

GlucoRx HCT Ketone 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 GlucoRx HCT, GlucoRx HCT Connect and GlucoRx HCT Connect i Blood Glucose & Ketone Monitoring System Owner's Manual before you use this test strip. Use only GlucoRx HCT Ketone Test Strip with GlucoRx HCT, GlucoRx HCT Connect and GlucoRx HCT Connect i Blood Glucose & Ketone 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 β -Ketone 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 Ketone Test Strip is intended for the quantitative measurement of β -Ketone in venous whole blood and fresh capillary whole blood from a fingertip. Testing is done outside the body (in vitro diagnostic use). They are indicated for use at home for single use or for healthcare professional use as an aid to monitor the effectiveness of diabetes control. GlucoRx HCT, GlucoRx HCT Connect and GlucoRx HCT Connect i Blood Glucose & Ketone Monitoring Systems are designed for home use.

Limitations

- ▶ Haematocrit: The haematocrit level is limited to between 10% and 70%. Please ask your healthcare professional if you do not know your haematocrit level.
- ▶ Neonatal Use: **This test strip must not be used for the testing of newborns.**
- ▶ Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.

The following conditions, when determined to be in excess of their limitation and tested with the GlucoRx HCT, GlucoRx HCT Connect and GlucoRx HCT Connect i Blood Glucose & Ketone Monitoring Systems, may produce elevated β -Ketone results:

Summary of substances and concentrations in excess of limitation with interference

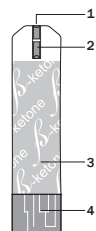
Substance	Limiting Concentration ($\mu\text{mol/L}$ or mmol/L)
Captopril	> 23 $\mu\text{mol/L}$
L-DOPA	> 30 $\mu\text{mol/L}$
Dopamine	> 5.8 $\mu\text{mol/L}$
Gentisic acid	> 117 $\mu\text{mol/L}$
Paracetamol	> 1.7 mmol/L
Uric acid	> 1.4 mmol/L
Ascorbic acid	> 227 $\mu\text{mol/L}$
Unconjugated bilirubin	> 342 $\mu\text{mol/L}$
Cholesterol	> 12.9 mmol/L
Triglycerides	> 17 mmol/L

Storage and Handling

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

- ▶ 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.
- ▶ Do not touch the test strips with wet hands.
- ▶ Do not bend, cut, or alter the test strip.
- ▶ Use each test strip immediately after taking it out of the vial. Close the vial immediately after taking out a strip.

Strip Appearance



- 1. Absorbent Hole**
Apply a drop of blood here.
The blood will be automatically absorbed.
- 2. Confirmation Window**
This is where you 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 go no further.

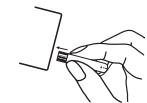
ATTENTION



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.

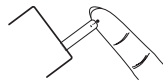
Testing Your β -Ketone

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 10 seconds, the meter will display your β -Ketone 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

The β -Ketone readings deliver plasma equivalent results and are displayed in millimoles of ketone per liter of blood (mmol/L).

The β -Ketone test measures Beta-Hydroxybutyrate (β -OHB), the most important of the three β -Ketone bodies in the blood. Normally, levels of β -OHB are expected to be less than 0.6 mmol/L . β -OHB levels may increase if a person fasts, exercises vigorously or has diabetes and becomes ill. If your β -Ketone result is "Lo", repeat the β -Ketone test with new test strips. If the same message appears again or the result does not reflect how you feel, contact your healthcare professional. Follow your healthcare professional's advice before you make any changes to your diabetes medication programme. If your β -Ketone result is between 0.6 and 1.5 mmol/L , this may indicate development of a problem that could require medical assistance. Follow your healthcare professional's instructions. If your β -Ketone result is higher than 1.5 mmol/L , contact your healthcare professional promptly for assistance. You may be at risk of developing diabetic ketoacidosis (DKA).

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 ketone control key.

PLEASE NOTE: Unusually high β -Ketone levels may be symptoms of a serious medical condition. If most of your results are unusually high, please contact your healthcare professional.

Quality Control Testing

You can check the performance of the meter, test strip and your technique by comparing the control test results with the range printed on your ketone strip foil packet using the ketone control key. Checking regularly can ensure your test results are accurate.

Please follow the instructions step by step for β -ketone Control Test.

For GlucoRx HCT (TD-4279)

1. Insert Ketone Control Key

Insert the ketone control key into your meter. The meter displays the following in sequence: CH and then " " and a flash " ".

2. Turn on the switch on the front side of the ketone control key.

3. Read and compare the result

After counting down to 0, the ketone control result will appear on the display. Compare this result with the range printed on your individual ketone strip foil packet and it should fall within this range. If not, please read the instructions again and repeat the control test. Make sure you turn off the switch on the front side of the ketone control key after removing it from your meter.

For GlucoRx HCT Connect / GlucoRx HCT Connect i (TD-4140/B)

1. Insert Ketone Control Key

Insert the ketone control key into your device. A "Waiting Optimization" message will then appear on the screen.

