MASTER

Before using the test strips carefully read these instructions for use and the user manual of the GlucoMen® areo 2K blood glucose and β-ketone monitoring system. If you have any questions, please contact the A. Menarini Diagnostics Customer Service.

INTENDED USE

The GlucoMen® areo β-Ketone Sensor (light purple coloured) is an *in vitro* diagnostic medical device intended to quantitatively measure β-ketone (β-hydroxybutyrate) in fresh capillary whole blood samples. The GlucoMen® areo β-Ketone Sensor is only for use with the GlucoMen® areo 2K meter. The GlucoMen® areo 2K system is an *in vitro* diagnostic medical device for home glucose and β-ketone testing. It may also be used in clinical settings by healthcare professionals.
The system is not intended for the diagnosis of DKA or for neonatal use. Do not alter your treatment on the basis of the β-ketone result without previously consulting your doctor or healthcare professional.

PRODUCT DESCRIPTION AND MEASUREMENT PRINCIPLE

Regular testing for ketones is an important part of diabetes mellitus and diabetic ketoacidosis (DKA) management. In particular, the availability of test strips capable to provide rapid and accurate quantitation of blood β-ketone offers the opportunity to simplify and significantly improve the management of DKA[1-3]. The GlucoMen® areo β-Ketone Sensor is designed to respond to blood β-hydroxybutyrate levels. When blood β-ketone mixes with the reagents on the test strip, an electrical current directly proportional to the β-hydroxybutyrate concentration is generated. The GlucoMen® areo 2K meter measures this current and calculates the plasma-equivalent concentration of β-ketone.

REAGENT COMPOSITION (PER CM²)

- D-3-Hydroxybutyrate Dehydrogenase (*Pseudomonas sp.*), 1.5% w/w
- Coenzyme (NAD^+), 0.7% w/w
- Redox mediator: 1.10-phenanthroline-5.6-dione, 20.0% w/w
- Non-reactive Ingredients, 77.8% w/w

STORAGE AND USAGE CONDITIONS

- Store the test strip foil pouch between 4 and 30 °C (39.2 – 86 °F); do not freeze or refrigerate.
- Avoid exposure to moisture, heat and direct sunlight.
- Do not use the test strips past their expiry date, as this may cause inaccurate results. Please check the expiration date on the foil pouch label.
- Use only the GlucoMen® areo β-Ketone Sensor for testing with your GlucoMen® areo 2K Meter.

WARNING AND SAFETY INFORMATION

- The GlucoMen® areo β-Ketone Sensor is for testing outside the body (*in vitro* diagnostic use **ONLY**).
- Incorrect results may occur in patients who are dehydrated, severely hypotensive, in shock, or in a hyperglycemic-hyperosmolar state.
- Do not test critically ill patients.
- If you are experiencing symptoms that are not consistent with your blood β-ketone test results **AND** you have followed all instructions described in your GlucoMen® areo 2K Meter user manual, call your healthcare professional.
- Never make significant changes to your diabetes control program without speaking with your healthcare professional.
- Keep the meter, test strips and other items out of the reach and sight of children. Small items may represent choking hazards.
- Handle the test strips with clean, dry hands.
- Dispose of used lancet and test strips according to local regulations.
- **HANDLING BLOOD CAN BE DANGEROUS**. You or other individuals could be infected by pathogenic microorganisms due to incorrect or imprecise procedures. **USE EXTREME CAUTION** when handling blood, test strips, lancets and meter.

SAMPLE COLLECTION AND PREPARATION

The GlucoMen® areo β-Ketone Sensor is specifically designed for use with fresh capillary whole blood from the fingertip. Plasma and serum samples cannot be used.

PROCEDURE FOR BLOOD β-KETONE TESTING

Materials provided. GlucoMen® areo β-Ketone Sensor test strips.
Materials required but not provided. GlucoMen® areo 2K meter, lancing device, lancets.
See the user manual of your GlucoMen® areo 2K meter for more details.

- For accurate test results, allow test strips and meter to equilibrate with ambient conditions (temperature and humidity) for at least 30 minutes before testing your blood β-ketone. Operating conditions are: temperature 10-40 °C (50-104 °F); relative humidity <85%.

