

GIMACARE Hemoglobin Test Strips

Use only with GIMACARE Multi-Functional Monitoring System.

Warnings

- For in vitro diagnostic use (for use outside of the body only).
- For single use only.
- Healthcare professionals and other users should handle everything that comes into contact with human blood carefully to prevent transmitting infectious diseases, including sanitized objects.
- Please read this sheet and your GIMACARE Multi-Functional Monitoring System Owner's Manual before you use this test strip. Use only GIMACARE Hemoglobin Test Strips with GIMACARE 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.
- Keep test strips and lancets away from small children. If swallowed, consult a doctor immediately for advice.
- If any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- The user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence.
- For self-testing used for the monitoring of a previously diagnosed existing disease or condition, the patient should only adapt the treatment if he or she has received the appropriate training to do so.

Intended Use

GIMACARE Hemoglobin Test Strips, when used together with GIMACARE Multi-Functional Monitoring System, allow your Hemoglobin (Hb) levels to be measured by yourself at home or by healthcare professionals. It is intended to be used for the quantitative measurement of hemoglobin in fresh capillary whole blood samples from finger and from venous whole blood sample.

Professionals may use test strips to test capillary and venous blood sample; home use is limited to capillary whole blood testing.

Test Principle

Your system measures the amount of hemoglobin in whole blood. The test is based on the measurement of electrical current generated by the reaction of the hemoglobin with the reagent of the strip. The meter measures the current, calculates the hemoglobin in the blood, and displays the result. The strength of the current produced by the reaction depends on the amount of hemoglobin in the blood sample.

Limitations

- Lipemic Effects: Blood triglycerides up to 1500 mg/dL (16.9 mmol/L) do not affect the results significantly, but may affect results at higher levels.
- Metabolites: Captopril, ascorbic acid, L-Dopa, gentisic acid, paracetamol, uric acid, unconjugated bilirubin, cholesterol, triglycerides, methyldopa, digoxin, acetylsalicylic acid, salicylic acid and tolbutamide at normal blood concentration do not significantly affect blood glucose test results.
- There are no significant interference in the presence of maltose, or fructose observed in hemoglobin tests.
- Altitude Effects: Altitudes up to 10,742 feet (3,275m) do not affect test results.
- Use only heparin for anticoagulation of fresh capillary or venous whole blood.
- Hematocrit: The hematocrit level is limited to between 20% to 70%. Please ask your healthcare professional if you do not know your hematocrit level.

The following compounds when determined to be in excess of their limitation and tested with the GIMACARE Multi-Functional Monitoring System may produce elevated glucose results:

Summary of substances and concentrations in excess of limitation with interference

Substance	Limiting Concentration (mg/dL)	Therapeutic / Physiologic Concentration Range (or Upper Limit) (mg/dL)
Captopril	> 500	100
Ascorbic Acid	> 4	2
Uric Acid	> 10	2 - 8

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 90% relative 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)
- 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)
- 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 strips.

Chemical Components

- > Shuttles 60%
- > Non-reactive ingredients 40%

Strip Appearance

- Absorbent Hole**
Apply a drop of blood here. The blood will automatically be absorbed.
- Confirmation Window**
This is where you confirm if enough blood has been drawn into the absorbent hole of the strip.
- Test Strip Handle**
Hold this part to insert the test strip into the slot.
- Contact Bars**
Insert this end of the test strip into the 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 might be wrong if the contact bar is not fully inserted into the test slot.

Calibration

Calibrate the meter every time you begin to use a new package 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 number printed on your test strip vial label/packet.

Code Chip

- Insert the code chip with the meter switched off. Wait until a number and "Hb" appears on display.
- 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 "Hb" 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 customer service for help.

Testing Your Hemoglobin and Hematocrit

PLEASE WASH AND DRY YOUR HANDS BEFORE PERFORMING ANY TESTING.

STEP 1

Insert the test strip fully into the slot of the meter until it will go no further.

STEP 2

When the strip is fully inserted, the meter will do several self-checks.

STEP 3

Collect a blood sample 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. The meter will start counting down. Do NOT apply a smeared blood sample.

After a few seconds, the meter will display your test result. The last reading will be automatically saved in the meter. Turn it off by removing the test strip and throw away the used test strip.

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

Reading Your Result

The measurement unit used for indicating the concentration of blood or plasma hemoglobin can either have a weight dimension (g/dL) or a molarity (mmol/L). The measurement range of this meter is 6.8 to 24 g/dL (4.22 to 14.89 mmol/L).

Reference values

Hemoglobin (Hb)	
Males	14.0 a 18.0 g/dl
Females	12.0 a 16.0 g/dl

Source: Laboratory Reference Range Values

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

Questionable or inconsistent results

- 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 expiration date of the test strips.

Unusually high or low hemoglobin or hematocrit levels may be symptoms of a serious medical condition. If most of your results are unusually high or low, please 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 foil packet. The countdown begins from 30 days to 1 day, which will be shown at the center 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 accurate results.

Performance Characteristics:

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: 10 to 12 seconds

System Measurement Range: 6.8 to 24 g/dL (4.22 to 14.89 mmol/L)

Hematocrit Range: 20% to 70%

Precision

Hemoglobin	Concentration		
	6.6 g/dL	13.6 g/dL	20.4 g/dL
Mean	6.5	13.5	20.3
SD	0.30	0.50	0.65
CV (%)	4.7	3.7	3.2

Clinical Performance

Accuracy

Hemoglobin	n = 320		
	Capillary samples	Range, mean	Venous samples
Regression	y = 1.0256 - 0.5726 R2 = 0.9724	Range: 6.7 to 22.4 Mean: 13.8	y = 1.0253x - 0.567 R2 = 0.9758

User performance

Hemoglobin	n = 320	
	Capillary samples	Range, mean
Regression	y = 0.9537x + 0.4434 R2 = 0.9814	Range: 6.7 to 22.4 Mean: 13.8

Symbol Information

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

EC REP	MedNet EC-REP GmbH Borkstraße 10 48163 Münster, Germany	TaiDoc Technology Corporation B1-7F, No. 127, Wugong 2nd Rd., Wugu Dist., 24888 New Taipei City, Taiwan www.taidoc.com
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Per l'autotest.

For self-testing.

Pour l'autocontrôle.

Para autodiagnóstico.

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