



# Blood Glucose Test Strips Instructions for Use

**Intended Use:** The TRUENESS™ blood glucose test strip is used only with TRUENESS™ and TRUENESS™ AIR blood glucose meters to quantitatively measure glucose in capillary whole blood from the finger. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of their diabetes control program. It is intended to be used by a single person and should not be shared. It is for *in vitro* diagnostic use only. It should not be used for the screening or diagnosis of diabetes. It is not intended for use on neonates.

### Limitations:

- For *in vitro* diagnostic use only.
- For self-testing.
- Not for use on the critically ill.
- Not for neonatal use.
- Not for screening or diagnosis of diabetes mellitus.
- Not for alternative site testing (AST) use.
- Xylose: Do not perform test during or soon after xylose absorption testing. High xylose level in the blood will cause inaccurate results.
- Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate results may also occur in individuals experiencing a hyperosmolar-hyperglycemic-state (HHS).
- For single patient use only and should not be shared.
- NOT intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities, including for routine assisted testing or as part of glycemic control procedures.
- The meter and lancing device are for single patient use! DO NOT share them with anyone including other family members! DO NOT use on multiple patients. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other blood borne pathogens.

### Important Safety Instructions:

Read this section before using the TRUENESS™ blood glucose test strip. Always take the following basic safety precautions:

- Insufficient sample may cause inaccurate test results.
- If you have symptoms that do not reflect your blood glucose test results, and you have followed all instructions described in this insert, call your healthcare professional.
- DO NOT change your treatment based on a single result that does not match how you feel.
- DO NOT use other brands of blood glucose test strips and control solutions with the TRUENESS™/TRUENESS™ AIR blood glucose meter.
- Before using any product to test your blood glucose level, read all instructions and practice a test. Do all quality control checks as directed and consult your diabetes healthcare professional.
- Keep the test strip vial and control solution bottle away from children. The test strip vial, test strip, and control solution bottles can be choking hazards. Do not drink the control solution.
- Test strips are considered biohazardous once they have been used for a blood test. They can potentially transmit infectious diseases, even after cleaning and disinfection.
- If your blood glucose result is below 70 mg/dL (or a low glucose level per your healthcare professional's instruction), or the meter displays "LO" (less than 40 mg/dL), retest with a new test strip. If you get a similar result, call your healthcare professional immediately.
- If your blood glucose result is above 200 mg/dL (or a high glucose level per your healthcare professional's instruction), or the meter displays "HI" (greater than 600 mg/dL), retest with a new test strip. If you get a similar result call your healthcare professional immediately.

### For further information, please refer to:

"FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Blood-borne Pathogens: Initial Communication", at <https://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>  
CDC website on "Infection Prevention during Blood Glucose Monitoring and Insulin Administration", at <https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>

**Test Principle:** A glucose test is based on measurement of electrical current caused by the reaction of glucose with the FAD glucose dehydrogenase enzyme on the electrode of the test strip. The blood or control solution sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with the FAD glucose dehydrogenase enzyme and generates electrons, which produce an electrical current. The blood glucose meter measures the electrical current and calculates the glucose result. The glucose result is displayed by the meter in mg/dL units.



**Composition:** FAD glucose dehydrogenase, potassium ferricyanide, buffer solution and stabilizer.

### Test Strip Storage and Shelf Life:

Shelf life: 24 months if stored between 41°F - 86°F, 10%-85%RH.

- Store the test strips in a cool dry place between 41°F - 86°F (5°C-30°C), and the relative humidity is 10%-85%. Keep away from direct sunlight and heat. Do not store in your car. Do not freeze.
- Keep your test strips in the original vial. Do not transfer them to any other vial or container.
- Only remove the test strip from the vial when you are ready to perform a test. Firmly grasp the vial immediately after removing a test strip.
- When using a new vial of test strips, write the date opened on the vial label. Discard any test strips 6 months after the written date or once the printed expiration date has passed, whichever comes first.
- Before handling the test strip, wash your hands with soap and water and dry them. Hold the sides of the test strip when removing it from the vial or inserting it into the blood glucose meter.
- Only apply blood or control solution to the tip of the test strip. Ensure that the reaction zone is completely filled. Do not place blood or control solution on any other part of the test strip. This may cause an inaccurate result.

### Test Environment:

Temperature: 50°F - 104°F (10 C - 40 C)

Relative Humidity: 10%-90%

### Sample Requirements:

Sample size: 1µL / Test time: 5 seconds

Sample type: capillary blood samples.

**Applicable Meter:** The TRUENESS™ blood glucose test strip is intended to be used with the TRUENESS™ and TRUENESS™ AIR blood glucose meters.

### Test Method:

Getting ready to test: Refer to the blood glucose meter owner's booklet for more detailed information.

