

Hb Hemoglobin Test Meter





HANGZHOU ALLTEST BIOTECH CO., LTD

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Chapter 1 Introduction

1.1 Intended Use

The Hb Hemoglobin Test Meter is intended for the quantitative determination of hemoglobin and calculated hematocrit (HCT) in non-anticoagulated capillary whole blood or anticoagulated venous whole blood. The Hemoglobin Test Strip includes a mesh covered sample reaction zone. Specimen is applied to the center of the sample reaction zone. The hemoglobin is converted to methemoglobin to cause a color change on the strip. The meter reads the reflection of the strip every second until the end point of the reaction is detected. The reflection at the end point is directly proportional to the hemoglobin concentration.

1.2 Scope of Application

The Hb Hemoglobin Test Meter works with certain reagents strips manufactured by Hangzhou ALLTEST Biotech Co., Ltd. for the quantitative detection. It's for *in vitro* diagnostic professional use only. It may be used in emergency departments, clinical departments or medical services (such as community health centers), etc.

1.3 Product Name and Model Type

Product Name: Hb Hemoglobin Test Meter **Model Type:** AHR-100/100ST

Chapter 2 Components and Structure

2.1 Standard Equipment List

Packing List

No.	Description	Quantity	Remark
1	Hb Hemoglobin Test Meter	1	1
2	Control Strip	2	1
3	Lancing Device	1	1
4	AAA Battery	3	1
5	Carrying Case	1	1
6	Meter User Manual	1	1
7	Warranty Card	1	1
8	Lancing Device Insert	1	1
9	Control Strip Insert	1	1
10	Quick Reference Guide	1	1
11	Test Strips	5 / 10	Start kit,
12	Code Chip	1	Optional
13	Alcohol Pads	5 / 10	
14	Lancets	5 / 10	
15	Capillary Droppers	5 / 10	
16	Test Strip Insert	1	
17	Power Plug And USB Cable	1	Optional

On receiving the box, please check the contents with this list and ensure that all the items mentioned in the list (Ref 2.1) are inside.

Note:

1) All accessories connected to the meter via the USB ports need to be meet IEC60950 requirements.

2) If some parts are missing or damaged, please contact with local distributor.

2.2 Components



Fig. 1

2.3 External View

2.3.1 Front View (Ref Fig 2)



Fig. 2

2.3.2 Rear View (Ref Fig 3)





2.3.2 Top View (Ref Fig 4)



Fig. 4

2.4 Technical Specification

Specification	Technical Parameters
Methodology	Reflectance Photometer
Test Time	<15 seconds
Measurement Range	4.5~25.6 g/dL ,45~256 g/L,0.03~0.16 mmol/L
Specimen	Whole Blood
Specimen Volume	10 µL
Power Source	3 AAA batteries
Battery Life	360 hours or 2700 tests
Units of Measure	g/dL, g/L, mmol/L
Memory	1000 records
Automatic Shut Off	6 minutes after last action
Meter Dimension	120mm*71mm*26mm
Display Size	47*41mm
Weight (without Batteries)	83g(Approx.)
Meter Connectors	USB cable for Data Transfer or Power (optional)

2.5 Working and Storage Condition

Parameters	Working Condition	Storage and Transport Condition
Temperature	10-40 ℃	-10-50 ℃
Relative Humidity	≤80%	≤90%
Atmospheric Pressure	86-106kPa	86-106kPa
Altitude	Up to 2000m	Up to 2000m
Place	Indoor use, stable table, avoid of direct strong light and strong electromagnetic interference source	Clean, Ventilative, Stable

Chapter 3 Preparation for Use

3.1 Checklist upon opening the Box

Before opening the box, check the packaging is in good condition and box was not damaged during transportation.

Open the box carefully, and check the contents according to **2.1 Standard** *Equipment List* to ensure it is complete. If any missing or damaging is found, please contact the manufacture or your local agent.

Note: Please keep the original box and packing materials for ant future shipping/reference purpose.

