RIGHTEST™ GT333 Blood Glucose Test Strip INSERT

Intended Use

RIGHTEST GT333 Blood Glucose Test Strip is used by individuals with diabetes. It's for checking on glucose levels of whole blood from capillary. Capillary blood can be sampled from the fingertip, palm and forearm and it provides results equivalent to a laboratory instrument (Plasma equivalent). RIGHTEST GT333 Blood Glucose Test Strip aid to diabetes control, could be used by healthcare professionals in clinical setting, also by people to use at home.

RIGHTEST GT333 Blood Glucose Test Strip is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. RIGHTEST GT333 Blood Glucose Test Strip should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

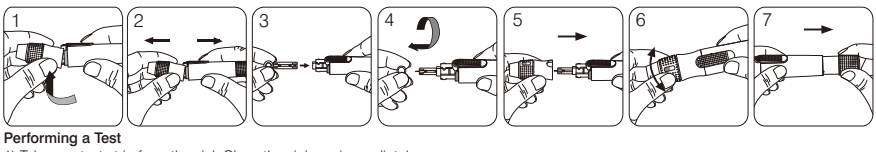
RIGHTEST GT333 Blood Glucose Test strip is designed for use with RIGHTEST GT300 or GT333 Blood Glucose Meter to obtain accurate results.

Test Procedure

Preparing the Lancing Device

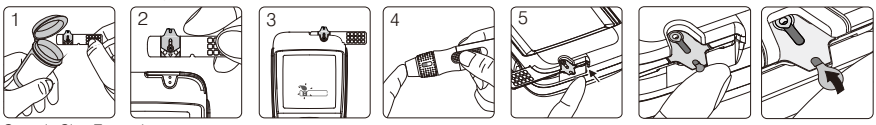
Wash your hands with warm soapy water and dry thoroughly before you start the test.

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) The adjustable cap with 7 depth levels allows you to select the depth of penetration by rotating the cap until the preferable depth display in 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) Take one test strip from the vial. Close the vial cap immediately.
2) 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.
3) 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).
4) Place the lancing device to your fingertip and press the release button.
5) 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.

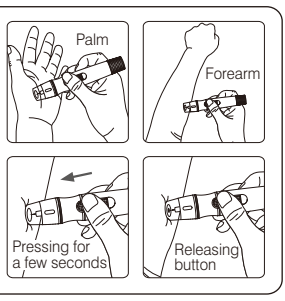


Sample Size Example

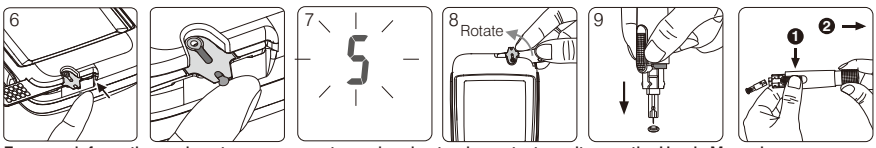
Please use a minimum blood drop size of 0.75 µL to perform the test on glucose monitoring system. Blood drop sizes greater than 3.0 µL are too large and may contaminate the test strip port of the meter.

Alternate site testing: palm or forearm blood sampling

- To perform a test using samples obtained from 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 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 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 Physician or the nearest Emergency Healthcare 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 Healthcare Services immediately.
- RIGHTEST Meter display results between 10 and 600 mg/dL. If your test result is below 10 mg/dL, " 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 Healthcare Services.
- If your test result is above 600 mg/dL, " 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 Healthcare Services.

Expected glucose values without diabetes [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 RIGHTEST Meter and Test Strips is exposed to a significant change in temperature, please wait at least 45 minutes before performing a test.
- If you want to purchase new control solutions, please contact Customer Service.
- Test results may vary if blood samples are taken from different sites or under certain conditions where glucose levels can change rapidly such as: following a drink, a meal, an insulin dose or exercise. In these cases, only the fingertip should be used.
- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device, control solution and test strips.

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.
- Please refer to the cleaning and disinfecting instructions in the User's Manual.

Limitations

- The meter readings of the blood glucose may be significantly lower than " true glucose levels " in a hyperglycemic-hyperosmolar state, with or without ketosis.
- Caution is advised when glucose values in the interpretation of glucose values are below 50 mg/dL or above 250 mg/dL . 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 RIGHTEST 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.
- Hands and fingers contaminated with sugar from foods or beverages may cause falsely elevated results.
- Flouoride should not be used as a preservative when collecting blood glucose samples.
- Storage of strips near bleach as well as bleach containing products will affect the results of RIGHTEST Blood Glucose T est strip.
- Inaccurate test results may be obtained at altitudes greater than 10,000 feet (3,048 meters) above sea level.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Do not perform the blood glucose test at temperatures below 10°C (50°F) or above 40°C (104°F), nor below 10% or above 90% relative humidity.The suggested temperature range for the control solution test is 15 - 40 °C (59 - 104 °F).
- RIGHTEST Blood Glucose Test strip are designed for use with capillary whole blood samples. Do not use serum or plasma samples.

