4SURE™
Blood Glucose Test Strip

312-0000001-246 Ver 1.0 2018/07

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 4SURE Test Strips with 4SURE 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.
- ►Please do not use 4SURE Blood Glucose Monitoring System on critically ill patients. While the blood glucose result is extreme hyperglycemia (over 33.3 mmol/L), the collection of capillary blood from the approved sample sites is not advised when the peripheral circulation is impaired as the delivery of physiological blood glucose level might not be a true reflection. The following circumstances may apply: severe dehydration as a result of diabetic ketoacidosis or due to stress hyperglycemic, 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

4SURE Blood Glucose test strips, when used together with 4SURE 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 with following indication.
Home use of blood glucose testing requires capillary blood samples from fingertip or alternate sites (AST) palm, forearm and upper arm. In addition, Health care professionals may also use arterial and venous blood samples, as well as neonatal blood from the heel.
For professional use of blood glucose testing, only use heparin for anticoagulation of arterial, venous and capillary whole blood samples.
This system is not intended for use in the diagnosis or screening of diabetes mellitus.

Limitations

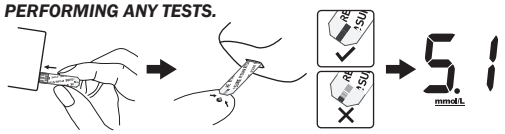
- Hematocrit: The hematocrit level should range between 0% and 70%. Please ask your healthcare professional if you do not know your hematocrit level.
- Altitude Effects: Altitudes up to 3,275 m (10,742 ft) do not affect test results. [5]
- The test strip has no interference with the following substances within and beyond the therapeutic or physiologic concentration range: Salicylic Acid, Bilirubin (Unconjugated), Cholesterol, Creatinine, Galactose, Gentisic Acid, Hemoglobin (Hemolysis Method), Heparin (Li), Heparin (Na), Ibuprofen, Icodextrin, Maltose and Tolbutamide. [1~4]
- The test strip has no interference with the following substances within the therapeutic or physiological concentration range. Concentrations outside therapeutic ranges may cause interference: Acetaminophen (Paracetamol), Ascorbic acid, Dopamine, Levo – Dopa, Methyl – Dopa, Tolazamide, Uric acid, Xylose and Lipemic Samples (Triglycerides).[1~4]
- Pralidoxime Iodide and Reduced Glutathione within the therapeutic or physiologic concentration range may produce elevated glucose results. [1~4]
- Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can produce elevated glucose results.
- Use **ONLY** heparin for anticoagulation of whole blood samples. Please do **NOT** use EDTA for anticoagulation. [1~4]

Storage and Handling

- ► Use each test strip immediately after taking it out of the vial, or unpacking from the foil packet.
- ► Close the vial immediately after taking out a strip.
- ► Test strips can be used from first opening until expiry date on vial.
- ► **IMPORTANT: Do not use the test strips if they have expired.**
- ► Keep the vial closed at all times.
- ► 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.
- ► Do not bend, cut, or alter the test strip.
- ► Store the test strips in a cool, dry place between 2°C and 30°C (35.6°F and 86°F) and below 85% relative humidity.
- ► Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.

Testing Your Blood Glucose

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTS.



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

Reference values

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meal	< 5.6 mmol/L
2 hours after meals	< 7.8 mmol/L

Source: American Diabetes Association (2012). Clinical Practice Recommendations. Diabetes Care, 35 (Supplement 1): S1-100.

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.

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 individual foil packet. 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 test strip lot. Make sure you check the range on the test strip vial label.

Chemical Components

> Glucose dehydrogenase *(E. coli)* 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 whole blood.
Sample Size: 0.5 µL
Reaction Time: 5 seconds
System Measurement Range: 0.5 - 33.3 mmol/L
Hematocrit Range: 0% to 70%

Performance

Accuracy

The table below displays how often 4SURE achieves this target. The chart is based on a study carried out on 100 patients (each patient was tested six times which resulted in 600 test results) to see how well 4SURE performed compared to Cobas Integra® 400 plus reference method results.[6]

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

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L*
33.3% (52/156)	73.7% (115/156)	98.7% (154/156)

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

Within ± 5%	Within ± 10%	Within ± 15%*
69.1% (307/444)	93.9% (417/444)	99.5% (442/444)

Table 3 Accuracy results for glucose concentrations between 2.22mmol/L to 25.3mmol/L

Within ± 0.83 mmol/L or ± 15%
99.3% (596/600)

*Acceptance criteria in EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., Cobas Integra® 400 plus reference values minus glucose values of 4SURE) should be within ±0.83 mmol/L for glucose concentration < 5.55 mmol/L, and within ±15% for glucose concentration ≥ 5.55 mmol/L. When test strip 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 in percentage.

User performance

160 subjects tested on the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how well 4SURE performed compared to Cobas C311 reference method 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	26/43 (60.5%)	37/43 (86.0%)	43/43 (100%)
Palm	27/42 (64.3%)	41/42 (97.6%)	42/42 (100%)
Forearm	31/42 (73.8%)	39/42 (92.9%)	42/42 (100%)
Upper arm	29/42 (69.0%)	38/42 (90.5%)	41/42 (97.6%)

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

Tested sites	Difference within ± 5%	Difference within ± 10%	Difference within ± 15 %
Fingertip	59/117 (50.4%)	102/117 (87.2%)	115/117 (98.3%)
Palm	49/118 (41.5%)	92/118 (78.0%)	118/118 (100%)
Forearm	43/118 (36.4%)	84/118 (71.2%)	115/118 (97.5%)
Upper arm	49/118 (41.5%)	87/118 (73.7%)	116/118 (98.3%)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 0.28 mmol/L for each glucose concentration < 5.55 mmol/L and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 5.55 mmol/L.

Reference

[1] McEnroe, J Robert, et al. National Committee for Clinical Laboratory Standards. Interference testing in clinical chemistry; Approved Guideline – 2nd edition. NCCLS : 2005 - EP7-A2, volume 25, number 27.
[2] EN ISO 15197:2015 (E): In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, Second edition, section 6.4.4 Interference Testing, pp, 28-30.
[3] Hardman JG, Limbird LE, Molinoff PB, et al. Goodman & Gilman's the Pharmacological Basis of Therapeutics. 9th ed. New York, NY: McGraw-Hill; 1996: 1570-1571.
[4] Zaloga GP, Macgregor D. The Critical Care Drug Handbook. 2nd ed. St Louis, MO: Mosby-Year Book; 1997.
[5] Kost GJ, Vu HT, Lee JH, et al. Multicenter study of oxygen-intensive handheld glucose point-of-care testing in critical care/hospital/ambulatory patients in the United States and Canada. Crit Care Med. 1998;26:581-590.
[6] Institut für Diabetes Technologie. System accuracy evaluation of FORA 6 Connect Multi-functional Monitoring System based on ISO 15197:2013 & EN ISO 15197:2015. Project No.: IDT-1739(2A)-FS; 2018

Symbol	Referent
IVD	*In vitro* diagnostic medical device
	Do not reuse
	Consult instructions for use
	Temperature limitation
	Use by
	Keep Dry
	Keep away from sunlight
CE	CE mark
LOT	Batch code
	Humidity limitation
	Do not use if package is damaged
	Manufacturer

For self-testing and point-of-care-testing of whole blood glucose

Model No.: ACS046
Use only with 4SURE One / Smart / Smart Duo Blood Glucose Monitoring System

NIPRO

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