

REF G134-906A	English
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PRINCIPLE AND INTENDED USE

The Go-Keto Blood Glucose Test Strips are thin strips. The strips have a chemical reagent system. They are for work with the Go-Keto Blood Glucose & Ketone Meter to measure the glucose concentration in whole blood. Blood is applied to the end tip of the test strip. Then the blood is automatically absorbed into the reaction cell. This is where the reaction takes place. A transient electrical current is formed during the reaction. The blood glucose concentration is calculated based on the electrical current detected by the meter. The result is shown on the meter display. The meters are calibrated to show plasma equivalent results.

For *in vitro* diagnostic use. Test strips can be used only outside the body for testing purposes. For self-testing and professional use. Go-Keto Blood Glucose Test Strips are used by people with diabetes at home and by healthcare professionals. They are used to measurement of glucose in capillary whole blood from the finger, forearm, and palm. The system is also used to monitor how well the diabetes control programs work.

COMPOSITION

Each test strip has reactive and non-reactive chemicals. These chemicals are: Glucose Oxidase < 25 IU, Mediator < 300 µg, Buffer, and Non-reactive Ingredient.

Each test strip vial has a drying agent.

STORAGE AND HANDLING

- Store test strips in their protective vial. Store with their cap on tight. This keeps them working good.
- Store test strips in a cool, dry place at 2-30°C (36-86°F).
- Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips at room temperature. This is to make sure you get the right results.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips, or control solution near things that have bleach in them.
- Keep the test strips in the vial they came with. Do not put the test strips in any other container.
- Put the vial cap back on right after taking out a test strip.
- Use the test strip right after you take it out of the vial.
- Use your test strips up to the unopened expiration date on the vial. Using test strips past the expiration date can give you wrong test results.
- Note: All expiration dates are printed in Year-Month-Date format.
- Use a new vial of test strips for only 6 months after opening. The opened vial expiration date is 6 months after the vial was first opened. Write the opened vial expiration date on the vial label after you open it.

PRECAUTIONS

- For *in vitro* diagnostic use. Use the test strips only outside the body. Use only for testing purposes.
- Do not use test strips after the expiration date on the vial. Expired test strips can give wrong blood glucose readings.
- Do not use test strips that are torn, bent, or damaged in any way.
- Do not reuse test strips.
- Only apply the sample to the tip of the test strip. Do not apply blood or control solution to the top of the test strip. This can give you false readings.
- Check the code chip before running a blood glucose test. Make sure to use the code chip that comes with that vial of strips. Insert the code chip into the code chip slot. Find the code chip slot on the left side of the meter.
- Throw away the vial and any unused test strips 6 months after you first open it. Constant exposure to air can destroy chemicals in the test strip. This damage can give you wrong readings.
- Keep the test strip vial away from children and animals.
- Talk to your physician or healthcare professional before making any changes in your treatment plan based on your blood glucose test results.

MATERIALS PROVIDED

- Blood Glucose Test Strips
- Code Chip
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Blood Glucose & Ketone Meter
- Glucose Control Solution
- Sterile Lancets
- Lancing Device

INSTRUCTIONS FOR USE

Before use, get complete instructions on getting blood samples from your User's Manual.

- Open the cap of the test strip vial only to take out a test strip for testing. Put the cap back on right after you take out a test strip. This protects the test strips still in the vial from moisture in the air.
- Follow the instructions in your user's manual to run the blood glucose test.
- The blood glucose test result will show on the meter display window. Make sure the result is in the target range told by your healthcare professional. If they are not, ask your healthcare professional what to do. Always talk to your healthcare professional before changing your treatment plan.

IMPORTANT: When testing blood glucose concentration, the Go-Keto Blood Glucose & Ketone Monitoring System allow alternative site testing. They are forearm and palm testing in addition to fingertip testing. You should know there are important differences between forearm, palm and fingertip samples.

Important information about forearm and palm glucose testing:

- When blood levels change fast (such as after a meal, insulin dose or exercise), blood from the fingertips may show these changes sooner than blood from other parts.
- Use your fingertips if you test within 2 hours of a meal, insulin dose, exercise. Or, any time you feel your glucose levels are changing fast.
- You should test with the fingertips anytime you think there is a chance of hypoglycemia.

RANGE OF EXPECTED VALUES

Work with your healthcare professional to best monitor your glucose. Together you can set your own range of expected blood glucose values, arrange your testing times and discuss the meaning of your blood glucose results.

Expected blood glucose levels for people without diabetes¹:

Time	Range (mg/dL)	Range (mmol/L)
Fasting and Before Meals	70 – 100	3.9 – 5.6
2 Hours After Meal	Less than 140	Less than 7.8

CHECKING THE SYSTEM

Be careful with your blood glucose meter. See your user's manual for how to take good care of your meter. Do a quality control test to make sure that the meter and test strips are working well together. See your user's manual to see how to run a quality control test. Three ranges CTRL 0, CTRL 1 and

CTRL 2 are shown on the test strip vial label. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working right, try to do a level 0 or level 2 test. Contact your distributor for information on buying control solution.

