**PRINCIPLE AND INTENDED USE**

The On Call Pro Blood Glucose Test Strips are thin strips. The strips have a chemical reagent system. They work with the On Call Pro Blood Glucose Monitoring System to measure the glucose level in whole blood. Blood is applied to the end tip of the test strip. The test strip then enters the instrument and measures the glucose level. A transient current is produced during the reaction and detected by the meter. The amount of glucose in the blood 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 Pro Test Strips are used to measure the amount of glucose in fresh capillary blood. The system is designed to use the capillary blood from the finger, forearm or palm. The system is used to monitor how well the diabetes control programs work. On Call Pro Test Strips can only be used outside the body.

The On Call Pro Blood Glucose Monitoring System is for professional use only. It is intended for multiple patient use by health care professionals in health care facilities as an aid to monitoring the effectiveness of a patient’s control program. It is not intended for single-use, auto-disabling devices. It is not intended for the diagnosis or screening of diabetes. It is intended for use on neonates.

The On Call Pro Blood Glucose Test Strips are used with the On Call Pro Express and On Call Pro Blood Glucose Monitoring Systems in the quantitative measurement of glucose in capillary blood.

The On Call Pro Blood Glucose Control Solutions are for use with the On Call Pro Express and On Call Pro Blood Glucose Monitoring Systems and On Call Pro Test Strips as a quality control check to verify the accuracy of blood glucose test results.

**COMPOSITION**

Each test strip contains reactive and non-reactive chemicals. These chemicals are: Glucose Oxidase (from Aspergillus niger) > 25 IU, Methanol < 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 properly.
- Store in a cool, dry place between 41-86 °F (5-30 °C) and 10-90% relative humidity and keep out of direct sunlight.
- Do not freeze or refrigerate.
- Use the test strip control temperature. This provides accurate results.
- 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 a new meter cleaner.
- Replace the vial cap as soon as you remove a test strip.
- Use the test strip soon as it is removed from the vial.
- Repeated insertion and removal of a test strip from a meter strip port may result in reading errors.
- Do not use test strips after the unexpired expiration date printed on the vial.

**Note:** All expiration dates are printed in Year/Month format. 2015/01 means January 2015.

**New vial of test strips may be used for 6 months after first opening. After 6 months they should be discarded.**

**PRECAUTIONS**

- For in vitro diagnostic use. The test strips are only to be used 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.
- Remember to follow all proper cleaning and disinfection procedure. Please refer to the “Caring for Your On Call Pro Blood Glucose Monitoring System” section in the User’s Manual. This procedure is important to prevent the potential transmission of infectious diseases.
- You can get more safety information at FDA Public Health Notification (http://www.fda.gov/MedicalDevices/Safety/Notices/AlertsandNotices/ucm224025.htm) or at CDC Clinical Reminder (http://www.cdc.gov/injectionsafety/Fingerstick-Devices/BOM.htm).
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give an 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 misleading result.
- 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 strips away from children and animals.
- Consult with your patients’ treating physician before making any changes to the treatment plans.

**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
- Alcohol Swabs
- Control Solution

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

**INSTRUCTIONS FOR USE**

See the User’s Manual for complete instructions for blood sample collection before use. 1. Open top of the test strip vial. Replace the cap immediately. This protects the test strips from moisture in the air. 2. Hold the test strip vertically, keep it clean and moist. 3. The test result will be shown on the meter display window. This result should fall within the target range. The treating physician should recommend the target range for each patient. If test results are higher or lower, ask the physician to do what to always consult your patient’s treating physician before changing their treatment plan.

**IMPORTANCE OF TEST STRIP S**

- The On Call Pro Blood Glucose Monitoring Systems allow alternative site testing. (AST). This includes testing capillary blood from forearm and palm. There are important differences in the sampling sites. For more information about forearm and palm glucose testing:
  - Blood from the fingertip may show changes in blood levels. Other sites may not require the same amount of glucose levels may change based on this current. The result is shown on the meter display. The meters are calibrated to display plasma equivalent results.
  - If testing within 2 hours of a meal, insulin dose or exercise, test with fingertip. Any time you feel the patient’s glucose levels may be changing rapidly, test with fingertip.
  - Test with the fingertips and normal capillary blood is from the forearm, hyperosmolar, or forearm patients cannot use this test.
  - Alternative site testing should not be used to calibrate continuous glucose monitors (CGMs). Do not use AST to calculate an insulin dose.

**RANGE OF EXPECTED VALUE**

Blood glucose monitoring requires knowledge of the treating physician. Together with the treating physician you can set your patients’ expected range of glucose values. This will help you schedule the patients’ testing times. In addition, you may want to discuss the blood glucose results together.

**Expected blood glucose levels for people with diabetes:**

<table>
<thead>
<tr>
<th>Time</th>
<th>Range, mg/dL</th>
<th>Range, mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting and before Meals</td>
<td>70 - 100</td>
<td>3.9 - 5.6</td>
</tr>
<tr>
<td>2 Hours after Meals</td>
<td>Less than 140</td>
<td>Less than 7.8</td>
</tr>
</tbody>
</table>

**CHECKING THE SYSTEM**

Be careful with the blood glucose meter. See the User’s Manual for proper care instructions. Do a quality control test to make sure that the meter and test strips are working well together. Follow the three control test procedure in the User’s Manual. The following shows glucose results for the three test strips:

**LIMITATIONS**

- The On Call Pro 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 test strips from other brands manufacturers or blood glucose meters.
- The On Call Pro Blood Glucose Monitoring Systems are professional use only. It is intended for the testing of capillary blood.
- Very high (above 60%) and very low (below 25%) hematocrit levels can cause false results. Consult with your patient’s treating physician to find their hematocrit level.
- The system levels may vary on different vials. This may result in the control range shown on the test strip vial, DO NOT use the system to test the blood. The system may be working normally. If you cannot confirm the problem, contact Customer Support for help.

