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|--------------|-------------------------------------|
| Part no. | 312-0000001-XXX |
| Product name | 雙罐試片說明書/GlucoRx HCT family/英文(DiME) |
| Spec | L250*W288mm/3折/雜誌紙65P/單面/黑 |
| Designer | Emily |
| Color | ■ K100 ■ K15 |

Glucorx HCT Glucose Test Strips

Warnings

- ▶ For **in vitro** diagnostic use (for use outside of the body only).
- ▶ For single use only.
- ▶ Please read this sheet and your Blood Glucose Monitoring System Owner's Manual before you use this test strip. Use only Glucorx HCT Glucose Test Strips with Glucorx HCT and Glucorx HCT Connect Blood Glucose Monitoring Systems 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 blood glucose level. It may apply under the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to stress hyperglycaemia, hyperosmolar non-ketotic coma, shock, decompensated heart failure NYHA Class IV or peripheral arterial occlusive disease.
- ▶ Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.

Intended Use

Glucorx HCT Glucose test strips, when used together with Glucorx HCT and Glucorx HCT Connect Blood Glucose Monitoring Systems, allow your blood glucose with HCT (Haematocrit) level to be measured by yourself at home for single use. It uses fresh capillary whole blood samples from the fingertips, and from venous whole blood. This system is not intended for use in the diagnosis or screening of diabetes mellitus. The test for Haematocrit(HCT), as part of the system, is intended for use in the in vitro quantification of packed red blood cell volume fraction in capillary whole blood as an aid in monitoring the status of total volume of red blood cells. The test reading of haematocrit(HCT) is used only to determine whether the blood test sample is within the acceptable range of blood glucose system. It should not be used for the diagnosis of anaemia or erythrocytosis.

Limitations

- ▶ Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- ▶ Haematocrit: The haematocrit level is limited to between 0% and 70%. Please ask your healthcare professional if you do not know your haematocrit level.
- ▶ Metabolites: Dopamine, L-Dopa, methyldopa, uric acid, ascorbic acid, and acetaminophen at normal blood concentration do not significantly affect blood glucose test results.
- ▶ There is no significant interference in the presence of galactose, maltose, or fructose observed in blood glucose tests.
- ▶ Lipemic Effects: Blood triglycerides up to 33.9 mmol/L do not affect the results significantly, but may affect results at higher levels.
- ▶ Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.
- ▶ Use only heparin for anticoagulation of whole blood.

The following compounds, when determined to be in excess of their limitation and tested with the Glucorx HCT and Glucorx HCT Connect Blood Glucose Monitoring Systems, may produce elevated glucose results:

Summary of substances and concentrations in excess of limitation with interference

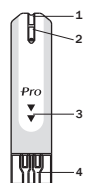
| Substance | Limiting Concentration (mmol/L) | Therapeutic / Physiologic Concentration Range (or Upper Limit) (mmol/L) |
|-----------------------------|---------------------------------|---|
| Acetaminophen (Paracetamol) | > 0.41 | 0.03 – 0.20 |
| Ascorbic Acid | > 0.28 | 0.11 |
| Pralidoxime Iodide | > 0.19 | ~ 0.38 (i.v. Dose 500 mg) |
| Uric Acid | > 0.53 | 0.11 – 0.42 |

Storage and Handling

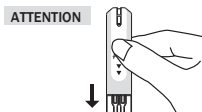
IMPORTANT: Do not use the test strips if they have expired.

- ▶ Test strips expire 6 months after first opening. Write the first opening date on the test strip vial when you first opened it.
- ▶ Store the test strips in a cool, dry place between 2°C and 30°C (35.6°F and 86°F) and below 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.
- ▶ Do not touch the test strips with wet hands.
- ▶ Use each test strip immediately after taking it out of the vial. Close the vial immediately after taking out a strip.
- ▶ Keep the vial closed at all times.
- ▶ Do not bend, cut, or alter the test strip.

Strip Appearance



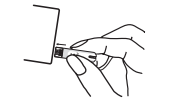
- 1. Absorbent Hole**
Apply a drop of blood here. The blood will automatically be absorbed.
- 2. Confirmation Window**
This is where you confirm if enough blood has been drawn into the absorbent hole of the strip.
- 3. Test Strip Handle**
Hold this part to insert the test strip into the slot.
- 4. Contact Bars**
Insert this end of the test strip into your meter. Push it in firmly until it will go no further.



