RIGHTEST™ ELSA BLOOD GLUCOSE TEST STRIP INSERT

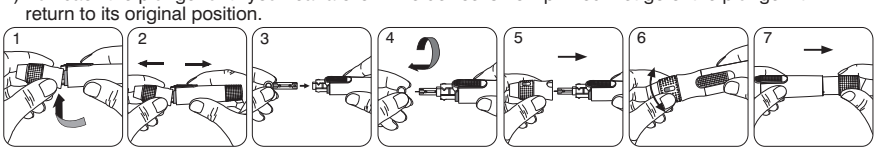
Intended Use

The RIGHTEST ELSA Blood Glucose Monitoring System is designed for *in vitro* diagnostic (for testing outside the body) use only and can be used by home user and healthcare professional.
The system can test glucose concentration in fresh capillary whole blood (drawn from fingertip, palm and forearm).
The glucose result displayed is calibrated into the plasma glucose testing equivalent.
The system is not intended for screening or diagnoses of diabetes mellitus.
RIGHTEST ELSA Blood Glucose Test Strips are designed for use only with the RIGHTEST ELSA Blood Glucose Meter.

Test Procedure

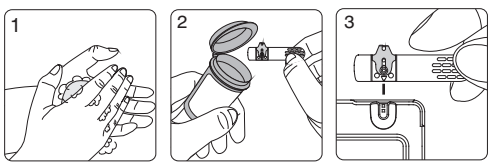
Preparing the Lancing Device

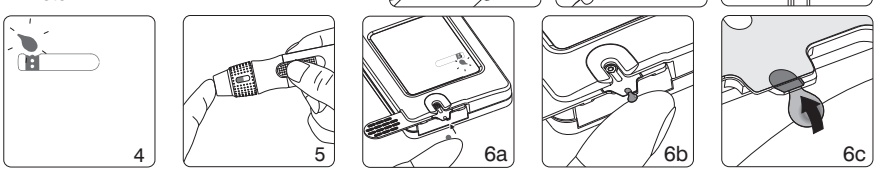
1) Hold the depth adjustable cap in one hand and hold the hub in the other hand. Bend the cap towards the down side, until a gap appears between the cap and hub.
2) Pull the cap and hub off in opposite directions, remove the cap.
3) Insert a new disposable lancet into the lancet carrier. Make sure it is held securely in place.
4) Twist off and set aside the protective cover of the disposable lancet.
5) Reattach the depth adjustable cap.
6) Rotate the clear top part of the cap to adjust the depth. Check the number of lines visible in the window. More lines corresponds to a greater depth. Try "▮" for soft or thin skin, "▮▮" for average skin, or "▮▮▮" for thick or calloused skin.
7) Pull back the plunger until you hear a click. The device is now primed. Let go of the plunger. It will return to its original position.



Performing a Test

1) Wash your hands with warm soapy water and dry thoroughly.
2) Take one test strip from the vial. Re-cap the vial cap immediately.
3) Insert the strip into the test strip port of the meter.





4) The drop symbol will flash continuously. This signifies that a blood sample should be applied within 2 minutes.
5) Place the lancing device against the pad of your fingertip and press the release button.

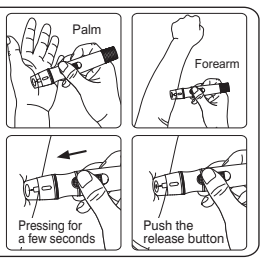
Sample Size Example

0.75 µL	1.0 µL	1.5 µL	2.0 µL	3.0 µL
•	●	●	●	●

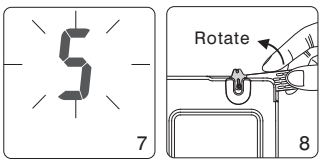
Use a minimum blood sample volume of 0.75 µL for blood glucose testing. Samples larger than 3.0 µL may contaminate the meter.

Alternative site testing - palm or forearm blood sampling

- To perform a test using samples obtained from alternative sites, install the clear cap on the lancing device. (For more information on how to install, see the Instructions for the Lancing Device.)
- Massage the target area on the palm or forearm for a few seconds to increase blood flow.
- Immediately after massaging, press and hold the lancing device against the target area.
- Press the release button.
- After pressing the release button continue holding the lancing device against the skin. Gradually push the device against your skin with increasing pressure until the blood droplet is of sufficient size.



