

### Intended Use

TRUE FOCUS Blood Glucose Test Strips are used only with TRUE FOCUS Meters to quantitatively measure whole blood glucose in fresh, human capillary whole blood taken from the fingertip or forearm. The TRUE FOCUS Blood Glucose Monitoring System is intended to be used by a single person and not shared.

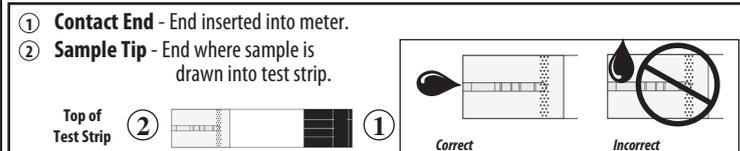
The blood glucose monitoring system is intended for self-testing at home (over-the-counter). Testing is performed outside the body (*in vitro* diagnostic use) by a single person with diabetes as an aid for monitoring the effectiveness of diabetes control. The blood glucose monitoring system is not to be used on neonates or for the diagnosis or screening of diabetes mellitus. Alternative site (forearm) testing can only be performed during steady-state blood glucose conditions.

### Test Principle

The TRUE FOCUS Test Strip is a plastic strip containing chemicals and electrodes. When inserted into a TRUE FOCUS Meter, glucose is measured using amperometric technology employing a glucose dehydrogenase-FAD reaction. When whole blood or TRUE FOCUS 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 stabilizers.



### 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 on the test strip vial label or 90 days after date opened, 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 59°F-86°F and at 10% - 90% Relative Humidity. **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.
- Discard any test strips or vials that appear damaged.
- Do not bend, cut, or alter test strips in any way.

### Important Information

- Use TRUE FOCUS Test Strips only with TRUE FOCUS Meters and TRUE FOCUS Control Solution. Using other meters or controls may give inaccurate results.
- Test strips are for *in vitro* testing only. Do not consume.
- Meter and lancing device is for self-testing and intended for use on one person ONLY. Do not share your meter or lancing device.
- Use fresh, capillary whole blood from fingertip or forearm. Do not use venous blood for testing.
- 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 fingertip.
- Alternative site testing should not be used to calibrate continuous blood glucose monitors (CGMs). Alternative site testing should not be used for insulin dose calculations.
- Use fingertip instead of forearm for more accurate results:<sup>1</sup>
  - 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.
- NEVER use serum, plasma, or clotted blood for testing.

### 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.
- Use test strip quickly after removing from vial. Recap vial right away. Test strips left outside of vial too long give an error message.
- 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.
- Do not change treatment plan based on the results from the System without the advice of your Doctor or Diabetes Healthcare Professional.
- Do not use on neonates (newborns).

### Cleaning and Disinfecting

- The TRUE FOCUS Blood Glucose Monitoring System is for one person use **ONLY**. **DO NOT** share your meter or lancing device with anyone, including family members.
- All parts of the blood glucose monitoring system can potentially transmit infectious diseases from bloodborne pathogens, even after cleaning and disinfecting.<sup>2</sup>
- 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 as contact with blood presents an infection risk.
- If the meter is being operated by a second person who provides testing assistance, the meter and lancing device should be disinfected prior to use by the second person.
- It is important to keep the meter and the lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see *Meter Cleaning and Disinfecting and Lancing Device Cleaning and Disinfecting* in the Owner's Booklet.

### Quality Control (QC) Testing

There are two quality control tests to let you know that the blood glucose monitoring system is working properly.

#### Automatic Self-Test

An Automatic Self-Test is performed each time a TRUE FOCUS Test Strip is inserted into a TRUE FOCUS 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.

#### Control Test

TRUE FOCUS Control Solution is used to check testing technique and blood glucose monitoring system performance. When Control Test results fall within ranges found on test strip vial label of test strips being used, the blood glucose monitoring 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 your blood glucose monitoring system is working properly and your testing technique is good. There are three levels of TRUE FOCUS Control Solution available that contain known amounts of glucose. For more information on obtaining different levels of control solution, call 1-800-803-6025.*

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

### Blood Glucose Testing

1. Check opened date and printed date on test strip vial label. Do not use if after either date printed on the test strip vial label or 90 days after date opened, whichever comes first.
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 Sample Tip from drop immediately after the meter begins to count down from 4.
  - If meter does not begin testing 5 seconds after touching test strip to blood drop, see *Troubleshooting* in the TRUE FOCUS 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.