3.2 Material Preparation

Prior to testing, read the user manual carefully and learn about all the components of the Hb Hemoglobin Test Meter. Depending on the package type you chose, some of the components may need to be purchased separately. The following items are needed to perform a test:

• Meter

Place the 3 AAA batteries correctly, install battery cover, place the meter on a level surface. Press \blacktriangleleft or \blacktriangleright arrow buttons to change the year, date and time, press 0 button to confirm the changes. (Ref Fig. 5) The meter will turn off after time setting.



Fig. 5

Press 0 button to turn on the meter, check the displaying icons on the LCD as Fig. 6.



Fig. 6

Note: This Meter is tested for immunity to electrostatic discharge and complies with the emission and immunity requirements described in IEC 61326-1 and IEC 61326-2-6. Use this meter in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging static discharges that may cause erroneous results. Do not use this meter in close proximity to sources of strong electromagnetic radiation, as these may interfere

with proper operation of the meter.

• Test Strip and Code Chip

The Hb Hemoglobin Test Strips are thin plastic strips which contain a chemical reagent system which works with the Hemoglobin Test Meter to measure the Hb Hemoglobin concentration in whole blood. Please refer to the package insert of the Hb Hemoglobin Test strip for detail information.

Each box of test strips is accompanied with a corresponding code chip, the curve of the test strips is stored in the code chip. The code number ink-jet printed on the code chip and on the strip canister label shall be the same.

Note: Only use Hb Hemoglobin Test Strips manufactured by Hangzhou ALLTEST Biotech Co., Ltd. for proper function and accurate results. Remove the strips from the closed canister. Use them as soon as possible. Tightly close the canister after removing the strips.

Control strip

The Hb Hemoglobin control strips are thin plastic strips which work with the Hb Hemoglobin Test Meter to ensure the optical system is working properly. After the control strip is inserted into the meter, the optical system of meter detects the color intensity of the control strip. The meter displays **YES** or **No** to show whether the meter is functioning properly. Refer to Section **4.4.2** Optical Check for **details**.

Note: Only use Hb Hemoglobin Control strips manufactured by Hangzhou ALLTEST Biotech Co., Ltd. for proper function and accurate results. Remove the control strip for immediate use. Put the control strip back and close the canister tightly immediately after use. Do not use contaminated, discolored, bent or damaged control strips. Store in the closed canister at room temperature within 2-30°C (36 - 86°F) and avoid exposing it to direct sunlight, extreme temperature or humidity. Do not freeze or refrigerate. Keep the control strip clean and do not bend. Do not touch the test area of the strip. Do not use after the expiration date.

• Lancing Device and Sterile Lancets

The lancing device is used with sterile lancets to prick the finger for blood specimen collection. Please refer to the package insert of Hb Hemoglobin Test Strip for more information.

3.3 Environmental Preparation

Prior to testing, bring the meter and reagent strips to the condition according to **2.5 Working and Storage Condition.**

Place the meter on a firm, level surface. Avoid strong magnetic field, vibration, shock, corrosive gas, direct sunlight, high humidity, and high temperature in work area, where the meter is placed for operation.

3.4 Power Supply Preparation

- Power supply: 3 AAA batteries
- In the use of dry batteries as power supply, please remove batteries if the meter remains unused for a few days or longer, to avoid of damaging to the meter caused by leakage of batteries.
- Please do not open the enclosure without authorization and it only to be inspected and provided by manufacture.
- Operations violating the manual's descriptions may cause the meter damaged.

Chapter 4 Directions for Use

Read this user manual and complete any necessary training before use. 4.1 Initialization

- Open the battery compartment cover, install three AAA batteries according the polarity mark in the battery compartment. The meter turns on, all icons display for 2 seconds approx and enter into initial setting which is for year, date and time setting.
- Close the cover.
- Place the meter on level surface. Do not place the meter in such a way that it is difficult to operate the meter. Please use the meter under the proper conditions mentioned in 2.5 Working and Storage Condition.
- Press ◀ or ▶ arrow button to set the year, date and time, press ७ button to save.
- After initial setting, the meter turns off automatically.

