OPTIUM OMEGA BLOOD GLUCOSE TEST STRIPS

Optium Omega Blood Glucose Test Strips-Product Information
For Use with Optium Omega Blood Glucose Meters

IMPORTANT: PLEASE READ THIS INFORMATION AND YOUR INSTRUCTIONS FOR USE BEFORE USING THE OPTIUM OMEGA STRIPS TO TEST YOUR BLOOD SUGAR. For help call your local customer care office.

Intended Use
The Optium Omega Blood Glucose Test Strips are used with Optium Omega Blood Glucose Meters to measure glucose (sugar) in whole blood. The Optium Omega Test Strips are used for testing outside the body (in vitro diagnostic use). The Optium Omega Blood Glucose Monitoring System is intended for self-testing, or use by healthcare professionals to monitor blood glucose levels.

Introduction
The Optium Omega Blood Glucose Test Strip, used with Optium Omega Blood Glucose Meters, will accurately measure your blood glucose value. When the edge of the Optium Omega Test Strip is touched to a drop of blood, the test strip draws the blood into the sample chamber and your glucose reading is displayed on the meter. The test measures glucose from 20 mg/dL to 500 mg/dL (1.1 mmol/L and 27.8 mmol/L). The Optium Omega Test Strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods
Please read your Optium Omega Blood Glucose Meter instructions for use. If you have any questions about your Optium Omega Meter or Optium Omega Test Strips, call your local customer care office.

WARNING:
- **Any change in medication based on the Optium Omega blood glucose test results without the consent and advice of a physician or healthcare professional is not recommended.**
- **Keep the test strip away from children.**
- **The cap or vial contains drying agents to protect the test strips. Drying agents may be harmful if inhaled or swallowed and may cause skin or eye irritation.**
- **Only control solutions intended for use with the Optium Omega Meter should be used with Optium Omega Test Strips. If you get Control Solution test results that fall outside the range printed on the test strip vial, repeat the test with a new test strip. If the test result is still outside the range printed on the test strip vial, the Optium Omega System may not be working properly. DO NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip vial label.**
- **Do not fill the test strip from both the left and right sample target areas during a single test. This may cause inaccurate test results.**
- **Intravenous therapy solutions such as some immunoglobulin preparations and peritoneal dialysis solutions containing icodextrin or compounds of Galactose ≥ 13 mg/dL (≥ 0.7 mmol/L), Maltose ≥ 20 mg/dL (≥ 0.6 mmol/L) or Lactose ≥ 10 mg/dL (≥ 0.3 mmol/L) causes overestimation of blood glucose results.**
- **Do not use during xylose absorption testing.**

Precautions
For in vitro diagnostic use (outside the body) only.
Low or high blood glucose readings can indicate a potentially serious medical condition. If your blood glucose reading is unusually low or high, or if you do not feel the way your reading indicates, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L) you should contact your healthcare professional and follow his or her treatment advice.
Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your physician immediately.
All devices contaminated with blood should be disposed of properly. Healthcare professionals should follow their institution's infection control protocols
Do not use test strips beyond the expiration date printed on the package since this may cause inaccurate results.

Storage and Handling
- Store at room temperature (40° - 86° f /4° - 30° C). Use test strips only within the system operating temperature range as outlined in your instructions for use.
- Store away from direct sunlight and heat.
- Use each strip immediately after removing it from the vial
- Store your test strips in their original vial only. The cap or vial contains drying agents to protect the test strips. Do not transfer test strips to a new vial or any other container.
- After removing a test strip from the vial, replace the vial cap immediately and close it tightly.
- Do not bend, cut, or alter an Optium Omega Test Strip in any way.
- With clean, dry hands you may gently touch the test strip anywhere when removing it from the vial or inserting it into the meter.