### Expected Results for people without diabetes:<sup>3</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 TRUE FOCUS 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 FOCUS Test Strips can be up to 70 mg/dL higher than venous laboratory results.<sup>4</sup> 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>5</sup>

### Troubleshooting

If your result is unusually high or low or doesn't match the way you feel, perform a Control Solution Test (see **Quality Control Testing**).

If the Control Test is within range:

- Read **Blood Glucose Testing** again.
- Recheck your results with a new TRUE FOCUS Test Strip.

If the results are not within range:

- Check the Use by Dates. Do not use if past either written date or date printed on test strip vial or control solution bottle, 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 Booklet.
- Check your testing technique. Perform another Control Test.
  - If the results still do not match the way you feel, check with your Doctor or Diabetes Healthcare Professional before changing your treatment program.

### Limitations<sup>6</sup>

- Therapeutic levels of n-acetylcysteine and elevated uric acid may affect results. Cholesterol up to 500 mg/dL or triglyceride up to 750 mg/dL does not significantly affect results.

The following will not affect accurate results:<sup>6</sup>

- Testing at altitudes up to and including 10,000 feet.
- Hematocrit 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):<sup>7</sup>

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

### Performance Characteristics<sup>6</sup>

**Accuracy:** The table below shows user TRUE FOCUS fingertip values. The fingertip data (N=201) were compared to parallel results obtained on a Yellow Springs Instrument (YSI).

#### TRUE FOCUS Fingertip Sample - < 75 mg/dL (fingertip vs. YSI)

$\pm 5$ mg/dL	$\pm 10$ mg/dL	$\pm 15$ mg/dL
16/26=62%	24/26=92%	26/26=100%

#### TRUE FOCUS Fingertip Sample - $\geq 75$ mg/dL (fingertip vs. YSI)

$\pm 5\%$	$\pm 10\%$	$\pm 15\%$	$\pm 20\%$
100/175=57%	164/175=94%	175/175=100%	175/175=100%

#### Fingertip Sample (User vs. YSI, n=201)

Slope 0.97	y-intercept 1.56 mg/dL	$r^2$ 0.99
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The table below shows how often user TRUE FOCUS forearm values achieve these goals when users' glucose values are not fluctuating.

#### TRUE FOCUS Forearm Sample - < 75 mg/dL (forearm vs. YSI)

$\pm 5$ mg/dL	$\pm 10$ mg/dL	$\pm 15$ mg/dL
10/26=38%	22/26=85%	26/26=100%

#### TRUE FOCUS Forearm Sample - $\geq 75$ mg/dL (forearm vs. YSI)

$\pm 5\%$	$\pm 10\%$	$\pm 15\%$	$\pm 20\%$
74/175=42%	128/175=73%	165/175=94%	172/175=98%

#### Forearm Sample (User vs. YSI, n=201)

Slope 0.98	y-intercept 0.01 mg/dL	$r^2$ 0.99
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**Precision:** Precision was measured with both venous blood samples and control solution in the laboratory. The blood results are shown below:

Mean Glucose Value	mg/dL	SD	CV%
	71.9	3.6	5.0%
	158.0	4.4	2.8%
	234.5	6.8	2.9%
	337.1	13.5	4.0%
	548.7	13.7	2.5%

**Additional Information:** See the Owner's Booklet for more detailed instructions.

Call Trividia Health, Inc. at 1-800-803-6025 (USA) or 1-954-677-4599 for assistance. Available 24/7 for assistance. For medical assistance, call your Doctor or Diabetes Healthcare Professional.

### 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. FDA Public Health Notification: *Use of Fingertip Devices on More than One Person Poses Risk for Transmitting Blood Borne Pathogens*. Retrieved June 21, 2012 from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.
3. Joslin Diabetes Center. *Goals for Blood Control Solution* [Electronic Version]. Retrieved July 25, 2011 from <http://www.joslin.org/info/Goals-for-Blood-Glucose-Control-Solution.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. 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.
6. Data on file.
7. Atkins, S. H., Dasmahapatra, A., Jaker, M.A., Chorost, M. I., Redd, S., *Fingertick Glucose Determination in Shock*. Annals of Internal Medicine, 114:1020-1024, 1991.

