RIGHTEST™ BLOOD GLUCOSE TEST STRIP GT200 INSERT

Intended Use

The RIGHTEST GT200 Blood Glucose Monitoring System is to be used by:

- Professionals needs to monitor the glucose level of patient or potential person. Sample sites include capillary, venous, arterial and neonatal whole blood samples. Capillary samples may be drawn from the fingertip, palm, forearm, and in the case of neonates, the heel.
- Any person with diabetes, for monitoring their glucose levels in capillary whole blood (CB) from the fingertip, palm and forearm;
- A single user to aid in the management of diabetes at home.

RIGHTEST GT200 Blood Glucose Test Strips:

- Are intended for testing outside the body (*in vitro* diagnostic use for self-testing only).
- Are designed for use only with RIGHTEST GT200 Blood Glucose Monitoring Meter to assure accurate results.

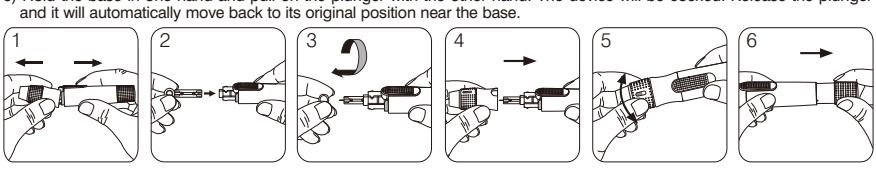
RIGHTEST GT200 Blood Glucose Monitoring System includes meter, test strips, control solutions, lancing device and lancets.

Special conditions for use statement(s): RIGHTEST GT200 Blood Glucose Monitoring System provides plasma equivalent results.

Test Procedure

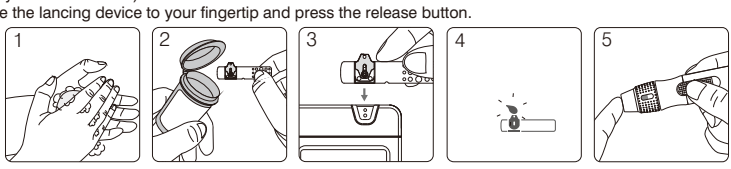
Preparing the Lancing Device

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. Pull the cap and hub off in opposite directions, remove the cap.
2) Insert a new disposable lancet firmly into lancet carrier.
3) Twist off and set aside the protective cover of the disposable lancet.
4) Replace the depth adjustable cap.
5) Choose a depth of penetration by rotating the top portion of the depth adjustable cap until your desired setting is visible in the window. Settings are based on skin type: " ▭ " for soft or thin skin; " ▭ " for average skin; " ▭ " for thick or calloused skin.
6) Hold the base in one hand and pull on the plunger with the other hand. The device will be cocked. Release the plunger and it will automatically move back to its original position near the base.

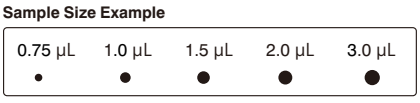


Performing a Test

1) Wash your hands in warm soapy water and dry.
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 sample window facing up. Push the strip in until it clicks and stops. The meter will automatically detect the code number.
4) When the blood drop icon flashes on the display window, blood sample is ready to be applied to the test strip port (apply within 2 minutes).
5) Place the lancing device to your fingertip and press the release button.



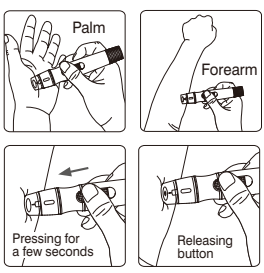
Sample Size Example



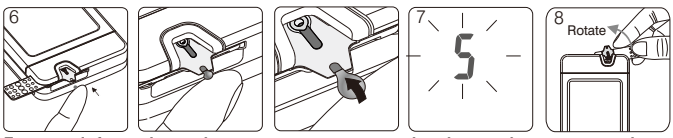
Please use a minimum blood drop size of 0.75 µL to perform the test on glucose monitoring system. Blood drop sizes greater than 3.0 µL are too large and may contaminate the test strip port of the meter.

Alternate site testing: palm or forearm blood sampling

- To perform a test using samples obtained from alternate sites, choose the clear cap and follow the steps above.
- Massage the intended puncture area of your palm or forearm for a few seconds.
- Immediately after massaging the area, press and hold the lancing device with the clear cap against your palm or forearm.
- Press the release button.
- Continue holding the lancing device against your palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient.
  (For more information on how to install the clear cap on the Lancing device, please refer to the Lancing Device instructions)
- DO NOT test on the palm or forearm if you are testing for hypoglycemia (low blood glucose).



