

GenUltimate!® Test Strips Instruction

IMPORTANT: Please read this entire pamphlet before using GenUltimate® Test Strips.
INTENDED USE

Genstrip® (and Genstrip50® and GenUltimate!®) Test Strips with calibration codes 4, 10, and 13 are for use with OneTouch® Ultra®, Ultra*2, and UltraMini® meters. They are used to quantitatively measure glucose in fresh capillary whole blood samples taken from the finger, forearm or palm. Testing is done outside the body (in vitro diagnostic use). They are indicated for use by people with diabetes in their home as an aid to monitor the effectiveness of diabetes control. The system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

STORAGE AND HANDLING

- Do not use your GenUltimate® Test Strips if the vial has been damaged or opened. This could cause incorrect test results or incorrect meter messages.
- Store test strips only in the original vial. This will avoid contamination or damage. Do not transfer test strips out of the original vial.
- Store test strips in a cool, dry place between 40°F - 86°F (4°C - 30°C). Do not refrigerate. Do not freeze. Do not expose to direct sunlight or heat. Extreme temperatures or humidity may cause inaccurate readings.
- Close vial tightly immediately after you remove a test strip.
- Use each test strip as soon as you take it out of the vial.
- The "Discard date" is 90 days after you first open a vial. Write this number on the vial. Discard any unused test strips after that date.
- Each box of test strips has an expiration date printed on it. Do not use test strips beyond the expiration date.
- Discard test strips on the expiration date or "Discard date", whichever comes first.
- Never get food, dirt or liquids on the test strip. Use only clean hands to touch the test strip. The test strip may be touched anywhere on its surface with clean, dry hands.
- Never bend, cut, damage, or change the test strips in any way.
- Use each test strip only once. Never reuse a test strip that has blood or control solution on it.
- After doing a test do not return the test strip to the vial.
- Use test strips only with OneTouch® Ultra® Control Solution, or whole blood.
- Your meter and test strips should be about the same temperature when you test.

WARNINGS

- Test strips are a choking hazard. Keep away from children. Do not swallow test strips.
- The vial contains a drying agent. This agent can cause injury if inhaled or swallowed or can irritate the skin or eyes.

PRECAUTIONS

- Code your Meter to match the code printed on your test strip vial.
[Caution: You MUST match the code on the Meter to the code on the test strip vial to get accurate readings. Make sure code numbers match each time you test. (See Diagram A.)]
- Your Meter uses a unit of measure to report test results (mg/dl or mmol/L). Make sure your Meter is set correctly. Refer to your Meter instructions for the correct unit of measure. If the unit of measure is not correct, contact the Meter Manufacturer for help.
- If you have symptoms that are not consistent with your test results and you have ruled out common errors described in instructions for your test strips and Meter, call your health care professional immediately.
- Do not change your diabetes treatment or ignore your symptoms without calling your healthcare professional.
- Review your 14-day and 30-day test averages periodically. If they do not seem correct, call your healthcare professional.



Diagram A

MEASURING BLOOD GLUCOSE

NOTE: In addition to GenUltimate® Test Strips, you will need your Meter, meter instructions, lancing device, and lancet.

Collect a blood sample

NOTE: Read Meter instructions for details about using a lancing device.

Step #1: Select a blood sample site. This may be your finger, forearm, or palm. Wash your hands and the site with warm, soapy water. Dry thoroughly.

Step #2: Use a lancing device and a sterile lancet to get a blood drop. The blood drop must be at least 1.0 microliter (1.0 µl). Do NOT squeeze the site too much.

CAUTION: Palm and forearm results may differ from fingertip results when glucose levels are changing rapidly. This can occur after a meal, after taking insulin, or during or after exercise.

Choose the right sample site

If you test:	Use a blood sample:
Regularly before meals	Fingertip, palm or forearm
Before or more than two hours after: A rapid-acting insulin injection Exercise A meal	Fingertip, palm or forearm
When your blood glucose is changing rapidly, such as: Within two hours after a meal Within two hours after a rapid-acting insulin injection or insulin pump bolus, or During or within two hours after exercise	Fingertip
When you are concerned about possible hypoglycemia	Fingertip

In addition, use fingertip blood and do not rely on palm or forearm test results, if:

- You are not aware of symptoms when you become hypoglycemic
- The site results do not agree with the way you feel
- During illness
- During times of stress
- AST measurements should never be used to calibrate continuous glucose monitors (CGMs)
- AST measurements should never be used in insulin dosing calculations



Diagram B

Consult your healthcare professional before you test palm or forearm sites.

Testing your blood glucose

Step #1: Remove test strip from vial. Immediately close the vial tightly. Insert test strip into Meter. Insert the contact bar end first with the strip facing up (See Diagram B.) Gently push test strip into Meter until it stops. This will turn on the Meter. Make sure the Meter and GenUltimate® Test Strip codes match.

Caution: OneTouch® Ultra®, Ultra*2 and UltraMini® meters require coding. Read Meter instructions for details on coding your Meter.

Step #2: The meter will show when it is ready for a blood sample. Some meters show the words "Apply Sample". Other meters use a flashing symbol that means "Apply Sample". Refer to your Meter instructions.



