TruePoint Generic Blood Glucose Test Strips

Intended Use

The TruePoint Generic Blood Glucose Test Strips are intended for use with the OneTouch® Ultra®, OneTouch® Ultra® 2, OneTouch® UltraMini®, and OneTouch® UltraSmart® meters. The OneTouch® Ultra® and OneTouch® UltraSmart® meters must have been purchased before April 2016, the OneTouch® UltraMini® meter must have been purchased before March 2021, and the OneTouch® Ultra® 2 meter must have been purchased before August 2023. The meters must be set at calibration code 49 and measure glucose (sugar) in whole capillary blood. The strips are meant for self-testing of blood glucose in a home setting, and as an aid to monitor the effectiveness of diabetes control.

They are for single patient use only and should not be shared.

They are used to quantitatively measure glucose in fresh capillary whole blood samples taken from the fingertip.

Testing is done outside the body (in vitro diagnostic use).

Not intended for the diagnosis of or screening for diabetes mellitus or for use on neonates.

Limitations of Procedure

This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. 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.

- Do not use for screening purposes.
- Do not use for the diagnosis of diabetes or for testing of neonates.
- Test strips are for single use only. Do not reuse. Do not share test strips.
- Use only fresh capillary whole blood. Do not use serum or plasma.
- Hematocrit levels below 30% may cause falsely high readings. Hematocrit levels over 55% may cause falsely low readings. If you do not know your hematocrit level, consult your healthcare professional.
- Do not use at altitudes greater than 10,000 feet (3,048 meters).
- Ascorbic acid (Vitamin C) in concentrations > 2mg/dL may cause significant interference (affect the results by greater than 10%) resulting in an inaccurate result. If you are taking Vitamin C, your glucose results may not be reliable. If you are unsure then ask your healthcare professional.
- If you are taking acetaminophen or acetaminophen containing medications (Tylenol, certain cold and flu remedies, or certain prescription drugs) then your blood glucose results may not be accurate (blood concentrations > 8 mg/dL). If you are unsure, then ask your healthcare professional.
- If you are taking ibuprofen or ibuprofen containing medications then your blood glucose results may not be accurate (blood concentrations > 20 mg/dL). If you are unsure, then ask your healthcare professional.
- If you have a disease or condition that elevates your blood uric acid level (>10mg/dL), such as gout, your blood glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
- If you undergo a Xylose Absorption test, your blood glucose results may not be reliable following the test. You should not use TruePoint Generic Blood Glucose Test Strips following Xylose Absorption tests. If you are unsure, then ask your healthcare professional.
- Cholesterol concentrations up to 650 mg/dL (16.8 mmol/L) or triglycerides up to 2,500 mg/dL (28.3 mmol/L) do not significantly affect test results. However, glucose values in specimens beyond these levels should be interpreted with caution.

Healthcare professionals- please note these extra limitations of procedure:

- Patients going through oxygen therapy may yield falsely low results.
- Test results may be falsely low if the patient is severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
- These test strips should not be used with meters to test critically ill patients.

Operating Conditions

TruePoint Operating Temperature:	42°–111°F (6°–44° C)
TruePoint Storage Temperature:	39°–104°F (4°–40°C) (Do not Freeze)
Relative Humidity:	10–90%
TruePoint Test Strip Vial Open:	90 days
Altitude:	10,000 feet (3,048 meters)

Taking care of your test strips:

Storage:

- Store the test strip vial in a cool dry place. Do not freeze.
- Keep away from direct sunlight, heat, cold or moisture (water).
- Failure to follow storage guidelines may result in wrong readings.
- Store your test strips in their original vial only.

Handling Your Test Strips:

- Do not take a test strip out of the vial until you are ready to use it.
- Close the test strip vial tightly as soon as you remove a test strip. Use each test strip right away after you remove it from the vial.
- Do not use test strips that are damaged, wet, or bent. Do not bend, cut or alter the strip in any way.
- You may touch the test strip on its surface with clean, dry hands.