The front side of the test strip should face up when inserting the test strip. Test results may be wrong if the contact bar is not **fully** inserted into the test slot.

Testing Your Blood Glucose with HCT level

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.



STEP 1

Insert the test strip fully into the slot of your meter until it will go no further. When the strip is fully inserted, the meter will do several self-checks.



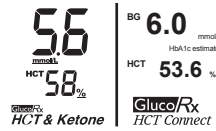
STEP 2

Collect a blood sample for about 1.0 µL with the test strip. A sufficient quantity of blood is required for the test to provide accurate results. Touch the blood drop with the absorbent hole of the test strip, and wait until the confirmation window is fully covered. **Do NOT** apply a smeared blood sample. The meter will start counting down.



STEP 3

Within 5 seconds, the meter will display your blood glucose test result with HCT level. The last reading will be automatically saved in the meter. Turn it off by removal and disposal of the used test strip.



Please refer to your Owner's Manual for further information.

The used lancet and test strip are potentially biohazardous. Please dispose of them carefully according to your local regulations.

Reading Your Result

Your blood glucose readings deliver plasma equivalent results and are displayed in millimoles of glucose per litre of blood (mmol/L). The measurement range of this meter is 0.5 to 38.9 mmol/L.

Reference values

| Time of day | Normal blood glucose range for people with diabetes (mmol/L) |
|-------------------------|--|
| Fasting and before meal | 4 to 7 mmol/L |
| 2 hours after meals | < 9 mmol/L |

Source: Diabetes UK. Blood glucose target. Balance: No.234, 2010 April. P.69

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 your test strip is completely filled with blood.
 - Check the expiration date of your test strips.
 - Check the performance of your meter and test strip with the control solution.

PLEASE NOTE: Unusually high or low blood glucose levels may be symptoms of a serious medical condition. If most of your results are unusually high or low, please contact your healthcare professional.

Quality Control Testing

Our control solution contains a known amount of glucose that can react with test strips. You can check the performance of the meter, test strip and your technique by comparing the control solution results with the range printed on the label of test strip vial. Checking regularly can ensure your test results are accurate. Please refer to your Owner's Manual for complete testing instructions.

IMPORTANT: The reference range of your control solution may vary with each new vial of test strips. Make sure you check the range on the label of your current vial.

Chemical Components

- > Glucose dehydrogenase (*E. coli*) 8%
- > Electron shuttle 55%
- > Enzyme protector 8%
- > Non-reactive ingredients 29%

Additional Information for Healthcare Professionals

Always wear gloves and follow your facility's biohazard control policy and procedures when performing tests involving patient blood samples. Use fresh whole blood samples only. Professionals may use test strips to test capillary and venous blood sample.

Sample Size: 1.0 µL

Reaction Time: 5 seconds

System Measurement Range: 0.5 to 38.9 mmol/L

Haematocrit Range: 0% to 70%

Accuracy

Diabetes experts have suggested that blood glucose meters should be within ±0.83 mmol/L of the reference method when the glucose concentration is lower than 5.55 mmol/L, and be within ±15% of the reference method when the glucose concentration is 5.55 mmol/L or higher. The tables below display how often Glucorx HCT and Glucorx HCT Connect Blood Glucose Monitoring Systems (TD-4279 and TD-4140) achieve this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well Glucorx HCT and Glucorx HCT Connect Blood Glucose Monitoring Systems (TD-4279 and TD-4140) performed compared to YSI-2300 reference method results.

TD-4279

Table 1 Accuracy results for glucose concentration < 5.55 mmol/L

| Within ±0.28 mmol/L | Within ±0.55 mmol/L | Within ± 0.83 mmol/L * |
|---------------------|---------------------|------------------------|
| 79.3% (257/324) | 98.8% (320/324) | 100% (324/324) |

Table 2 Accuracy results for glucose concentration ≥ 5.55 mmol/L

| Within ±5 % | Within ±10 % | Within ±15 %* |
|-----------------|-----------------|----------------|
| 66.2% (421/636) | 95.9% (610/636) | 100% (636/636) |

Table 3 Accuracy results for glucose concentrations between 1.79 mmol/L to 42.83 mmol/L

| Within ±0.83 mmol/L or ±15 % |
|------------------------------|
| 100% (960/960) |