You should confirm your control solution results. Make sure the Control Solution 0 tests fall within the CTRL 0 range, the Control Solution 1 tests fall within the CTRL 1 range, and the Control Solution 2 tests fall within the CTRL 2 range. When testing with Control Solution 1, make sure you are matching the results to the CTRL 1 range on the vial label.

CAUTION: If your quality control test result is outside of the control range shown on the test strip vial, DO NOT use the system to test your blood. This might mean the system is not working right. Contact your distributor for help if you cannot correct the problem.

LIMITATIONS

- The Go-Keto Blood Glucose Test Strips and other components have been designed, tested and proven to work effectively with the Go-Keto Blood Glucose & Ketone Meters to provide accurate blood glucose measurements. Do not use components from other brands.
- Do not use the meter in any way that is not specified by the manufacturer. If this happens, the system might not work the way it is supposed to.
- Test only fresh capillary whole blood with the Go-Keto Blood Glucose Test Strips. Do not use with serum or plasma samples.
- The Go-Keto Blood Glucose & Ketone Monitoring System are for professional use. They are also for over the counter sale. Both professionals and self-testing users can use the test strips to test fresh capillary blood samples.
- Your hematocrit should be within the range of 20%-70%. Very high (above 70%), and very low (below 20%) hematocrit can give you wrong results. Talk to your healthcare professional to find out your hematocrit level.
- Abnormally high levels of Vitamin C (> 3 mg/dL) or other reducing substances will produce false high blood glucose measurements.
- The system gives accurate glucose readings between 0.6-33.3 mmol/L (10 to 600 mg/dL).
- Fats (Triglycerides up to 3,000 mg/dL or Cholesterol up to 500 mg/dL) have no major effect on test results.
- The Go-Keto Blood Glucose Test Strips have been tested and shown to work properly up to 10,000 ft (3,048 meters).
- If you are very ill, do not run the glucose test with the Go-Keto Blood Glucose & Ketone Monitoring System.
- Blood samples from patients in shock, with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested. We do not recommend these samples for blood glucose testing with Go-Keto Blood Glucose & Ketone Monitoring System.
- Not for persons undergoing Oxygen therapy.
- Throw away blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow all local regulations when getting rid of blood samples and materials.

PERFORMANCE CHARACTERISTICS

The Go-Keto blood glucose test strips when used with Go-Keto meter complies with the requirements of EN ISO 15197:2015 / ISO 15197:2013 (*In vitro* diagnostic test systems - requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus). The Go-Keto Blood Glucose & Ketone meter are calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.

Reproducibility and Precision

Ten replicate assays were each run on ten Go-Keto Blood Glucose & Ketone Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results show the following estimates:

MEAN	2.2 mmol/L (40.4 mg/dL)	4.4 mmol/L (79.6 mg/dL)	7.2 mmol/L (128.9 mg/dL)	11.1 mmol/L (198.9 mg/dL)	17.8 mmol/L (320.4 mg/dL)
Standard Deviation (mg/dL) or Coefficient of Variation (CV)	(0.09 mmol/L) 1.62 mg/dL (SD)	(0.14 mmol/L) 2.52 mg/dL (SD)	3.0%	2.7%	3.1%

Intermediate Precision

Ten replicate assays taken from three strip lots were run on ten Go-Keto Blood Glucose & Ketone Meters. The test was run on each day for a total of 10 days. Control solutions at three concentration levels were used in the testing. The results show the following estimates:

#	MEAN	Standard Deviation mmol/L (mg/dL) or Coefficient of Variation (CV)
Strip Lot 1	2.3 mmol/L (41.3 mg/dL)	0.06 mmol/L (1.05 mg/dL) (SD)
	6.4 mmol/L (114.4 mg/dL)	2.7%
	17.5 mmol/L (314.3 mg/dL)	2.1%
Strip Lot 2	2.3 mmol/L (41.0 mg/dL)	0.06 mmol/L (1.15 mg/dL) (SD)
	6.3 mmol/L (113.5 mg/dL)	2.3%
	17.6 mmol/L (317.2 mg/dL)	2.2%
Strip Lot 3	2.3 mmol/L (40.7 mg/dL)	0.06 mmol/L (1.00 mg/dL) (SD)
	6.3 mmol/L (113.6 mg/dL)	2.5%
	17.3 mmol/L (310.8 mg/dL)	2.1%

System Accuracy

Trained technician took capillary blood glucose measurements from >100 study subjects using the Go-Keto Blood Glucose & Ketone Meter (y). Capillary blood samples were taken from fingertip, palm and forearm sampling sites. This is for the Go-Keto Blood Glucose & Ketone Meter testing. Fingertip samples from the same subjects were also tested with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared and show in the table below:

Linear Regression Results: Go-Keto (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept	R	N
Fingertip	1.0677	-11.8902	0.9930	684
Palm	0.9996	-6.3141	0.9923	654
Forearm	1.0448	-8.6032	0.9913	654

Fingertip samples were used for YSI reference measurement.

