Blood Glucose Test Strips

Package Insert

REF C902005-10, C902005-25, C902005-50, C902005-100	English

PRINCIPLE AND INTENDED USE

The *Acuteck* Blood Glucose Test Strips work with *Acuteck* Blood Glucose Test Meter to quantitatively measure glucose in fresh capillary whole blood or venous whole blood. Blood Glucose Test Strips are thin strips. The strips have a chemical reagent system. Blood is applied to the end tip of the test strip. The blood is then absorbed into the reaction cell.The test strips rely on glucose dehydrogenase (GDH) to generate the glucose-specific electrochemical signal. After the glucose is oxidized, a mediator is commonly used to transfer the signal from enzyme to the working electrode. The resulting current can be detected by meter. Then the concentration of blood glucose is calculated based on this current, and the result is shown on the screen of the meter. The test procedure is automated.

Blood Glucose Monitoring System is an automatic *in vitro* monitoring system for quantitative detection of glucose concentration in fresh capillary whole blood or venous whole blood.

The system is intended for self-testing by people with diabetes or people suspected of having diabetes at home, and for near-patient testing by healthcare professionals in clinical settings.

The system is only used for the monitoring of blood glucose levels and the preliminary screening of blood glucose abnormalities, and is not suitable for the diagnosis of diabetes.

COMPOSITION

Each test strip contains reactive and non-reactive chemicals. These chemicals are: glucose dehydrogenase < 25 IU, mediator < 300 μg, buffer, and non-reactive ingredient.

STORAGE AND HANDLING

- Store the test strips in desiccant vial. Store them with their cap closed tightly. This keeps them working properly.
- Store the test strip vial at temperatures between 2-30°C and keep out of direct sunlight.
- Store the test strip vial ≤90 % relative humidity.
- Shelf life: 24 months.
- Do not freeze.
- Use the test strips between 10-40°C. 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 any other container.
- 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.
- A new vial of test strips may be used for 3 months after first opening. After 3 months they will expire. Write the opened expiration date on the vial label after opening.

WARNING AND 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 the required pre-cleaning procedure. Please refer to the corresponding section in the user's manual of Acuteck Blood Glucose Monitoring System. This procedure is important to prevent the potential transmission of infectious diseases.
- 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 3 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 with your doctor before making any changes to the treatment plans.
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give an incorrect result.
- If the outer packaging is seriously damaged during transportation, please contact your local dealer. Please check the completeness of the product. Check the use by date on the product. Do not use the product after that date.

MATERIALS

MATERIALS PROVIDED

- Blood Glucose Test Strips
- Sterile Lancets
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Blood Glucose Test Meter
- Lancing Device
- Blood Glucose Control Solution

ADAPTATION MODEL

The *Acuteck* Blood Glucose Test Strips is designed for below dedicated test meters.

DO NOT use other brand of test meters with Acuteck Blood Glucose Test Strips.

- *Acuteck* GOH-101 Blood Glucose Test Meter
- *Acuteck* GOH-101Pro Blood Glucose Test Meter
- *Acuteck* GOH-201 Blood Glucose Test Meter

For more ordering information, please contact 400-853-5577 or email ‘contact@diareagent.com’.

SAMPLE COLLECTION AND PREPARATION

The specimen type could be fresh capillary whole blood or venous whole blood.

For fresh capillary whole blood from the finger: fresh capillary blood should be used immediately. To obtain a drop of blood, follow these steps:

Step 1: Wipe the test site with alcohol (75%) or Isopropyl alcohol (75%) or soapy water

Step 2: Prepare lancing device according to the User’s manual.

Step 3: Puncture and get a drop of blood. Avoid pressing too hard against the punctured site.

For venous whole blood, a blood sample should be collected by a medical professional.

Venous blood glucose tests need to be performed within 30 minutes of obtaining the blood samples.

If anticoagulant blood collection tubes are required, the recommended anticoagulants are heparin or EDTA.

EXAMINATION PROCEDURE

See the User's Manual for complete instructions for blood sample collection before use.

1. 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.
2. Perform the test following the instructions in the User’s Manual.
3. The test result will be shown on the meter display screen.

For detailed information on the test procedure, please refer to the User’s Manual.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a physician. Together with the treating physician you can set your patients’ range of expected blood 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:

Time	Range, mg/dL	Range, mmol/L
Fasting and Before Meals	70-110	3.9-6.1
2 Hours After Meal	Less than 140	Less than 7.8

READINGS

If “Lo” appears on the screen, your blood glucose level is lower than 0.6 mmol/L (10 mg/dL). If “Hi” appears, that your blood glucose level is higher than33.3 mmol/L (600 mg/dL). When you get any questions for the readings, check the following items first and then repeat the test. If the results are still questionable, consult your healthcare professional:

1. If the test strips are within the expiration date.
2. Make sure the drop of blood in the whole reaction zone.
3. Check meter and test strip performance with Blood Glucose Control Solutions.

CAUTION:

Any low or high blood glucose readings can indicate a potentially serious medical condition. If the readings do not reflect your symptoms, repeat the test with a new test strip. Contact your healthcare professional when your reading is:

A. Not consistent with your symptoms.

B. Less than 3.3 mmol/L (60 mg/dL).

C. Higher than 13.3 mmol/L (240 mg/dL).

LIMITATIONS

- The Monitoring System is designed for using with whole blood samples. Do not use serum or plasma samples..
- Severe dehydration and excessive water loss may cause false low results. If you think you may be dehydrated, consult your healthcare professional immediately.
- The system can also be intended for neonatal heel blood.

QUALITY CONTROL

To ensure proper performance of the meter and accuracy of the test result, it is important to perform control tests with the control solution on a regular basis. The control solution is used to check the performance of the Blood Glucose Monitoring System, which including meter and test strips, and user’s test skill. The system is performing adequately if the control solution test result falls within the indicated control range listed on the control solution label.