- Not for screening or diagnosis of diabetes mellitus.
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
- Not for neonatal use
- Alternate site testing should not be used to calibrate continuous glucose monitoring systems (CGMs).
- Alternate site testing should only be done during steady-state times (when glucose is not changing rapidly).
- Results from alternate site testing should not be used in insulin dose calculation.

NOTE
- Keep meter free of dust and liquids including water.
- Suggest not to use this meter close to source of strong electromagnetic radiation, to avoid interference with proper operation.

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% - 90% relative humidity.
- Replace vial cap immediately and close cap 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 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 RIGHTEST User's Manual.

You may also contact your local distributor for customer service or or visit our website at www.bionime.com. (Off-work hour you could contact your healthcare professional for help)

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
Data generated using Rightest GT333 Meter, this meter is the representative model of RIGHTEST GT300 and GT333 Meter.

Precision
The precision was evaluated with (i) venous whole blood sample-the blood samples are collected over a span of time not to exceed one day per meter and reagent lot combination. (ii) 3 levels glucose control solutions in period of 10 days, by 10 meters and 3 batches of strips.

(i) venous whole blood sample

Sample	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)	46.4 (2.6)	102.8 (5.7)	123.8 (6.9)	221.1 (12.3)	332.8 (18.5)
(3) SD mg/dL (mmol/L)	1.4 (0.08)	2.0 (0.11)	2.0 (0.11)	3.8 (0.21)	5.7 (0.32)
(4) CV (%)	3.0 %	2.0%	1.6%	1.7%	1.7%

(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)	46.0 (2.6)	118.2 (6.6)	298.5 (16.6)
(3) SD mg/dL (mmol/L)	1.2 (0.07)	1.8 (0.10)	3.8 (0.21)
(4) CV (%)	2.6%	1.5%	1.3%

Accuracy
For the alternate site testing:
The accuracy of Rightest GT333 Blood Glucose Monitoring System was tested by comparing fingertip whole blood (plasma equivalent) glucose values measured by Rightest GT333 Meter 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)	26 - 740	25 - 475	26 - 474
Within ± 15mg/dL (0.83 mmol/L) or within ± 15 %	660 (100.0%)	660 (100.0%)	660 (100.0%)

Table 2: represents samples for glucose results lower than 100 mg/dL.

Difference range: RIGHTEST GT333 Blood Glucose Meter and YSI	The percent (and number) of different sampling sites.		
	Fingertip	Palm	Forearm
Within ± 5 mg/dL	140/198 (70.7%)	133/198 (67.2%)	117/198 (59.1%)
Within ± 10 mg/dL	190/198 (96.0%)	188/198 (94.9%)	181/198 (91.4%)
Within ± 15 mg/dL	198/198 (100.0%)	198/198 (100.0%)	198/198 (100.0%)

Table 3: represents samples for glucose results greater than 100 mg/dL.

Bias range: RIGHTEST GT333 Blood Glucose Meterand YSI	The percent (and number) of different sampling sites.		
	Fingertip	Palm	Forearm
Within ± 5 mg/dL	373/462 (80.7%)	321/462 (69.5%)	310/462 (67.1%)
Within ± 10 mg/dL	459/462 (99.4%)	453/462 (98.1%)	442/462 (95.7%)
Within ± 15 mg/dL	462/462 (100.0%)	458/462 (99.1%)	456/462 (98.7%)

Note: * 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 value are compared in percentage.

Lay User Evaluation
A total of 106 users were enrolled. Each user tested their fingertip blood samples with 3 lots of RIGHTEST GT333 Blood Glucose Test strip and RIGHTEST GT333 Blood Glucose 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 RIGHTEST GT333 BGMS values were within ± 15% of YSI values at glucose concentrations ≧ 100 mg/dL and within ± 15 mg/dL at glucose concentrations < 100 mg/dL.

Hematocrit(Hct)
Hematocrit should be between 20% - 60%. If you do not know your hematocrit, ask your healthcare professional.

Interferences
Substance and possible level may interfere the glucose measurement:
Uric acid ≧ 16 mg/dL (0.95mmol/L),
Glutathione reduced ≧ 70 mg/dL (2.28 mmol/L),
Ascorbic acid (Vitamin C) ≧ 6 mg/dL (0.34 mmol/L)
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, Hemoglobin, Triglycerides, Uric acid, Maltose, Xylose, Galactose, Lactose, Icodextrin) in two blood sample concentrations.

Reagents
Each Blood Glucose Test Strip contains the following reagents:

Glucose Oxidase (Aspergillus niger) (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 Mar. 02,2018 from www.labtestsonline.org/understanding/analytes/glucose/test.html
2) Review of Glucose Oxidases and Glucose Dehydrogenases: A Bird's Eye View of Glucose Sensing Enzymes. J Diabetes Sci Technol 2011 Sep; 5(5): 1068–1076 (2011).

IVD For *in vitro* diagnostic use | For single use only | EC REP EC Representive | Manufacturer
Consult the instruction for use | CE 0197 CE-mark (with No. of notified body) | LOT Lot number
4°C 30°C Store between temperature 4°C and 30°C (39°F and 86°F) | Biological risks | Expiry date

Rev. Date:2019-10

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