How to do the Test
1. **Set Up**
   Clean the site you have chosen for the test. Use warm, soapy water. Rinse and thoroughly dry. Warm water helps to get the blood flowing to the site you want to lance.
   If you use an alcohol swab, make sure that the site you will lance is completely dry before lancing.
   Put a strip in the meter. Press "m" to turn meter on.
   Make sure the code matches the code printed on the test strip vial label. If the code does not match, see your instructions for use for how to code the meter.
2. **Do the test**
   Use the Lancing Device to obtain the right size blood drop.
   Refer to your instructions for use for how to lance your finger.
   When the prompt to apply the sample appears on the screen, lance the site you have chosen, and obtain a blood sample about the size of a pinhead.
   Gently touch only one edge of the test strip to the blood sample. You may fill the test strip from either side, but not both sides. When the strip is full, you will see the moving lines on the display.
   Do not press the edge of the strip against the test site. Do not put the sample on top of the sample target area.
3. **Read results**
   Read the test results on the meter display. Refer to your instructions for use for the average test time.
   The result will be stored in the meter memory.

See your Optium Omega Blood Glucose Meter instructions for use for a step-by-step guide on how to do the test.

- Use the Optium Omega Blood Glucose Meter only with Optium Omega Test Strips.
- Be sure that the code on the meter display screen matches the code on the test strip vial. If it does not match, see your instructions for use for how to code the meter.
- Fill the strip from only one side of the test strip for any one glucose test.
- Do not use test strips that are beyond their expiration date. Check the test strip vial for the discard date.
- Avoid exposing test strips to extreme temperatures.

What Do Your Results Mean?
Blood glucose test results are shown as either mg/dL or mmol/L depending upon the preset for your country.

Normal Glucose Values
The normal fasting glucose range for a non-diabetic adult is 70 to 110 mg/dL (3.9 mmol/L to 6.1 mmol/L).[3] One to two hours after meals, normal glucose values should be less than 120 mg/dL (6.7 mmol/L).[4] Consult your physician or healthcare professional for the target glucose values that are right for you.

Low Glucose Values
The Optium Omega Meter displays results between 20 and 500 mg/dl (1.1 mmol/L and 27.8 mmol/L). If your test result is lower than 20 mg/dL (1.1 mmol/L), "Low" (LO) will appear on the meter display. This indicates severe low blood sugar (hypoglycemia). **You should immediately treat low blood glucose as recommended by your healthcare professional.**

High Glucose Values
If your test result is above 500 mg/dL (27.8 mmol/L), "High" (HI) will appear on the meter display screen. This indicates severe high blood sugar (hyperglycemia). You **should immediately treat high blood sugar as recommended by your healthcare professional.**

Unexpected Results
Low or high blood sugar readings can indicate a potentially serious medical condition. If your blood sugar is unusually low or high, or if you do not feel the way your results indicate, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), you should contact your healthcare professional and follow his or her treatment advice

Limitations
The Optium Omega Blood Glucose Test Strips give accurate results when the following limitations are observed:
1. The test strips are for single use only. Do not reuse test strips.
2. Use fresh, whole capillary blood from the site you have selected to test.
3. Clean the site with warm soapy water and dry thoroughly before testing.
4. There is no effect from altitude up to 10,000 feet (3048 meters) above sea level.
5. Hematocrit range: 15% to 65%.

Additional Information for Healthcare Professionals:
1. A venous whole blood sample may also be used. Venous whole blood results are usually about 7% lower than a capillary sample from the same person with normal glucose levels. Use venous blood within 30 minutes after drawing. Common anticoagulants (potassium oxalate, heparin, EDTA) may be used.
2. Optium Omega Test Strips are not validated for and should not be used for testing neonatal blood specimens.
3. Cholesterol up to 500 mg/dL (27.8 mmol/L) or triglycerides up to 3,000 mg/dL (34 mmol/L) do not significantly affect test results. However, glucose values in specimens beyond these levels, should be interpreted with caution.
4. Do not use during xylose absorption testing.

Checking the System
The control solution is used to check the performance of the Optium Omega meter, test strips, and your testing technique. The system is performing correctly if the control solution test result falls within the specific control solution range listed on your Optium Omega Test Strip vial.
A control solution test should be performed when you question your results and want to confirm that you monitor and strips are working properly.
When a control solution test is done, you should get results within the expected range printed on the test strip vial. If control solution test results fall outside this range, repeat the test. Results that fall outside the range may be caused by:
- error in performing the test
- expired or contaminated control solution
- improper coding of the meter
- test strip deterioration
- meter malfunction

WARNING: If you continue to get Control Solution test results that fall outside the range printed on the test strip vial, the Optium Omega System may not be functioning properly. DO NOT use the system to test your blood until you get a control solution test result within the range printed on the test strip vial label. Contact your local customer care office for assistance.