6) Touch and hold the drop to the edge of sample port until you hear a " beep " (if volume is turned on) and the sample window is completely filled with blood. If the view window is not completely filled with blood the test will not start. If this is the case, discard the test strip and repeat the test with a new test strip.
7) The countdown mode will begin on the display window. After 5 seconds your test result will appear.
8) Remove the test strip from the meter. Please follow your local regulations to properly discard the used strip.
9) To remove the lancet, pull off the depth adjustable cap of the lancing device. Without touching the used disposable lancet, insert the lancet tip into the protective cover. Hold the release button of the lancing device in one hand and pull on the plunger with the other hand to safely eject the used disposable lancet into an appropriate puncture-proof or biohazard container.



For more information on how to use your meter and understand your test results, see the RIGHTEST GT200 User's Manual.

Test Result

- Blood glucose test results are shown on the meter as mg/dL or mmol/L
- 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 Solutions GC700 to check your meter and test strip. If the test result still remains unusually high or low, contact your Physician or the nearest Emergency Health Care Services 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 insert, contact your Physician or the nearest Emergency Health Care Services immediately
- The RIGHTEST GT200 Blood Glucose Monitoring Meter display results between 10 and 600 mg/dL(0.6-33.3 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 Physician or the nearest Emergency Health Care Services.
- 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 your Physician or the nearest Emergency Health Care Services.

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 test strip vial. Do not use expired test strips.
- Close the test strip vial immediately after taking test strip out from the vial.
- Do not perform a control solution test with expired control solution.
- Do not bend or twist the test strip. A damaged test strip may cause incorrect test results.
- 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 GT200 Blood Glucose Monitoring Meter is exposed to a significant change in temperature, please wait at least 30 minutes before performing a test.
- If you want 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 your Physician immediately.

Limitations

- Blood glucose meter readings may be significantly lower than " true glucose levels " in a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested by the RIGHTEST GT200 Blood Glucose Monitoring System, or if they are, they should be tested with extreme caution.
- Caution is advised when glucose values are 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 regarding the use of the RIGHTEST GT200 Blood Glucose Monitoring System regularly. To accomplish this, it is recommended that blood glucose monitoring results be compared with a concurrently obtained laboratory measurement on the same blood sample. A proven clinical laboratory method employing hexokinase or glucose oxidase should be used as the comparative method.
- Fluoride 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 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 GT200 Test Strips.
- RIGHTEST GT200 Test Strips are designed for use with whole blood samples. Do not use serum or plasma samples.
- Inaccurate test results may be obtained at altitudes greater than 3,048 meters (10,000 feet) above sea level.
- Venous, arterial, and neonatal blood testing is limited to healthcare professional use only.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Do not perform the blood glucose test at temperatures below 6°C (43°F) or above 44°C (111°F), nor below 10% or above 90% relative humidity.

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 - 30°C (39°F - 86°F) and relative humidity below 90%. Do not freeze.
- Replace vial cap immediately and close lid tightly after removing a test strip. If the strip is exposed to the air too long, it will absorb the moisture and cause inaccurate test results.
- When you open a new vial of test strips please write the opening date on the label. Use test strips within 12 months after first opening or until the expiration date printed on the label (whichever comes first).

Quality Control
Please refer to the Quality Control section of the RIGHTEST GT200 Blood Glucose Monitoring System User's Manual.

Troubleshooting and Customer Service
For more information on error messages and troubleshooting, please refer to the Error Messages and Troubleshooting section of the RIGHTEST GT200 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 rightest@bionime.com .

Additional Information for Healthcare Professionals

Detection Principle[2]
The glucose Dehydrogenase 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
Measurement Range
The measurement range of the RIGHTEST GT200 Blood Glucose Monitoring System is 10 to 600 mg/dL (0.6 to 33.3 mmol/L).

Precision
The precision was evaluated with (i) venous whole blood sample (ii) 5 different glucose concentrations in 10 days by 10 meters.