4.2 Turn On The Meter

Press $\, \mho \,$ button, the meter turns on and enters into code chip interface. (Ref Fig. 7)



Fig. 7

4.3 Insert Code Chip

A new code chip is packaged with each box of test strips, insert the code chip into the meter when the corresponding strips want to be tested.

- Take the code chip from the test strip box. Compare the code number on the code chip with the code number printed on the test strip canister label. Results may be inaccurate if the two numbers are not identical.
- Insert the new code chip into the code chip slot of the meter. The code chip should remain in the meter during testing. Do not take it out until a new box of test strips is needed. The code number will appear on the Initial Screen after start-up. (Ref Fig. 8)



Fig. 8

Note: If the code chip is not properly inserted into the code chip slot, or if it is missing, the meter will display three dashes as Fig. 7.

4.4 Settings

With the meter power off, press the \circ button until "**SET**" appears in the LCD, release the pressing and the meter enters setting mode. The test number setting screen is displayed. The relationship between setting models as Ref Fig. 9.



Fig. 9

4.4.1 Test Number Set

The test number can be set according to this section (Ref Fig. 10)

- In test number setting screen, press 也 button to enter test number setting;
- Press ◀ or ▶ arrow button to set the target test number, press and hold lift or right arrow button to quickly cycle the target test number.
- Press 🖞 button to save the set and turn to exit screen.

Note: Once the meter reaches test number 999, the next test number will be 1.



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4.4.2 Optical Check

Press ◀ or ▶ button to select the optical check mode as Fig. 11.



Fig. 11

- Press button to enter this mode.(Ref Fig. 12)
- Insert the control strip into the strip holder in the same direction as the arrows indicated on the strip.
- Press Φ button to start the optical check, If the meter displays "YES", the meter is normal. If the meter displays "no", the meter is not functioning properly.
- If the meter displays "no", check the control strip for contamination or if it is bent or damaged. If there are any visible signs of damage or contamination, discard the control strip and retest using a new control strip.
- Press ◀ or ▶ button to turn to exit screen.

Note: The optical check should be performed under normal lab lighting conditions. Do not perform under sunlight or extreme lighting conditions.







4.4.3 System Set

Press ◀ or ▶ button to select the system set mode as Fig. 13.



Fig. 13

• Press 🙂 button to enter this mode.

- Press ◀ or ▶ button to select target year, press Ů button to save the year set and enter into month and date set.
- Press ◀ or ▶ button to select target month, press ↺ button to save the month set and enter into date set. Press ◀ or ▶ button to select target date, press ↺ button to save the date set and enter into time set.
- Press ◀ or ▶ button to select target time, press ↺ button to save the time set and enter into start test number set. (Ref Fig. 14)



Fig. 14

Press ◀ or ▶ button to select "On" or "OFF" to set the start test number. The start test number will reset to 1 for each day if "On" is selected, and the start test number will continue increase for each day if "OFF" is selected. (Ref Fig. 15)





Fig. 15

- Press 😃 button to enter units set.
- Press ◀ or ▶ button to select target unit, press Ů button to enter sound set.(Ref Fig. 16)



Fig. 16

Press ◀ or ▶ button to select "On" or "OFF" to set the sound. The sound will be turned on and sound symbol will appear on display if "On" is selected. (Ref Fig. 17)



Fig. 17

• Press 🙂 button to turn to exit screen. (Ref Fig. 18)



Fig. 18

4.4.4 Report Transmit

Press ◀ or ► button to select the report transmit mode as Fig. 19.





- Press 也 button to enter this mode.(Ref Fig. 20)
- Connect meter to PC via USB cable.
- Press 0 button to start transmitting the test report.
- After transmitting complete, the meter turns to exit.



Fig. 20

4.4.5 Report Delete

• Press • or • button to select the report delete mode as Fig. 21.

Press ◀ or ▶ button to select "YES" or "NO". Press ♡ button to select "YES" to delete all the reports in the meter and turn to exit screen. Press ♡ button to select "NO" to give up delete, and turn to exit screen.



4.4.6 Exit Setting

In exit screen, press & button to enter into test mode Screen.

