Acuteck™

Blood Glucose Test Strips Package Insert

REF EGS-101

PRINCIPLE AND INTENDED USE

The Blood Glucose Test Strips are thin strips. The strips have a chemical reagent system. They work with the Blood Glucose Monitoring System 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.
Blood Glucose Test Strips are used to measure the amount of glucose in fresh whole blood. Blood sample can be fresh capillary whole blood or venous whole blood.
The system is used to monitor how well the diabetes control programs work. Test strips can only be used outside the body (*In Vitro* diagnostic use). They are used by diabetics for self-testing purpose. The system is not to be used on neonates and not for the diagnosis of or screening for diabetes mellitus.

COMPOSITION

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

STORAGE AND HANDLING

- Store test strips in their protective vial. Store them with their cap closed tightly. This keeps them working properly.
- Store in a cool, dry place between 2-30 °C (35.6-86°F) and keep out of direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips at room 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 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 test strips after the unopened expiration date printed on the vial.
- 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.
- EGS-101 test strip is designed for EG-101 and EG-102 blood glucose meters. DO NOT use other model of blood glucose meter with EGS-101 test strip.
- 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 Blood Glucose monitoring System section in the user's manual. 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.

MATERIALS PROVIDED

Materials Provided

- Test Strips
- Package Insert
- Code chip
- Sterile Lancets

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Control Solution
- Lancing Device

SAMPLE COLLECTION AND PREPARATION

The specimen type could be fresh capillary whole blood from the finger or venous whole blood. Use the blood sample immediately. To obtain a drop of blood, follow these steps:
Step 1: Wash and dry your hands thoroughly.
Step 2: Prepare lancing device according to the manual.
Step 3: Use an alcohol swab. Make sure that your finger is entirely dry before lancing.
Step 4: Puncture and get a drop of blood. Avoid pressing too hard against the punctured site.

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	70-100	3.9-5.6
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 20 mg/dL (1.1 mmol/L). If "HI" appears, that your blood glucose level is higher than 600 mg/dL (33.3 mmol/L). 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 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 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 60 mg/dL (3.3 mmol/L) .
C. Higher than 240 mg/dL (13.3 mmol/L).

LIMITATIONS

- The Blood Glucose Monitoring System is designed for using with whole blood samples. Do not use serum or plasma samples.
- DO NOT test on neonatal samples (new born).
- Inaccurate test results may be obtained at high altitude more than about 3048 meters.
- Hematocrit range: 30% to 55%. Hematocrit below 30% may cause higher results, and hematocrit above 55% may cause lower results.
- Severe dehydration and excessive water loss may cause false low results. If you think you may be dehydrated, consult your healthcare professional immediately.
- DO NOT test at temperature beyond range of 8-37°C (46.4-98.6°F).
- Not for person undergoing Oxygen therapy.
- Interfering substances, such as acetaminophen, ascorbate, urate and bilirubin, beyond the range of physiological concentration may cause inaccurate measurement.
- Cholesterol lower than 500mg/dL and triglycerides lower than 3000mg/dL will not cause influence.

PERFORMANCE CHARACTERISTICS

The test range is in the range of 20 to 600 mg/dL (1.1~33.3mmol/L). Validate the test strips performance in both laboratory and clinical tests.
The reference values for all the studies below were obtained by YSI 2300.

Repeatability Evaluation

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

Glucose concentration (mmol/L)	1.7-2.8	2.9-6.1	6.2-8.3	8.4-13.9	14.0-22.2
grand average	2.39	4.94	7.54	10.81	18.35
pooled variance	0.0119	0.0479	0.1180	0.2439	0.6295
pooled standard deviation	0.11	0.22	0.34	0.49	0.79
pooled CV	-	-	4.6%	4.6%	4.3%

Intermediate Precision Evaluation

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:

Glucose concentration (mmol/L)	1.7-2.8	5.3-8.0	15.5-23.3
grand average	2.43	5.89	19.63
pooled variance	0.0107	0.0684	0.8275
pooled standard deviation	0.10	0.26	0.91
pooled CV	-	4.44%	4.63%

System Accuracy Evaluation

106 samples were measured in this evaluation, using 3 batches of test strips and 2 blood glucose meter. Results of these 636 tests are summarized as below:

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)
110/186 (59.1%)	167/186 (89.8%)	182/186 (97.8%)

System accuracy results for glucose concentration ≥ 5.55 mmol/L (≥100 mg/dL)

Within ± 5%	Within ± 10%	Within ± 15%
397/450 (88.2%)	434/450 (96.4%)	445/450 (98.9%)

System accuracy results for glucose concentration between 1.1mmol/L (19.8mg/dL) and 27mmol/L(486 mg/dL)

Within ± 0.83 mmol/L or ± 15% (Within ± 15 mg/dL or ± 15%)
627/636 (98.6%)

Interference Evaluation

All of the 24 substances specified in EN ISO 15197:2015 would not affect the test strip when measuring blood glucose except ascorbate. Results of blood glucose would not exceed criteria only when concentration of ascorbate was below 3 mg/dL.

Acetaminophen (1.66 mmol/L)	Galactose (0.84mmol/L)	L-DOPA (5mg/dL)
Ascorbate (4mg/dL)	Gentisic acid (117μmol/L)	Maltose (*)
Bilirubin (342μmol/L)	Glutathione (3mmol/L)	Methyl-DOPA (71μmol/L)
Cholesterol (500mg/dL)	Haemoglobin (*)	PAM (1.6mg/dL)
Creatinie (442μmol/L)	Heparin (3000U/L)	Salicylate (4.34mmol/L)
Dopamine (5.87μmol/L)	Ibuprofen (2425μmol/L)	Tolbutamide (2.17mmol/L)
EDTA (45mg/dL)	Icodextrin (*)	Tolazamide (100mg/dL)
Triglycerides (3000mg/dL)	Urate (1.4mmol/L)	Xylose (*)

Note: the substances marked with "*" means that they were evaluated by Non-experimental evaluation instead of Experimental evaluation, such as referring to the existed literature.

Packed cell volume

Hematocrit range: Samples with hematocrit in the range of 30%-55% would affect blood glucose test strip insignificantly. Hematocrit below 30% may cause higher results, and hematocrit above 55% may cause lower results.

User Performance Evaluation

A study evaluating glucose values from fingertip capillary blood samples obtained by 100 lay persons showed the following results:

96.6% 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 98.6% within ± 15% of the medical laboratory values at glucose concentrations above 5.55 mmol/L (100 mg/dL).

REFERENCES

1. ADA Standards of Medical Care in Diabetes 2015
2. EN ISO 15197:2015.

Index of Symbols

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical		Use by
	Manufacturer		Contains sufficient for
	Do not reuse	SN	Serial Number
EC REP	Authorized representative in the European Community		
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

Acuteck

CE 0197

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