6) Touch and hold the blood droplet to the test strip sample entry port until you hear a " beep " and the Viewing Window is filled with blood. If the Viewing Window is not completely filled with blood or the test does not start, please discard the test strip and repeat the test with a new test strip.
7) You will see a countdown on the screen. After 5 seconds, the test result will appear.
8) Remove the test strip from the meter. Please follow local regulations and discard the used strip properly.



9) Remove the cap from the lancing device. Do not touched the used lancet. Press the lancet tip into the protective cover. Hold down the release button and pull back the plunger to eject the lancet. Discard the lancet into a suitable sharps biohazard container.

For more information on how to use your meter and lancing device and how to understand your test results, see the User's Manual.

Test Result

- Blood glucose test results are shown on the meter in mg/dL or mmol/L, depending on the preset of your meter.
- If your blood glucose result is unusually high or low and you have doubts about the accuracy, repeat the test with a new test strip. You can also run a Quality Control Test with the RIGHTEST Control Solution GC570 to check your meter and test strip. If the test result still remains unusually high or low, contact your healthcare professional immediately.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all the instructions in this manual, contact your healthcare professional immediately.
- The RIGHTEST ELSA Meter displays results between 10 and 600 mg/dL or 0.6 and 33.3 mmol/L. If your test result is below 10 mg/dL (0.6 mmol/L) , " Lo " will appear on the screen. Please repeat the test with a new strip. If " Lo " still appears, contact your healthcare professional immediately.
- If your test result is above 600 mg/dL (33.3 mmol/L), " Hi " will appear on the screen. Please repeat the test with a new strip. If " Hi " still appears, contact your healthcare professional.

Expected values [1]

Fasting Blood Glucose	
GLUCOSE LEVEL	INDICATION
70 to 99 mg/dL (3.9 to 5.5 mmol/L)	Normal fasting glucose
100 to 125 mg/dL (5.6 to 6.9 mmol/L)	Pre-diabetes (Impaired fasting glucose)
126 mg/dL (7.0 mmol/L) and above on more than one testing occasion	Diabetes

Precautions

- Check the expiration date printed on the strip vial. Do not use expired test strips.
- Close the vial cap immediately after taking a test strip out of the vial.
- Do not perform quality control tests with expired control solution.
- Do not bend or twist the test strip. Damaged test strips may give incorrect results.
- Do not reuse test strips and lancets.
- Discard the used disposable lancet and strip into an appropriate sharps biohazard container.
- If the RIGHTEST Meter and Test Strips are exposed to temperature environments outside the operating range of 10 - 40°C (50 - 104°F), wait at least 30 minutes before testing.
- To purchase new control solutions, please contact your authorized Bionime representative.

Warning

- Keep the test strips and vial cap away from children. They may cause a choking hazard. If a test strip or vial cap is swallowed, contact a healthcare professional immediately.

Limitations

- The meter readings of the blood glucose may be significantly lower than " true glucose levels " in the hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested by the RIGHTEST System, or tested with extreme caution.
- Caution is advised in interpreting glucose values below 50 mg/dL (2.8 mmol/L) or above 250 mg/dL (13.9 mmol/L). Consult a healthcare professional as soon as possible if these values are obtained.
- Healthcare professionals should occasionally check their glucose testing technique and the technique of their patients. It is recommended to compare the meter result with a laboratory result acquired using the same blood sample. A well characterized clinical laboratory method using hexokinase or glucose oxidase should be used as the comparative method.
- Flouoride should not be used as a preservative when collecting blood glucose samples.
- Hands and fingers contaminated with sugar from foods or beverages may cause falsely high results.
- Storage of strips near bleach as well as bleach containing products will affect the results of RIGHTEST Test Strips.
- RIGHTEST Blood Glucose Test Strips are designed for use with capillary whole blood samples. Do not use serum or plasma samples.
- Incorrect test results may be obtained at high altitudes of more than approximately 3,048 meters (10,000 feet) above sea level.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- RIGHTEST Blood Glucose Monitoring System has not been validated for use on neonates. DO NOT use it test for neonates.

- Do not perform blood glucose tests at temperatures below 10°C (50°F) or above 40°C (104°F), or below 10% or above 90% relative humidity. The suggested temperature range for the control solution test is 15 - 40°C (59 -104°F).

NOTE
- Suggest not to use this meter close to source of strong electromagnetic radiation, to avoid interference with proper operation.
- Suggest to keep meter free of dust, water or any liquid.

