



Blood Ketone Test Strip Package Insert

REF GK134-10A	English
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PRINCIPLE AND INTENDED USE

The *On Call*[®] Blood Ketone Test Strips are thin strips with a chemical reagent system which work with the *On Call*[®] GK Dual Blood Glucose & Ketone Meter to measure the blood β -Ketone (beta-hydroxybutyrate) concentration in whole blood. Blood is applied to the end tip of the test strip, and then automatically absorbed into the reaction cell where the reaction takes place. A transient electrical current is formed during the reaction and the blood β -Ketone concentration is calculated based on the electrical current detected by the meter, then the result is shown on the meter display. The meters are calibrated to display plasma equivalent results.

For *in vitro* diagnostic use. Test strips are only to be used outside the body for testing purposes. *On Call*[®] Ketone Test Strips are used by people at home and by healthcare professionals for the quantitative measurement of β -Ketone in capillary whole blood only from the finger. Professionals may also test venous blood samples.

COMPOSITION

Each test strip contains the following reactive chemicals:

3-Hydroxybutyrate dehydrogenase < 10 IU, Mediator < 100 μ g, Buffer, Non-reactive Ingredient. Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Test strips should be stored tightly capped in their protective vial to keep them in good working condition.
- Store test strips in a cool, dry place at room temperature, 5-30°C (41-86°F). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips at room temperature. This is to ensure accurate results.
- Do not store the test strips outside their protective vial. Test strips must be stored in the original vial with the cap tightly closed.
- 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 bleach or cleaners that contain bleach.
- Do not transfer the test strips to a new vial or any other container.
- Replace the vial cap immediately after removing a test strip.
- Use the test strip immediately after removing it from the vial.
- Do not use your test strips past the unopened expiration date printed on the vial. Using test strips past the expiration date may produce incorrect test results.
- Note:** All expiration dates are printed in Year-Month format. 2014-01 means January, 2014.
- A new vial of test strips may be used for 6 months after first being opened. Write the opened vial expiration date on the vial label after opening.

PRECAUTIONS

- For *in vitro* diagnostic use. The test strips are to be used only outside the body for testing purposes.
- Do not use test strips after the expiration date shown on the vial. Expired test strips may give incorrect blood β -Ketone 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 may result in an inaccurate reading.
- Check the code number before running a blood β -Ketone test. Make sure the code number on the vial of test strips you are using matches the code number that appears on the meter display.
- Discard the vial and any unused test strips 6 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This damage can cause incorrect readings.
- Keep the test strip vial away from children and animals.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your blood Ketone test results.

MATERIALS PROVIDED

- On Call*[®] Blood Ketone Test Strips
- On Call*[®] Ketone Code Chip
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- On Call*[®] GK Dual Blood Glucose & Ketone Meter
- Lancing Device
- On Call*[®] Ketone Control Solution
- Sterile Lancets

INSTRUCTIONS FOR USE

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

- Open the cap of the test strip vial only to remove a test strip for testing. Replace the cap immediately to protect the remaining test strips from moisture in the air.
- Run the blood β -Ketone test following the instructions contained in your user's manual.
- The blood β -Ketone test result will be shown on the meter display window. This result should fall within the target range recommended by your healthcare professional. If your blood β -Ketone test results are higher, ask your healthcare professional what to do. Always consult your healthcare professional before making any changes to your treatment plan.

IMPORTANT: The *On Call*[®] Ketone Test Strips are designed to be used with fresh capillary blood from fingertip only. Blood samples from forearm or palm can not be used.

REFERENCE FOR THE TEST RESULTS

- The blood β -Ketone test results are shown on the meter only in millimolar of β -Ketone per liter of blood (mmol/L).
- The meter display blood β -Ketone test results between 0.0 and 8.0 mmol/L.
- The normal adult blood β -Ketone range for 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 your blood β -Ketone test result is between 0.6 and 1.5 mmol/L, and glucose is higher than 300 mg/dL (16.7 mmol/L), this may indicate development of a medical concern. You need to contact with your healthcare professional for assistance.

- If your blood β -Ketone test result is more than 1.5 mmol/L and glucose is higher than 300 mg/dL (16.7 mmol/L), contact with your healthcare professional immediately. This indicates a risk of developing diabetic ketoacidosis (DKA).