1. Remove a test strip from the foil pouch with clean, dry hands.
- The test strips are for single-use only. Do not use test strips if wet, damaged, or stored in an open/damaged foil pouch.
- Use the test strip immediately.

2. Insert the test strip into the strip port with the contact bars end first and facing up. Push the sensor in firmly until it will go no farther.
3. Collect blood using a lancing device and a new lancet, according to the relative instructions for use.
4. Apply the drop of blood to the tip of the sensor until blood has been drawn into the strip (visually confirm that the strip is full through the check window at the tip of the sensor).
- Do not test blood that runs or spreads out from the puncture site.
- Do not smear blood onto the test strip.
- Do not forcefully push the test strip against the puncture site.
- Do not touch the test strip after the meter starts the countdown.

5. The test result will appear on the screen once the test is completed and will blink until the meter switches off.
6. Press the release button to remove the test strip.
- Test strips and lancets qualify as biohazardous waste once used to test your blood β-ketone. Dispose of used test strips and lancets according to local regulations on biohazardous waste.

UNDERSTANDING YOUR TEST RESULTS

- Blood β-ketone test results are shown on the meter in millimoles of β-ketone per liter of blood (mmol/L).
- The normal adult blood β-ketone range for a person without diabetes is less than 0.6 mmol/L. Consult with your healthcare professional for the blood β-ketone range that is appropriate for you.
- If the blood β-ketone result is between 0.6 to 1.5 mmol/L and glucose is more than 300 mg/dL (16.7 mmol/L), this may indicate development of a medical concern. Contact your healthcare professional for assistance.
- If the blood β-ketone result is more than 1.5 mmol/L and glucose is more than 300 mg/dL (16.7 mmol/L), contact your healthcare professional immediately. It indicates a risk of developing DKA.

IF THE TEST RESULT DOES NOT MATCH WITH HOW YOU FEEL

Make sure you performed the test correctly as explained in the user manual. If no procedural errors were made, conduct a control solution test to check that the system is working properly. If the system is working properly and your blood test results still do not match with how you feel, contact your doctor or healthcare professional.

CONTROL SOLUTION TEST

If you need to perform a control solution test, read the user manual of your GlucoMen® areo 2K meter and the instructions for use of your GlucoMen® areo Ket Control solution.

RESTRICTIONS

- Use only fresh capillary whole blood from your fingertip for testing. Do not use serum or plasma.
- The GlucoMen® areo β-Ketone Sensor is not intended for alternative site testing (AST).
- DO NOT test on neonatal (newborn) samples.
- DO NOT test on arterial blood samples.
- Altitudes up to 3150 m (10335 feet) will not affect the test results.
- Allowed haematocrit range: 20 - 60%.
- Allowed operating temperature and humidity conditions for meter and test strip are 10 to 40 °C (50 to 104 °F) and <85% relative humidity, respectively.

MEASUREMENT RANGE

The GlucoMen® areo β-Ketone Sensor provides results equivalent to the plasma β-hydroxybutyrate concentration. The measurement range of the GlucoMen® areo 2K system is 0.1 – 8.0 mmol/L.

CALIBRATION AND TRACEABILITY

The GlucoMen® areo 2K system is calibrated using reference plasma values determined by means of the *Stanbio β-Hydroxybutyrate LiquiColor® Procedure No. 2440* (Stanbio Laboratory, 1261 North Main Street, Boerne, Texas 78006). The analyzer used to run the Stanbio kit (secondary reference measurement procedure) is calibrated using a series of β-hydroxybutyrate standards (primary calibrators) prepared gravimetrically at Stanbio Laboratory.

PERFORMANCE OF GLUCOMEN® AREO β-KETONE SENSOR

The performance of GlucoMen® areo β-Ketone Sensor was tested in laboratory.

Precision. Within-run repeatability results relative to 3 lots of GlucoMen® areo β-Ketone Sensor are shown in *Fig. 1*.