Expiration:

- Write the discard date (date opened plus 3 months) on the vial label when you first open it.
- Do not use test strips beyond the expiration (printed on vial label) or discard date, whichever comes first. Your test results may be wrong if you use expired test strips.

Disposal:

- Do not return the used test strip to the vial.
- Used test strips may be considered biohazardous waste in your area. Be sure to follow your healthcare professional's recommendations for proper disposal.

Accuracy:

- Make sure your meter and test strips are about the same temperature before you test.
- You may not have correct readings if your test strips are left in the heat, cold or get wet.
- Test strips are for single use only. Never reuse a test strip that had blood or control solution applied to it.

⚠ **WARNING**:

- Keep the test strip vial away from children. Test strips are a choking hazard.
- Do not swallow test strips.
- The test strip vial may contain drying agents that are harmful if inhaled or swallowed, and may cause skin or eye irritation.
- Do not ingest or swallow any items.

Blood Glucose Test Procedure

For instructions on performing a blood test (including blood sample collection), refer to the User Guide that came with your system.

⚠ **CAUTION**: Some meters require coding. For these meters, matching the code on the meter and the code on the test strip vial is vital to obtain correct results. Each time you test, check to make sure the code numbers match. For instructions on coding the meter, refer to the User Guide that came with your system.

Test Results

Blood glucose management requires the help of a healthcare professional. Together you can set your blood glucose target ranges, arrange your testing times, and interpret your blood glucose results.

Low Glucose Values

If your test result is below 20 mg/dL, a warning message will appear showing a low glucose level. This may be a sign of severe low blood glucose. Treat this condition right away, as directed by your healthcare professional. Although this message could be due to a test error, it is safer to treat first, and then do another test.

High Glucose Values

If your test result is above the maximum value, repeat your test with a new strip to confirm this reading. If the high results should appear again, call your healthcare professional right away.

Reference Values: The normal adult fasting blood glucose range for a non-diabetic person is less than 100 mg/dL and less than 140 mg/dL up to 2 hours after meals. These are expected values for people without diabetes. Users are to work with their healthcare professional to determine their target blood glucose values.

Source: American Diabetes Association. Classification and diagnosis of diabetes. Sec. 2. In Standards of Medical Care in Diabetes – 2016. Diabetes Care 2016;39(Suppl. 1):S16.

If You Get Unexpected Results

If your blood glucose result is below 70 mg/dL, showing low blood glucose, or above 180 mg/dL, showing high blood glucose, you should contact and follow your health professionals' treatment advice. If you keep on getting unexpected results, check your system with OneTouch® control solution. If you are feeling symptoms that are not consistent with your blood glucose test results AND you have followed all instructions described in your User Guide, call your healthcare professional. Never ignore symptoms. Never make major changes to your diabetes control program without speaking to your healthcare professional.

Checking the System

A control solution test is performed to check that the meter and test strips are working together properly and that you are doing the test correctly. For instructions on how and when to check the system by doing a control solution test, refer to the User Guide that came with your system.

Use only OneTouch® control solution and follow the instructions on the package insert.

Test Principle

The OneTouch® Ultra® family of meters are plasma-calibrated to allow easy comparison of results with laboratory methods. Glucose in the blood sample mixes with special chemicals on the TruePoint Generic Blood Glucose Test Strips and a small electrical current is produced. This current is measured by the OneTouch® Ultra® family of meters and displayed as your blood glucose result. The strength of the current changes with the amount of glucose in the blood sample.

Reagent Composition

Each TruePoint Generic Blood Glucose Test Strip contains: Glucose oxidase (Aspergillus niger) 20IU ; Potassium ferricyanide 0.12mg; Non-reactive ingredients 1.8mg

Performance Characteristics

The following results apply to TruePoint Generic Blood Glucose Test Strips in use with OneTouch® Ultra®, OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® blood glucose meters.