4.5 Testing

Prior to performing any test, please read this manual for detailed instructions. The following steps show how to use each component to measure the hemoglobin concentration.

4.5.1 Specimen Collection

The Hb Hemoglobin Test Meter requires a very small specimen which may be obtained from the venous whole blood or fingertip whole blood.

• Fingertip Blood Collection

The blood specimen can be obtained by using the lancing device provided with the meter and the lancet provided with the test strips. Refer to the instructions for lancing device use procedure.

Step 1: Unscrew the lancing device cover from the body of the lancing device.(Ref Fig. 22)

Step 2: Insert a sterile lancet into the lancet holder and push it until stop in the lancet holder.(Ref Fig. 23)



Step 3: Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet, then pull the safety tab off. Save the safety tab for lancet disposal.(Ref Fig. 24)



Fig. 24

Step 4: Carefully screw the cover back to the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully seated on the lancing device.(Ref Fig. 25)



Fig. 25

Step 5: Adjust the puncture depth by rotating the lancing device cover. There are a total of 6 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.(Ref Fig. 26)



Fig. 26

Step 6: Pull the cocking barrel back to set the lancing device. A click may be heard. The device is now loaded and ready for obtaining a drop of fingertip blood.(Ref Fig. 27)



Fig. 27

Step 7: Prior to collecting the capillary blood specimen, make sure the patient's hand is warm and relaxed. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow. Clean the testing site with an alcohol swab and then dry the testing site thoroughly.

Step 8: Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick the fingertip. A click should be heard as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. (Ref Fig. 28)



Fig. 28

Step 9: Wipe away the first drop of blood. Apply light pressure to obtain a second drop of blood. Use the capillary dropper to absorb about 10 μ L blood samples, add to the specimen application area of the strip. (Ref Fig. 29)



Fig. 29

Step 10: Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to eject the used lancet. Place the lancing device cover back on the lancing device.(Ref Fig. 30)

Note: Dispose of the used lancet according to local regulations.



Fig. 30

• Venous Blood Collection

For fresh whole blood venous specimens, collect the venous blood in a closed container with EDTA or heparin anticoagulants. Whole Blood must be tested within 8 hours of collection. Mix the specimens well before testing in order to ensure the cellular components are evenly distributed. Anticoagulants other than EDTA are not recommended for use.

4.5.2 Strip Testing

During operation, you will likely be exposed to a blood specimen. It is recommended to wear protective gloves to avoid direct contact with blood specimens especially in contact with infectious blood specimens.

Ensure the meter is set up properly before the strip testing starts. Allow the materials to reach room temperature (15-30 $^\circ\!C$) prior to testing. In order to obtain accurate results, the specimen collected from venous blood or fingertip blood shall be applied to specimen area of strips with capillary transfer droppers or pipettes.

- Press 🖞 button to turn on the meter.
- Insert the code chip provided with the strip. Compare the number displayed on the LCD with the number printed on the strip canister label. The strip symbol will flash when the meter is ready for strip to be inserted.
- Insert a test strip into the strip holder in the same direction as the arrows indicated on the strip. Ensure that the test strip is inserted to the end of the strip holder.
- The blood drop symbol will flash when the meter is ready for the specimen to be applied. (Ref Fig. 31)
- Align the tip of the capillary transfer dropper or pipette with the specimen application area of the strip to apply the blood specimen (approximately 10 µL)

Note: Do not touch the strip with the capillary transfer dropper or pipette. The capillary blood should be tested immediately after collected.

• The meter will begin testing automatically with three dashes in a line flashing on the LCD indicating the test is in progress. The test result (Hb concentration and Hct value) will be displayed in 15 seconds. (Ref Fig. 32, Fig. 33)

Note: If the concentration of hemoglobin is less than 45 g/L the meter will display **Lo**. The meter will display **Hi** if the concentration is more than 256 g/L.

• Remove the used test strip. The meter will return to the initial screen ready for another strip to be inserted and a test to be performed.

Note: Discard all blood specimens, used test strips and materials carefully. Treat all blood specimens as if they were infectious materials. Follow proper precautions and obey all local regulations when discarding blood specimens and materials.