Storage and Handling
- Store the strips in the original capped vial at temperatures between 4°C to 30°C (39°F to 86°F) and 10 to 90% relative humidity. Do not freeze.
- Close the vial cap immediately and tightly after taking a test strip out. Do not leave the vial open. If strips are exposed to the air for too long, it will absorb moisture and cause inaccurate test results.
- Every time when you open a new vial of test strips, please write the opening date on the label. Use test strips within 3 months after opened or until the expiration date printed on the label (whichever comes first).

Measurement Range
The measurement range of the RIGHTEST ELSA is 10 to 600 mg/dL or 0.6 to 33.3 mmol/L.

Quality Control Section
Please refer to the Quality Control section of the User's Manual.

Troubleshooting and Customer Service
For more information on error messages and trouble shooting, please refer to the Error Messages and Trouble Shooting section of the User's Manual.
If you have any questions or issues with your RIGHTEST products, please contact your local Bionime distributor or send an email to info@bionime.com .

Additional Information for Healthcare Professionals

Detection Principle [2]
The glucose oxidase and potassium ferricyanide in the strip react with glucose in the sample to produce an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration.

Performance Characteristics

Precision
The precision was evaluated by including (i) venous whole blood samples - the blood samples were collected over a span of time so as not to exceed one day per meter and reagent lot combination and (ii) 3 control solutions of different glucose concentrations (across a period of 10 days with 10 meters and 3 batches of strips).

(i) Venous whole blood sample:

Glucose levels	P-01	P-02	P-03	P-04	P-05
(1) Total test numbers (n)	300	300	300	300	300
(2) Mean mg/dL (mmol/L)	41.2 (2.3)	86.9 (4.8)	145 (8.1)	198.8 (11)	370.1 (20.6)
(3) SD mg/dL (mmol/L)	2.4 (0.13)	2.7 (0.15)	3.4 (0.19)	5.8 (0.32)	6.5 (0.36)
(4) CV (%)	5.8%	3.1%	2.4%	2.9%	1.8%

(ii) Control solution:

Glucose levels	CS-L	CS-N	CS-H
(1) Total test numbers (n)	300	300	300
(2) Mean mg/dL (mmol/L)	47.3 (2.6)	85.6 (4.8)	247.5 (13.8)
(3) SD mg/dL (mmol/L)	1.7 (0.09)	2.8 (0.25)	6.4 (0.36)
(4) CV (%)	3.5%	3.3%	2.6%

Accuracy
The accuracy of the RIGHTEST ELSA Blood Glucose Monitoring System was tested by comparing fingertip whole blood (plasma equivalent) glucose values measured by the RIGHTEST ELSA with plasma glucose values obtained from a YSI 2300 reference instrument.
The YSI 2300 was calibrated with NIST (SRM) 917c reference. The results are shown in the tables below:

Table 1: Accuracy basic information

	Fingertip	Palm	Forearm
Test range in mg/dL (mmol/L)	31 - 471 (1.72 - 26.17)	29 - 464 (1.61 - 25.78)	29 - 468 (1.61 - 26.0)
Within ± 15 mg/dL (0.83 mmol/L) or within ± 15%	636/636 (100.0%)	636/636 (100.0%)	636/636 (100.0%)

Table 2: Represents samples for glucose results < 100 mg/dL (5.55 mmol/L).

Difference range: RIGHTEST ELSA and YSI	The percent (and number) of samples was the difference between RIGHTEST ELSA and the YSI value within the following intervals.		
	Fingertip	Palm	Forearm
Within ± 5 mg/dL (0.28 mmol/L)	82.1% (197/240)	79.6% (191/240)	65.0% (156/240)
Within ± 10 mg/dL (0.56 mmol/L)	100.0% (240/240)	97.1% (233/240)	97.1% (233/240)
Within ± 15 mg/dL (0.83 mmol/L)	100.0% (240/240)	100.0% (240/240)	100.0% (240/240)

Table 3: Represents samples for glucose results ≧ 100 mg/dL (5.55 mmol/L).

