eBfine Blood Glucose Test Strips GDH

Please read this instruction before using eBfine Blood Glucose Test Strips.

Intended Use

The eBfine Blood Glucose Monitoring System is designed for people self-testing with diabetes to measure glucose concentration in capillary whole blood from the fingers and venous whole blood. These test strips are for in vitro diagnostic use only. The test results are whole-blood calibrated. The measuring range of glucose concentration in capillary whole blood is from 1.1 to 33.3 mmol/L.

Storage

- Store the test strips at room temperature between 4-30°C. DO NOT freeze.
- Use test strips at temperatures between 10°C and 40°C, and less than 85% humidity.
- Store your test strips in their original vial only; DO NOT transfer them into a new vial or another container.
- Always close the container with container cap immediately after use.
- Write the discard date on the vial label when you open it for the first time. Discard remaining eBfine Blood Glucose Test Strips after 3 months from the first opening of the vial.

Keep the test strip vial away from children; the cap is a choking hazard. The cap or vial may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

System Measurement Range

The measurement range of the eBfine Blood Glucose Monitoring System is 1.1 to 33.3 mmol/L.

Performing a Blood Glucose Test

When the calibrated meter is set and the code number matches the number on the strips, you may begin testing.

Step 1. Remove the cap from the lancing device.

Step 2. Firmly insert a lancet into the lancet holder. Twist and remove the protective cover from the lancet.

Step 3. Put the cap back onto the lancing device.

Step 4. Adjust the depth setting of lancing device. Choose a desired skin penetration depth by rotating the top portion of the adjustable tip until the setting number lines up to the arrow.

Step 5. Slide the ejection/cocking control back until it clicks.

Step 6. Wash your hands with warm, soapy water. Rinse and dry thoroughly.

Step 7. Open a new vial of test strips. Take out a test strip from the vial and fasten the cap properly. Make sure the triangle sign is facing up and insert the electrical contact end of the test strip fully into the test slot. The meter will be turned on automatically and the code number will be shown on the screen. Make sure that this number matches the code number on the vial of test strips.

Step 8. To obtain a drop of blood, press the tip of the lancing device against your fingertip and press the release button. Gently squeeze your finger to form a small drop of blood.

Step 9. Touch the drop of blood to the semicircle-shaped cutout on the top of the narrow channel of the test strip. The blood will be drawn into the strip automatically. Hold your blood to the strip until after the meter beeps. The meter starts counting down from 5 seconds. If you have enough blood inside the reaction chamber of the strip, the indication slot located inside triangle sign turns red (filled with blood). If the indication slot does not completely turn red before the meter begins to count down, discard the strip and do not try to add more blood to the strip.

Step 10. After 5 seconds, your test result appears on the screen and is stored automatically in the meter's memory.

Step 11. The meter will switch off by removing the test strip.

Step 12. Dispose of the used test strip into a sealed container.

Step 13. Remove the cap from the lancet device. Put the protective cover back onto the lancet and push the lancet out.

Step 14. Dispose of the used lancet in a sealed container.

Quality Control Testing (Optional)

eB-series glucose control solution is used to check that if the monitoring system (meter working together with test strips) is functioning properly.

When to do a control solution test:

1. When you open a new vial of test strips.
2. Whenever you suspect that the meter or test strips are not working properly.
3. After dropping the meter.
4. Whenever you question your blood glucose results.

Steps for performing a control solution test

Step 1. Remove a test strip from the vial and fasten the cap properly. Make sure the triangle sign is facing up and insert the electrical contact end of the test strip fully into the test slot. The meter will switch on automatically and the code number will be shown on the screen. Make sure that this number matches the code number on the vial of test strips.

Step 2. Open a bottle of eB-series glucose control solution. The storage period of eB-series glucose control solution is only for 3 months after the first opening or up to the expiry date, whichever comes first. Always write down the discard date on the bottle.

Step 3. Hold the bottle and gently squeeze the bottle to form a small drop of control solution on the tip of the bottle.
*Always shake the bottle well, discard the first drop before applying the control solution.

Step 4. Touch the drop of control solution to the semicircle-shaped cutout on the top of the narrow channel of the test strip. The control solution will be drawn into the strip automatically. The meter starts counting down from 5 seconds.

Step 5. After 5 seconds, your test result appears on the screen.

Step 6. Compare the result with the range printed on the vial of the test strips. The result should be within the range.

Range of Expected Values

Blood glucose monitoring requires the help of healthcare professionals in setting the expected range of your own blood glucose values, arranging your testing times, and discussing the meaning of your blood glucose results.

Expected blood glucose levels for people without diabetes [1] :

* Fasting and before meals: Less than 5.6 mmol/L

* 2 hours after meals: Less than 7.8 mmol/L

REMEMBER TO REPEAT THE TEST IF THE TEST RESULT FALLS OUTSIDE THE EXPECTED RANGE

If you get unexpected results:
Low or high blood glucose readings can indicate a potentially serious medical condition. Please consult your healthcare professional and follow his or her treatment advice.