4.6 Review Reports

In test mode screen, press ◀ or ▶ button to enter report interface. Press ◀ or ▶ button to review the reports in sequence. Press and hold ↺ button to return to initial screen. (Ref Fig. 34)





4.7 Shutdown

The meter can be shut down by hold pressing the \circ button for a few second in use. The meter will turn off automatically after 6 minutes of inactivity.

Chapter 5 Precautions

Observe the precautions listed below to ensure accurate results and proper operation of the meter.

- The protection provided by the meter may be impaired if used in a manner not defined in this user guide.
- Make sure that the strips are within the expiry period, if not, inaccurate result may incur.
- During operation, you will likely be exposed to a blood specimens. It is recommended to wear protective gloves to avoid direct contact with blood specimens especially in contact with infectious blood specimens.
- When you touch components and parts labeled with biological symbols, please pay attention to protection, wearing protective gloves to avoid direct contact with the skin.
- Avoid storing or operating the meter in direct sunlight, excessive temperature, or high humidity.
- Keep the unit clean. Wipe it frequently with a soft, clean and dry cloth. Use fresh water when needed.
- Do not clean the unit with substances such as gasoline, paint thinner or other organic solvents to avoid any damage to the meter.
- Do not clean the LCD or sensor area with water. Lightly wipe with a soft, clean, dry rag.
- The strip holder must be kept clean. Lightly wipe with a soft, clean, dry rag each day. Use water as needed.
- Discard all blood specimens, used test strips and materials carefully. Treat all blood specimens as if they were infectious materials. Follow proper precautions and obey all local regulations when discarding blood specimens and materials.
- Operating the meter should be according to specifications of Lab Waste Disposal and meter maintenance.
- Do not get water or other liquids inside the meter. Keep the meter dry and avoid exposing it to extreme temperatures or humidity.
- Do not drop the meter or get it wet. If meter is dropped or has gotten wet, ensure the meter is working properly by running an calibration.
- Store control strips in the closed canister at room temperature within 2-30°C (36 86°F) and avoid exposing it to direct sunlight, extreme temperature or humidity. control strips should be stored tightly capped in their protective canister to keep them in good working condition. Do not freeze or refrigerate. Keep the control strip clean and do not bend. Do not touch the test area of the strip.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.

Chapter 6 Troubleshooting

The meter can work normally if all operations and maintenance are performed according to this user manual. When the meter detects some abnormal situation, it will display an error message in order to alarm operator. It is recommended to contact with the distributor or manufacturer for help. The following is a list of error messages. It lists error mode, error contents and solutions.

Error Code	Error Message	Solutions		
E-1	The sensor area is damaged, dirty, or blocked at turn-on, such as a used test strip left in the meter.	Ensure the sensor area is clean and that there are no objects covering the sensor area. Refer to Section 7 Maintenance. Restart the meter. Contact your local distributor if the sensor area window is broken.		
E-2	The CODE chip is expired.	Check the code chip information		
E-3	Test strip was removed during the test.	Repeat the test and ensure the test strip remains in place.		
E-4	Specimen was applied to the test strip too soon.	Repeat the test and apply specimen after blood drop symbol appears.		
E-5	Insufficient specimen.	Repeat test and apply enough specimen. Use around 10 µL of whole blood.		
E-6	Batteries have discharged and meter will not allow more tests until discharged batteries are replaced.	Replace the batteries		
E-7	The light is too light during testing.	Do not have the detection under a direct sunlight condition.		
	No code chip in the meter; Code chip is damaged or inserted incorrectly.	Insert the code chip that accompanied the box of test strips. If the code chip is damaged, use a new code chip with the correct code number. If the code chip is inserted incorrectly, remove the code chip and insert it into the code chip slot.		
Lo	The test result is lower than 45 g/L.	If the specimen was taken from a specimen container, ensure the specimen is mixed well and repeat test.		
	Insufficient specimen less than 1µL	Repeat test and apply enough specimen. Use around 10 µL of whole blood.		
н	The test result is higher than 256 g/L.	If the specimen was taken from a specimen container, ensure the specimen is mixed well and repeat test.		

