RIGHTEST™ ALPHA BLOOD GLUCOSE TEST STRIP INSERT

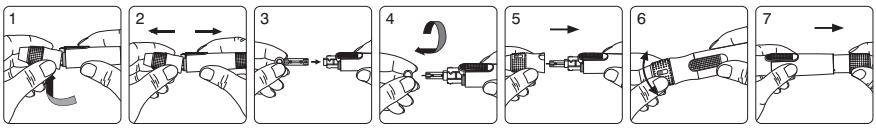
Intended Use

The RIGHTEST ALPHA 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.
The RIGHTEST ALPHA Blood Glucose Test Strip is designed for use only with the RIGHTEST ALPHA Blood Glucose Meter to obtain accurate results.

Test Procedure

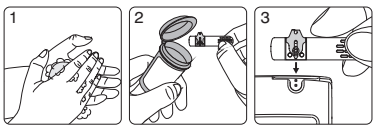
Preparing the Lancing Device

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 firmly into lancet carrier
4) Twist off and set aside the protective cover of the disposable lancet.
5) Replace the depth adjustable cap.
6) Choose a depth of penetration by rotating the top portion of the depth adjustable cap until the setting depth matches the window. Settings are based on skin type "▮▯" for soft or thin skin; "▮▮▯" for average skin; "▮▮▮▯" for thick or calloused skin.
7) Hold the hub in one hand and pull on the plunger in the other hand. The device will be cocked. Release the plunger, it will automatically move back to its original position near the hub.

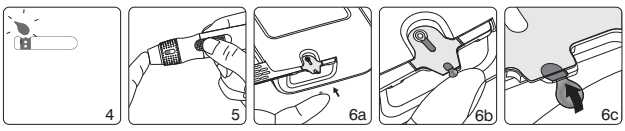


Performing a Test

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



4) While the blood drop symbol is flashing, you are ready to apply the blood sample within 2 minutes.
5) Place the lancing device against the pad of your fingertip and press the release button.



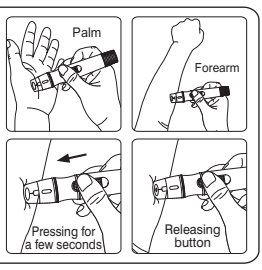
Sample Size Example

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

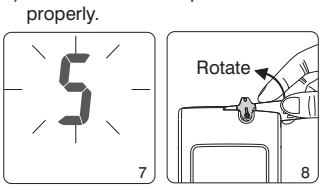
Please take a minimum of 0.75 µL to do the test on glucose monitoring system. Blood sample size above 3.0 µL might contaminate the meter.

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).
- To increase the blood flow, massage the puncture area of palm or forearm for a few seconds.
- Immediately after massaging the puncture area, press and hold the lancing device with the clear cap against palm or forearm.
- Then press the release button.
- Continue holding the lancing device against palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient (Refer to Instructions for the lancing device).



6) Touch and hold the drop to the edge of sample entry until you hear a "beep" (if volume is turned on) and the View Window is totally filled with blood. If the View Window is not totally 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 the countdown mode on the screen. After 5 seconds, the test result appears.
8) Remove the test strip from the meter. Please follow the local regulation and discard the used strip properly.



9) To remove the lancet, pull off the depth adjustable cap of lancing device. Without touching the used disposable lancet, stick the lancet tip into the protective cover. Hold the release button of lancing device in one hand and pull on the plunger in the other hand will safely eject the used disposable lancet into an appropriate puncture-proof or biohazard container.

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

Test Result

- Blood glucose test results are shown on the meter as mg/dL or mmol/L, depending on the preset of your meter.
- If your blood glucose result is unusually high or low, or if you question your results, 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 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 your test with a new strip. If you still get a " Lo " result, you should immediately contact your healthcare professional.
- If your test result is above 600 mg/dL (33.3 mmol/L), " Hi " will appear on the screen. Please repeat your test with a new strip. If you still get a " Hi " result, you should immediately contact healthcare professional.

Expected values [1]

Fasting Blood Glucose	
GLUCOSE LEVEL	INDICATION
From 70 to 99 mg/dL (3.9 to 5.5 mmol/L)	Normal fasting glucose
From 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 test strip out from the vial.
- Do not perform quality control test with expired control solution.
- Do not bend or twist the test strip. Damage of test strip may cause wrong result.
- Do not reuse test strips and lancets.
- Discard the used disposable lancet and strip into an appropriate puncture-proof or biohazard container.
- If the RIGHTEST meters or strips are exposed to temperature environments outside the operating range of 10 - 40°C (50 - 104°F) please wait at least 30 minutes before measurement.
- If you want to purchase new control solutions, please contact your authorized Bionime representative.

