

# PLUS Blood Glucose Test Strip

## Warnings

- For *in vitro* diagnostic use (for use outside of the body only).
- For single use only.
- Healthcare professionals and other users testing multiple patients with this system should handle everything that comes into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- Please read this sheet and your Blood Glucose Monitoring System Owner’s Manual before you use this test strip. Use only **PLUS** Test Strips with **PLUS** Blood Glucose Monitoring System to obtain accurate results, and be covered by the manufacturer’s warranty.
- Results may be inaccurate when testing on patients with abnormally low blood pressure or those who are in shock.
- For patients with impaired peripheral circulation, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. It may apply under the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to stress hyperglycemia, hyperosmolar non-ketotic coma, shock, decompensated heart failure **NYHA** Class IV or peripheral arterial occlusive disease.
- Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

## Intended Use

**PLUS** test strips, when used together with **PLUS** Blood Glucose Monitoring System, allow your blood glucose levels to be measured by yourself at home or by healthcare professionals. It uses fresh whole blood samples from the finger, palm, upper arm and forearm. This system is not intended for use in the diagnosis or screening of diabetes mellitus. Professionals may use test strips to test capillary and venous blood sample; home use is limited to capillary whole blood testing.

## About Alternative Site Testing (AST)

**IMPORTANT:** There are limitations for performing AST. Please read the **PLUS** Blood Glucose Monitoring System Owner’s Manual and consult the doctor before you perform AST.

- Alternative site testing (AST) is when individuals check their blood glucose levels using areas of the body other than the fingertip. The **PLUS** test strips allow AST to be performed on sites other than the fingertip. We strongly recommend that you perform AST **ONLY** at the following times:
- During a pre-meal or fasting state (more than 2 hours since the last meal).
  - Two hours or more after taking insulin.
  - Two hours or more after exercise.
- Do **NOT** use AST if:
- You think your blood glucose is low.
  - You may not notice if you are hypoglycemic.
  - Your AST results are inconsistent with the way you feel.
  - You are testing for hyperglycemia.
  - Your routine glucose results often fluctuate.
- To obtain a blood sample from the alternative sites, please rub the puncture site for approximately 20 seconds before following the procedures of “Testing Your Blood Glucose”.

## Limitations

- Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- Hematocrit: The hematocrit level is limited to between 35% and 60%. Please ask your healthcare professional if you do not know your hematocrit level.
- Metabolites: Dopamine, L-Dopa, methylpoda, uric acid, ascorbic acid, and acetaminophen at normal blood concentration do not significantly affect blood glucose test results.
- There are no significant interference in the presence of galactose, maltose, or fructose observed in blood glucose tests.
- Lipemic Effects: Blood triglycerides up to 3000 mg/dL (33.9 mmol/L) do not affect the results significantly, but may affect results at higher levels.
- Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.
- Use only heparin for anticoagulation of fresh capillary or venous whole blood.

The following compounds when determined to be in excess of their limitation and tested with the **PLUS** glucose meter may produce elevated glucose results:

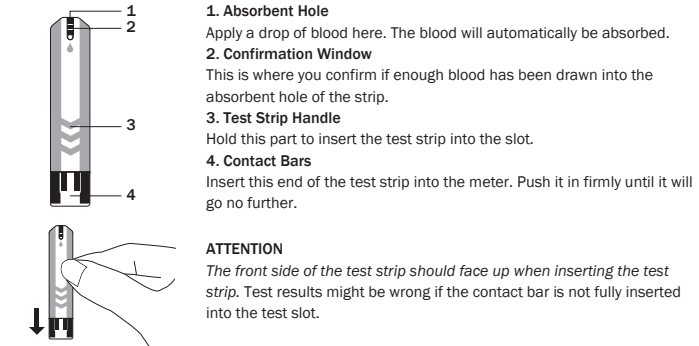
Summary of substances and concentrations in excess of limitation with interference		
Substance	Limiting Concentration (mg/dL)	Therapeutic / Physiologic Concentration Range (or Upper Limit ) (mg/dL)
Acetaminophen (Paracetamol)	> 6.25	0.45 - 3
Ascorbic Acid	> 5	2
Pralidoxime Iodide	> 5	~ 10 (IV Dose 500 mg)
Uric Acid	> 10	2 - 8