CHECKING THE SYSTEM

Your meter must be handled carefully. See your user's manual for detailed instructions for meter care. The Ketone quality control test should be used to check that the *On Call*[®] GK Dual Blood Glucose & Ketone Meter and the *On Call*[®] Blood Ketone Test Strips are working together properly. Follow the test procedure in your user's manual to run a Ketone 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 correctly, you may also want to do a level 0 or level 2 test. Contact your distributor for information on purchasing the *On Call*[®] Ketone Control Solution Kit.

For confirmation of results, Control Solution 0 tests should fall within the CTRL 0 range, Control Solution 1 tests should fall within the CTRL 1 range and Control Solution 2 tests should 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 falls outside the control range shown on the test strip vial, DO NOT use the system to test your blood, as the system may not be working properly. If you cannot correct the problem, contact your distributor for help.

LIMITATIONS

- The *On Call*[®] GK Dual Blood Glucose & Ketone Meter, *On Call*[®] Blood Ketone Test Strips and other *On Call*[®] components have been designed, tested and proven to work together effectively to provide accurate blood β -Ketone measurements. Do not use components from other brands.
- Do not use the meter in any manner not specified by the manufacturer. Otherwise, the protection provided by the meter may be impaired.
- The *On Call*[®] Ketone Test Strips are for testing fresh capillary or venous whole blood. Do not use with arterial, neonatal, serum or plasma samples.
- The *On Call*[®] GK Dual Blood Glucose & Ketone Monitoring System is indicated for professional use and over the counter sale. Professionals may use the Ketone test strips to test capillary or venous blood samples; Self-testing user is limited to capillary whole blood testing.
- Blood β -Ketone measurement with venous blood must be performed within 15 minutes of sample collection.
- Anticoagulant preservatives such as heparin or EDTA are recommended for best results in using venous blood. Do not use anticoagulants such as iodoacetate, sodium citrate, or those containing fluoride.
- Very high (above 70%) and very low (below 20%) hematocrit can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- Vitamin C (ascorbic acid) when occurring in blood at normal concentration level does not significantly affect results. Abnormally high levels of Vitamin C (ascorbic acid) or other reducing substances will produce falsely high blood β -Ketone measurements.
- N-acetylcysteine when in blood at normal concentration level does not significantly affect results. N-acetylcysteine in the blood at abnormally high levels will cause interference and produce falsely high blood β -Ketone measurements. Do not use during or soon after N-acetylcysteine treatment.
- The system is tested to accurately read the measurement of β -Ketone in whole blood within the range of 0.0-8.0 mmol/L.
- Fatty substances (Triglycerides) up to 3,000 mg/dL or Cholesterol up to 500 mg/dL have no major effect on blood β -Ketone test results.
- The *On Call*[®] Blood β -Ketone Test Strip has been tested and shown to give accurate results up to 10,000 ft (3,048 meters).
- Test results may be erroneous if the patients is severely dehydrated, or severely hypotensive, in shock or in a hyperglycaemic-hyperosmolar state.)
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of blood samples and materials.

PERFORMANCE CHARACTERISTICS

Reproducibility and Precision

Ten replicate assays of *On Call*[®] Blood Ketone Test Strips were each run on ten *On Call*[®] GK Dual Blood Glucose & Ketone Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results concluded the following reproducibility and precision estimates.

MEAN	0.56 mmol/L	1.33 mmol/L	3.74 mmol/L	5.60 mmol/L	6.84 mmol/L
Standard Deviation (mmol/L) or Coefficient of Variation (CV)	0.029 mmol/L (SD)	2.2%	1.5%	1.6%	1.6%

Intermediate Precision

Ten replicate assays drawn from 3 *On Call*[®] Blood Ketone strip lots were run on ten *On Call*[®] GK Dual Blood Glucose & Ketone Meters each day for a total of 10 days. Control solutions at three concentration levels were used in the testing. The results concluded the following intermediate precision estimates.