Fingertip blood sample range was 2.5-27.6 mmol/L (44.2-497 mg/dL) for Go-Keto Blood Glucose & Ketone Meter testing. The sample range for palm and forearm sites was 2.9-27.6 mmol/L (52.2-497 mg/dL) for Go-Keto Blood Glucose & Ketone Meter testing.

Fingertip Site: System accuracy results for glucose concentration < 5.55 mmol/L (100 mg/dL)				
Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83 mmol/L (15 mg/dL)		
132/186 (71.0%)	186/186 (100.0%)	186/186 (100.0%)		
Fingertip Site: System accuracy results for glucose concentration ≥ 5.55 mmol/L (100 mg/dL)				
Within ± 5%	Within ± 10%	Within ± 15%		
239/498 (48.0%)	409/498 (82.1%)	493/498 (99.0%)		

Palm Site: System accuracy results for glucose concentration < 5.55 mmol/L (100 mg/dL)				
Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83 mmol/L (15 mg/dL)		
95/156 (60.9%)	147/156 (94.2%)	156/156 (100.0%)		
Palm Site: System accuracy results for glucose concentration ≥ 5.55 mmol/L (100 mg/dL)				
Within ± 5%	Within ± 10%	Within ± 15%		
197/498 (39.6%)	384/498 (77.1%)	497/498 (99.8%)		

Forearm Site: System accuracy results for glucose concentration < 5.55 mmol/L (100 mg/dL)				
Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83 mmol/L (15 mg/dL)		
103/156 (66.0%)	152/156 (97.4%)	156/156 (100.0%)		
Forearm Site: System accuracy results for glucose concentration ≥ 5.55 mmol/L (100 mg/dL)				
Within ± 5%	Within ± 10%	Within ± 15%		
253/498 (50.8%)	407/498 (81.7%)	494/498 (99.2%)		

System accuracy results for glucose concentration between 2.5 mmol/L (44.2 mg/dL) and 27.6 mmol/L (497 mg/dL)				
Within ± 15% or ± 0.83 mmol/L (15 mg/dL)				
Fingertip Site	Palm Site	Forearm Site		
679/684 (99.3%)	653/654 (99.8%)	650/654 (99.4%)		

System accuracy according to EN ISO 15197:2015 / ISO 15197:2013, >99% of measured glucose values fall within the minimum acceptable performance criteria.

Consumer Study

A consumer study was done. Three test strip lots with capillary blood sample were tested. Participants and trained technician both used the Go-Keto Blood Glucose & Ketone Monitoring System. This study shows that the patient can run the test as well as a trained technician.

Go-Keto tests: Linear regression of Participant (y) versus YSI Reference value, and Linear regression of Technician (x) versus YSI Reference value					
Strip Lot	Test By	Slope	y-Intercept	R	N
Strip Lot 1	Layperson	1.0684	-11.5243	0.9920	218
Strip Lot 1	Technician	1.0681	-11.8661	0.9927	218
Strip Lot 2	Layperson	1.0687	-12.0051	0.9924	218
Strip Lot 2	Technician	1.0725	-12.7736	0.9926	218
Strip Lot 3	Layperson	1.0749	-11.8991	0.9936	218
Strip Lot 3	Technician	1.0806	-14.1872	0.9927	218

The study evaluating glucose values from fingertip capillary blood samples obtained by 109 lay persons showed the following results:

100% within ± 0.83 mmol/L (± 15 mg/dL) of the medical laboratory values at glucose concentrations below 5.55 mmol/L (100 mg/dL), and >98% within ± 15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L (100 mg/dL).

Neonatal Study

The neonatal blood glucose measurements from 104 participants were taken by a trained technician using the Go-Keto Blood Glucose & Ketone Meter (y). The neonatal blood samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared in the table below.

Linear Regression Results: Go-Keto (y) vs. YSI Reference (x)				
Blood Sample	Slope	Intercept	R	N
Neonatal	0.9866	1.4789	0.9805	208

For complete testing instructions, please refer to the user's manual included with your meter. For additional questions or issues with this product, please contact your distributor for help.

REFERENCES

- ADA Clinical Practice Recommendations, 2011.

INDEX OF SYMBOLS

	Control instructions for use		Use by		Code Number
	<i>In vitro</i> diagnostic medical device		Lot Number		Control Range
	Temperature limit		Manufacturer		Catalogue Number
	Contains sufficient for <n> tests		Do not reuse		Authorized Representative in the European Community



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Nummer: 1151210101
Datum des Inkrafttretens: 2020-09-30