0.3 mmol/L (5 mg/dL)	±0.6 mmol/L (10 mg/dL)	±0.8 mmol/L (15 mg/dL)
18/33 = 55%	31/33 = 94%	33/33 = 100%

≥4.2 mmol/L (75 mg/dL)

±5%	±10%	±15%	±20%
66/167 = 40%	121/167 = 72%	149/167 = 89%	166/167 = 99%

98.8% of Health-care Professional (HCP) TRUEresult twist Meter forearm values fell within 0.83 mmol/L (15 mg/dL) of the fingertip results at glucose levels < 4.2 mmol/L (75 mg/dL) and within 20% at glucose levels ≥ 4.2 mmol/L (75 mg/dL) when users' glucose values are not fluctuating.

Forearm Capillary Blood (HCP forearm vs. HCP finger)

<4.2 mmol/L (75 mg/dL)

±0.3 mmol/L (5 mg/dL)	±0.6 mmol/L (10 mg/dL)	±0.8 mmol/L (15 mg/dL)
10/15 = 67%	13/15 = 87%	14/15 = 93%

≥4.2 mmol/L (75 mg/dL)

±5%	±10%	±15%	±20%
159/325 = 49%	275/325 = 85%	305/325 = 94%	322/325 = 99%

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

Blood (Within Lot): N=100


Mean (mmol/L)	2.4	4.4	6.7	10.3	16.0
Mean (mg/dL)	43	79	120	185	288
SD (mmol/L)	0.01	0.11	0.17	0.44	0.67
SD (mg/dL)	1.8	2.0	3.1	8.0	12.0
CV%	4.3	2.5	2.6	4.3	4.2

Blood (Within Vial): N=10

Mean (mmol/L)	2.4	4.4	6.7	10.3	16.0
Mean (mg/dL)	43	79	120	185	288
SD (mmol/L)	0.09	0.09	0.16	0.40	0.56
SD (mg/dL)	1.6	1.7	2.8	7.2	10.0
CV%	3.8	2.2	2.3	3.9	3.5

Glucose Control: N=100

Mean (mmol/L)	2.4	7.2	17.4
Mean (mg/dL)	44	129	314
SD (mmol/L)	0.06	0.20	0.71
SD (mg/dL)	1.1	3.6	12.7
CV%	2.4	2.8	4.0



DIAGNOSTICS

2400 NW 55 Ct
Fort Lauderdale FL 33309 U.S.A.

EC REP

Nipro Europe NV
Weihoek 3H
1930 Zaventem
Belgium

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