Warning

- Keep the test strips or vial cap away from children. They may cause a choking hazard. If a test strip or vial cap is swallowed, contact your physician 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 the interpretation of glucose values below 50 mg/dL (2.8 mmol/L) or above 250 mg/dL (13.9 mmol/L). Consult a physician as soon as possible, if values in this range are obtained.
- Healthcare professionals should evaluate their technique and their patients' technique at periodic intervals. To accomplish this, it is recommended that BGM results be compared with a concurrently obtained laboratory measurement on the same blood sample. A well characterized clinical laboratory method employing 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 or fingers contaminated with sugar from foods or beverages may cause false elevated results.
- The results of blood glucose measurements are different for measurements with whole blood and plasma.
- Storage of strips near bleach as well as bleach containing products will affect the results of the 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 altitude more than about 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 the blood glucose test at temperatures below 10°C (50°F) or above 40°C (104°F), 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.
- Replace the vial cap immediately and close tightly after taking test strip out from the vial. Do not leave the cap of vial opened. If the strip is exposed to the air too long, it will absorb the moisture and cause wrong test result.
- 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 System 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 RIGHTEST User's Manual.

If you have any questions or in case of problems with the RIGHTEST products, please contact local Bionime distributor or email to info@bionime.com .

Additional Information for Healthcare Professionals

Detection Principle [2]

The glucose oxidase and potassium ferricyanide in the strip react with the 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)	47.3 (2.6)	105.6 (5.9)	139.5 (7.7)	234.9 (13.0)	374.0 (20.8)
(3) SD mg/dL (mmol/L)	1.5 (0.08)	2.0 (0.11)	2.8 (0.15)	4.3 (0.24)	5.5 (0.31)
(4) CV (%)	3.2%	1.9%	2.0%	1.8%	1.5%

(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)	46.7 (2.6)	98.7 (5.5)	289.9 (16.1)
(3) SD mg/dL (mmol/L)	1.2 (0.06)	2.0 (0.11)	4.1 (0.23)
(4) CV (%)	2.5%	2.0%	1.4%

Accuracy

The accuracy of the RIGHTEST ALPHA Blood Glucose Monitoring System was tested by comparing fingertip whole blood (plasma equivalent) glucose values measured by the RIGHTEST ALPHA Blood Glucose Meter with plasma glucose values obtained from a YSI 2300 reference instrument.

The YSI 2300 was calibrated with NIST (SRM) 917c reference.

The results and variations between the two methods, RIGHTEST ALPHA Blood Glucose Monitoring System and YSI 2300 (as the reference method) are shown in the tables below.

Table 1: Accuracy basic information

	Fingertip	Palm	Forearm
Test range in mg/dL (mmol/L)	29 - 466 (1.61 - 25.89)	29 - 461 (1.61 - 25.61)	32 - 463 (1.78 - 25.72)
Within ± 15 mg/dL (0.83 mmol/L) or within ± 15%	636/636 (100%)	635/636 (99.8%)	631/636 (99.2%)

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

Difference range in values between the YSI value and the RIGHTEST ALPHA BGMS	The percent (and number) of samples was the difference between the RIGHTEST ALPHA BGMS and the YSI value within the following intervals.		
	Fingertip	Palm	Forearm
Within ± 5 mg/dL (0.28 mmol/L)	87.5% (210/240)	77.1% (185/240)	62.9% (151/240)
Within ± 10 mg/dL (0.56 mmol/L)	100.0% (240/240)	95.4% (229/240)	96.3% (231/240)
Within ± 15 mg/dL (0.83 mmol/L)	100.0% (240/240)	99.6% (239/240)	100.0% (240/240)

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

Difference range in values between the YSI value and the RIGHTEST ALPHA BGMS	The percent (and number) of samples was the difference between the RIGHTEST ALPHA BGMS and the YSI value within the following intervals.		
	Fingertip	Palm	Forearm
Within ± 5%	72.5% (287/396)	71.2% (282/396)	65.9% (261/396)
Within ± 10%	95.5% (378/396)	95.7% (379/396)	88.6% (351/396)
Within ± 15%	100.0% (396/396)	100.0% (396/396)	98.7% (391/396)

*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), difference values are expressed in mg/dL (mmol/L), and for glucose concentrations ≧ 100 mg/dL (5.55 mmol/L), difference values are compared in percentage.

Lay User Evaluation

A total of 108 users were enrolled. Each user tested their fingertip blood samples with 3 lots of strip ALPHA and ALPHA meter. Then the professional collected blood samples were centrifuged immediately after collection to obtain plasma. Analyze the plasma by the lab instrument (YSI 2300 analyzer). 100% of the ALPHA BGMS 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.

Interferences

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).

IVD For *in vitro* diagnostic use	For single use only	EC REP EU Representive	Manufacturer
Consult the instruction for use	CE-mark (with No. of notified body)	Importer	LOT Lot number
Storage temperature limitation	Humidity limitation	Biological risks	Expiry date

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BIONIME
BIONIME CORPORATION
No. 100, Sec. 2, Daqing St., South Dist.,
Taichung City 40242, Taiwan
Tel: +886 4 23692388 Fax: +886 4 22617586
Email: info@bionime.com http://www.bionime.com

EC REP
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands
Email: EmergoVigilance@ul.com

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