Rightest™ BLOOD GLUCOSE TEST STRIP *GS720* INSERT

Intended Use

The ***Rightest***™ blood glucose monitoring system GM720 is 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™ blood glucose test strips GS720 are intended for testing outside the body in vitro diagnostic use, for self-testing only.

The intended blood sample results of the Rightest GM720 are equivalent to a laboratory instrument.

The ***Rightest***™ blood glucose test strip GS720 is designed for use only with the ***Rightest***™ blood glucose meter GM720 to obtain accurate results.

Test procedure

Please refer to the ***Rightest***™ blood glucose monitoring system GM720 user manual for the test procedure.

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 solutions GC700 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 GM720 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 your 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 the test strip may cause wrong result.
- Do not reuse test strips.
- Do not reuse lancets. Discard used lancets properly.
- If the ***Rightest***™ meters and strips are exposed to a high temperature difference, please wait 30 minutes before measurement.
- If you want to purchase new control solutions, please contact your local 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

- Grossly lipemic (fatty) samples may influence the test results. To be aware of such interferences, patients under the supervision of their physician should have baseline glucose values established by a clinical laboratory method prior to the start of home glucose monitoring. These baseline values should be checked periodically.
- 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.
- 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 strips near bleach as well as bleach containing products will affect the results of the ***Rightest***™ blood glucose test strips GS720.
- ***Rightest***™ blood glucose test strips GS720 are designed for use with capillary and venous 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.
- 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.
- 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

- It is recommended not to use this meter close to source of strong electromagnetic radiation, to avoid interference with proper operation.
- It is recommended 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.
- Replace the vial cap immediately and close tightly after taking test strip out of 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 4 months after first opening or until the expiration date printed on the label (whichever comes first).

Measurement range

The measurement range of the ***Rightest***™ blood glucose monitoring system GM720 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 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***™ GM720 user 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 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

Precision

The precision was evaluated including (i) venous whole blood sample (ii) 3 levels glucose 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)	44.2 (2.5)	98.4 (5.5)	140.0 (7.8)	233.9 (13.0)	360.2 (20.0)
(3) SD mg/dL (mmol/L)	1.2 (0.07)	2.2 (0.12)	2.8 (0.16)	4.3 (0.24)	6.1 (0.34)
(4) CV (%)	2.7 %	2.2 %	2.0 %	1.8 %	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)	63.6 (3.5)	109.6 (6.1)	258.4 (14.4)
(3) SD mg/dL (mmol/L)	1.7 (0.09)	2.7 (0.15)	5.9 (0.33)
(4) CV (%)	2.7 %	2.5 %	2.3 %

Accuracy

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

Analyze the plasma by the lab instrument - Olympus AU400. 100 % of ***Rightest***™ meter were within ± 15 mg/dL (0.83 mmol/L) of the Olympus values at concentrations < 100 mg/dL (5.55 mmol/L) and within ± 15 % at concentrations ≧ 100 mg/dL (5.55 mmol/L). The results and differences between the two methods, ***Rightest***™ System and Olympus AU400 (as the reference method) are proved in the tables below.

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

Difference range in values between the Olympus value and the ***Rightest***™ GM720 meter value	The percent (and number) of samples of alternative site were the difference between the ***Rightest***™ and the Olympus value within the range shown in the side row.			
	Fingertip	Palm	Forearm	Venous blood
Within± 5 mg/dL (0.28 mmol/L)	71.0 % (44/62)	87.1% (54/62)	75.8 % (47/62)	45.9 % (34/74)
Within± 10 mg/dL (0.56 mmol/L)	100 % (62/62)	100 % (62/62)	95.2 % (59/62)	87.8 % (65/74)
Within± 15 mg/dL (0.83 mmol/L)	100 % (62/62)	100 % (62/62)	100 % (62/62)	100 % (40/40)

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

Difference range in values between the Olympus value and the ***Rightest***™ GM720 meter value	The percent (and number) of samples of alternative site were the bias between the ***Rightest***™ and the Olympus value within the range shown in the side row.			
	Fingertip	Palm	Forearm	Venous blood
Within ± 5%	76.4 % (113/148)	81.1 % (120/148)	75.0 % (111/148)	71.3% (97/136)
Within ± 10%	99.3 % (147/148)	98.6 % (146/148)	98.0 % (145/148)	96.3% (131/136)
Within ± 15%	100 % (148/148)	100 % (148/148)	100 % (148/148)	100 % (136/136)

* 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.

Interferences

The following compounds may interfere with the glucose measurement at the concentrations listed: 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 Dec 21, 2015 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	EC REP	EU Representative	LOT	Lot number
CE 0197	CE-mark (with No. of notified body)		For single use only		Manufacturer
	Consult the instruction for use		Biological risks		Use by
4°C 30°C	Store between temperature 4℃and 30℃(39℉and 86 ℉)				

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