Limitations

Blood glucose test strips give accurate results when the following limitations are observed:

- The test strips should not be used for the testing of neonates.
- The test strips are for single use only. DO NOT reuse.
- The test strips are used only with fresh whole blood. DO NOT use serum or plasma.
- Hematocrit values less than 20% may cause falsely high test results; hematocrit values higher than 60% may cause falsely low test results (consult your healthcare professional regarding your hematocrit value).
- The altitudes that are up to 8000 feet have no effect on eBfine blood glucose measurements.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with blood glucose meters.
- Interferences: Pralidoxime iodide, Gentisic acid, Hemoglobin and Glutathione. Please see the table below for the certain concentrations which can affect the function of the meter.

Substance	No Interference
Acetaminophen	< 1.32 mmol/L
Creatinine	< 0.88 mmol/L
Dopamine	< 5.88 μmol/L
Galactose	< 0.83 mmol/L
Gentisic acid	< 0.13 mmol/L
Glutathione	< 2.28 mmol/L
Hemoglobin	< 0.80 g/dL
Maltose	< 7.30 mmol/L
Pralidoxime iodide	< 0.38 mmol/L
Uric acid	< 1368 μmol/L

Test Principle

The technology used for the eBfine Blood Glucose Monitoring System is based on the principle that a small electrical current produced when blood glucose reacts with the reagent immobilized on the reaction area of the eBfine test strip and the current change is proportional to the amount of glucose in the blood.

Reagent Composition

Each eBfine Blood Glucose Test Strip contains:

- FAD glucose dehydrogenase(GDH-FAD)(*microorganism*) ・・・ ≧ 3 IU
- Potassium ferricyanide ・・・・・・・・・・・・・・・・・・ ≧ 0.06 mg
- Other ingredients ・・・・・・・・・・・・・・・・・・・・ ≧ 1.25 mg

Performance Characteristics

The eBfine Blood Glucose Monitoring System is calibrated by means of glucose oxidase method to display plasma equivalent results, which is traceable to an NIST standard SRM917d. The whole blood was used for calibration.

Accuracy

The accuracy was assessed by comparing the eBfine test strips readings with the reference values using YSI 2300 STAT PLUS glucose analyzer.
The glucose concentrations of capillary blood samples were measured using eBfine meter. The glucose concentrations of the venous blood samples were analyzed using the YSI 2300 glucose analyzer (glucose oxidase method). The results shown below are from a total of 100 subjects for the 3 lots of strips attending the outpatient clinic.

Number of sample	Slope	Intercept	Correlation Coefficient
600	1.0065	-0.1448	0.9963

According to EN ISO15197 (2015) all samples were within the minimum acceptable performance criteria.

< 5.6 mmol/L	N=167	
Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
134/167 (80.2 %)	151/167 (90.4 %)	167/167 (100 %)
≧ 5.6 mmol/L	N=433	
Within ±5 %	Within ±10 %	Within ±15 %
360/433 (83.1 %)	403/433 (93.1 %)	433/433 (100 %)

Within ± 0.83 mmol/L or within ±15 %	600/600 (100 %)

Lay-user (eBfine) fingerstick vs. YSI analyzer

The linear regression analysis was assessed by comparing the eBfine readings performed by lay-user with the reference values using YSI 2300 glucose analyzer. The results shown below are from a total of 150 patients.

Number of sample	Slope	Intercept	Correlation Coefficient
150	1.0023	-0.0247	0.9968

< 5.6 mmol/L	N=34	
Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
28/34 (82.4 %)	33/34 (97.1 %)	34/34 (100 %)
≧ 5.6 mmol/L	N=116	
Within ±5 %	Within ±10 %	Within ±15 %
96/116 (82.8 %)	116/116 (100 %)	116/116 (100 %)

Precision

Precision was determined using coefficients of variation (CVs) calculated from 100 measurements in series. To produce the 5 different glucose concentrations for the 3 lots of strips, venous whole blood samples from healthy volunteers were spiked using different concentrations of glucose solutions.

Repeatability

Glucose levels (mmol/L)	**2.4**	**5.3**	**7.6**	**12.4**	**19.8**
Average (mmol/L)	2.3	5.5	7.8	12.7	19.7
SD (mmol/L)	0.1	0.2	0.2	0.4	0.5
C.V. (%)	5.1	3.0	2.7	2.7	2.4

Intermediate

Glucose levels (mmol/L)	**2.6**	**7.2**	**19.4**
Average (mmol/L)	2.4	7.4	19.8
SD (mmol/L)	0.1	0.2	0.4
C.V. (%)	5.3	2.9	2.1

Reference:

1. American Diabetes Association (2010), Clinical Practice Recommendation, Diabetes Care 34 (Supplement 1):S11-S61.

Labeling and Information

	Do not re-use		Consult instructions for use
	Keep dry		Caution, consult accompanying documents
IVD	In vitro diagnostic medical device		Use-by date
+4°C +30°C	Store temperature limitation	+10°C +40°C	Operating temperature limitation
	Keep away from sunlight	LOT	Batch number
EU REP	Authorized representative in the European Community/ European Union		Manufacturer
	Recycling	CE	This product meets the requirements of Directive 98/79/EC in vitro diagnostic medical devices.

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