#	MEAN	Standard Deviation (mmol/L) or Coefficient of Variation (CV)
Strip Lot 1	1.22 mmol/L	0.05 mmol/L (SD)
	3.18 mmol/L	2.6%
	5.70 mmol/L	2.4%
Strip Lot 2	1.19 mmol/L	0.04 mmol/L (SD)
	3.05 mmol/L	3.0%
	5.39 mmol/L	3.0%
Strip Lot 3	1.22 mmol/L	0.04 mmol/L (SD)
	3.10 mmol/L	2.4%
	5.41 mmol/L	2.4%

System Accuracy

The capillary blood β -Ketone measurements from at least 100 participants were taken by a trained technician using the *On Call*[®] GK Dual Blood Glucose & Ketone Meter (y). Capillary blood samples were obtained only from fingertip for the *On Call*[®] GK Dual Blood Glucose & Ketone Meter testing. Fingertip samples from the same subjects were also analyzed with Abbott Optium Blood β -Ketone Test Strips. The results were compared in the table below.

Linear Regression Results: *On Call*[®] GK Dual (y) vs. Abbott Optium Reference (x)

Sample Site	Slope	Intercept	R	N
Fingertip	0.9780	0.0517	0.9979	226

Fingertip samples were used for Abbott Optium reference measurement.

The sample range was 0.0 to 7.6 mmol/L for *On Call*[®] GK Dual Blood Glucose & Ketone Meter testing with blood sampled from fingertip site.

System accuracy results for β -Ketone concentration < 1.5 mmol/L

Within $\pm$ 0.1 mg/dL	Within $\pm$ 0.15 mg/dL	Within $\pm$ 0.2 mg/dL	Within $\pm$ 0.3 mg/dL
112/156 (71.8%)	122/156 (78.2%)	155/156 (99.4%)	156/156 (100%)

System accuracy results for β -ketone concentration $\geq$ 1.5 mmol/L

Within $\pm$ 5%	Within $\pm$ 10%	Within $\pm$ 15%	Within $\pm$ 20%
42/70 (60%)	60/70 (85.7%)	68/70 (97.1%)	70/70 (100%)

Consumer Study

A consumer study was performed by testing three *On Call*[®] Blood Ketone test strip lots with capillary blood sample. Participants and a trained technician both used the *On Call*[®] GK Dual Blood Glucose & Ketone Monitoring System. This study showed that the patient can run the test as well as a trained technician.

On Call[®] Blood Ketone tests: Linear regression of Participant (y) versus Abbott Optium Reference value, and Linear regression of Technician (x) versus Abbott Optium Reference value

Strip Lot	Test By	Slope	y-Intercept	R	N
Strip Lot 1	Layperson	0.9593	0.0418	0.9929	162
Strip Lot 1	Technician	0.9843	0.0470	0.9914	162
Strip Lot 2	Layperson	0.9581	0.0349	0.9910	162
Strip Lot 2	Technician	0.9212	0.0626	0.9861	162
Strip Lot 3	Layperson	0.9581	0.0349	0.9910	162
Strip Lot 3	Technician	0.9607	0.0376	0.9846	162

Venous Study

The venous blood β -Ketone measurements from 100 participants were taken by a trained technician using the *On Call*[®] GK Dual Blood Glucose & Ketone Meter (y). The venous blood samples from the same subjects were also analyzed with Randox assay kit on Mindray BA-88A Semi Auto-Biochemical Analyzer (S-Auto-BCA) as reference (x). The results were compared in the table below.

Linear Regression Results: *On Call*[®] Blood Ketone tests (y) vs. S-Auto-BCA Reference (x)

Blood Sample	Slope	Intercept	R	N
Venous	1.0225	-0.0551	0.9942	216

For complete instructions, please refer to the *On Call*[®] GK Dual Blood Glucose & Ketone Monitoring System user's manual. For additional questions or issues with this product, please contact your dealer for help.

REFERENCES

- ADA Clinical Practice Recommendations, 2011.

INDEX OF SYMBOLS

	Consult instructions for use		Use by		Code Number
	For <i>in vitro</i> diagnostic use only		Lot Number		Control Range
	Store between 5-30°C (41-86°F)		Manufacturer		Catalog #
	Contains sufficient for <n> tests		Authorized Representative in the European Community		



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