2. Turn on the switch on the front side of the ketone control key.

Turn on the switch on the front side of the ketone control key after the message of "take blood samples" appears on the screen; the "processing" message will appear on your Smart phone screen. Your device will tag this measurement as QC test automatically.

3. Read and Compare the Result

After the "Processing" message appears, the ketone control result will appear on the display. Compare this result with the range printed on your individual ketone strip foil packet and it should fall within this range. If not, please read the instructions again and repeat the control test. Make sure you turn off the switch on the front side of the ketone control key after removing it from your device.

Chemical Components

- > β -Hydroxybutyrate Dehydrogenase (*Pseudomonas sp.*) ≥ 0.5 U
- > Mediator 55%
- > NAD ≥ 0.5 μg
- > 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 capillary whole blood samples only. Professionals may use test strips to test capillary and venous whole blood.

Sample Size: 1.0 μL

Reaction Time: 10 seconds

System Measurement Range: 0.1 mmol/L ~ 8 mmol/L

Haematocrit Range: 10% to 70%

Accuracy

Accuracy testing shows that results are comparable between trained professionals and lay users. Accuracy was assessed with 111 patients (each patient was tested three times which had 333 test results) for GlucoRx HCT (TD-4279) and 120 patients (each patient was tested three times which had 360 test results) for GlucoRx HCT Connect / GlucoRx HCT Connect i (TD-4140/B) respectively by comparing whole blood β -OHB results with plasma results obtained using reference laboratory instruments. Please see Table 1 for GlucoRx HCT, GlucoRx HCT Connect and GlucoRx HCT Connect i Blood Glucose & Ketone Monitoring Systems (TD-4279 and TD-4140/B).

The reference method is B-Hydroxybutyrate LiquiColor[®]. The reagent can quantifiably detect the presence of ketones in patients with suspected diabetic ketoacidosis. The results show high correlation in Table 1 for GlucoRx HCT, GlucoRx HCT Connect and GlucoRx HCT Connect i Blood Glucose & Ketone Monitoring Systems (TD-4279 and TD-4140/B).

Precision

Precision testing shows that the CV% is 3.06% for GlucoRx HCT (TD-4279) and 3.12% for GlucoRx HCT Connect / GlucoRx HCT Connect i (TD-4140/B) - Please see Table 2

TD-4279

Table 1-Accuracy						
Test meter with ketone strips	Test results of the test device fulfilling specified error limits at ketone value < 2 mmol/L			Test results of the test device fulfilling specified error limits at ketone value ≥ 2 mmol/L		
	Within \pm			Within \pm		
	n	$\pm 0.3\text{mmol/L}$	$\pm 0.5\text{mmol/L}$	n	15%	20%
Capillary blood sampling (Subjects, n=333)						
BGMs	306	306 (100%)	306 (100%)	27	23 (85.2%)	27 (100%)

Table 2-Precision

	Low	Mid
Mean mmol/L	0.487	2.89
SD mmol/L	0.051	0.088
CV%	—	3.06

TD-4140 (GlucoRx HCT Connect)

Table 1-Accuracy						
Test meter with ketone strips	Test results of the test device fulfilling specified error limits at ketone value < 2 mmol/L			Test results of the test device fulfilling specified error limits at ketone value ≥ 2 mmol/L		
	Within \pm			Within \pm		
	n	$\pm 0.3\text{mmol/L}$	$\pm 0.5\text{mmol/L}$	n	15%	20%
Capillary blood sampling (Subjects, n=720)						
BGMs	318	294 (92.5%)	318 (100%)	42	38 (90.5%)	42 (100%)

Table 2-Precision

	Low	Mid
Mean mmol/L	0.520	2.887
SD mmol/L	0.055	0.090
CV%	—	3.12%

TD-4140B (GlucoRx HCT Connect i)

Table 1-Accuracy						
Test meter with ketone strips	Test results of the test device fulfilling specified error limits at ketone value < 2 mmol/L			Test results of the test device fulfilling specified error limits at ketone value ≥ 2 mmol/L		
	Within \pm			Within \pm		
	n	$\pm 0.3\text{mmol/L}$	$\pm 0.5\text{mmol/L}$	n	15%	20%
Capillary blood sampling (Subjects, n=720)						
BGMs	318	294 (92.5%)	318 (100%)	42	38 (90.5%)	42 (100%)

Table 2-Precision

	Low	Mid
Mean mmol/L	0.520	2.887
SD mmol/L	0.055	0.090
CV%	—	3.12%

Symbol Information

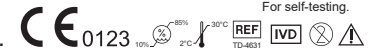
Symbol	Referent	Symbol	Referent
	In vitro diagnostic medical device		Manufacturer
	Consult instructions for use		Do not re-use
	Caution		Authorized representative in the European Community
	Temperature limit		Batch code
	CE mark		Humidity limitation
	Catalogue number		Use-by date

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Use Only With GlucoRx HCT, GlucoRx HCT Connect and GlucoRx HCT Connect i Blood Glucose & Ketone Monitoring Systems.



For self-testing.