prolife

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BLOOD GLUCOSE MONITORING SYSTEM PROLIFE TEST STRIP

Prolife PT200 plus

INSERT

INTENDED USE

Test strips Prolife PT200 plus are used with the Blood Glucose Monitoring System Prolife PM200 / Rightest GM550. It's for checking on glucose levels of whole blood from capillary. Capillary blood can be sampled from the fingertip, palm and forearm.

Test Strips Prolife PT200 plus were designed for self-testing outside the body (in vitro diagnostic use).

The Blood Glucose Monitoring System Prolife PM200 aid to diabetes control, it could be used by healthcare professionals in clinical setting, also by people to use at home.

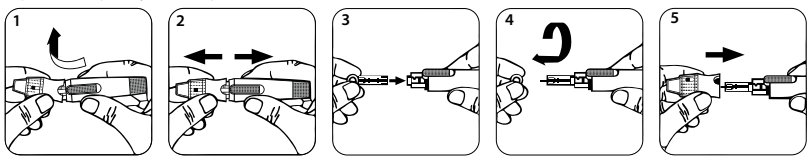
The Blood Glucose Monitoring System **Prolife PM200** tests the capillary blood and provides results equivalent to a laboratory instrument (Plasma equivalent).

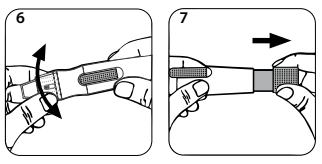
Test Strip is designed for use only with the Blood Glucose Monitoring System **Prolife PM200** to obtain accurate results.

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.

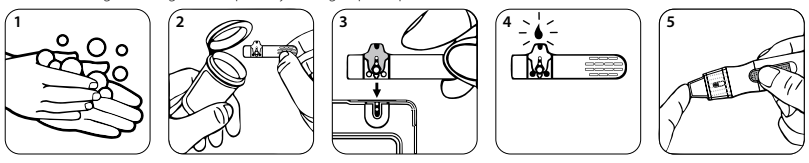




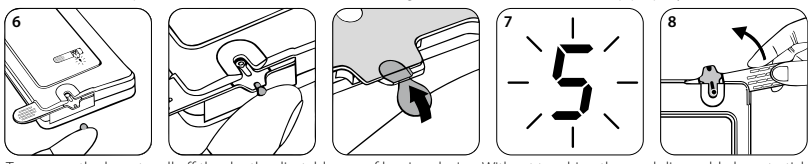
6. Choose a depth of penetration by rotating the top portion of the depth adjustable cap until the setting depth matches the window. Settings are based on skin type for soft or thin skin; for average skin; for thick or calloused skin.
7. Hold the hub in one hand and pull on the plunger in the other hand. 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. Re-cap the vial cap immediately.
3. Insert the strip into the strip port of the meter with the indication symbol facing down.
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.



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 proof or biohazard container.

SAMPLE SIZE EXAMPLE

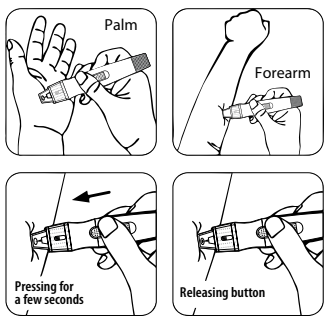
Please take a minimum of 0.75 µL to do the test on glucose monitoring system. Blood sample size above 3.0 µL might contaminate the meter.

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

ALTERNATIVE SITE TESTING-PALM OR FOREARM BLOOD SAMPLING

1. To perform a test using samples oblained 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).
2. To increase the blood flow, massage the puncture area of palm or forearm for a few seconds.
3. Immediately after massaging the puncture area, press and hold the lancing device with the clear cap against palm or forearm.
4. Then press the release button.
5. 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).

   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 or 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. 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 Blood Glucose Monitoring System **Prolife** 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.

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 proof or biohazard container.
- If the Blood Glucose Monitoring System **Prolife PM200** meters and strips are exposed to a high temperature difference, please wait 30 minutes before measurement.

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 Blood Glucose Monitoring System **Prolife PM200** 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 oblained.
- Healthcare professionals should evaluate their technique and their patients' technique at periodic intervals. To accomplish this, it is recommended that Blood Glucose Monitoring System **Prolife PM200** results be compared with a concurrently oblained 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.
- Hands and fingers contaminated with sugar from foods or beverages may cause false elevated results.
- Storage of strips near bleach as well as bleach containing products will affect the results of the Test Strips.
- Test Strips **Prolife PT200 plus** are designed for use with capillary whole blood samples.
- Do not use serum or plasma samples.
- Incorrect test results may be oblained 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.
- Blood Glucose Monitoring System **Prolife PM200** has not been validated for use on neonates. Therefore, it should not be used 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 relative humidity below 90 %. 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.
- When you open a new vial of test strips please write the discard 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 the Blood Glucose Monitoring System **Prolife PM200** 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 Prolife User's Manual.
- If you have any questions or problems with Prolife products, please contact local distributor.

