

EasyTouch®

Hemoglobin Test Strips

For in vitro diagnostic use only.

Important

Please read this information and the EasyTouch® Series Hemoglobin Monitoring System User's Manual before using EasyTouch® Hemoglobin Test Strips. If you have any questions and/or need assistance, please contact our authorized distributors in your country.

Intended Use

EasyTouch® Hemoglobin Test Strips are designed for in vitro diagnostic use with the EasyTouch® Series Hemoglobin Meter for self-testing hemoglobin level in fresh capillary whole blood. It is suitable for anemia management at home or professional use.

Summary

The EasyTouch® Series Hemoglobin Monitoring System is designed for quantitative measurement of hemoglobin level in fresh capillary whole blood. This measurement is based on determination of the current changes caused by the reaction of hemoglobin with the reagent on the electrode of the strip. When the blood sample gently touches the sample target area of the strip, the blood is automatically drawn into the reaction zone of the strip. The test result will be displayed on the screen after 6 seconds.

Measurement Range

The measurement range of the EasyTouch® Series Hemoglobin Monitoring System is from 7 to 26 g/dL (4.3 mmol/L to 16.1 mmol/L).

Reagent

Each EasyTouch® Hemoglobin Test Strip contains the following reagent.

Hemoglobin catalyst	≥0.1 mg
Non-reactive ingredients	≥0.3 mg

Storage and Handling

- Store the test strips at temperature between 4°C to 30°C (40°F to 86°F).
- Do not freeze.
- Keep away from direct sunlight and heat.
- Do not use the test strips after the expiration date.
- Mark the first opening date on the vial. The test strips should be used within 2 months after first opening.
- Tightly seal the vial cap immediately after removing a test strip.
- Do not handle the test strips with wet or dirty hands.

Warning and Precautions

- Do not cut, bent, scratch, or alter the test strip in any way.
- Discard each test strip after single use.
- Do not use the test strips after the expiration date.
- The test strips should be used within 2 months after first opening.
- Code (calibrate) the EasyTouch® Series Hemoglobin Meter to match the code number printed on the EasyTouch® Hemoglobin Test Strips Vial.
- If your blood hemoglobin test results are not consistent with your expected results and you have followed all instructions described in the EasyTouch® Series Monitoring System User's Manual, call your healthcare professional.
- Never make significant changes to your anemia control program or ignore physical symptoms without consulting with your healthcare professional.
- Be sure to follow your local regulation for proper disposal of used test strips and lancets.
- Keep the test strips vial away from children. The cap or vial may contain drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.
- Do not use tincture of iodine to disinfect fingertip.

Materials Needed to Test Your Hemoglobin

- EasyTouch® Series Hemoglobin Meter
- EasyTouch® Hemoglobin Test Strips (REF SH-102-25)
- Lancets (not included)
- Puncturer (lancing device)
- Alcohol swab (not included)
- EasyTouch® Series Hemoglobin Monitoring System User's Manual
- Log Book

Sample Collection and Preparation

The EasyTouch® Series Hemoglobin Monitoring System is designed to determine hemoglobin level in fresh capillary whole blood (i.e., from fingertip). To obtain a drop of blood, follow these steps:

- Step 1: Wash your hands with soap and warm water, then dry thoroughly
- Step 2: Prepare puncturer according to the instructions
- Step 3: Using an alcohol swab, and making sure that your finger is completely dry before lancing your finger.
- Step 4: Using the puncturer to obtain a drop of blood. Avoid excessive squeezing of the puncture site.

Code Strips Procedure

When you use a new vial of test strips, the EasyTouch® Series Hemoglobin Meter must be calibrated with the new code key packaged in the box for obtaining an accurate hemoglobin test result.

- Find the CODE number on the vial of EasyTouch® Hemoglobin Test Strips.

- Insert the code key into the code key slot of the meter. Make sure the code number is facing up.
- Insert a test strip into the test strip slot of the meter, it will automatically turn on and display the code number on the LCD screen.
- It is important that the code number on the meter matches the code number on the vial of test strips.

Blood Hemoglobin Testing

Wash and dry your hands thoroughly. Insert the lancet into the puncturer. Prepare the puncturer according to the instructions. To test your hemoglobin level, follow these steps:

- Step 1: **Insert Test Strip.** Remove a test strip from the vial and immediately seal the vial cap. Insert the test strip into the test strip slot, and the meter will turn on automatically. Code number will appear briefly. Then make sure the code number on the screen matches the code number on the test strip vial. If the code number does not match, code the meter correctly.
- Step 2: **Apply sample.** Obtain a drop of blood using the sample collection procedure described above. When "▲" symbol is displayed, applying your blood sample to the sample target area of the test strip. The blood is automatically drawn into the reaction zone of test strips. The meter will begin measuring hemoglobin level.
- Step 3: **Read the result after 6 seconds.** Your hemoglobin measurement will appear on the screen after 6 seconds. The results will be automatically stored. Turn the meter off by removing the test strip.

For detailed information on the procedure, please refer to the EasyTouch® Series Hemoglobin Monitoring System User's Manual.

Quality Control

It is recommended to check the performance of EasyTouch® Series Hemoglobin Monitoring System under the following conditions:

- When your hemoglobin test results are not consistent with what you expected, or when you feel your results are not accurate.
- Whenever you suspect that the meter or test strips are not working correctly.
- When you drop the meter.
- When you begin to use a new vial of test strips. To check the performance of the meter, test strips and your testing technique, run the control solution test by following the instructions detailed in EasyTouch® Series Hemoglobin Monitoring System User's Manual. The EasyTouch® Hemoglobin Control Solutions are only designed for using with EasyTouch® Hemoglobin Test Strips. Other control solutions may provide incorrect results.

