ACCUGENCE® Blood β-Ketone Test Strips Package Insert

EN

➢ **Specification**

Model: SM311

Catalog: SM3111011, SM3111012, SM3111013

➢ **Intended Use**

ACCUGENCE® Blood β-Ketone Test Strips are used with ACCUGENCE® Multi-Monitoring Meter to quantitatively measure the β-ketone concentration in fresh capillary whole blood samples. ACCUGENCE® Blood β-Ketone Test Strips and applicable meter are intended to be used only outside the body (in vitro diagnostic use) by people with diabetes at home, as an aid to monitor the effectiveness of diabetes control. They are only for self-testing, not for near-patient testing.

The test strips shall not be used for screening, diagnosis, or aid to diagnosis of diabetes. They are not automated.

➢ **Test Principle**

When blood sample is applied to the end tip of the test strip, the sample is then automatically absorbed into the reaction cell where the β-ketone in the sample reacts with the chemicals on the test strip. A transient electrical current is formed during the reaction and measured by the meter. The β-ketone result is then calculated based on this current and is shown on the meter display.

➢ **Composition**

Each test strip contains reactive and non-reactive chemicals. These chemicals are: β-Hydroxybutyrate Dehydrogenase <5 IU, NAD <10 ug, Mediator <100 µg, Buffer, Non-reactive Ingredient.

Each test strip vial contains drying agents.

➢ **Storage and Handling**

- Store test strips in a cool dry place at 2-35 °C (36-95 °F) and 10-90% relative humidity. Do not freeze. Keep away from heat and direct sunlight. Exposure to temperatures and/or humidity outside the storage limits may cause inaccurate readings.
- The unopened expiration date is printed on the vial.

  Note: *All expiration dates are printed in Year-Month-Day format. 2020-01-01 means January 1th, 2020.*
- A new vial of test strips may be used for 6 months after first opening. Write the opened expiration date on the vial label when you open a new vial.
- Do not use your test strips beyond the unopened expiration date or the opened expiration date whichever comes first. Discard any unused test strips beyond the expiration date, because they may cause inaccurate results.
- Store unused test strips only in the original vial with the cap closed tightly. Do not transfer the test strips to any other container.
- Do not store the meter, the test strips or control solutions near bleach or cleaners with bleach.
- Open the vial only when taking out a test strip for use.
- Close the vial cap tightly immediately after removing a test strip. Use each test strip as soon as you take it out of the vial.
- Use the test strips at temperatures between 5-45 °C (41-113 °F).
- Use the test strips at 10%-90% relative humidity. Do not store or use the test strips in high heat and moisture areas such as the bathroom or kitchen.
- Make sure your meter and test strips are about the same temperature before you test.
- Do not use test strips that are torn, bent, damaged, altered, or contaminated.
- Do not use test strips from a vial that is damaged or left open to air.
- Test strips are for single use only. Do not reuse test strips.
- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.

➢ **Precautions**

- Do not use new test strips if the vial is open or damaged in any way. This could lead to error messages or inaccurate results.
- Matching the code number on the meter to the code number on the test strip vial is essential to obtain accurate results. Refer to the User's Manual for the detailed instructions about coding.
- Use universal blood precautions when handling, and disposing of, blood β-ketone monitoring materials. All patient samples and materials with which they come in contact are considered biohazards and should be handled as if capable of transmitting infection even after you have performed cleaning and disinfection. Follow proper precautions in accordance with all local regulations when disposing of all materials.
- Do not use a lancet that has been used by others.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Keep your meter and lancing device clean.
- Apply sample only to the tip of the test strip. Do not apply to the top of the test strip. This may result in a false reading.
- Do not put the used test strips back in the vial after taking a test.
- Keep the test strip vial away from children and animals.
- Always consult your doctor before making any changes to your treatment plan.
- Any serious incident shall be reported to manufacturer and competent authority of the Member State in which user and/or patient is established.

➢ **Materials Provided**

- Test Strips
- Calibration Chip
- Package Insert

➢ **Materials Required but Not Provided**

- Multi-monitoring meter (Model: PM900)
- Sterile Lancets
- Lancing Device
- Control Solution

➢ **Coding Procedure**

Note: *The meter must be calibrated with the calibration chip from test strip package before using a new lot of test strips. It is essential for obtaining accurate results.*

1. Insert the calibration chip into the strip port of the meter, then the calibration chip will automatically code the meter and the code number together with code type will be displayed on the LCD screen of the meter.
2. Confirm that code type displayed on the meter is "KET".
3. Confirm that the code number displayed on the meter match the code number shown on strip vial label and calibration chip.

➢ **Instructions for Use**

See your User's Manual for complete instructions for blood sample collection before use.

1. Open the cap of the test strip vial, remove a test strip. Reclose the vial cap immediately to protect the unused test strips from humidity.
2. Run the test following the instructions in your User's Manual.
3. The test result will be shown on the meter display window. This result should fall within the target range. Your doctor should recommend your target range. If your results are higher or lower, ask your doctor what to do.

➢ **Explanation of Test Results**

- ACCUGENCE® Blood β-Ketone Test Strips measure the Beta-Hydroxybutyrate (β-OHB), the most important of the three ketone bodies in the blood[1]. The test results are shown on the meter only in the unit of millimolar per liter (mmol/L).
- Normally, levels of β-OHB are expected to be less than 0.6 mmol/L, β-OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill[1-3].
- If your blood β-ketone result is between 0.6 and 1.5 mmol/L, and your blood glucose result is higher than 16.7 mmol/L (300 mg/dL), this may indicate development of a medical concern. You need to contact with your healthcare professional for assistance.
- If your blood β-ketone result is more than 1.5 mmol/L and your glucose result is higher than 16.7 mmol/L (300 mg/dL), contact with your healthcare professional immediately. This indicates a risk of developing diabetic ketoacidosis (DKA).
- **"Hi"** means that your meter has determined that you blood β-ketone result is higher than 8.0 mmol/L.

