

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 has come 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 GlucoCheck Key Test Strips with GlucoCheck Key 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 II or peripheral arterial occlusive disease.
- Keep the test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.
- Discard the used test strips and lancets according to your local infection control procedures.
- Patients undergoing oxygen therapy may yield falsely low results.

Intended Use

GlucoCheck Key Test Strips, when used together with GlucoCheck Key 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, nor for the use on newborns.**

About Alternative Site Testing (AST)

IMPORTANT: There are limitations for performing AST. Please read the GlucoCheck KEY Blood Glucose Monitoring System Owner's Manual and consult your healthcare professional 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 GlucoCheck KEY 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 obtaining a blood drop as described in your Blood Glucose Monitoring System Owner's Manual.

Limitations

- Hematocrit: The hematocrit level is limited to between 30% and 55%. Please ask your healthcare professional if you do not know your hematocrit level.
 - Neonatal Use: This test strip must not be used for the testing of newborns.
 - Metabolites: Dopamine, L-Dopa, methyldopa, 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 xylitol, maltose, or fructose observed in blood glucose tests.
 - Lipemic Effects: Blood triglycerides up to 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.
- The following compounds when determined to be in excess of their limitation and tested with the GlucoCheck KEY glucose meter may produce elevated glucose results:

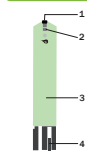
Summary of substances and concentrations in excess of limitation with interference

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
Praktodime Iodide	> 5	~ 10 (IV Dose 500 mg)

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.
- Store the test strips in a cool, dry place between 4°C and 40°C and 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.
- Do not touch the test strips with wet hands.
- Use each test strip immediately after taking it out of the vial. Close the vial immediately after taking out a strip.
- Keep the vial closed at all times.
- Do not bend, cut or alter the test strip.

Strip Appearance



- 1. Absorbent Hole**
Apply a drop of blood here. The blood will automatically be absorbed.
- 2. Confirmation Window**
This is where you confirm if enough blood has been drawn into the absorbent hole of the strip.
- 3. Test Strip Handle**
Hold this part to insert the test strip into the slot of the glucose meter
- 4. Contact Bars**
Insert this end of the test strip into the meter. Push it in firmly until it will go no further.

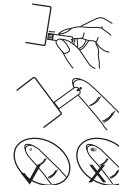
ATTENTION



Test results might be wrong if the contact bar is not fully inserted into the test slot. The front side of the test strip should face up when inserting the test strip.

Testing Your Blood Glucose

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.



- STEP 1**
Insert the test strip fully into the slot of the meter until it will go no further. When the strip is fully inserted, the meter will switch on automatically and display the blood drop symbol. No coding of the meter is needed.
- STEP 2**
Collect a blood sample of 0.7 µL with the test strip. A sufficient quantity of blood is required for the test to provide accurate results. Touch the blood drop with the absorbent hole of the test strip, and wait until the confirmation window is fully covered. Do NOT apply a smeared blood sample. The meter will start counting down.
- STEP 3**
After a few seconds, the meter will display your blood glucose level. The last reading will be automatically saved in the meter. Turn it off by removing the test strip and throw away the used test strip.



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 infection control procedures.

Reading Your Result

Your blood glucose readings deliver plasma equivalent results and are displayed in millimoles of glucose per liter of blood (mmol/L). The measurement range of this meter is 1.1-33.3 mmol/L.

Reference values

Time of day	Normal plasma glucose range for people with diabetes
Fasting and before meal	4.0 - 7.0 mmol/L
2 hours after meals	5.0 - 10.0 mmol/L

Source: Aroda A et al. SEMDSA 2017 Guidelines for the Management of Type 2 Diabetes Mellitus, JEMDSA 2017:22(1):S34-S37.

Blood glucose reference values may be individualised for Type 1, newly diagnosed, young, elderly and high risk patients.

Please consult your healthcare professional regarding the appropriate blood glucose reference range 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 expiration 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. You can check the performance of meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial. Checking regularly can ensure your test results are accurate. 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 of test strips. Make sure you check the range on the label of your current vial.