(i) Venous whole blood sample:

Glucose levels	P-01	P-02	P-03	P-04	P-05
(1) Total test numbers	300	300	300	300	300
(2) Mean mg/dL (mmol/L)	42.2 (2.3)	98.2 (5.5)	131.6 (7.3)	233.5 (13.0)	352.6 (19.6)
(3) SD mg/dL (mmol/L)	1.1 (0.06)	1.8 (0.10)	2.8 (0.16)	4.5 (0.25)	5.8 (0.32)
(4) CV	2.6%	1.9%	2.1%	1.9%	1.6%

(ii) Control solution:

Glucose levels	CS-L	CS-N	CS-H
(1) Total test numbers	300	300	300
(2) Mean mg/dL (mmol/L)	57.5 (3.2)	108.4 (6.0)	272.3 (15.1)
(3) SD mg/dL (mmol/L)	1.8 (0.10)	2.5 (0.14)	6.3 (0.35)
(4) CV	3.1%	2.3%	2.3%

Accuracy
The accuracy of RIGHTEST GT200 Blood Glucose Monitoring System was tested by comparing fingertip whole blood (plasma equivalent) glucose values measured by RIGHTEST GT200 with plasma glucose values obtained from a YSI 2300 (Calibrated with NIST 917c) reference instrument.
The result is shown in the tables below.

Table 1: Accuracy basic information

	Fingertip	Palm	Forearm
Test range in mg/dL (mmol/L)	25-599 (1.39-33.28)	26-599 (1.44-33.28)	24-599 (1.33-33.28)
Within ±15mg/dL (0.83 mmol/L) or within ±15 %	624/624 (100.0%)	624/624 (100.0%)	624/624 (100.0%)

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

Capillary samples collected from different testing sites	The percent (and number) of samples for which the variation between the RIGHTEST GT200 Blood Glucose Meter value (Alternate site) and the YSI 2300 value were within the following intervals.		
	Within ± 5 mg/dL (0.28 mmol/L)	Within ± 10 mg/dL (0.56 mmol/L)	Within ± 15 mg/dL (0.83 mmol/L)
Fingertip	150/204 (73.5%)	201/204 (98.5%)	204/204 (100.0%)
Palm	145/204 (71.1%)	200/204 (98.0%)	204/204 (100.0%)
Forearm	140/204 (68.6%)	192/204 (94.1%)	204/204 (100.0%)

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

Capillary samples collected from different testing sites	The percent (and number) of samples for which the difference between the RIGHTEST GT200 Blood Glucose Monitoring Meter value (Alternate site) and the YSI 2300 value were within the following intervals.		
	Within ± 5%	Within ± 10%	Within ± 15%
Fingertip	318/420 (75.7%)	411/420 (97.9%)	420/420(100.0%)
Palm	300/420 (71.4%)	412/420 (98.1%)	420/420(100.0%)
Forearm	296/420 (70.5%)	395/420 (94.0%)	420/420(100.0%)

*Acceptance criteria in ISO 15197 : 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 inpercentage.

Lay User Evaluation
A total of 104 users were enrolled. Each user tested their fingertip blood samples with RIGHTEST GT200 test strip and 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 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 concentration < 100 mg/dL (5.55 mmol/L).

Hematocrit(Hct)
Hematocrit(Hct) should be between 20%-70% when blood glucose ≤ 200 mg/dL (11.1 mmol/L), Hct 20%-60% when blood glucose > 200 mg/dL (11.1 mmol/L). If you do not know your hematocrit , ask your healthcare professional.

Interferences
26 toxic amount tested substances (Acetaminophen, Ascorbic acid, Dopamine, EDTA, Gentisic acid, Heparin, Ibuprofen, L-dopa, Methyldopa, Pralidoxime iodide, Salicylic Acid, Tetracycline, Tolazamide, Tolbutamide, Bilirubin, Cholesterol, Creatinine, Glutathione, Haemoglobin, Triglycerides, Uric acid, Maltose, Xylose, Galactose, Lactose, Icodextrin) in two blood sample concentrations.
Substance and possible level may interfere the glucose measurement:
Ascorbic acid ≧ 5 mg/dL (0.28 mmo/L)
Uric acid ≧ 20 mg/dL (1.19 mmol/L)
Xylose ≧ 20 mg/dL (1.33 mmol/L)

Reagents
Each Blood Glucose Test Strip contains the following reagents:
1. FAD-Glucose dehydrogenase 12.4 %
2. Potassium Ferricyanide 49.6 %
3. Non-reactive Ingredients 38.0 %

References

1) Diabetes Information - American Association for Clinical Chemistry (AACC)〔Electronic Version〕Retrieved Mar. 02, 2018 form 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 | Manufacturer | EC REP EC Representive | LOT Lot number
Expiry date | 4°C 30°C Store between temperature 4°C and 30°C (39°F and 86°F) | Do not reuse
CE 0197 CE-mark (with No. of notified body) | Biological risks | Consult the instruction for use

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