

# Original GlucoRx Test Strips

TD-4230

## Warnings

- For in-vitro diagnostic use (external use only).
- For single use only.
- Healthcare professionals and other users testing multiple patients with this system, please handle everything that has contact with human blood carefully to prevent transmitting infectious diseases, including sanitised objects.
- Please review this instruction sheet and the GlucoRx TD-4230 Blood Glucose Monitoring System Owner's Manual before you use GlucoRx Test Strips. For reliable results and to maintain the manufacturer's complete service, support, and warranty, use GlucoRx Test Strips only.
- Severely hypotensive individuals, patients in shock and individuals in a hyperglycaemic-hyperosmolar state, with or without ketosis, may experience inaccurate results. Critically ill patients should not be tested with blood glucose meters.
- Discard the used test strips and lancets according to your local regulation.
- Keep test strips and lancets away from small children. If swallowed, promptly see a doctor for help.

## Intended Use

The GlucoRx Test Strips, in combination with GlucoRx TD-4230 Blood Glucose Monitoring System are intended for the quantitative measurement of blood glucose in fresh capillary whole blood from the finger and the following alternative sites: palm, forearm, upper arm, calf and thigh. They are intended for use by healthcare professionals and people with diabetes mellitus at home. **They are not intended for the detection or diagnosis of diabetes mellitus, and should not be used on newborns.**

## Purpose of Use

Routine blood glucose (sugar) testing can provide you and your doctor with information on how your treatment programme affects your blood glucose level. Testing blood glucose regularly can help keep your diabetes under control too. As with any other health regimen, discuss your blood glucose management with your qualified medical professional.

## Storage and Handling

**IMPORTANT:** Do not use the test strips after the expiry date or results will be inaccurate.

- Test strips expire 3 months after opening. Write the opening date on the test strip vial immediately after opening.
- Store the test strips in a cool dry place between 4°C and 40°C (39.2°F and 104°F). Do not freeze.
- Use the test strips in an environment between 10°C and 40°C (50°F and 104°F), with less than 85% humidity.
- Keep the test strips away from direct sunlight.
- Test strips must be stored in their original vial ONLY. Do not transfer them to a new vial or other container.
- Do not touch the test strips with wet hands.
- Use each strip promptly after taking it out from the vial. Quickly close the vial lid after taking out a new strip.
- Keep the vial lid closed at all other times.
- Do not bend, cut or alter the test strip; doing so will lead to inaccurate results.

## About Alternative Site Testing (AST)

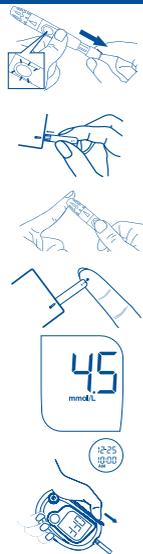
**IMPORTANT:** There are limitations for doing AST. Please read the GlucoRx TD-4230 Blood Glucose Monitoring System Owner's Manual and consult your healthcare professional before you begin AST.

Alternative site testing (AST) refers to when individuals check their blood glucose levels using areas of the body other than the fingertip. GlucoRx Test Strips allow AST at palm, forearm, upper arm, calf or thigh with results as reliable as those obtained from fingertip testing. We strongly recommend that you do AST ONLY in the following intervals:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.
- To obtain a blood sample from the alternative sites, please rub the puncture site for approximately 20 seconds before following the penetration procedures in the GlucoRx TD-4230 Blood Glucose Meter Owner's Manual.

## Testing your blood glucose

WASH AND DRY YOUR HANDS BEFORE ALL NEXT STEPS.



STEP1 Set the lancing device according to the GlucoRx TD-4230 Blood Glucose Monitoring System Owner's Manual.

STEP2 Fully insert the test strip into the meter with the contact bars end first. The meter turns on automatically and finally displays the blood drop symbol.

STEP3 Select the puncture site. Hold the lancing device firmly against the puncture site. Press the release button.

STEP4 Gently squeeze the punctured area so that a drop of blood forms. Do not squeeze excessively.

STEP5 Apply the blood drop to the absorbent hole of the test strip until blood has completely filled the confirmation window. It requires at least 0.7 microliters blood for a glucose test.

STEP6 The meter will count down and then displays a result. The reading will be automatically stored in the meter memory.

STEP7 Shut the meter off by ejecting the strip. Discard the used strip.

Please read the GlucoRx TD-4230 Blood Glucose Monitoring System Owner's Manual for more detailed testing procedures and information on AST.

**Note: The used lancet and the used test strip are potentially biohazardous. Please discard them carefully according to your healthcare provider's instructions.**

## Reading Your Result

Your blood glucose readings deliver whole blood equivalent results and in millimole of glucose per liter of blood mmol/L (mg/dL). The meter is able to display test results from 1.1 to 33.3 mmol/L (20 to 600 mg/dL).

If your result is below 1.1 mmol/L (20mg/dL), the meter will read "Lo". This indicates very low blood glucose levels or severe hypoglycaemia. Repeat your test with a new strip. If these results are similar, contact your healthcare professional immediately.

If your results are above 33.3 mmol/L (60mg/dL), the meter will read "Hi". This indicates very high blood glucose levels or severe hyperglycaemia. Repeat your test with a new strip. If these results are similar, contact your healthcare professional immediately.