Accuracy:

According to the internal test results, 100% of tests for which the differences fell within ±15 mg/dL for glucose concentration <75 mg/dL, and 100% within 20% at glucose concentration ≥75 mg/dL. A study for OneTouch® Ultra®2, OneTouch® UltraMini® and OneTouch® UltraSmart® evaluating glucose values from fingertip capillary blood samples obtained by 140 lay persons, and a study for OneTouch® Ultra® evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons in lot 1 showed the following results.

Samples for glucose results lower than (<) 75 mg/dL

Meter	Test Site	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
OneTouch® Ultra®2	Fingertip	25/40 (62.5%)	37/40 (92.5%)	40/40 (100%)
OneTouch® UltraMini®	Fingertip	26/40 (65%)	34/40 (85%)	40/40 (100%)
OneTouch® UltraSmart®	Fingertip	26/40 (65%)	36/40 (90%)	40/40 (100%)
OneTouch® Ultra®	Fingertip	13/20 (65%)	17/20 (85%)	20/20 (100%)

Samples for glucose results greater than (≥) 75 mg/dL

Meter	Test Site	Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
OneTouch® Ultra®2	Fingertip	66/100 (66%)	92/100 (92%)	97/100 (97%)	100/100 (100%)
OneTouch® UltraMini®	Fingertip	68/100 (68%)	93/100 (93%)	99/100 (99%)	100/100 (100%)
OneTouch® UltraSmart®	Fingertip	70/100 (70%)	91/100 (91%)	96/100 (96%)	100/100 (100%)
OneTouch® Ultra®	Fingertip	52/80 (65%)	71/80 (88.8%)	80/80 (100%)	80/80 (100%)

Linear regression analysis:

Meter	Test Site	Linearity	R^2
OneTouch® Ultra®2 *Purchased before August 2023*	Fingertip	Y=0.9813x + 3.1541	0.9991
OneTouch® UltraMini® *Purchased before March 2021*	Fingertip	Y=0.9825x + 2.8152	0.9991
OneTouch® UltraSmart® *Purchased before April 2016*	Fingertip	Y=0.9806x + 1.3315	0.9853
OneTouch® Ultra® *Purchased before April 2016*	Fingertip	Y=0.9982x + 1.2235	0.9827

Precision:

Within Run

Repeatability		Lot I					Lot II					Lot III				
OneTouch® Ultra®2 *Purchased before August 2023*	Mean (mg/dL)	39.6	78.0	125.4	199.3	290.5	39.3	78.7	124.5	199.6	290.5	39.0	78.8	125.2	198.7	291.8
	SD	2.7	2.9	4.0	5.6	8.7	2.7	2.9	3.7	6.7	8.5	3.3	3.1	4.1	5.7	8.6
	CV (%)	6.8%	3.7%	3.2%	2.8%	3.0%	7.0%	3.7%	2.9%	3.4%	2.9%	8.4%	3.9%	3.3%	2.9%	3.0%
	n	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150
OneTouch® UltraMini® *Purchased before March 2021*	Mean (mg/dL)	39.6	78.6	125.2	198.8	291.2	39.6	78.5	125.0	199.5	291.8	39.6	78.7	124.9	199.5	291.7
	SD	2.9	3.0	3.5	6.2	9.9	2.9	3.1	3.7	6.4	9.3	2.9	2.9	3.9	6.4	8.4
	CV (%)	7.4%	3.8%	2.8%	3.1%	3.4%	7.3%	4.0%	3.0%	3.2%	3.2%	7.3%	3.7%	3.1%	3.2%	2.9%
	n	150	150	150	150	150	150	150	150	150	150	150	150	150	150	150
OneTouch® UltraSmart® *Purchased before April 2016*	Mean (mg/dL)	42.5	79.0	129.2	199.0	324.1	42.0	78.8	129.1	198.3	325.5	41.6	79.5	130.0	199.0	325.6
	SD	1.3	1.2	2.8	4.5	6.5	1.4	1.1	2.7	4.4	7.9	1.4	1.4	2.6	4.0	7.6
	CV (%)	3.1%	1.5%	2.2%	2.3%	2.0%	3.2%	1.5%	2.1%	2.2%	2.4%	3.4%	1.8%	2.0%	2.0%	2.3%
	n	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50
OneTouch® Ultra® *Purchased before April 2016*	Mean (mg/dL)	42.9	79.1	129.2	201.5	325.6	43.0	79.0	128.8	201.3	324.2	42.9	79.1	129.0	201.3	324.2
	SD	1.4	1.5	2.8	4.1	6.8	1.4	1.5	2.7	4.2	7.8	1.5	1.4	2.5	4.7	6.8
	CV (%)	3.2%	1.8%	2.1%	2.0%	2.1%	3.2%	1.9%	2.1%	2.1%	2.4%	3.5%	1.8%	1.9%	2.3%	2.1%
	n	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100

