Part no.	312-4216000-XXX
Product name	乳酸/單罐(單片包)試片說明書/GlucoRx X6/EN/GlucoRx/
Spec	L250*W288mm/雜誌紙65P/單面/黑/4折(短邊對一折再長邊對三折)完成尺寸L125*W36mm
Designer	JF
Color	K 100

GlucoRx X6

ver 1.0 2021/08
312-4216000-XXX

Lactate Test Strips

Use only with GlucoRx X6 Multi-Functional Monitoring System.

Warnings

- ► For *in vitro* diagnostic use (outside of the body) only.
- ► For single use only.
- ► Healthcare professionals and other users testing multiple patients with this system should handle everything that comes into contact with human blood carefully to prevent transmitting infectious diseases, including sanitised objects.
- ► Please read this manual and your GlucoRx X6 Multi-Functional Monitoring System Owner's Manual before you begin. Only use GlucoRx X6 Lactate Test Strips with GlucoRx X6 Multi-Functional Monitoring System to obtain accurate results, and be covered by the manufacturer's warranty.
- ► Results may be inaccurate when testing on patients with abnormally low blood pressure, or those who are in shock.
- ► For patients with impaired peripheral circulation, collection of capillary blood from the approved sample sites is not advised as the results may not be a true reflection of the physiological lactate level.
- ► Keep test strips and lancets away from young children. If swallowed, consult a doctor immediately.

Intended Use

GlucoRx X6 Lactate Test Strips, when used together with GlucoRx X6 Multi-Functional Monitoring System, allow you to measure lactate levels by yourself at home or by healthcare professionals. It uses fresh capillary whole blood samples from the fingertips, and from venous whole blood. The system should not be used for diagnosis or screening of diseases. The Multi-Functional Monitoring System uses electrochemical methodologies. Professionals may use test strips to test capillary and venous blood sample immediately; home use is limited to capillary whole blood testing immediately.

Limitations

- ► Haematocrit: The haematocrit level is limited to between 10% and 65%. Please ask your healthcare professional if you do not know your haematocrit level.
- ► *In vitro* paracetamol up to 20 mg/dL, uric acid up to 10 mg/dL and ascorbic acid up to 5.0 mg/dL showed no interference.
- ► Altitude Effects: Altitudes up to 11,500ft (3,500m) do not affect test results.

Storage and Handling

⚠ Do not use the test strips if they have expired.

- ► Test strips expire 3 months after first opening. Write the first opening date on the test strip vial when you first opened it. (For strip vial only)
- ► Store the test strips in a cool, dry place between 2°C and 30°C (35.6°F and 86°F) and between 10% and 85% relative humidity.
- ► Keep the test strips away from direct sunlight. Do not store the test strips in high humidity.
- ► Store the test strips in their original vial ONLY. Do not transfer them to a new vial or any other containers. (For strip vial only)
- ► Do not touch the test strips with wet hands.
- ► Use each test strip immediately after taking it out of the vial or individual foil packet. Close the vial immediately after taking out a strip. (For strip vial only)
- ► Keep the vial closed at all times. (For strip vial only)
- ► Do not bend, cut, or alter the test strip.

Strip Appearance

1. Absorbent Hole
Apply blood sample here. The blood will be automatically absorbed.

2. Confirmation Window
This is where you can confirm if enough blood has been applied to the absorbent hole in the strip.

3. Test Strip Handle
Hold this part to insert the test strip into the slot.

4. Contact Bars
Insert this end of the test strip into your meter. Push it in firmly until it will not go any further.

Calibration

Calibrate the meter every time you begin to use a new box of test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the meter does not match the code printed on your test strip vial label/packet.

Code Chip

1. Insert the code chip with the meter switched off. Wait until a number and "LAC" appears on display.
2. Remove the code chip. The display will show "OFF", and then the meter will automatically switch off.

Checking the Code Number

Make sure that the number and "LAC" displayed on the meter matches the number on your test strip vial label/packet before you proceed. If the numbers match, you can proceed with the test. If they do not match, please stop testing and insert the correct code chip. If the problem persists, contact GlucoRx Customer care for help.

Testing Your Blood Lactate

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING. ALWAYS REFER TO THE OWNER'S MANUAL AND LANCET INSERT ON HOW TO COLLECT A BLOOD SAMPLE.

