On·Call® Plus Blood Glucose Test Strips Package Insert

REF G133-111, REF G133-112, REF G133-114, REF G133-118, REF G133-119, REF G133-211	English

PRINCIPLE AND INTENDED USE

The *On Call® Plus* Blood Glucose Test Strips are thin strips with a chemical reagent system. They work with the *On Call® Plus* and *On Call® EZ* Blood Glucose Meters to measure the glucose concentration in whole blood. Blood is applied to the end tip of the test strip, then automatically absorbed into the reaction cell where the reaction takes place. A transient electrical current is formed during the reaction and the blood glucose 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-like concentration results.
For *in vitro* diagnostic use. Test strips are to be used only outside the body for testing purposes. For self-testing and professional use.

COMPOSITION

Each test strip contains the following reactive chemicals: Glucose oxidase < 25 IU, Mediator < 300 µg.
Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Store test strips in a cool, dry place at room temperature, 15-30°C (59-86°F). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- To ensure accurate results, use the test strips at room temperature.
- 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. 2012-01 means January 2012.
- Use a new vial of test strips for only 3 months after opening. The opened vial expiration date is 3 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. 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 glucose readings.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- The sample must only be applied to the tip of the test strip. Do not apply blood or control solution to the top of the test strip as this may result in an inaccurate reading.
- Before running a blood glucose test, make sure that the code chip contained with that vial of strips is inserted into the code chip slot on the right side of the meter.
- Discard the vial and any unused test strips 3 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 our treatment plan based on your blood glucose test results.

MATERIALS PROVIDED

- Test Strips
- Code Chip
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Sterile Lancets
- Lancing Device
- Control Solution

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 only to remove a test strip for testing. Replace the cap immediately to protect the remaining test strips from moisture in the air.
2. Run the blood glucose test following the instructions contained in your User's Manual.
3. The blood glucose 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 glucose test results are higher or lower, ask your healthcare professional what to do. Always consult your healthcare professional before making any changes to your treatment plan.

IMPORTANT: *On Call® Plus* and *On Call® EZ* Blood Glucose Monitoring Systems allows alternative site testing for forearm and palm testing in additional to fingertip testing. There are important differences between forearm, palm and fingertip samples that you should know. Important information about forearm and palm glucose testing:

- When blood levels are changing rapidly such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- Fingertips should be used if testing is within 2 hours of a meal, insulin dose or exercise and any time you feel glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a healthcare professional. 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 diabetes:[1]

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70 – 100	3.9 – 6.1
2 Hours After Meal	Less than 140	Less than 7.8

CHECKING THE SYSTEM

Your blood glucose meter must be handled carefully. See your User's Manual for detailed instructions for meter care. The quality control test should be used to check that the meter and test strips are working together properly. Follow the test procedure in your User's Manual to run a quality control test. Two ranges CTRL 1 and CTRL 2 are shown on the test strip vial label (or on the foil pouch). 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 2 test. Contact your dealer for information on purchasing control solution.
For confirmation of results, 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 dealer for help.

LIMITATIONS

- The *On Call® Plus* and *On Call® EZ* meters, test strips and other components of the *On Call® Plus* and *On Call® EZ* Blood Glucose Monitoring Systems have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- Use only with whole blood. Do not use with serum or plasma samples.
- Do not use for testing newborns.
- Very high (above 55%) and very low (below 30%) hematocrit levels can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- Abnormally high levels of vitamin C and other reducing substances will produce false high blood glucose measurements.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 1.1-33.3 mmol/L (20 to 600 mg/dL).
- Fatty substances (triglycerides up to 166.7 mmol/L (3,000 mg/dL) or cholesterol up to 27.7 mmol/L (500 mg/dL) have no major effect on blood glucose test results.
- The *On Call® Plus* Blood Glucose Monitoring System has been tested and shown to work properly up to 10,000ft (3,048 meters).
- Severely ill persons should not run the glucose test with the *On Call® Plus* Blood Glucose Monitoring System.
- 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 materials.

PERFORMANCE CHARACTERISTICS

The *On Call® Plus* and *On Call® EZ* meters are calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.

Reproducibility, Precision

Ten replicate assays were each run on ten *On Call® Plus* Blood Glucose Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results provided the following reproducibility, precision estimates.