Intermediate Precision		Lot I					Lot II					Lot III				
OneTouch® Ultra®2 *Purchased before August 2023*	Mean (mg/dL)	40.3	79.9	121.4	199.6	300.4	40.4	79.2	121.7	199.4	301.4	40.9	79.4	122.9	198.9	298.7
	SD	2.8	3.1	3.5	5.8	10.1	2.9	3.1	3.4	5.1	8.1	3.2	3.1	3.7	6.5	9.5
	CV (%)	7.0%	3.8%	2.9%	2.9%	3.4%	7.1%	3.9%	2.8%	2.5%	2.7%	7.9%	4.0%	3.0%	3.3%	3.2%

Intermediate Precision		Lot I					Lot II					Lot III				
OneTouch® UltraMini® *Purchased before March 2021*	Mean (mg/dL)	41.0	79.9	121.6	200.5	301.8	39.6	79.1	122.2	200.7	300.7	39.7	79.7	121.7	200.3	300.0
	SD	3.3	2.9	3.8	6.1	8.1	3.1	2.6	3.7	6.5	8.8	3.0	3.1	3.9	4.9	7.8
	CV (%)	8.1%	3.6%	3.2%	3.0%	2.7%	7.9%	3.2%	3.0%	3.2%	2.9%	7.6%	3.9%	3.2%	2.5%	2.6%

Intermediate Precision		Lot I	Lot II	Lot III
OneTouch® Ultra®2 OneTouch® UltraMini® OneTouch® UltraSmart® *Purchased before April 2016*	Mean (mg/dL)	39.0	118.9	260.5	39.0	119.2	259.7	39.0	119.0	260.3
	SD	0.8	3.2	8.0	0.8	3.1	7.7	0.8	3.3	8.0
	CV (%)	2.1%	2.7%	3.1%	2.1%	2.6%	3.0%	2.1%	2.8%	3.1%
OneTouch® Ultra® *Purchased before April 2016*	Mean (mg/dL)	39.1	119.2	258.1	39.0	118.5	256.6	39.0	119.2	257.6
	SD	1.4	4.6	9.6	1.4	4.6	9.5	1.4	4.6	10.0
	CV (%)	3.6%	3.8%	3.7%	3.6%	3.9%	3.7%	3.6%	3.9%	3.9%

⚠ **IMPORTANT**: For complete operating instructions and other important technical information, refer to the User Guide that came with your system.

References

1. Beaser, R.S. and Hill, Joan: The Joslin Guide to Diabetes. New York: Simon and Schuster (1995), p. 158 2. Data on file.

For in vitro diagnostic testing only.

For single patient use only.

Please refer to the meter user manual for cleaning and disinfection instructions.

All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

⚠ **IMPORTANT: Please read this information and your OneTouch® Ultra® Family of Meters' User Guide before using TruePoint Generic Blood Glucose Test Strips. Do not use your TruePoint Generic Blood Glucose Test Strips if your vial is open or damaged in any way, as this could lead to error messages or inaccurate blood glucose values. Contact TruePoint Customer Service immediately if the test strip vial is open or damaged, or if the instructional materials or your meter results seem unclear.**

For questions or comments
please call **1.866.432.9804** (Toll Free)
Monday–Friday 8:30am–5:30pm (EST)

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