Bias range: RIGHTEST ELSA and YSI	The percent (and number) of samples was the difference between RIGHTEST ELSA and the YSI value within the following intervals.		
	Fingertip	Palm	Forearm
Within ± 5%	66.9% (265/396)	62.1% (246/396)	56.8% (225/396)
Within ± 10%	92.4% (366/396)	90.7% (359/396)	85.4% (338/396)
Within ± 15%	100.0% (396/396)	99.2% (393/396)	97.7% (387/396)

*Acceptance criteria in ISO15197 : 2013 are that 95% of all differences in glucose values should be within ± 15 mg/dL (0.83 mmol/L) at glucose concentrations < 100 mg/dL (5.55 mmol/L), and within ± 15% at glucose concentrations ≧ 100 mg/dL (5.55 mmol/L).
Note: For glucose concentrations < 100 mg/dL (5.55 mmol/L), ranges are expressed in mg/dL (mmol/L), and for glucose concentrations ≧ 100 mg/dL (5.55 mmol/L), ranges are expressed as a percentage.

Lay User Evaluation
A total of 104 users were enrolled. Each user tested their fingertip blood samples with 3 lots of ELSA strip and ELSA meter. Collected blood samples were then centrifuged immediately after collection to obtain plasma. Plasma analysis was performed using a lab instrument (YSI 2300 analyzer). 100% of the ELSA BGM values were within ± 15% of YSI values at glucose concentrations≧ 100 mg/dL (5.55 mmol/L) and within ± 15 mg/dL (0.83 mmol/L) at glucose concentrations < 100 mg/dL (5.55 mmol/L).

Hematocrit (Hct)
Hematocrit (Hct) should be between 30 - 57%. If you do not know your hematocrit, ask your healthcare professional.

Interfering Substances
26 substances were tested in low and high glucose concentrations using the blood glucose measuring device. Only 3 substances may interfere with glucose measurement:
Ascorbic acid ≧ 6 mg/dL (0.34 mmol/L)
Glutathione reduced ≧ 70 mg/dL (2.28 mmol/L)
Uric Acid ≧ 16 mg/dL (0.95 mmol/L)
Other 23 substances within specified concentration may not interfere with glucose measurement : Acetaminophen ≤ 20 mg/dL (1.32 mmol/L); Dopamine ≤ 2.5 mg/dL (0.13 mmol/L); EDTA ≤ 0.1 mg/dL (0.003 mmol/L); Gentisic Acid ≤ 7.5 mg/dL (0.49 mmol/L); Heparin ≤ 18.75 U/mL; Ibuprofen ≤ 50 mg/dL (2.42 mmol/L); L-Dopa ≤ 3 mg/dL (0.15 mmol/L); Methyldopa ≤ 1.5 mg/dL (0.06 mmol/L); Pralidoxime Iodide≤ 4 mg/dL (0.15 mmol/L); Salicylic Acid ≤ 60 mg/dL (4.34 mmol/L); Tetracycline ≤ 1.5 mg/dL (0.03 mmol/L); Tolazamide ≤ 15 mg/dL (0.48 mmol/L); Tolbutamide ≤ 64 mg/dL (2.37 mmol/L); Bilirubin ≤ 50 mg/dL (0.86 mmol/L); Cholesterol ≤ 700 mg/dL (18.10 mmol/L); Creatinine ≤ 10 mg/dL (0.67 mmol/L); Hemoglobin ≤ 6000 mg/dL (0.94 mmol/L); Triglycerides ≤ 3000 mg/dL (99.22 mmol/L); Maltose ≤ 200 mg/dL (5.55 mmol/L); Xylose ≤ 40 mg/dL (2.66 mmol/L); Galactose ≤ 200 mg/dL (11.10 mmol/L); Lactose ≤ 50 mg/dL (1.46 mmol/L); Icodextrin ≤ 500 mg/dL (30.84 mmol/L).

Reagents
Each Blood Glucose Test Strip contains the following reagents:

Glucose Oxidase (GOD)	18.8%
Potassium Ferricyanide	37.7%
Non-reactive Ingredients	43.5%

References

1) Diabetes Information - American Association for Clinical Chemistry (AACC)（Electronic Version） Retrieved Jan. 26, 2021 from www.labtestsonline.org/understanding/analytes/glucose/test.html
2) *In vitro* Diagnostics in Diabetes: Meeting the Challenge. Clinical Chemistry 45:9, 1596-1601 (1999).

Consult instructions for use | EC REP EU Representative | Manufacturer | LOT Lot number
IVD For *in vitro* diagnostic use | CE 0197 CE Mark with number of Notified Body | Importer | Expiry date
Storage temperature limitation | For single use only | humidity limitation | Biological risks

Rev. Date:2021-06

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