Diagram C

Step #3: Hold the blood drop to the narrow channel at the tip of the test strip (See Diagram C.)

- Do not apply blood to the top surface or underside of the strip.
- Do not press the strip against the test site. Touch only the blood drop with the tip of the test strip.
- Do not smear blood.

Look at the test strip confirmation window. It needs to be completely filled before the Meter counts down. Do not add more blood to the test strip if window is not full- discard test strip. Use a new test strip and repeat the test. If the window is not full, you may get an inaccurate reading or a Meter error message. If you have a problem filling the test strip, contact GenUltimate® Customer Service for help.

Step #4: Your meter will count down from 5 to 1. This will take about 5 seconds. It will then display your test results.

Test Results

Your Meter can display results from 20 to 600 mg/dl (1.1-33.3 mmol/L). Results below 20 mg/dl (1.1mmol/L) will trigger a Meter error message. This could indicate severe hypoglycemia (very low blood glucose). Results above 600 mg/dl (33.3 mmol/L) will trigger a Meter error message. This may indicate severe hyperglycemia (very high blood glucose). If your readings are very low or high, retest. If results are still low or high, call your healthcare professional or seek medical help immediately.

If your results are not what you expect (below 70mg/dl or 3.9 mmol/L which indicates very low blood sugar; or above 180mg/dl or 10.0 mmol/L which indicates very high blood sugar) you should contact your healthcare professional immediately. Check your meter results with control solution. If your symptoms are not consistent with your test results contact your healthcare professional immediately.

EXPECTED VALUES

People without diabetes have these expected blood glucose levels:

Before meals	70 – 130 mg/dl (3.9 - 7.2 mmol/L)
2 hour after any meal	Less than 180 mg/dl (10.0mmol/L)



Diagram D

CHECKING THE SYSTEM

NOTE: Control solution testing must be done only between 68°F (20°C) and 77°F (25°C).

Apply control solution as shown in Diagram D. Squeeze the control solution bottle until a large drop appears. Touch the drop to the tip of the test strip.

Run a Control Solution Test:

- At least weekly.
- When you open a new vial of test strips.
- If you think the Meter or test strips are not working correctly.
- If you have repeated results that do not seem correct.
- If you drop or damage the Meter.
- If you have exposed the test strips to extreme heat, cold, or high humidity.

Use only OneTouch® Ultra® Control Solution. Refer to Meter instructions for full details.

If control solution results fall outside of the range printed on the GenUltimate® Test Strip vial, repeat the test and refer to Meter instructions.

CAUTION: If 2 to 3 control solution results fall out of range, your test strips or Meter may not be working correctly. Do not test your blood with the test strips and Meter until you get control solution results that are in range. If you continue to have problems, contact GenUltimate® Customer Service or Customer Service for your Meter manufacturer for help.

LIMITATIONS

- Do not use with newborns.
- Use each test strip only once. Do not reuse.
- Use only fresh capillary whole blood. Do not use serum or plasma
- Hematocrit means the percentage of red blood cells in your blood. Hematocrit levels under 30% may cause falsely high readings. Hematocrit levels above 55% may cause falsely low readings. Consult your healthcare professional if you do not know your Hematocrit level.
- Use at relative humidity levels between 20% and 80%. Use at temperatures between 43°F and 111°F (6 °C to 44°C).
- Do not use at altitudes above 9,945 feet (3,031 meters).
- Interferences: Abnormally high concentrations of L-dopa, ascorbic acid, acetaminophen, uric acid and gentisic acid may cause falsely high results.
- For nominal glucose levels of 30 mg/dl (1.7 mmol/L) interferences occur for Ldopa at concentrations of >3.0 mg/dl in all three meters claimed; for acetaminophen at concentrations >7.5 mg/dl in all three meters claimed; for uric acid at concentrations >5.0 mg/dl in all three meters claimed; and for gentisic acid at concentrations >7.5 mg/dl in all three meters claimed. Levels seen in normal blood or with normal therapeutic concentrations do not significantly affect results.
- Lipemic samples: Cholesterol levels up to 758 mg/dl and triglycerides up to 3000 mg/dl do not affect results. Grossly lipemic samples have not been evaluated. Do not test such samples with these test strips.

INFECTION CONTROL

Treat all patient samples and materials they contact as biohazards. Use universal blood handling precautions. Dispose of all materials as per local regulations.

CAUTION: To reduce the chance of infection:

- Do not share a lancet or lancing device.
- Use lancets only once.
- Always use a new, sterile lancet.
- Keep Meter and lancing device clean.
- Wash testing sites with soap and water before testing.

TEST PRINCIPAL

Glucose in blood combines with an enzyme in the test strip. This produces an electric current in the Meter in proportion to the glucose level. The Meter converts the current flow into a glucose reading on the Meter. The GenUltimate® test strip gives results calibrated to plasma. This allows direct comparison with laboratory results.

REAGENT COMPOSITION

Each strip contains: ≤ 2 IU of Glucose Oxidase (*Aspergillus niger*), ≤ 1 mg potassium ferricyanide, and non-reactive ingredients.