## Reference values

|   | Time of day                       |                                     |
|---|-----------------------------------|-------------------------------------|
|   | Fasting and before meals          | 2 hours after meals                 |
| Plasma glucose range mmol/L (mg/dL) for people without diabetes | 3.5-5.5 mmol/L (63.3 - 100 mg/dL) | Less than 8 mmol/L (145.45 mg/dL)   |
| Children with Type 1 diabetes (NICE 2004)                       | 4-8 mmol/L (72.72-145.45 mg/dL)   | Less than 10 mmol/L (181.81 mg/dL)  |
| Adults with Type 1 diabetes (NICE 2004)                         | 4-7 mmol/L (72.72-127.27 mg/dL)   | Less than 9 mmol/L (163.63 mg/dL)   |
| Type 2 diabetes (NICE 2008)                                     | 4-7 mmol/L (72.72-127.27 mg/dL)   | Less than 8.5 mmol/L (154.54 mg/dL) |

\* Diabetes UK's reference: [http://www.diabetes.org.uk/Guide-to-diabetes/Treatment\\_your\\_health/Monitoring/Blood\\_glucose/Blood-glucose-target-ranges/](http://www.diabetes.org.uk/Guide-to-diabetes/Treatment_your_health/Monitoring/Blood_glucose/Blood-glucose-target-ranges/)  
Please work with your doctor to determine a target range of blood glucose values that meets your specific needs.

## Questionable or Inconsistent Results

- If you are receiving test results that are unusual or inconsistent with how you are feeling:
- Make sure that the drop of blood completely fills the test area of the test strip.
- Make sure that the test strips have not expired.
- Check the performance of the meter and test strips using the control solution. Consistently high or low blood glucose levels may indicate a serious medical condition. If your results continue to be unusually high or low, consult your healthcare professional.

## Quality Control Testing

TaiDoc control solutions contain a known amount of glucose that reacts with test strips. By comparing your control solution test results with the expected range printed on the test strip vial label, you can ensure that the meter and the test strips are working together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure your results are correct. Read the GlucoRx TD-4230 Blood Glucose Monitoring system Owner's Manual for complete testing details.

**IMPORTANT:** The control range may vary with each new vial of test strips. Always use the control range on the label of your current vial of test strips.

## For Use With The GlucoRx TD-4230 Only.

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## When to perform a quality control test

- When you first get your Glucose Meter.
- When you begin using a new vial of test strips.
- At least once a week.
- Whenever you suspect that the meter or test strips are not working properly.
- When your blood glucose test results are inconsistent with how you feel, or when you think your results are inaccurate.
- When your test strips are exposed to extreme environmental conditions (See Storage and Handling section of this package insert).
- When you want to practice running the test.
- If you drop the meter.

## If the Quality Control test result falls outside the specified range

- Checking Testing with TaiDoc Control Solution Section of the TD-4230 Blood Glucose Monitoring System Owner's Manual to confirm your procedure and techniques.
- Repeat the quality control test.
- Check the expiration date of your test strips and control solutions.
- Check your meter for damage (dropping the meter, immersing in liquid).

**If the problem persists, contact your customer service line for further assistance.**

## Test Principle

GlucoRx Test Strips provide a quantitative measurement of glucose in whole blood. When the absorbent hole is filled by blood sample, the blood glucose and chemical components in the strip react together to generate an electrical current. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

## Chemical components in sensor

- Glucose oxidase (A. Niger).....10%
- Electron shuttle..... 50%
- Enzyme protector..... 8%
- Non-reactive ingredients.....32%

## Limitations

- Hematocrit Effect: The hematocrit level is limited between 20% and 60%. Please consult your healthcare professional if you do not know your hematocrit level.
- Neonatal Use: The test strips should not be used on newborns.
- This test strips are used for testing fresh capillary whole blood.
- Uric acid, ascorbic acid, and acetaminophen at normal blood concentration do not significantly affect blood glucose test results.
- Lipemic Effects: Elevated blood triglycerides up to 22.8 mmol/L (2000 mg/dL) may slightly affect the results.
- Altitude Effects: Test strips are accurate at altitudes up to 10,724 feet (3,275m).

## Performance characteristics

### Accuracy

Within 0.83 mmol/L ( $\pm 15$  mg/dL) at glucose concentration < 4.2 mmol/L (75 mg/dL) and within  $\pm 20\%$  at glucose concentration  $\geq 4.2$  mmol/L (75 mg/dL).

### Precision

CVs (%) of intermediate precision and repeatability are less than 5%. The product has been tested to meet the requirements of ISO 15197.

## Symbol Information

| Symbol | Referent                         | Symbol | Referent  |
|--------|----------------------------------|--------|---|
|        | For in vitro diagnostic use only |        | Manufacturer  |
|        | Do not reuse                     |        | Serial number                                       |
|        | Read instructions before use     |        | Caution, consult accompanying documents             |
|        | Keep away from sunlight          |        | Authorised representative in the European Community |
|        | Keep dry                         |        | Do not use if package is damaged                    |
|        | Temperature limitation           |        | Use within 3 months after opening                   |
|        | Use by                           |        | CE mark   |
|        | Batch code                       |        |   |

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