## Storage and Handling

- IMPORTANT:** Do not use the test strips if they have expired.
- Test strips expire 6 months after first opening. Write the first opening date on the test strip vial when you first opened it. (For strip vial only)
  - Store the test strips in a cool, dry place between 2°C and 30°C (35.6°F and 86°F), between 10% and 85% relative humidity.

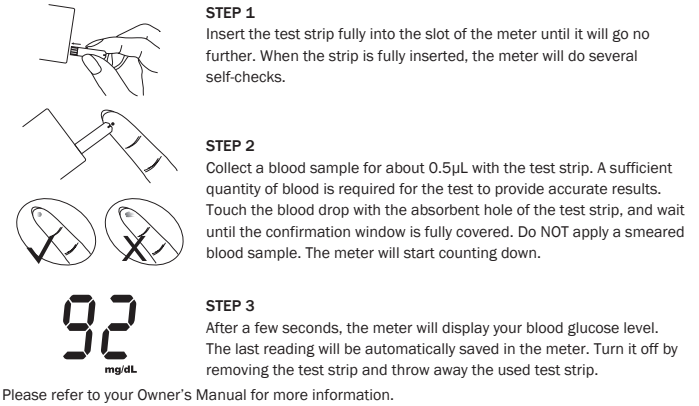
- Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- Store the test strips in their original vial **ONLY**. Do not transfer them to a new vial or any other containers. (For strip vial only)
- Do not touch the test strips with wet hands.
- Use each test strip immediately after taking it out of the vial or individual foil packet. Close the vial immediately after taking out a strip. (For strip vial only)
- Keep the vial closed at all times. (For strip vial only)
- Do not bend, cut, or alter the test strip.

## Strip Appearance



## Testing Your Blood Glucose

**PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.**



Please refer to your Owner’s Manual for more information.

The used lancet and test strip are potentially biohazardous. Please dispose of them carefully according to your local regulations.

## Reading Your Result

Your blood glucose readings deliver plasma equivalent results and are displayed either in milligrams of glucose per deciliter of blood (mg/dL) or in millimoles of glucose per liter of blood (mmol/L). The measurement range of this meter is 20–600 mg/dL (1.1–33.3 mmol/L).

Reference values	
Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meal	< 100 mg/dL (5.6 mmol/L)
2 hours after meals	< 140 mg/dL (7.8 mmol/L)

Source: American American Diabetes Association. Standards of medical care in diabetes-2016; 39 (supp.1 Diabetes Care):S16.

**Please consult your doctor to determine a target range that works best for you.**

## Questionable or inconsistent results

- If your test results are unusual or inconsistent with how you are feeling:
- Make sure the confirmation window of the test strip is completely filled with blood.
  - Check the expiry date of the test strips
  - Check the performance of your meter and test strip with the control solutions.
- PLEASE NOTE:** Unusually high or low blood glucose levels may be symptoms of a serious medical condition. If most of your results are unusually high or low, please contact your healthcare professional.

## Quality Control Testing

Our control solutions contain a known amount of glucose that can react with test strips. If you suspect the meter or test strips are not working properly, you can check the performance of the meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial or on the package. Please refer to the Owner’s Manual for complete testing instructions.

**IMPORTANT:** The reference range of the control solutions may vary with each new vial or package of test strips. Make sure you check the range on the label of your current vial or on the current package.

## Chemical Components

Glucose dehydrogenase ( <i>E. coli</i> ) 8%	Enzyme protector 8%
Electron shuttle 55%	Non-reactive ingredients 29%

## Additional Information for Healthcare Professionals

Always wear gloves and follow your facility’s biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only. Professionals may use test strips to test capillary and venous blood sample.