PERFORMANCE CHARACTERISTICS

Specificity: Test strips measure D-glucose. They do not react to other blood sugars.

Measurement range: 20 – 600 mg/dl (1.1 – 33.3 mmol/L)

Precision: Precision was evaluated with six glucose levels in whole blood and three levels of control solution. Results show strip-to-strip variability in blood tests of 3.2% or less.

Precision Test	Test Sample	CV	
Within Run	Blood	42 mg/dl (2.3 mmol/L)	3.2%
		84 mg/dl (4.7 mmol/L)	1.9%
		134 mg/dl (7.4 mmol/L)	2.1%
		233 mg/dl (12.9 mmol/L)	1.8%
		384 mg/dl (21.3 mmol/L)	1.7%
		493 mg/dl (27.4 mmol/L)	2.2%
Total	Control	Level 1 (40 mg/dl) (2.2 mmol/L)	4.3%
		Level 2 (118 mg/dl) (6.5 mmol/L)	2.5%
		Level 3 (454 mg/dl) (25.1 mmol/L)	2.4%

Accuracy

The accuracy of the GenUltimate® Test Strip when used with the OneTouch® Ultra®, Ultra*2, and UltraMini® meter was evaluated at one clinical center. Blood glucose meter results from 152 persons with diabetes were compared with laboratory reference instrument results (YSI Model 2300D Glucose Analyzer.) The results are shown below:

METER	Within ± 0.28 mM/L (± 5 mg/dL)	Within ± 0.56 mM/L (± 10 mg/dL)	Within ± 0.83 mM/L (± 15 mg/dL)
UltraMini®	79%, 22/28	100%, 28/28	100%, 28/28
OneTouch® Ultra®	83%, 15/18	100%, 18/18	100%, 18/18
Ultra*2	78%, 18/23	100%, 23/23	100%, 23/23

METER	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
UltraMini®	46%, 474/1036	77%, 800/1036	95%, 980/1036	99%, 1029/1036
OneTouch® Ultra®	45%, 353/740	77%, 567/740	94%, 694/740	99%, 736/740
Ultra*2	49%, 362/739	79%, 584/739	95%, 699/739	99%, 733/739

	YSI < 75 mg/dL (< 4.2 mM/L)			YSI > 75 mg/dL (> 4.2 mM/L)			
	Within 5 mg/dL (0.3 mM/L)	Within 10 mg/dL (0.6 mM/L)	Within 15 mg/dL (0.8 mM/L)	Within 5%	Within 10%	Within 15%	Within 20%
UltraMini®							
Finger	75%, 9/12	100%, 12/12	100%, 12/12	46%, 204/444	77%, 341/444	94%, 416/444	99%, 441/444
Palm	63%, 5/8	100%, 8/8	100%, 8/8	50%, 147/296	84%, 248/296	96%, 284/296	99%, 293/296
Arm	100%, 8/8	100%, 8/8	100%, 8/8	42%, 123/296	71%, 211/296	95%, 280/296	100%, 295/296

Ultra®							
Finger	88%, 7/8	100%, 8/8	100%, 8/8	41%, 120/296	74%, 218/296	93%, 276/296	99%, 294/296
Palm	60%, 3/5	100%, 5/5	100%, 5/5	54%, 120/222	82%, 181/222	93%, 207/222	98%, 218/222
Arm	100%, 5/5	100%, 5/5	100%, 5/5	43%, 95/222	76%, 168/222	95%, 211/222	100%, 221/222

Ultra*2							
Finger	75%, 6/8	100%, 8/8	100%, 8/8	46%, 135/296	77%, 229/296	95%, 281/296	99%, 293/296
Palm	88%, 7/8	100%, 8/8	100%, 8/8	55%, 121/221	83%, 183/221	95%, 209/221	100%, 220/221
Arm	71%, 5/7	100%, 7/7	100%, 7/7	48%, 105/222	77%, 172/222	94%, 209/222	99%, 220/222

This study shows that the GenUltimate® Test Strip used with the OneTouch® Ultra®, Ultra*2 and UltraMini® meters gives results similar to a laboratory method.

REFERENCES

1. American Diabetes Association Standards of Medical Care in Diabetes – 2012, Diabetes Care Vol. 35; Suppl. 1:S11-S63.

CUSTOMER SERVICE

It is our goal to provide you with accurate glucose testing products and exceptional customer service. If you are not satisfied with this product, or for any other reason wish to reach our Customer Service representatives, please call Customer Service at 1-844-874-2762 (24 hours/day; 7 days/week). If you need help at other times, please call your healthcare professional.

GenUltimate® test strips are a product of PharmaTech Solutions, Inc. and are not manufactured, distributed, endorsed, approved by, nor associated with Lifescan®, Inc., a Johnson & Johnson® Company, manufacturers and distributors of the OneTouch® Ultra® Family of Meters and OneTouch® Ultra® test strips.

GenUltimate® Test Strips are manufactured for and distributed by:
PharmaTech Solutions, Inc. Westlake Village, CA 91361 USA