

On-Call Vivid Blood Glucose Test Strips Package Insert

REF G135-102	English
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PRINCIPLE AND INTENDED USE

The *On Call[®] Vivid* Blood Glucose Test Strips are thin strips. The strips have a chemical reagent system. They work with the *On Call[®] Vivid* or *On Call[®] Vivid Pal* Blood Glucose Meters to measure the glucose level in whole blood. Blood is applied to the end tip of the test strip. The blood is then absorbed into the reaction cell. This is where the reaction takes place. A transient electrical current is formed during the reaction and detected by the meter. The amount of glucose is then calculated based on this current. The result is shown on the meter display. The meters are calibrated to display plasma equivalent results.

For *in vitro* diagnostic use. *On Call[®] Vivid* Test Strips are used to measure the amount of glucose in fresh capillary whole blood. This blood can be from the finger, forearm or palm. The system is used to monitor how well the diabetes control programs work. *On Call[®] Vivid* Test Strips can be used only outside the body. They are used by diabetics for self-testing purposes. *On Call[®] Vivid* or *On Call[®] Vivid Pal* Blood Glucose Monitoring System is for single patient use only. Do not share with others.

COMPOSITION

These chemicals are: Glucose Oxidase (from *Aspergillus Niger*) <25 IU, Mediator <300 µg, Buffer, and Non-reactive Ingredient.
Each test strip vial contains 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. Store at 41-86°F (5-30°C). Avoid heat and direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips at room temperature. This provides precise results.
- Keep the test side up and blank side down when you insert the strip contact bars into the strip port.
- 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 with bleach.
- Do not transfer the test strips to a new vial or any other container.
- Replace the vial cap as soon as you remove a test strip.
- Use the test strip as soon as it is removed from the vial.
- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.
- Do not use your test strips past the unopened expiration date. The date is printed on the vial. Otherwise, you may get incorrect test results.
- Note:** All expiration dates are printed in Year-Month-Date format. 2018-01-30 means January 30th, 2018.
- A new vial of test strips may be used for 6 months after first opening. After 6 months they will expire. Write the opened 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.
- All components that come into contact with blood samples are considered biohazards capable of transmitting viral disease, even after disinfection.
- Do not use a lancet that has been used by others and never share your meter and lancing device with another person; this includes a family member.
- Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.
- Keep your meter and lancing device clean.
- To minimize the risk of transmission of blood-borne pathogens, pre-cleaning and disinfection procedures should be performed as recommended in the User's Manual for your meter (See "Pre-cleaning and Disinfection" section).
- You can get more safety information at FDA Public Health Notification (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>) or at CDC Clinical Reminder (<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>).
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give incorrect result.
- Do not use test strips that are torn, bent, or damaged.
- Do not reuse test strips.
- 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.
- 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 can cause false readings.
- Keep the test strip vial away from children and animals.
- Consult your doctor before making any changes to your treatment plan.

MATERIALS PROVIDED

- Test Strips
- Package Insert

Please contact Customer Support at 1-800-838-9502 for information about purchasing test strips.

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Sterile Lancets
- Lancing Device
- Control Solution

Please contact Customer Support at 1-800-838-9502 to obtain a control solution kit.

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. Remove a test strip. Replace the cap immediately. This protects the test strips from moisture in the air.
- Run the test following the instructions in your User's Manual.
- 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. Always consult your doctor before changing your treatment plan.

IMPORTANT: *On Call[®] Vivid* and *On Call[®] Vivid Pal* Blood Glucose Monitoring Systems allow Alternative Site Testing (AST). These include testing forearm and palm. There are important differences for each site. Important information about forearm and palm glucose testing:

- Blood from the fingertip may show sudden changes in blood levels. Other sites may not. Blood glucose levels may change instantly after a meal, insulin dose, or exercise.
- If testing within 2 hours of a meal, insulin dose or exercise, test with fingertip. Any time you feel glucose levels are changing rapidly, test with fingertip.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.
- Alternative Site Testing (AST) should not be used to calibrate continuous glucose monitors (CGMs). Do not use AST to calculate an insulin dose.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a doctor. Together you can set your own range of expected blood glucose values. You can also arrange your testing times. In addition, you should discuss the meaning of your blood glucose results together. Expected blood glucose levels for people without diabetes:¹

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. Follow the control test procedure in your User's Manual. Two ranges 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 2 test. Contact Customer Support for information on purchasing control solution. You should confirm your control solution results. Make sure the Control Solution 1 tests fall within the CTRL 1 range. Make sure 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 falls outside the control range shown on the test strip vial, DO NOT use the system to test your blood. The system may not be working properly. If you cannot correct the problem, contact Customer Support for help.