**Sample Size:** 0.5 µL      **System Measurement Range:** 20 mg/dL to 600 mg/dL (1.1 to 33.3 mmol/L)

**Reaction Time:** 5 seconds      **Hematocrit Range:** 35% to 60%

## Accuracy

Diabetes experts have suggested that glucose meters should be within ±15 mg/dL (0.83 mmol/L) of the reference method when the glucose concentration is lower than 100 mg/dL (5.55 mmol/L), and be within ±15% of the reference method when the glucose concentration is 100 mg/dL (5.55 mmol/L) or higher. The tables below display how often **PLUS** achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well **PLUS** performed compared to YSI-2300 reference method results.

**Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)**

Model	Within ±5 mg/dL (Within ±0.28 mmol/L)	Within ±10 mg/dL (Within ±0.55 mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
PLUS One	55.1% (172/312)	88.8% (277/312)	99.4% (310/312)
PLUS Talking	78.8% (246/312)	99.7% (311/312)	100% (312/312)
PLUS Compact	59.3% (185/312)	93.9% (293/312)	100% (312/312)
PLUS Mini	78.8% (246/312)	99.7% (311/312)	100% (312/312)

**Table 2 Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)**

Model	Within ±5% (Within ±10%)	Within ±10% (Within ±15%*)
PLUS One	51.4% (333/648)	85.2% (552/648)
PLUS Talking	65.9% (427/648)	95.2% (617/648)
PLUS Compact	58.0% (376/648)	87.7% (568/648)
PLUS Mini	65.9% (427/648)	95.2% (617/648)

**Table 3 Accuracy results for glucose concentrations of 960 test results**

Model	Distribution	Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
PLUS One	28.5 mg/dL (1.58 mmol/L ) to 544.0 mg/dL (30.22 mmol/L)	98.1% (942/960)
PLUS Talking	34 mg/dL (1.89 mmol/L ) to 522 mg/dL (29.0 mmol/L)	99.8% (958/960)
PLUS Compact	33.5 mg/dL (1.86 mmol/L ) to 544 mg/dL (30.22 mmol/L)	98.3% (944/960)
PLUS Mini	34 mg/dL (1.89 mmol/L ) to 522 mg/dL (29.0 mmol/L)	99.8% (958/960)

\*Acceptance criteria in EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., YSI-2300 reference values minus **PLUS**'s glucose values) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

**Note:** When **PLUS** Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while those above 100 mg/dL (5.55 mmol/L) are in percent.

## User performance

154 subjects tested on the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how well **PLUS** performed compared to YSI-2300 reference method results.

**Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)**

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	26/46 (56.5%)	40/46 (87.0%)	46/46 (100%)
Palm	19/57 (33.3%)	50/57 (87.7%)	57/57 (100%)
Forearm	16/57 (28.1%)	44/57 (77.2%)	57/57 (100%)
Upper arm	22/57 (38.6%)	47/57 (82.5%)	57/57 (100%)

**Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)**

Tested sites	Difference within ±5 %	Difference within ±1 %	Difference within ±15 %
Fingertip	54/108 (50.0%)	93/108 (86.1%)	105/108 (97.2%)
Palm	30/97 (30.9%)	68/97 (70.1%)	97/97 (100%)
Forearm	28/97 (28.9%)	68/97 (70.1%)	96/97 (99.0%)
Upper arm	25/97 (25.8%)	61/97 (62.9%)	96/97 (99.0%)

## Precision

The CV (%) is less than 5% both in intermediate precision and repeatability precision.

## Symbol Information

Symbol	Referent	Symbol	Referent
	<i>In vitro</i> diagnostic medical device		Manufacturer
	Consult instructions for use		Authorized representative in the European Community
	Temperature limitation		Do not reuse
	Use by		CE mark
	Batch code		Humidity limitation

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**Use Only With PLUS Blood Glucose Monitoring System**

For self-testing