When **EasyTouch®** Hemoglobin Control Solution test results fall within the expected ranges printed on the test strip vial label, the system is performing properly. If your control solution test results are not within the expected range, repeat the control solution test. DO NOT use the system to test your blood until you get a control solution test result within the expected range. Results that fall outside the range may be caused by:

- Error in performing the test.
- Expired or contaminated control solution.
- Improper coding of the meter
- Test strip deterioration
- Meter malfunction

Test Results

The unit of hemoglobin test results displayed on the screen is either g/dL or mmol/L, depending on which unit of measurement you have selected. The g/dL and mmol/L results will always include a decimal point. When you have any questions or inconsistent test results, check the following items, then repeat the test.

1. Be sure the drop of blood completely filled the reaction zone of the test strips.
2. Check if the strips are within the expiration date.
3. Check if the code number of the test strips matches the code number displayed on the screen.
4. Check meter performance with the check strip.
5. Check meter and test strip performance with **EasyTouch®** Control Solutions.

When test results are still questionable or inconsistent, consult your healthcare professional before making any changes to your anemia medication program.

Caution

If your hemoglobin test results are abnormal, or you do not feel comfortable with your test results, repeat the test with a new test strip. If your test result is not consistent with your expectation, you should contact your healthcare professional and follow his or her treatment advice. The **EasyTouch®** Series Hemoglobin Monitoring System should not be used for the diagnosis of anemia or for the testing of newborns.

Expected Values

The expected hemoglobin value for a normal person is as following:

Male: 13.5 ~ 16.5 g/dL (8.4 ~ 10.2 mmol/L)
 Female: 12.1 ~ 15.1 g/dL (7.5 ~ 9.4 mmol/L)

The above range is just a reference, and it's not suitable for every person.

Consult your physician for the range appropriate for you.

Limitations

EasyTouch® Hemoglobin Test Strips are designed only for use with **Fresh Capillary Whole Blood Sample**.

- DO NOT use serum or plasma samples.
- DO NOT use venous or arterial blood samples.
- The system is designed to use at temperature between 57.2°F to 104°F (14°C to 40°C). Outside this range, the system may yield false results.
- Extremes in humidity may affect the results. A relative humidity greater than 85% may cause false results.
- Do not reuse the test strips.
- Do not use sodium fluoride or iodoacetic acid as a preservative for blood samples.
- Hematocrit:
 The test strip results are not significantly affected by hematocrits in the range of 20% to 70%. Hematocrit levels less than 20% may cause false high readings while hematocrit levels greater than 70% may cause false low readings. If you do not know your hematocrit level, consult your healthcare professional.

■ Neonatal:
EasyTouch® Hemoglobin Test Strips used for testing neonatal blood specimens are not validated.

- Interferences:
 Blood specimens containing Ascorbic Acid (Vitamin C) greater than 150mg/dL, L-Dopa greater than 20 mg/dL, Dopamine greater than 20 mg/dL and Methyl-Dopa greater than 4 mg/dL may give **inaccurate hemoglobin results**.
- Patients undergone oxygen therapy may yield false results.
- Lipaemic samples: Cholesterol up to 500 mg/dL or triglycerides up to 3000 mg/dL do not significantly affect the results. Grossly lipaemic patient samples have not been test and are not recommended for testing with the **EasyTouch®** Series Hemoglobin Monitoring System.
- The system is not recommended for use at the altitude of up to 8,000 feet above sea level.
- Test results may be false if the patient is severely dehydrated or severely hypotensive, in shock or in hypoglycemic-hyperosmolar state (with or without ketosis).
- Critically ill patients should not be tested at home using the **EasyTouch®** Series Hemoglobin Monitoring System.
- Do not use tincture of iodine to disinfect fingertip.

Performance Characteristics

The performance of the **EasyTouch®** Series Hemoglobin Monitoring System is evaluated both in laboratory and clinical tests. This system use Celltac α analyzer as reference.

1. Accuracy:

The specimens ranged from: 8.1 g/dL to 21.7 g/dL (5.02 mmol/L to 13.46 mmol/L)

Number of Samples	100
Range (g/dL)	8.1 ~ 21.7
Slope	0.9761
Intercept (g/dL)	0.5641
r ² (corr. coef.)	0.9667

2. Precision













The Precision data was obtained in a laboratory study using the **EasyTouch®** Series Hemoglobin Monitoring System to analyze fresh heparinized venous blood sample (n=100 per level):

Average (g/dL)	7.7	13.2	19.0	24.3
S.D. (g/dL)	0.77	0.6	0.85	0.81
CV(%)	-	4.5	4.5	3.4

Reference

1. Tietz N; Fundamentals of Clinical Chemistry, 3rd Ed., W.B. Saunders Co., Philadelphia, PA, 1987, P.427
2. Biosensors: Microelectrochemical Devices, Institute of Physics Publishing Bristol, Philadelphia and New York, 1992
3. Burtis, C. A. & Ashwood, E. R., Clinical Chemistry, Third Edition, Philadelphia, W.B. Saunders Co. (1999) P.1815

Labeling and Information

 Do not reuse	 Consult instruction for use
 In vitro diagnostic device	 Temperature limitation
 Batch code	 Catalog number (Product number)
 Used by	 EU Representative
 Manufacturer	 Control
 Keep away from sunlight	 Keep Dry

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