LIMITATIONS

- The *On Call[®] Vivid* and *On Call[®] Vivid Pal* meters, test strips and other components have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- The *On Call[®] Vivid* Test Strips test fresh capillary whole blood. Do not use with serum or plasma samples.
- The *On Call[®] Vivid* and *On Call[®] Vivid Pal* Blood Glucose Monitoring Systems are for self-testing users to test fresh capillary blood. For over the counter sale.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your doctor to find out your hematocrit level.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 20-600 mg/dL.
- Fatty substances have no major effect on test results. These include triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL.
- The *On Call[®] Vivid* and *On Call[®] Vivid Pal* Blood Glucose Monitoring Systems have been tested to work properly up to 8,516 ft (2,595 meters).
- Blood samples from patients in shock, severe dehydration or a hyperosmolar state (with or without ketosis) have not been tested. It's not recommended to test those samples with *On Call[®] Vivid* and *On Call[®] Vivid Pal* Blood Glucose Monitoring Systems.
- On Call[®] Vivid* and *On Call[®] Vivid Pal* Blood Glucose Monitoring Systems are not for use in critically ill patients.
- Dispose of blood samples and materials with care. Treat all blood samples as if they are infectious materials. Follow all local regulations.
- Acetaminophen, uric acid and ascorbic acid (vitamin C) (when occurring in blood at normal or at high therapeutic concentration) do not significantly affect results. However, abnormally high concentration in blood may cause inaccurately high results.

PERFORMANCE CHARACTERISTICS

The *On Call[®] Vivid* and *On Call[®] Vivid Pal* meter are calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument. It is traceable to NIST reference standard.

Reproducibility, Precision

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

MEAN	43 mg/dL	78.5 mg/dL	134mg/dL	199 mg/dL	286 mg/dL
Standard Deviation mg/dL or Coefficient of Variation (CV)	1.57 mg/dL	3.1%	3.1%	2.3%	2.7%

Intermediate Precision

Ten replicate assays from three strip lots were run on ten *On Call[®] Vivid* Blood Glucose Meters. These tests were run each day for a total of ten days. Control solutions at three concentration levels were used in the testing. The results provided the following estimates.

#	MEAN	Standard Deviation mg/dL or Coefficient of Variation (CV)
Strip Lot 1	36.0 mg/dL	1.58 mg/dL
	118.9 mg/dL	2.8%
	359.3 mg/dL	2.4%
Strip Lot 2	36.6 mg/dL	1.52 mg/dL
	121.2 mg/dL	2.8%
	355.2 mg/dL	3.3%

Strip Lot 3	37.2 mg/dL	1.57 mg/dL
	122.4mg/dL	3.5%
	359.7mg/dL	3.0%

System Accuracy

A trained technician tested the capillary blood using the *On Call[®] Vivid* Blood Glucose Meter (y). The blood was from more than 100 participants. The blood was taken from fingertip, palm and forearm. 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: <i>On Call[®] Vivid</i> (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept	R	N
Fingertip	1.0265	-1.8674	0.9947	113
Palm	0.9956	-0.5644	0.9947	105
Forearm	1.0318	-1.8220	0.9914	105

Fingertip samples were used for YSI reference measurement.

The sample range was 40.0 to 562.5 mg/dL for *On Call[®] Vivid* Blood Glucose Meter testing with blood sampled from fingertip sites. The sample range was 48.1 to 444.0 mg/dL for *On Call[®] Vivid* Blood Glucose Meter testing with blood sampled from palm and forearm.

Fingertip Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
63/96 (65.6%)	88/96 (91.7%)	96/96 (100%)	96/96 (100%)
Fingertip Site: System Accuracy Results for Glucose Concentration <75mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 10 mg/dL
13/17 (76.5%)	17/17 (100%)	17/17 (100%)	

Palm Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
60/93 (64.5%)	89/93 (95.7%)	93/93 (100%)	93/93 (100%)

Palm Site: System Accuracy Results for Glucose Concentration <75mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 10 mg/dL
8/12 (66.7%)	12/12 (100%)	12/12 (100%)	

Forearm Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
52/93 (55.9%)	76/93 (81.7%)	92/93 (98.9%)	93/93 (100%)

Forearm Site: System Accuracy Results for Glucose Concentration <75mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 10 mg/dL
10/12 (83.3%)	12/12 (100%)	12/12 (100%)	

Consumer Study

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

<i>On Call[®] Vivid</i> 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	R	N
Lot 1	Layperson	1.0422	-3.9315	0.9940	210
Lot 1	Technician	1.0501	-5.3099	0.9949	210
Lot 2	Layperson	1.0410	-3.2938	0.9934	210
Lot 2	Technician	1.0373	-2.9511	0.9949	210
Lot 3	Layperson	1.0171	-4.7358	0.9947	210
Lot 3	Technician	1.0460	-7.2036	0.9948	210

For complete instructions, please refer to the User's Manual included with your meter. For additional questions or issues with this product, please contact Customer Support at 1-800-838-9502, 24 hours a day, 365 days a year.

REFERENCES

- Jennifer Mayfield and Stephen Havas, "Self-Control: A Physician's Guide to Blood Glucose Monitoring in the Management of Diabetes – An American Family Physician Monograph"
- ADA Clinical Practice Recommendations., 2011. Diabetes Care, 2011, Vol. 34, Supplement 1. S62-S69.



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