Blood Glucose Test Strip Pakage Insert

PRICING AND INTENDED USE

The AHG Blood Glucose Test Strips are thin strips. The strips have a chemical reagent system. They work with the AHG blood glucose meters to measure the glucose level in fresh capillary 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.

AHG blood glucose monitoring system is designed to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by people with diabetes at home as a way to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening of diabetes. This system is intended to be used for *in vitro* diagnostic use only, and used by a single person and should not be shared.

The AHG Blood Glucose Control Solution is for use with the AHG blood glucose meters and AHG Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.

COMPOSITION

These chemicals are: Glucose Oxidase (from Aspergillus Niger) <25 IU, Mediator <300 pg, Buffer, and Non-reactive Ingredient.
Each test strip vial contains a drying agent. Each test strip pouch 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 between 36-86°F. Store at 10-90% humidity. Avoid heat and direct sunlight.
- Use the test strips at temperature (41-113°F). Use the test strips between 10-90% humidity.
- 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. Use the test strip as soon as it is removed from foil pouch.
- 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 label or on the foil pouch. Otherwise, you may get incorrect test results.

Note: *All expiration dates are printed in Year-Month-Day format. 2025-01-01 indicates 1st January, 2025.*

- A new vial of test strips may be used for 4 months after first opening. After 4 months they will expire. Write the opened expiration date on the vial label after opening.
- Do not use the torn, bent, or damaged test strips. Do not reuse test strips.
- Keep the test strip away from children. Do not swallow test strips.
- Never ignore symptoms or make significant change to your diabetes control programme without speaking to your healthcare professional.
- All parts of kit are considered biohazardous and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection.
- Please refer to the user's manual for complete cleaning and disinfection information.

PERFORMING A BLOOD GLUCOSE TEST

Material provided: Test Strips and package insert
Material required but not provided: meter, User's Manual, safety lancets and control solution.
See your User's Manual for complete instructions for blood sample collection before use.
1. Select the punch site. Wash your hands in warm, soapy water. Dry your hands thoroughly.
2. Prepare the safety lancets.
3. Check the expiration date and discard date. The expiration date is printed on the strip vial label or on the foil pouch. Do not use your test strips past the unopened expiration date or discard date.
4. Insert the test strip into the meter. The meter turns on.
5. Lance the punch site to get a round drop of blood.
6. Touch the blood drop to the strip tip. And then the meter beeps. Do not apply blood on the top of test strip.
7. The meter counts down from 5 to 1. And then, your test result will appear.

CHECKING THE SYSTEM

Use only AHG Control Solutions.

For complete details about checking the system, refer your User's Manual.
When to check:
- At least once a week
- Before using a new box of test strip
- When you suspect that the meter or test strips are not working properly.
- If you suspect your meter is damaged.
- After cleaning your meter
- When you dropped the meter
- When you suspect your test result. Or if they do not match with how you feel. on the vial label or on the foil pouch. Otherwise, you may get incorrect test results.

You should confirm your control solution results. Make sure the Control Solution 1 tests fall within the level 1 range. Make sure the Control Solution 2 tests fall within the level 2 range. Make sure the Control Solution 3 tests fall within the level 3 range. When testing with Control Solution 2, make sure you are matching the results to the level 2 range on the strip vial label or on the foil pouch.

CAUTION: *If your control test result falls outside the control range,* ***DO NOT*** *use the system to test your blood. The system may not be working properly. If you cannot correct the problem, contact AHG Customer Support at: www.americanhealthgate.com*

LIMITATIONS

- For single-patient use only.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your health care professional to find out your hematocrit level.
- If you are taking vitamin C (ascorbic acid > 3 mg/dL) then your glucose results using this meter may not be reliable.
- Do not use if on oxygen therapy
- Not for use on critically ill patients.
- Not for use on patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis).
- The AHG Monitoring Systems should not be used following xylose absorption procedures.
- Not for neonatal use.
- Not for screening or diagnosis of diabetes mellitus.
- Not for use in hypotensive individuals.
- Do not use at altitudes above 13123ft (4000 meters) above sea level.
- The meter is not intended for use in healthcare or assisted-use settings. such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

PERFORMANCE CHARACTERISTICS

Repeatability, Precision

Repeatability-Blood		
Interval	Glucose concentration	Coefficient of Variation (CV)
1	49.5 mg/dL	4.6%
2	78.1 mg/dL	3.2%
3	133.5 mg/dL	3.0%
4	200.7 mg/dL	2.9%
5	357.5 mg/dL	2.8%
Intermediate Precision-Control Solution		
Interval	Glucose concentration	Coefficient of Variation (CV)
1	50.5 mg/dL	4.8%
2	117.5 mg/dL	2.7%
3	360.0 mg/dL	2.4%

Consumers Accuracy Study

352 lay persons tested the capillary blood using the AHG Blood Glucose Meter (y). The blood was taken from fingertip.
Fingertip blood samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared.

Linear Regression Results: AHG (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept (mg/dL)	R	N
Fingertip	1.0137	2.3501	0.9977	352

Fingertip blood samples were used for YSI reference measurement. The glucose concentration range was 23.3 to 516.0 mg/dL for AHG Blood Glucose Meter testing with blood sample from fingertip test sites.

Fingertip Site: Consumers Accuracy Results			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
71.9% (253/352)	96.6% (340/352)	100% (352/352)	100% (352/352)

Accurate Results (Meter result is +/-15% of laboratory result)	352 out of 352 (100% of results)
More Accurate Results (Meter result is +/-10% of laboratory result)	340 out of 352 (96.6% of results)
Most Accurate Results (Meter result is +/-5% of laboratory result)	253 out of 352 (71.9% of results)

For complete instructions, please refer to the User's Manual included with your meter. For additional questions or issues with this product, please contact AHG Customer Support at www.americanhealthgate.com

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