A control test should be proceeded:

- Before you first use your meter.
- 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 your test results are inaccurate, or if they are inconsistent with how you feel.
- When you suspect your meter is damaged.

The control solution test result should fall within the control range listed on the control solution label. Please repeat the test with a new test strip if the test result falls outside the range.

Results that fall outside the range may be caused by:

- Inaccurate in performing the test.
- Contaminated or expired control solution.
- Meter or strip deterioration or malfunction.

Important:

The control range may change with each new vial of control solution. Always check the control range marked on the label of the current label of control solution.

Warnings:

Do not use the meter to do the test until you can get the control solution test result falls within the control range. It indicates that your system does not function properly if you continue to get the control solution test results outside the range.

PERFORMANCE CHARACTERISTICS

Metrological traceability and calibration: The *Acuteck* Blood Glucose Test Meters are calibrated by using YSI (Model 2500) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.
System Measurement Range: 0.6~33.3mmol/L (10 to 600 mg/dL)
Sample Size: 0.6μL
Test Time: 5 seconds

1. Repeatability of measurement results for blood glucose:

Five heparinized venous blood samples at five concentration levels were measured in the test, using three batches of test strips in the laboratory. Summary results are shown below:

Average	mmol/L	2.51	5.55	7.25	12.05	18.56
Standard deviation	mmol/L	0.14	0.17	0.23	0.28	0.47
Coefficient of variation (%)		/	3.06%	3.17%	2.32%	2.53%

2. Intermediate precision of measurement results for blood glucose:

Control solutions at three levels were measured by ten meters in the test, using three batches of test strips in the laboratory. Summary results are shown below:

Average	mmol/L	2.45	7.06	19.50
Standard deviation	mmol/L	0.11	0.23	0.43
Coefficient of variation (%)		/	3.23%	2.18%

3. System Accuracy

For venous whole blood test

Blood glucose system accuracy results for glucose concentration < 5.55 mmol/L (<100 mg/dL):

Within ± 0.28 mmol/L (within ± 5 mg/dL)	Within ± 0.56 mmol/L (within ± 10 mg/dL)	Within ± 0.83 mmol/L (within ± 15 mg/dL)
36/75 (48.0%)	67/75 (89.3%)	75/75 (100%)

Blood glucose system accuracy results for glucose concentration ≥ 5.55 mmol/L (≥100 mg/dL):

Within ± 5%	Within ± 10%	Within ± 15%
77/133 (57.9%)	129/133 (97.0%)	133/133(100%)

For capillary whole blood test

Blood glucose system accuracy results for glucose concentration < 5.55 mmol/L (<100 mg/dL):

Within ± 0.28 mmol/L (within ± 5 mg/dL)	Within ± 0.56 mmol/L (within ± 10 mg/dL)	Within ± 0.83 mmol/L (within ± 15 mg/dL)
28/55 (50.9%)	51/55 (92.7%)	55/55 (100%)

Blood glucose system accuracy results for glucose concentration ≥ 5.55 mmol/L (≥100 mg/dL):

Within ± 5%	Within ± 10%	Within ± 15%
81/160 (50.6%)	142/160 (88.8%)	159/160 (99.4%)

4. Packed cell volume

Packed cell volume in the range of 0%-70% would affect blood glucose test strip insignificantly. Hematocrit above 70% may cause lower results.

5. User Performance Evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 106 lay persons showed the following results: 100.00% within ±0.83 mmol/L (±15 mg/dL) of the medical laboratory values at glucose concentrations below 5.55 mmol/L (100 mg/dL), and 100.00% within ± 15% of the medical laboratory values at glucose concentrations above 5.55 mmol/L (100 mg/dL).

6. Interfering substances

The following concentrations of interfering substances have no effect on blood glucose test results.

Interfering substance	Concentration	Interfering substance	Concentration
Acetaminophen	15.6mg/dL	Ibuprofen	21.9mg/dL
Ascorbic Acid	5.25mg/dL	Icodextrin	1094.4 mg/dL
Conjugated Bilirubin	40mg/dL	L-DOPA	0.75 mg/dL
Unconjugated Bilirubin	40mg/dL	Maltose	360mg/dL
Cholesterol	400 mg/dL	Methyl-DOPA	285mg/dL
Creatinine	15 mg/dL	Pralidoxime Iodide (PAM)	1.6mg/dL
Dopamine	0.0621mg/dL	Salicylate	20mg/dL
EDTA	0.099mg/dL	Tolbutamide	54.9mg/dL
Galactose	60mg/dL	Tolazamide	4.50mg/dL
Gentisic acid	1.50mg/dL	Triglycerides	1500mg/dL
Glutathione	3mmol/L	Uric acid	23.5mg/dL
Haemoglobin	1000mg/dL	Xylose	600mg/dL
Heparin	330units/dL		

SUMMARY OF SAFETY AND PERFORMANCE

Intended users and patients can log in to the European database on medical devices (Eudamed) to request the summary of safety and performance(SSP) of the device or contact the manufacturer to obtain it.

REFERENCES

1. ADA Standards of Medical Care in Diabetes 2021
2. EN ISO 15197:2015 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

INDEX OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use or consult electronic instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse	EU REP	Authorized representative in the European Community
UDI	Unique device identifier		Date of manufacture
CE	CE marking		

CE 0197

Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50, Moganshan Road,
Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China
Tel: (86)571-81022690; Fax: (86)571-88865920
Website: www.diareagent.com

EC REP **CMC Medical Devices & Drugs S.L**
C/Horacio Lengo Nº 18, CP 29006,
Málaga-Spain