➢ **Checking the System**

The meter must be handled carefully. See the user's manual for detailed instructions for meter care. Perform a quality control test to make sure your meter and the ACCUGENCE® blood β-ketone test strips are working together properly. Follow the test procedure in user's manual to run a quality control test. Contact your distributor for information on purchasing the ACCUGENCE® β-Ketone Control Solutions kit.

There are 3 levels for ACCUGENCE® β-Ketone Control Solutions. When a control test completed, determine whether the test result is within the range printed on the test vial. If the obtained results fail outside this range, repeat the control test.

CAUTION: *If the quality control test result falls outside the control range shown on the strip package label,* ***DO NOT*** *use the system to test your blood ketone, as the system may not be working properly. If you cannot correct the problem, contact your distributor for help.*

➢ **Limitation**

- Do not use the meter in any way that is not specified by the manufacturer. Otherwise, the system might not work the way it is supposed to.
- The test strips are for testing fresh capillary whole blood. Do not use with serum or plasma samples.
- The test strips should not use for the testing of newborns.
- Very high (above 70%) and very low (below 10%) hematocrit levels can cause false results. Talk to your doctor to find out your hematocrit level.
- Fatty substances (triglycerides up to 33.9 mmol/L (3000 mg/dL) or cholesterol up to 12.9 mmol/L (500 mg/dL)) have no significant effect on test results.
- Ascorbic acid (vitamin C), acetaminophen, uric acid, salicylates, and other reducing substances when occurring in normal blood or normal therapeutic concentrations do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- The test strips may be used at altitudes up to 10,000 feet (3,048 meters).
- Test results may be inaccurate if the patients are severely dehydrated, or severely hypotensive, in shock or in a hyperglycaemic-hyperosmolar state.
- The test strips are **not** recommended for use in critically ill patients.

➢ **Performance Characteristics**

Calibration and Traceability: The ACCUGENCE® Blood β-Ketone Test Strips are calibrated to reflect plasma β-Hydroxybutyrate by using Randox β-Hydroxybutyrate assay kit, a laboratory reference method.

System measurement range: 0.0-8.0 mmol/L

Required sample size: 0.9 µL

Tested time: 5 seconds

Reproducibility and Precision

The evaluation was conducted with 10 meters, 3 strip lots, and 5 blood samples with different β-ketone concentrations, and 10 measurements were performed with each combination of meter, strip lot and sample. The results are shown below.

Blood Sample	1	2	3	4	5
N	300	300	300	300	300
Grand Mean (mmol/L)	0.48	0.94	1.99	3.81	6.21
Pooled SD (mmol/L)	0.04	0.03	0.05	0.07	0.11
Pooled CV (%)	7.4	3.5	2.3	1.7	1.7

Intermediate Precision

The evaluation was conducted with one measurement of each sample per day and was conducted with 10 meters, 3 strip lots and control solutions at 3 concentration levels over 10 days. The results are shown below.

Control Solutions	Level 1	Level 2	Level 3
N	300	300	300
Grand Mean (mmol/L)	0.60	2.43	5.05
Pooled SD (mmol/L)	0.02	0.05	0.10
Pooled CV (%)	3.0	2.1	2.0

System Accuracy

System accuracy was evaluated with fresh fingertip capillary blood samples by comparing measured values from the ACCUGENCE® Multi-Monitoring Meters tested with ACCUGENCE® Blood β-Ketone Test Strips to Laboratory instrument reference values, and the evaluation were conducted with 100 different subjects taking duplicate measurements from each of 3 strip lots by trained operators. The following results were obtained.

System accuracy results for β-ketone concentration <1.5 mmol/L		
Within ±0.1 mmol/L	Within ±0.2 mmol/L	Within ±0.3 mmol/L
319/450 (70.9%)	441/450 (98.0%)	448/450 (99.6%)

System accuracy results for β-ketone concentration ≥1.5 mmol/L			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
65/150 (43.3%)	115/150 (76.7%)	145/150 (96.7%)	150/150 (100%)

System accuracy results for β-ketone concentration between 0.0 mmol/L and 7.0 mmol/L
Within ±0.3 mmol/L or ±20%
598/600 (99.7%)

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

➢ **Reference**

1. Schade DS, Eaton RP. Metabolic and clinical significance of ketosis. Special Topics in Endocrinology and Metabolism 1982; 4:1-27.
2. Wiggam MI, O'Kane MJ, Harper R, Trimber ER, Bell PM. Treatment of diabtes ketoacidosis using normalization of blood 3- Hydroxybutyrate concentration as the endpoint of emergency management. Diabetes Care 1997;20:1347-52.
3. Harano Y, Kosugi K, Hyosu T, Suzuki M, Kashiwagi A, Uno S, Shigeta Y. Ketone bodies as markers for type 1 (Insulin-dependent) Diabbetes and their value in the monitoring of diabetes control. Diabetologia 1984; 26:343-8.

➢ **Index of Symbols**

	Consult instructions for use		Use by	CODE	Code Number
IVD	For *in vitro* diagnostic use only	LOT	Lot Number	REF	Catalog #
	Store between 2-35°C (36-95 °F)		Manufacturer		Do not reuse
Σ	Contains sufficient for <n> tests	EC REP	Authorized Representative	6M	6 months expiry date from the date of first open vial
CE	CE Marking	UDI	Unique Device Identifier		For self-testing

➢ **The summary of safety and performance**

Intended users can log in to the European database on medical devices (Eudamed) to request the summary of safety and performance (SSP) of the device or contact the manufacturer to obtain it.

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CE 0123

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