1. Insert the test strip fully into the slot of your meter until it will not go any further. When the strip is fully inserted, the meter will perform several self-checks.
2. Collect a blood sample with the test strip. Wipe off the first drop of blood with a clean cotton swab if perform a capillary blood sample. Perform a capillary or venous blood test immediately after drawing the sample. Make sure there is a sufficient quantity of blood in order to provide accurate test results. Apply the blood drop to the absorbent hole of the test strip, and wait until the confirmation window is fully filled. The meter will start counting down. **Do NOT** apply a smeared blood sample.
3. After a few seconds, the meter will display your blood lactate level. The last reading will be automatically saved in the meter. The meter will turn off automatically after the test strip is removed.

The used lancet and test strip are potentially biohazardous. Please dispose of them carefully according to your local regulations. Please refer to your Owner's Manual for further information.

Reading Your Result

Your lactate readings deliver plasma equivalent results and are displayed in millimoles of lactate per liter of blood (mmol/L).

Reference values

Lactate*1	0.3 to 2.4 mmol/L

*1: Mary A. Williamson, L. Michael Snyder, 10th ed, 2015. Wallach's interpretation of diagnostic tests : pathways to arriving at a clinical diagnosis. Philadelphia : Wolters Kluwer.

Please consult your doctor to determine a target range that works best for you.

Questionable or inconsistent results

If your test results are unusual or inconsistent with how you are feeling:

- ● Make sure the confirmation window of the test strip is completely filled with blood.
- ● Check the expiry date of the test strips.
- ● Check the performance of your meter and test strip with the control solution.

⚠ If your test results are significantly different from what you expect, or in unusually high or low levels, please repeat the test with a new test strip or contact your healthcare professional.

Expiry Date Reminder

For your convenience, the expiry date reminder will activate and notify you the number of days remaining until the strip's expiry date shown on the vial label or on the packet. The count down begins from 30 days to 1 day, which will be shown at the centre of the display screen. When you see the date reminder, please use the remaining test strips before they expire.

⚠ The error message E-2 will appear in the following situations:

- ● The test strip is expired;
- ● The code chip is expired; or
- ● On the initial set-up, the date has been set incorrectly on the meter.

If the error message E-2 appears, please repeat the test with a new lot of test strip to get your results.

Chemical Components

Lactate oxidase (*Microorganism*) ≥ 0.5 U
Mediator 52%
Enzyme protector 6%
Non-reactive ingredients 32%

Quality Control Testing

Our control solution contains a known amount of lactate that will react with the test strips. If you suspect your meter or test strips are not working properly, you can check the performance of meter, test strip and your technique by comparing the control solution result with the range printed on the test strip packaging. Please refer to the Owner's Manual for step-by-step quality control test instructions.

⚠ The reference range on the control solution may vary with each new test strips. Make sure you check the range on your strip packaging.

Additional Information for Healthcare Professionals

Always wear gloves and follow your local biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only.
Sample Size: 0.8 µL
Reaction Time: 5 seconds
System Measurement Range: 0.3 to 22 mmol/L
Haematocrit Range: 10% to 65%

Accuracy

Accuracy outlines how well the readings from a testing system (meter and test strips) agree with the readings from an internationally accepted reference system (laboratory analyser) and is performed according to an internationally recognised standard. Prepared samples were tested on this meter and compared to the readings from the Cobas C311 analyser.

Lactate	n = 480	
	Capillary samples	Range, mean
Regression	y = 0.9781x + 0.0522 R² = 0.9858	Range: 0.8 to 18.2 (mmol/L) Mean: 2.6 (mmol/L)

Lactate	n = 480	
	Venous samples	Range, mean
Regression	y = 0.9674x + 0.0623 R² = 0.9915	Range: 0.8 to 19.0 (mmol/L) Mean: 2.2 (mmol/L)

User performance

Lactate	n = 160	
	Capillary samples	Range, mean
Regression	y = 0.9757x + 0.0412 R² = 0.9619	Range: 0.6 to 15.4 (mmol/L) Mean: 2.7 (mmol/L)

Precision

Lactate	Concentration		
	1.8 mmol/L	8.5 mmol/L	18 mmol/L
Mean	1.8	8.5	18.1
SD	0.056	0.245	0.515
CV (%)	3.19	2.89	2.85

Symbol Information

Symbol	Referent
IVD	*In vitro* diagnostic medical device
	Consult instructions for use
	Temperature limit
	Use-by date
LOT	Batch code
	Caution
REF	Catalogue number

Symbol	Referent
	Manufacturer
EC REP	Authorised representative in the European Community
	Do not re-use
CE 0123	CE mark
	Humidity limitation
RoHS	RoHS Compliance

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CE 0123 IVD 10% 85% 2°C 30°C REF TD-4663 For self-testing.