MEAN	2.6 mmol/L (46 mg/dL)	4.4 mmol/L (79 mg/dL)	8.3 mmol/L (149 mg/dL)	13.6 mmol/L (244 mg/dL)	21.1 mmol/L (380 mg/dL)
Standard Deviation (mg/dL) or Coefficient of Variation (CV)	0.14 mmol/L (2.5 mg/dL)	3.30%	3.00%	3.10%	2.40%

Intermediate Precision

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

#	MEAN	Standard Deviation (mg/dL) or Coefficient of Variation (CV)
Strip Lot 1	2.4 mmol/L (43 mg/dL)	0.11 mmol/L (1.9 mg/dL)
	7.5 mmol/L (136 mg/dL)	3.7% (CV)
	20.2 mmol/L (363 mg/dL)	3.3% (CV)
Strip Lot 2	2.1 mmol/L (37 mg/dL)	0.12 mmol/L (2.2 mg/dL)
	7.2 mmol/L (129 mg/dL)	3.7% (CV)
	19.4 mmol/L (349 mg/dL)	3.8% (CV)
Strip Lot 3	2.2 mmol/L (39 mg/dL)	0.11 mmol/L (1.9 mg/dL)
	7.3 mmol/L (131 mg/dL)	4.3% (CV)
	20.6 mmol/L (370 mg/dL)	2.8% (CV)

System Accuracy

The capillary blood glucose measurements from 107 participants were taken by a trained technician using the *On Call® Plus* Blood Glucose Meter (y). Capillary blood samples were obtained from fingertip, palm and forearm sampling sites for the *On Call® Plus* Blood Glucose Meter testing. Fingertip samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared.

Linear Regression Results: *On Call® Plus* (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept (mmol/L) / (mg/dL)	R	N
Fingertip	0.9972	-0.2563 / -4.6130	0.9924	244
Palm	0.9702	0.1575 / 2.8354	0.9821	214
Forearm	0.9419	0.3108 / 5.5952	0.9778	214

Fingertip samples were used for YSI reference measurement.
The sample range was 2.4 to 26.3 mmol/L (43 to 473 mg/dL) for *On Call® Plus* Blood Glucose Meter testing with blood sampled from fingertip sites. The sample range was 2.6 to 22.2 mmol/L (47 to 399 mg/dL) for *On Call® Plus* Blood Glucose Meter testing with blood sampled from palm and forearm sites.

Fingertip Site: System Accuracy Results for Glucose Concentration ≥ 4.17mmol/L (75mg/dL)			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
97/208 (46.6%)	159/208 (76.4%)	194/208 (93.3%)	208/208 (100%)

Fingertip Site: System Accuracy Results for Glucose Concentration < 4.17mmol/L (75mg/dL)		
Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83mmol/L (15 mg/dL)
11/36 (30.6%)	29/36 (80.6%)	36/36 (100%)

Palm Site: System Accuracy Results for Glucose Concentration ≥4.17mmol/L (75mg/dL)			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
88/198 (44.4%)	144/198 (72.7%)	187/198 (94.4%)	197/198 (99.5%)

Palm Site: System Accuracy Results for Glucose Concentration < 4.17mmol/L (75mg/dL)		
Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83mmol/L (15 mg/dL)
10/16 (62.5%)	16/16 (100.0%)	16/16 (100.0%)

Forearm Site: System Accuracy Results for Glucose Concentration ≥ 4.17mmol/L (75mg/dL)			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
73/198 (36.9%)	131/198 (66.2%)	172/198 (86.9%)	197/198 (99.5%)

Forearm Site: System Accuracy Results for Glucose Concentration < 4.17mmol/L (75mg/dL)		
Within ± 0.28 mmol/L (5 mg/dL)	Within ± 0.56 mmol/L (10 mg/dL)	Within ± 0.83mmol/L (15 mg/dL)
14/16 (87.5%)	16/16 (100.0%)	16/16 (100.0%)

Consumer Study

A consumer study was performed by testing three test strip lots. Participants and a trained technician used the *On Call® Plus* Blood Glucose Monitoring System. This study showed that the patient can run the test as well as the trained technician.

On Call® Plus tests: Linear regression of Participant (y) versus YSI Reference value and Linear regression of Technician (y) versus YSI Reference value					
Strip Lot	Tested By	Slope	Intercept (mmol/L) / (mg/dL)	R	N
Lot 1	Layperson	0.9881	-0.1317 / -2.3647	0.9862	214
Lot 1	Technician	0.9927	-0.2033 / -3.6585	0.9857	214
Lot 2	Layperson	0.9355	0.2520 / 4.5351	0.9867	214
Lot 2	Technician	0.9457	0.1492 / 2.6854	0.9851	214
Lot 3	Layperson	0.9700	0.3296 / 5.9324	0.9827	214
Lot 3	Technician	0.9931	0.2300 / 4.1391	0.9843	214

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 dealer for help.

REFERENCES

1. ADA Clinical Practice Recommendations, 2011.

INDEX OF SYMBOLS

	Attention, see instructions for use		Use by	CODE	Code Number
IVD	For *in vitro* diagnostic use only	LOT	Lot Number	CTRL	Control Range
15°C 30°C	Store between 15-30°C		Manufacturer	REF	Catalog #
Σ	Contains sufficient for <n> tests	EC REP	Authorized Representative		

ACON®
ACON Laboratories, Inc.
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