TD-4140

Table 1 Accuracy results for glucose concentration < 5.55 mmol/L

| Within ±0.28 mmol/L | Within ±0.55 mmol/L | Within ± 0.83 mmol/L * |
|---------------------|---------------------|------------------------|
| 61.0% (183/300) | 91.0% (273/300) | 99.3% (298/300) |

Table 2 Accuracy results for glucose concentration ≥ 5.55 mmol/L

| Within ±5 % | Within ±10 % | Within ±15 %* |
|-----------------|-----------------|-----------------|
| 60.5% (399/660) | 88.8% (586/660) | 99.1% (654/660) |

Table 3 Accuracy results for glucose concentrations between 2.22 mmol/L to 30.33 mmol/L

| Within ±0.83 mmol/L or ±15 % |
|------------------------------|
| 99.2% (952/960) |

*Acceptance criteria in EN ISO 15197:2015, 95% of all differences in glucose values (i.e., YSI-2300 reference values minus Glucorx HCT and Glucorx HCT Connect's glucose values) should be within ±0.83 mmol/L for glucose concentration < 5.55 mmol/L, and within ±15% for glucose concentration ≥ 5.55 mmol/L.

Note: When Glucorx HCT Glucose Test strip results are compared to the reference values, difference values below 5.55 mmol/L are expressed in mmol/L, while those above 5.55 mmol/L are in percent.

Consensus Error Grid (CEG)

The analysis of the Consensus Error Grid showed 100% of test results were within zone A and zone B compared to the Yellow Spring 2300 reference method. (100% of test results were within zone A, while 0% was within zone B, with no results in zones C, D, or E).

Figure 1-2 Error grid analysis of the Consensus Error Grid (mmol/L)

Figure 1 TD-4279

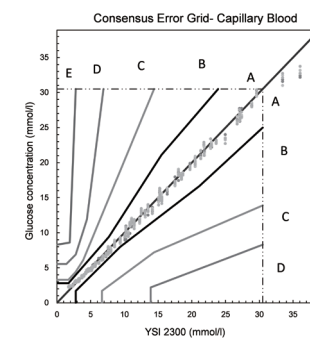


Figure 2 TD-4140

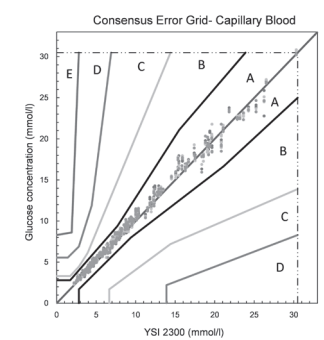


Table 1 Definitions of the Error Grid Zones (CEG)

| Risk level (CEG zone) | Percentage | Risk to diabetic patient |
|-----------------------|------------|--|
| 100% | A | No effect on clinical action. |
| 0% | B | Altered clinical action – little or no effect on clinical outcome. |
| 0% | C | Altered clinical action – likely to affect clinical outcome. |
| 0% | D | Altered clinical action – could have significant medical risk. |
| 0% | E | Altered clinical action – could have dangerous consequences. |

User performance

TD-4279

A study evaluating glucose values from fingertip capillary blood samples obtained by 153 lay persons showed the following results:
100% within ±0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 99.1% within ±15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

TD-4140

A study evaluating glucose values from fingertip capillary blood samples obtained by 155 lay persons showed the following results:
100% within ±0.83 mmol/L of the medical laboratory values at glucose concentrations below 5.55 mmol/L, and 99.5% within ±15% of the medical laboratory values at glucose concentrations at or above 5.55 mmol/L.

Precision

The CV (%) is less than 5% both in intermediate precision and repeatability precision.

Symbol Information

| Symbol | Referent | Symbol | Referent |
|--------|------------------------------------|--------|---|
| | in vitro diagnostic medical device | | Manufacturer |
| | Consult instructions for use | | Do not reuse |
| | Temperature limitation | | Authorised representative in the European Community |
| | Use by | | Batch code |
| | CE mark | | Humidity limitation |

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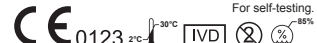
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EC REP MedNet GmbH

Borkstraße 10, 48163, Münster, Germany

Use Only With Glucorx HCT and Glucorx HCT Connect Blood Glucose Monitoring Systems



For self-testing.