Performance Characteristics
The performance of the Optium Omega Test Strips have been tested both in laboratory and clinical studies. The testing range of the Optium Omega System is 20 mg/dL to 500 mg/dL.

Accuracy
The accuracy of the Optium Omega System was tested by comparing blood glucose results obtained by study subjects with those obtained using a YSI Model 2300 Glucose Analyzer. The results below were obtained from subjects with Type 1 or 2 diabetes. The regression statistics are derived from a plot of the Optium Omega arm data versus YSI capillary data.

Slope	0.931
y-intercept	+ 8.1 mg/dL or + 0.48 mmol/L
Correlation coefficient (R)	0.969
Number of samples tested in duplicate	197
Range tested	51 to 487 mg/dL or 2.8 to 27.05 mmol/L

Precision
Within-lot and within-vial precision of Optium Omega Test Strips was measured with venous blood samples in the laboratory. The pooled precision data for fifty-four test strip lots (n= 5,184) is shown in the tables below:

WITHIN-LOT PRECISION

Average Glucose Concentration (mmol/L)	2.4	10.8	21.1
Average Glucose Concentration (mg/dL)	43	194	380
SD (mmol/L)	0.13	0.34	0.76
SD (mg/dL)	2.4	6.2	13.7
CV (%)	5.6	3.2	3.6

WITHIN-VIAL PRECISION

Average Glucose Concentration (mmol/L)	2.4	10.8	21.1
Average Glucose Concentration (mg/dL)	43	194	380
SD (mmol/L)	0.1	0.2	.41
SD (mg/dL)	1.8	3.6	7.4
CV (%)	4.1	1.8	2.0

Variability in blood tests from strip to strip was 5.6% or less.

Chemical Composition
PQQ Glucose Dehydrogenase	≥ 1.0 Unit
Other ingredients (buffer, mediator, etc.)	≥ 0.01 mg

1 American Diabetes Association: Consensus statement on self-monitoring of blood glucose. Diabetes Care 1995; 18: 47-52.
2 The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Eng J Med 1993; 329: 977-986.
3 Burtis CA, Ashwood ER, eds. : Tietz Textbook of Clinical Chemistry. 2nd Edition. W. B. Saunders. Philadelphia. 1994. p. 2190.
4 Krall LP and Beaser RS: Joslin Diabetes Manual. Lea and Febiger. Philadelphia. 1989. p. 138.

OPTIUM OMEGA 血糖试纸

Optium Omega 血糖试纸 - 产品信息
与 Optium Omega 血糖仪配合使用

重要事项：在使用 OPTIUM OMEGA 试纸测试您的血糖之前，请阅读本资料和您的使用说明。若需帮助，请致电您当地的客户服务中心。

用途
Optium Omega 血糖试纸与 Optium Omega 血糖仪配合使用，用于测量全血中的葡萄糖含量。Optium Omega 试纸仅用于体外测试（供体外诊断用）。Optium Omega 血糖监测系统用于进行自我监测，或供专业医护人员用于监测血糖数值。

前言
Optium Omega 血糖试纸与 Optium Omega 血糖仪配合使用，可以准确测量您的血糖值。将 Optium Omega 试纸的边缘接触到血滴时，试纸会将血液吸入样本区，而血糖仪上将会显示您的血糖读数。血糖测试的测量范围为 20 mg/dL 至 500 mg/dL（1.1 mmol/L 和 27.8 mmol/L）。Optium Omega 试纸已校正为显示等值的血浆葡萄糖数值，让您可以方便地将结果与实验室方法进行比较。
请阅读您的 Optium Omega 血糖仪使用说明。如果您有任何关于 Optium Omega 血糖仪或 Optium Omega 试纸的疑问，请致电您当地的客户服务中心。

