

RIGHTEST™ MAX BLOOD GLUCOSE TEST STIRP INSERT

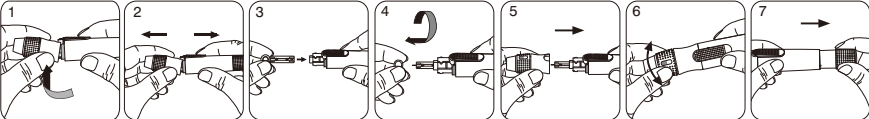
Intended Use

RIGHTEST Max and Max Plus Blood Glucose Monitoring Systems are used by individuals with diabetes. It's for checking on glucose levels in 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. It's as an aid in management of diabetes at home and clinical sites. RIGHTEST Max Blood Glucose Test Strips were designed for self-testing outside the body (*in vitro* diagnostic use). The RIGHTEST Blood Glucose Monitoring System aids to diabetes control, could be used by healthcare professionals in clinical setting, also by people to use at home. The RIGHTEST System tests whole blood samples, and provides results equivalent to plasma results of the laboratory instrument. The RIGHTEST Max Blood Glucose Test Strip is designed for the following meters to obtain accurate results: RIGHTEST Max Blood Glucose Meter RIGHTEST Max Plus Blood Glucose Meter

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. Re-cap the vial cap immediately.
- 2) Insert the test strip into the test strip port of the meter with the indication symbol facing up.
- 3) While the blood drop symbol is flashing, you are ready to apply the blood sample within 2 minutes.
- 4) Place the lancing device against the pad of 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

| | | | | |
|---------|--------|--------|--------|--------|
| 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) You will see the countdown mode on the screen. After 5 seconds, the test result appears.
- 7) Remove the test strip from the meter. Please follow the local regulation and discard the used strip properly.
- 8) 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 RIGHTEST Max Control Solution 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.
- 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 RIGHTEST Meter and Test Strips are exposed to temperature environments out of operating range— below 6°C (43°F) or above 44°C (111°F)— please wait 30 minutes before testing again.
- 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 to compare the meter result with a laboratory result using the same blood sample. A well characterized 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 false elevated results.
- The results of blood glucose measurements are different for measurements with whole blood and plasma.

- Storage of test strips near bleach or bleach containing products will affect the results of the RIGHTEST Max Blood Glucose Test Strips.
- RIGHTEST Max Blood Glucose Test Strips are designed for use with capillary, venous, arterial and neonatal 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.
- 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), 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 to 30°C (39°F to 86°F) and relative humidity below 90%. Do not freeze.
- Close the vial cap immediately and 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.
- 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).

Measurement Range

The measurement range of 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 RIGHTEST Max / Max Plus User's Manual.
If you have any questions or in case of problems with the RIGHTEST products Max / Max Plus, please contact local Bionime distributor or email to rightest@bionime.com.

Additional Information for Healthcare Professionals

Detection Principle⁽²⁾

The FAD-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

Data generated using RIGHTEST Max Plus Blood Glucose Meter. RIGHTEST Max plus Blood Glucose Meter is the representative of the RIGHTEST Max Blood Glucose Meter family (included Max and Max Plus Blood Glucose Meter).

Precision

The precision was evaluated including (i) 5 glucose levels of venous whole blood samples (blood samples were collected with heparin tube and altered for test after 8 hours) (ii) 3 glucose levels of control solution, in period of 10 days, by 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) | 45.3 (2.5) | 94.3 (5.2) | 133.4 (7.4) | 197.6 (11.0) | 296.2 (16.5) |
| (3) SD mg/dL (mmol/L) | 1.7 (0.09) | 1.9 (0.10) | 3.1 (0.17) | 2.8 (0.16) | 4.7 (0.26) |
| (4) CV (%) | 3.8 % | 2.0 % | 2.3 % | 1.4 % | 1.6 % |

(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) | 55.6 (3.1) | 117.4 (6.5) | 267.0 (14.8) |
| (3) SD mg/dL (mmol/L) | 1.5 (0.08) | 2.5 (0.14) | 4.1 (0.23) |
| (4) CV (%) | 2.8 % | 2.2 % | 1.6 % |

Accuracy

The accuracy of the test study of the RIGHTEST Max Plus was demonstrated by comparing whole blood (plasma equivalent) glucose values on RIGHTEST Max Plus with plasma glucose values on a lab instrument.

A total of 105 patients were enrolled. A trained healthcare professional collected blood samples (from the fingertip, palm, forearm and vein) using RIGHTEST Max Plus. Then the blood samples were centrifuged immediately after collection to obtain plasma.

Analyze the plasma by the lab instrument - YSI 2300.

Table 1 : represents samples for glucose concentrations < 100 mg/dL (5.55 mmol/L).

| Difference range in values between the YSI value and the RIGHTEST Max Plus meter value | The percent (and number) of samples of alternative site were the difference between the RIGHTEST Max Plus blood glucose meter and the YSI value within the range shown in the side row. | | | |
|--|---|-------------------|-------------------|-------------------|
| | Fingertip | Palm | Forearm | Venous blood |
| Within± 5 mg/dL (0.28 mmol/L) | 64.2 % (131/204) | 65.7 % (134/204) | 68.1 % (139/204) | 54.3 % (140/258) |
| Within± 10 mg/dL (0.56 mmol/L) | 99.5 % (203/204) | 99.5 % (203/204) | 97.5 % (199/204) | 98.1 % (253/258) |
| Within± 15 mg/dL (0.83 mmol/L) | 100.0 % (204/204) | 100.0 % (204/204) | 100.0 % (204/204) | 100.0 % (258/258) |

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

| Bias range in values between the YSI value and the RIGHTEST Max Plus meter | The percent (and number) of samples of alternative site were the bias between the RIGHTEST Max Plus blood glucose meter and the YSI value within the range shown in the side row. | | | |
|--|---|-------------------|-------------------|-------------------|
| | Fingertip | Palm | Forearm | Venous blood |
| Within ± 5 % | 74.9 % (319/426) | 70.0 % (298/426) | 71.1 % (303/426) | 64.8 % (241/372) |
| Within ± 10 % | 99.5 % (424/426) | 97.7 % (416/426) | 97.7 % (416/426) | 96.8 % (360/372) |
| Within ± 15 % | 100.0 % (426/426) | 100.0 % (426/426) | 100.0 % (426/426) | 100.0 % (372/372) |

* 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 in percentage.

Lay User Evaluation

A total of 105 users were enrolled. Each user tested their fingertip blood samples with 3 lots of Max strip and Max Plus 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 RIGHTEST Max Plus 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 10% to 70%. 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, Methylidopa, 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 mmol/L)

Uric acid ≥ 16 mg/dL (0.95 mmol/L)

Xylose ≥ 16 mg/dL (1.07 mmol/L)

Glutathione ≥ 93 mg/dL (3.03 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 May 08, 2019 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).


 For *in vitro* diagnostic use


 For single use only


 EC Representative


 Manufacturer


 Consult the instruction for use

 CE-mark (with No. of notified body)
0197

 Lot number

 Store between temperature 4°C and 30°C (39°F and 86°F)

 Biological risks

 Expiry date

Rev. Date:2019-05



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