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.

PERFORMANCE CHARACTERISTICS

Precision

The precision was evaluated including **(i)** venous whole blood sample-the blood sample are collected over a span of time not to exceed one day per meter and reagent lot combination. **(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)	46.6 (2.6)	100.7 (5.6)	135.5 (7.5)	224.1 (12.5)	358.9 (19.9)
(3) SD mg/dL (mmol/L)	1.3 (0,07)	2.2 (0.12)	2.9 (0.16)	4.2 (0.23)	4.9 (0.27)
(4) CV (%)	2.7%	2.2%	2.1%	1.9%	1.4%

(ii) Control solution			
Control solution	CS-L	CS-N	CS-H
(1) Total test numbers (n)	300	300	300
(2) Mean mg/dL (mmol/L)	49.6 (2.8)	96.6 (5.4)	259.8 (14.4)
(3) SD mg/dL (mmol/L)	1.4 (0.08)	2.2 (0.12)	5.4 (0.30)
(4) CV (%)	2.9 %	2.3 %	2.1 %

Accuracy

The accuracy of the Blood Glucose Monitoring System **Prolife PM200** was tested by comparing fingertip whole blood (plasma equivalent) glucose values measured by the Blood Glucose Monitoring System **Prolife** with plasma glucose values obtained from a YSI 2300 reference instrument.

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

The results and variations between the two methods, Blood Glucose Monitoring System **Prolife PM200** and YSI 2300 (as the reference method) are shown in the tables below.

Table 1: Represents samples for glucose results < 100 mg/dL (5.55 mmol/L)

Difference range in values between the YSI value and the Blood Glucose Monitoring System **Prolife PM200**	The percent (and number) of samples was the difference between the Blood Glucose Monitoring System **Prolife PM200** and the YSI value within the following intervals		
	Finger	Palm	Forearm
Within±5 mg/dL (0.28 mmol/L)	82.1% (197/240)	79.6% (191/240)	65.0% (156/240)
Within±10 mg/dL (0.56 mmol/L)	100.0% (240/240)	97.1% (233/240)	97.1% (233/240)
Within±15 mg/dL (0.83 mmol/L)	100.0% (240/240)	100.0% (240/240)	100.0% (240/240)

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

Difference range in values between the YSI value and the Blood Glucose Monitoring System **Prolife PM200**	The percent (and number) of samples was the difference between the Blood Glucose Monitoring System **Prolife PM200** and the YSI value within the following intervals		
	Finger	Palm	Forearm
Within ± 5 %	66.9% (265/396)	62.1% (246/396)	56.8% (225/396)
Within ± 10 %	92.4% (366/396)	90.7% (359/396)	85.4% (338/396)
Within ± 15 %	100.0% (396/396)	99.2% (393/396)	97.7% (387/396)

*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 104 users were enrolled. Each user tested their fingertip blood samples with 3 lots of **Prolife strip** and **Prolife meter**. Then the professional collected blood samples were centrifuged immediately after collection to oblain plasma. Analyze the plasma by the lab instrument (YSI 2300 analyzer). 100% of the Blood Glucose Monitoring System **Prolife PM200** 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 toxic amount tested substances: (acetaminophen, ascorbic acid, bilirubin, cholesterol, creatinine, dopamine, EDTA, galactose, gentisic acid, glutathione, haemoglobin, heparin, ibuprofen, icodextrin, L-DOPA, maltose, Methyl-DOPA, pralidoxime iodide, salicylate, tolbutamide, tolazamide, triglycerides, uric acid, xylose, lactose) in two blood sample concentrations.

Substance and possible level may interfere the glucose measurement:

Ascorbic acid	≥6 mg/dL (0,28 mmo/L)
Glutathione reduced	≥70 mg/dL (2,28 mmol/L)
Uric Acid	≥16 mg/dL (0,95 mmol/L)

Reagents:

Each Blood Glucose Test Strip **Prolife PT200 plus** contains the following reagents:

Glucose Oxidase (GOD)	18.8%
Potassium Ferricyanide	37.7%
Non-reactive Ingredients	43.0%

For in vitro diagnostic use	IVD	Manufacturer	
Consult the instruction for use		Lot number	LOT
Store between temperature 4 °C and 30 °C (39°F and 86°F)	30°C 4°C	CE-mark (with No. of notified body)	CE 0197
Do not reuse		EU Representative	EC REP
The expiration date is indicated on the vial		Biological risks	

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