Chapter 7 Maintenance

7.1 Regular Maintenance and Notices

A good operation specification needs to be established at the very beginning. A regular maintenance is necessary to extend the service lifetime and keep the output of the service correct.

For best results, the meter should be cleaned after each day of testing. A cotton cloth can be used to clean the surface of the meter. Use a damp cotton cloth if necessary. A dry, soft cloth may be used to clean the LCD and the sensor area. It is recommended that the meter be stored in the carrying case after each use. Take care to avoid getting liquids, residue, or control solutions in the meter through the Strip holder, Code Chip Slot or USB Port.

Wipe down the Meter Sensor Area with a cotton swab. Do not to scratch the transparent window covering the sensor.



Note: Do not use any type of solvent, oil, grease, silicone spray, or lubrication on any part of the meter.

7.2 Replace the Batteries

When the battery icon is flashing, the battery is running low and should be replaced as soon as possible. An E-6 error message will appear if the battery is too low to perform any more tests. The meter will not function until the battery is replaced.

Make sure the meter is off before removing the batteries. Press the battery cover tab on the top and lift the cover to open it. Remove and discard the old batteries. Insert three AAA batteries in the battery compartment correctly.

Close the battery cover and make sure that it snaps shut. Recheck and reset the clock setting as necessary after battery replacement to ensure time is set correctly.



Chapter 8 Service, Repair and Disposal

Hb Hemoglobin Test Meter does not require special maintenance except for keeping it clean. If service is required, please contact with the local distributor. Hemoglobin meter's internal parts, including the circuit boards, optical detection modules and display, can only be provided by manufacturer. Such items should not be sourced from any third-party, even if they claim to provide the same function. When issues related to the meter, contact the local distributor. We provide technical support for users to perform troubleshooting. If the meter needs to be sent back to manufacturer, please contact local distributor and/ or Hangzhou ALLTEST Biotech Co., Ltd. It normally takes about a week to fix problems. If it turns out not repairable within warranty period, we will replace it with a new one. If for any reason the meter needs to be disposed of, please follow local regulations.

We provide technical support and software maintenance, including functional maintenance, corrective maintenance, software fixes or upgrade. We are only responsible and provide services when the meter is properly used in compliance with the manufacturer's user manual, otherwise any damages incurred will not be covered

This product is required to comply with the European Unions' Waste Electrical & Electronic Equipment (WEEE) Directive. If you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.



Chapter 9 Manufacturer Information

Name: Hangzhou ALLTEST Biotech Co., Ltd.

Address: # 550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P. R. China.

Tel: +86-571-56267891

Web: www.alltests.com.cn

Email: info@alltests.com.cn

Index of Symbols

ī	Consult Instructions For Use	Σ	Tests per kit	IVD	<i>In vitro</i> diagnostic medical device
-10°C	Temperature limit -10-50 °C	REF	Catalog #	EC REP	Authorized Representative in the EU
	Manufacturer	CE	CE Mark	Ť	Keep dry
L .	Fragile, handle with care	×	Keep away from sunlight		Protect from heat and radioactive sources
\square	Caution	Сў	Biological risks	UDI	Unique device identifier
Hangzhou AllTest Biotech Co.,Ltd. #550,Yinhai Street Hangzhou Economic & Technological Development Area					



i AllTest Biotech Co.,Ltd. 94 #550, Yinhai Street Hangzhou Economic & Technological Development Area Hangzhou, 310018 P.R. China Web: www.alltests.com.cn Email: info@alltests.com.cn

EC REP MedNet EC-REP GmbH Borkstrasse 10

48163 Muenster Germany

STATEMENT: Information about manufacturer of lancet, alcohol pad and lancing device is placed on the packaging.

> Number: H145001104 Revision Date: 2023-04-23

Hangzhou AllTest Biotech Co.,Ltd.



#550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou, 310018 P.R. China Web: www.alltests.com.cn Email: info@alltests.com.cn