警告：
- **建议不要在未经医师或专业医护人员同意或建议的情况下，根据 Optium Omega 血糖测试结果改变用药。**
- **请将试纸存放在儿童接触不到的地方。**
- **盖内或小瓶中含有用于保护试纸的干燥剂。如果不慎吸入或吞服干燥剂，则可能导致皮肤或眼睛发炎。**
- **只能将与 Optium Omega 血糖仪配合使用的质控液用于 Optium Omega 试纸。如果质控液测试结果超出试纸小瓶上印刷的范围，则请使用新试纸重新进行测试。如果测试结果仍然超出试纸小瓶上印刷的范围，则 Optium Omega 系统可能无法正常工作。请勿使用该系统来测试您的血液，直到所获得的质控液测试结果处于试纸小瓶上印刷的范围内。**
- **在单次测试中，不要同时将血液添加到试纸的左右两个样本目标区域。这可能会导致错误的测试结果。**
- **一些静脉注射溶液（例如免疫球蛋白制剂）和腹膜透析溶液含有淀粉类多糖，或者半乳糖含量 ≥ 13 mg/dl（≥ 0.7 mmol/L）、麦芽糖含量 ≥ 20 mg/dL（≥ 0.6 mmol/L）或乳糖含量 ≥ 10 mg/dl（≥ 0.3 mmol/L），这会导致血糖测试结果偏高。**
- **不要在木糖吸收测试期间使用。**

预防措施
仅用于体外诊断。
血糖读数很低或很高表明可能有严重的健康状况。如果您的血糖读数异常低或异常高，或者您自己的感觉与读数所示的不相符，请使用新试纸重新进行测试。如果您的读数与您的症状不相符，或者您的血糖测试结果低于 60 mg/dL（3.3 mmol/L）或高于 240 mg/dL（13.3 mmol/L），您应与专业医护人员联系并遵照您收到的治疗建议治疗。
严重脱水和过量失水可能导致错误的低血糖结果。如果您确定自己严重脱水，请立即咨询您的医师。
所有污染了血液的装置都应适当处理。专业医护人员应遵循他们所在机构的传染控制规定。
请勿使用超出包装上印刷的有效日期的试纸，因为这可能导致错误的结果。

存放和处理
- 在室温下存放（40° - 86° f/4° - 30° C）。仅在使用说明中所指示的系统工作温度范围内使用试纸。
- 存放时请避免阳光直射和高温。
- 从小盖中取出每条试纸后，请立即使用。
- 仅将试纸存放在它们原来的小瓶中。盖内或小瓶中含有用于保护试纸的干燥剂。不要将试纸转移到新的小瓶或任何其他容器。
- 从小瓶中取出试纸之后，请立即将瓶盖盖紧。
- 不要以任何方式弯折、切割或改变 Optium Omega 试纸。
- 从小瓶中取出试纸或将试纸插入血糖仪中时，您可以使用干净、干燥的手轻轻地接触试纸的任何位置。

如何进行测试
1. **准备**
   清洁选择用于进行测试的部位。请使用温的肥皂水。请洗并完全擦干。温水有助于血液流过要采血的部位。如果您使用的是酒精棉片，请确保要采血的部位在采血之前完全变干。
   在血糖仪中插入试纸。按下"m"打开血糖仪。
   请确保编码与试纸小瓶标签上印刷的编码匹配。如果编码不匹配，请参阅您的使用说明，了解如何设置血糖仪编码。
2. **进行测试**
   使用采血笔来获取血据适当的血滴。
   请参阅您的使用说明，了解如何对手指采血。
   当屏幕上显示添加血液样本的提示时，对所选择的部位进行采血，并获取大约针头大小的血液样本。
   仅将试纸的一个边缘轻轻地接触血液样本。您可以从任意一侧为试纸添加血液，但不能同时从两侧添加。当试纸血量已满时，示屏幕上将显示移动的短线。
   不要对着测试部位按压试纸边缘。不要使样本处于样本目标区域顶部。
3. **查看结果**
   查看血糖仪显示屏幕上的测试结果。请参阅您的使用说明，了解平均测试时间。
   结果将保存在血糖仪内存中。

请参阅您的 Optium Omega 血糖仪使用说明，了解如何进行测试的逐步操作指南。

- 仅将 Optium Omega 血糖仪与 Optium Omega 试纸配合使用。
- 请确保血糖仪显示屏幕上的编码与试纸小瓶上的编码匹配。如果编码不匹配，请参阅您的使用说明，了解如何设置血糖仪编码。
- 对于任意一次血糖测试，仅从试纸一侧为试纸添加血液。
- 不要使用超出有效日期的试纸。请检查试纸小盖查看丢弃日期。
- 避免将试纸暴露于极高温度下。

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