Accuracy. The accuracy of the GlucoMen® areo 2K system was assessed by comparing the blood β-ketone test results obtained using three lots of GlucoMen® areo β-Ketone Sensor (200 tests per lot, 600 in total) with those obtained using the *Stanbio β-Hydroxybutyrate LiquiColor® Procedure No. 2440*. As shown in *Fig. 2*, the GlucoMen® areo 2K system compared well with the laboratory reference method.

Interference Testing. The substances listed in *Fig. 3* have been tested for interference with the GlucoMen® areo 2K system. The table reports the maximum concentrations having no interference on the β-ketone readings.

REFERENCES

1. Laffel, L. 1999. Ketone Bodies: A Review of Physiology, Pathophysiology and Application of Monitoring of Diabetes. *Diabetes Metab. Res. Rev.* 15: 412-426.
2. Porter, W.H., Yao, H.H., Karounos, D.G. 1997. Laboratory and Clinical Evaluation of Assay for betahydroxybutyrate. *Am. J. Clin. Pathol.* 107: 333-358.
3. Byrne, H.A., Tieszon, K.L., Hollis, S., Doran, T.L., and New J.P. 2000. Evaluation of an Electrochemical Sensor for Measuring Blood Ketone. *Diabetes Care* 23: 500-503.

	REPEATABILITY (Blood Samples, N=300 per level)				
β-ketone level	**# 1**	**# 2**	**# 3**	**# 4**	**# 5**
Average (mmol/L)	0.47	2.22	3.91	6.12	7.39
SD (mmol/L)	0.07	0.11	0.15	0.21	0.19
CV%	NA	5.0	3.8	3.4	2.6

Fig. 1

ACCURACY FOR CAPILLARY BLOOD SAMPLES (β-Ketone concentration range: 0.14 to 7.91 mmol/L, N = 600)	
β-Ketone concentration < 1.5 mmol/L (N = 180)	
Within ± 0.1 mmol/L	160/180 (88.9%)
Within ± 0.2 mmol/L	178/180 (98.9%)
Within ± 0.3 mmol/L	180/180 (100.0%)
β-Ketone concentration ≥ 1.5 mmol/L (N = 420)	
Within ± 10%	396/420 (94.3%)
Within ± 15%	419/420 (99.8%)
Within ± 20%	420/420 (100.0%)
Combined results (N=600)	
Within ± 0.3 mmol/L or ± 20%	600/600 (100%)

Fig. 2

SUBSTANCE	TEST CONCENTRATION
Acetaminophen	20 mg/dL
Acetone	10 mg/dL
Acetoacetate	10 mg/dL
Ascorbic acid	4 mg/dL
Bilirubin	10 mg/dL
Captopril	10 mg/dL
Cholesterol	500 mg/dL
Creatinine	6 mg/dL
Dopamine	2 mg/dL
Glucose	900 mg/dL
Ibuprofen	50 mg/dL

SUBSTANCE	TEST CONCENTRATION
L-DOPA	3 mg/dL
Methyl-Dopa	7.5 mg/dL
N-Acetylcysteine	10 mg/dL
Salicylate	30 mg/dL
Tetracycline	10 mg/dL
Tolazamide	15 mg/dL
Tolbutamide	45 mg/dL
Triglycerides	750 mg/dL
Uric Acid	20 mg/dL
EDTA	180 mg/dL
Heparin	18 IU/mL

Fig. 3

SYMBOLS	
	Manufacturer
	Caution, read instructions for use
REF	Catalogue number
LOT	Batch code
	Temperature limitation
	Use by
CE 0123	CE marking. The product fulfills the requirements for directive 98/79/EC
IVD	*In Vitro* Diagnostic Medical Device
	Significant additions or changes from previous instructions for use revision
	Recyclable package

AVAILABILITY

REF **XXXXX** GlucoMen® areo β-Ketone Sensor 10: 1 box x 10 pouched test strips

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Made in Taiwan

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If you have any question about GlucoMen® areo β-Ketone Sensor, please contact:

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GlucoMen® areo β-Ketone Sensor

β-Ketone test strips

IVD

• *Instructions for use*

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