Chemical Components

- > Glucose oxidase (*A. niger*) 10%
- > Electron shuttle 50%
- > Enzyme protector 8%
- > Non-reactive ingredients 32%

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. Healthcare professionals may use test strips to test capillary whole blood. Sample Size: 0.7 µL. Reaction Time: 7 seconds. System Measurement Range: 1.1 to 33.3 mmol/L. Hematocrit Range: 30% to 55%

Accuracy

Diabetes experts have suggested that glucose meters should be within 0.83 mmol/L of the reference method when the glucose concentration is lower than 5.55 mmol/L and be within ±15% of the reference method when the glucose concentration is 5.55 mmol/L or higher. The tables below display how often GlucoCheck KEY 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 GlucoCheck KEY performed compared to YSK2300 reference method results.

GlucoCheck KEY

Table 1 Accuracy results for glucose concentration < 5.55 mmol/L

Within ±0.28 mmol/L	Within ±0.55 mmol/L	Within ±0.83 mmol/L*
56.7% (143/252)	91.3% (230/252)	100% (252/252)

Table 2 Accuracy results for glucose concentration ≥ 5.55 mmol/L

Within ±5 %	Within ±10 %	Within ±15 %*
45.9% (325/708)	81.9% (580/708)	96.5% (683/708)

Table 3 Accuracy results for glucose concentrations between 1.79 mmol/L to 28.33 mmol/L

Within ±0.83 mmol/L or ±15 %
97.4% (935/960)

*Acceptance criteria in EN ISO 15197: 2015. 95% of all differences in glucose values (i.e., YSK-2300 reference values minus GlucoCheck KEY's glucose values respectively) should be within ±0.83 mmol/L for glucose concentration < 5.55 mmol/L and within ±15% for glucose concentration ≥ 5.55 mmol/L. **Note:** When GlucoCheck KEY Test Strips results are compared to the reference values, difference values below 5.55 mmol/L are expressed in mmol/L while those above 5.55 mmol/L are in percent.

User performance

GlucoCheck KEY A study evaluating glucose values from fingertip capillary blood samples obtained by 156 lay persons showed the following results:

Table 1 Difference distribution for glucose concentration < 5.55 mmol/L

Tested sites	Difference within ±0.28 mmol/L	Difference within ±0.55 mmol/L	Difference within ±0.83 mmol/L
Fingertip	20/38 (52.6%)	34/38 (89.5%)	38/38 (100%)

Table 2 Difference distribution for glucose concentration ≥ 5.55 mmol/L

Tested sites	Difference within ±5 %	Difference within ±10 %	Difference within ±15 %
Fingertip	54/118 (45.8%)	92/118 (78.0%)	114/118 (96.6%)

And 160 participants completed alternative sites evaluation using capillary blood of palm, forearm and upper arm presented in table 3-4.

Table 3 Difference distribution for glucose concentration < 5.55 mmol/L

Tested sites	Difference within ±0.28 mmol/L	Difference within ±0.55 mmol/L	Difference within ±0.83 mmol/L
Palm	23/57 (40.4%)	46/57 (80.7%)	57/57 (100%)
Forearm	13/57 (22.8%)	44/57 (77.2%)	57/57 (100%)
Upper arm	17/57 (29.8%)	48/57 (84.2%)	57/57 (100%)

Table 4 Difference distribution for glucose concentration ≥ 5.55 mmol/L

Tested sites	Difference within ±5 %	Difference within ±10 %	Difference within ±15 %
Palm	36/103 (35.0%)	73/103 (70.9%)	102/103 (99%)
Forearm	24/103 (23.3%)	70/103 (68.0%)	100/103 (97.1%)
Upper arm	22/103 (21.4%)	61/103 (59.2%)	98/103 (95.1%)

Precision

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

Symbol Information

Symbol	Referent	Symbol	Referent
	In vitro diagnostic medical device		Manufacturer
	Consult instructions for use		Authorized representative in the European Community
	Temperature limit		Do not re-use
	Use-by date		CE mark
	Batch code		Humidity limitation
	Caution		Catalogue number