- Allow blood glucose 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.
- Check the opening date and printed expiry date on test strip vial label. Do not use after either date printed on the test strip vial label or 6 months after date opened, whichever comes first. Discard vial and test with new vial.
- Wash hands with soap and water and wipe dry.
- Remove one test strip from vial. Recap vial right away.
- Insert test strip into test strip port of blood glucose meter. Blood glucose meter turns on. Do not remove test strip from blood glucose meter until testing is finished.
- Obtain blood drop. Refer to lancing device Instructions for Use for detailed instructions on cleaning and disinfecting the fingertip.
- With test strip still in blood glucose meter, apply the blood sample to the tip of the Test Strip Reaction Zone. Allow blood to be drawn into test strip. Remove test strip from drop immediately after the blood glucose meter beeps.

- Result is displayed. Record result.
- Hold blood glucose meter with test strip pointing down. Press strip eject button to discard test strip into appropriate trash container.

**WARNING!** Treat used test strips and lancets as a biological risk. Discard used test strips and lancets carefully according to your healthcare professional's instructions or dispose them in an appropriate trash container.



Sample Tip  
Reaction Zone

### Expected Results for people without diabetes:

**Plasma Blood Glucose Result<sup>1</sup>**

**Before Eating** <100 mg/dL

**2 hours after a meal** <140 mg/dL

For people with diabetes: Please consult your healthcare professional for your blood glucose range. If you have poor circulation, testing your own blood glucose may not be suitable for you. Ask your healthcare provider. You should treat your low or high blood glucose as recommended by your healthcare provider.

With these test strips, your blood glucose meter displays blood concentrations that refer to plasma values although you apply whole blood to the test strip. For further information, please visit our website at [www.trividiahealth.com](http://www.trividiahealth.com) or please contact Customer Care at 1-800-803-6025, Monday-Friday, 8AM-8PM EST.

### Explanation of Test Results:

Unusual test results: If "LO" is displayed on your blood glucose meter, your blood glucose may be below 40 mg/dL. If "HI" is displayed on your blood glucose meter, your blood glucose may be over 600 mg/dL. For detailed information on error codes, please refer to your meter Owner's Booklet. If your blood glucose result does not match how you feel, follow these steps:

- Repeat blood glucose test with a new test strip.
- Perform a control test with control solution.
- Check this list to help you solve the problem:
  - Check the expiration date of the test strips.
  - Ensure that the cap on the test strip vial is always closed tightly.
  - Ensure that you use the test strip immediately after removing it from the vial.
  - Check that the test strips were stored in a cool, dry place.
  - Check that you followed the test steps.
- Please refer to Owners Booklet for proper maintenance and handling procedures.
- If the blood glucose results are too low, too high, or doubtful, please contact your healthcare professional.

### Performance Characteristics:

The TRUENESS™ test strip complies with the requirements of ISO 15197:2013 (*in vitro* diagnostic test systems- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus).

**Detection limit:** (lowest value displayed): 40 mg/dL.

**System measurement range:** 40 - 600 mg/dL.

**Calibration:** The system is calibrated with venous blood containing various glucose concentrations. The reference values are obtained using a validated test method. This test method is referenced to the hexokinase method and is traceable to a NIST standard.

### Accuracy for Home Use by Lay-Users:

The TRUENESS™ and TRUENESS™ AIR meter results may vary slightly from your actual blood glucose value due to slight differences in testing technique and the natural variation in test technology. The table below shows the results where typical users enrolled in a clinical study used the TRUENESS™ AIR meter to measure their blood glucose levels. For example, in this study, the TRUENESS™ AIR meter displayed results within 15% of their actual blood glucose level in 345 out of 354 measurements as compared to an approved lab instrument.

Difference range between the actual blood glucose level and the TRUENESS AIR meter result	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Percent (and number) of samples within specified range	52.3% (185/354)	82.2% (291/354)	97.5% (345/354)	99.7% (353/354)

### Precision:

Within Run Precision (300 Venous Blood Tests per glucose level)

Mean, mg/dL	Pooled Standard Deviation, mg/dL	Pooled Coefficient of Variation, %
43.4	1.8	4.0%
102.3	3.5	3.5%
132.1	4.2	3.3%
212.5	6.3	3.0%
339.8	9.7	2.9%

Intermediate Precision (300 Control Solution Tests per Glucose Level)

Control Level	Mean, mg/dL	Pooled Standard Deviation, mg/dL	Pooled Coefficient of Variation, %
1	45.0	1.9	4.3%
2	98.2	2.5	2.6%
3	137.8	3.3	2.4%
4	204.1	4.2	2.1%
5	381.7	9.2	2.4%

### Attention:

- Testing your blood glucose regularly may help you better manage your diabetes.
- Since this product includes small parts that could be swallowed and lead to choking, please keep it away from children.
- Please read the test strip Instructions for Use before you perform blood glucose testing. If you need assistance, please contact Customer Care at 1-800-803-6025, Monday- Friday, 8AM-8PM EST. Please call your healthcare professional when Customer Care is closed.

### References:

1. American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes January 2023 Volume 46, Supplement 1: S19-S40

### Manufactured by:

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