**PERFORMANCE CHARACTERISTICS**

The On Call Pro meter is calibrated by using the YSI (Model 2300 STAT PLUS) Glucose Analyzer (4). The results were compared with the YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared with the YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared.

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.

For additional questions or issues with this product, please contact Customer Support at 1-800-838-9502. Please refer to the YSI User’s Manual. Three ranges are provided for each patient target range.

Intermediate Precision

Ten replicate assays drawn from three test strip lots were performed on ten On Call Pro Blood Glucose Meters. These tests were performed 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:

<table>
<thead>
<tr>
<th>#</th>
<th>MEAN</th>
<th>Standard Deviation mg/dL or Coefficient of Variation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strip Lot 1</td>
<td>41.8 mg/dL</td>
<td>2.7%</td>
</tr>
<tr>
<td>Strip Lot 2</td>
<td>41.5 mg/dL</td>
<td>3.1 mg/dL</td>
</tr>
<tr>
<td>Strip Lot 3</td>
<td>40.6 mg/dL</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

**System Accuracy**

A trained technician tested capillary blood using the On Call Pro Blood Glucose Meter (x). The blood samples were from more than 100 participants. Capillary blood samples were taken from fingertip, palm and forearm. Fingerpimples from the same subjects were also analyzed with the YSI Model 2200 STAT PLUS glucose analyzer (4). The results were compared.

<table>
<thead>
<tr>
<th>Fingerpimples</th>
<th>System Accuracy Results for Glucose Concentration</th>
<th>7.6 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palm</td>
<td>System Accuracy Results for Glucose Concentration</td>
<td>7.6 mg/dL</td>
</tr>
<tr>
<td>Forearm</td>
<td>System Accuracy Results for Glucose Concentration</td>
<td>7.6 mg/dL</td>
</tr>
<tr>
<td>Intermediate</td>
<td>System Accuracy Results for Glucose Concentration</td>
<td>7.6 mg/dL</td>
</tr>
</tbody>
</table>

**REFERENCES**

1. ADA Standards of Medical Care in Diabetes 2015.

ACON Laboratories, Inc.
San Diego, CA 92121, USA
Customer Support: 1-800-838-9502
www.oncallometers.com
The On Call® Pro Control Solution contains a known concentration of glucose. It is used to confirm that the On Call® Pro Test Strips and On Call® Express Pro or On Call® Pro Blood Glucose Meter are working together properly and that you are performing the test correctly.

You should perform a quality control test:

- Before you use the meter for the first time. This will help you get used to this test.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that test results are inaccurate, or if they do not match how your patient feels.
- If you suspect the meter is damaged.
- At least once a week.
- After cleaning the meter.
- According to the guidelines of your institution.

Three levels of control solution are available. They are Control Solution 0, Control Solution 1 and Control Solution 2. Control Solution 1 is sufficient for most needs, but you should consult the policies of your institution. If you think the meter or strips may not be working correctly, you may also want to do a level 0 or level 2 test.

**COMPOSITION**

Control Solution 0 contains less than 0.1% glucose (active ingredient), Control Solution 1 contains less than 0.2% glucose (active ingredient) and Control Solution 2 contains less than 0.4% glucose (active ingredient). All have preservatives in an aqueous based mixture.

**STORAGE AND HANDLING**

- Store in a cool, dry place between 41-86 °F (5-30 °C) and 10-90% relative humidity and keep out of direct sunlight.
- Do not freeze or refrigerate.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Do not use control solution after the unopened expiration date printed on the bottle.

*Note:* All expiration dates are printed in Year/Month format. 2015/01 indicates January, 2015.

- Use the control solution only for 6 months after you first open the bottle. After 6 months it will expire.
- Write the opened expiration date on the bottle label after opening.

**PRECAUTIONS**

- *For in vitro diagnostic use. Use the control solution only to test outside the body. Do not swallow or inject.* For professional use only.
- Shake well before using.
- To get accurate results, do control solution testing between 50 and 104°F (10-40°C).
- The control ranges shown on the test strip vial (or on the foil pouch) are not a recommended range for your patients’ blood glucose level. Personal blood glucose target ranges should be determined by the treating physician.
- Do not touch the end of the test strip to the control solution bottle. This could cause contaminants to enter the control solution bottle.
- Use the On Call® Pro brand control solution only with On Call® Pro test strips and On Call® Express Pro or On Call® Pro meter.

**EXPECTED RESULTS**

Make sure the control solution test results are within the control range. The ranges for CTRL 0, CTRL 1 and CTRL 2 are displayed on the test strip vial (or on the foil pouch). 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. If the test results are within the respective ranges, this means the Blood Glucose Monitoring System is working properly and you are performing the procedure correctly.

If the control solution test results do not fall within the respective ranges:

- Check the expiration date of the test strip and control solution. Make sure that the test strip vial and the control solution bottle have not been opened for more than 6 months. Throw away any expired test strips or control solution.
- Make sure the temperature in which you are testing is between 50 and 104 °F (10 and 40 °C).
- Make sure that the test strip vial and the control solution bottle have been tightly capped.
- Make sure that you are using On Call® Pro brand control solution.
- Make sure that you followed the test procedure correctly.

After checking everything listed above, repeat the control solution test with a new test strip. If your results still fall outside the range indicated on the test strip vial label or on the foil pouch, the meter may not be working properly. DO NOT use the system to test blood. Contact Customer Support for help. For complete instructions, please refer to the User’s Manual included with the 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.

**MATERIALS PROVIDED**

- Control Solution
- Package Insert

Please contact Customer Support at 1-800-838-9502 for more information on obtaining a control solution kit.