



Clarity HbCheck

Hemoglobin Testing System

Quick Reference Guide

**Simple instructions to help
you start testing**

Manufactured for:
Clarity Diagnostics, LLC.
Boca Raton, Florida 33487

Technical /Customer Support: 877-485-7877

Made in China

For *in vitro* diagnostic use only



► Meter Kit

Components

1. Meter
2. Optical Verifiers
3. 4 AAA Batteries
4. Carrying Case
5. Warranty Card
6. Package Inserts



► Test Cartridges

Components

1. Test Cartridges
2. Code Chip
3. Package Insert



► Control Solution

Components

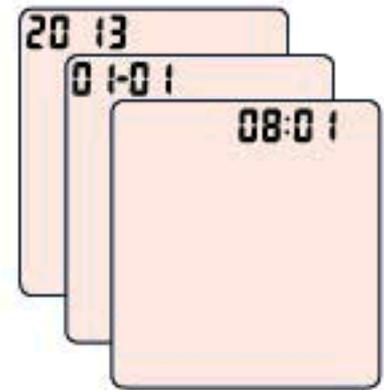
1. Control Solution 0
2. Control Solution 1
3. Control Solution 2
4. Package Insert



1 Meter Setup

A Installing Batteries

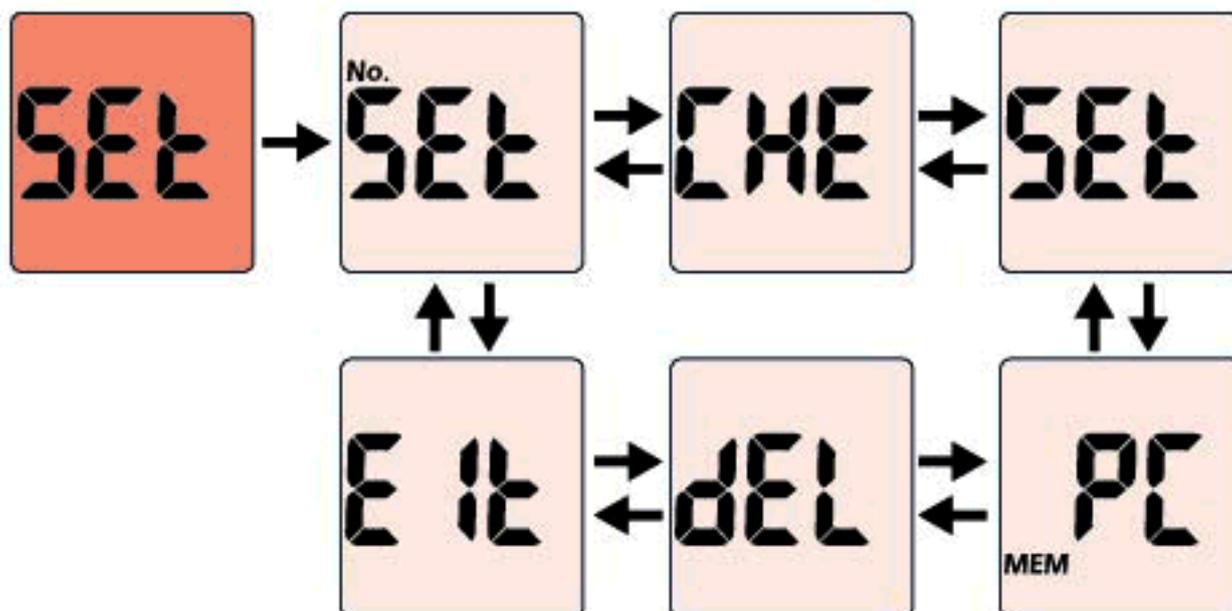
Insert 4 AAA batteries (1.5V), the meter will turn on automatically and display the date and time setup screen. Press ◀ or ▶ to finish the setup, then the meter will automatically turn off.



If an E6 error occurs, check the expiration date of the test cartridges. Discard the cartridges if they are expired. If not expired, check to see that the meter displays today's date and time. If not, reset the meter's date and time.

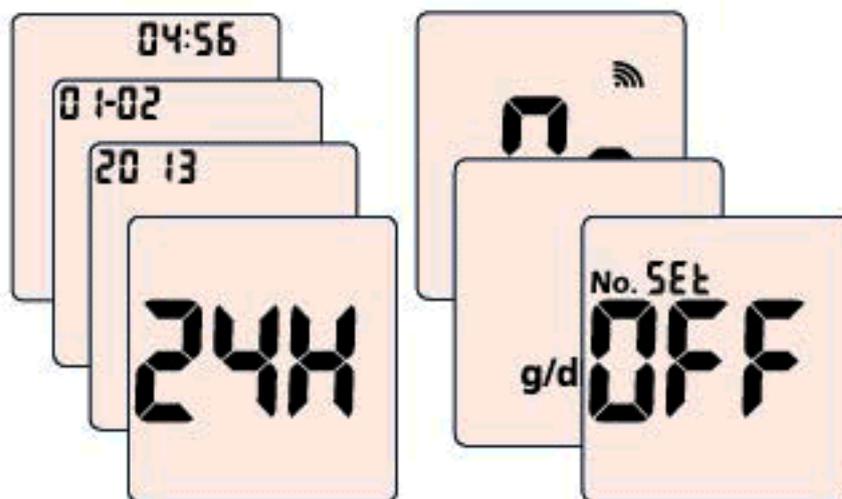
B Entering Setup Mode

With the meter turned off, press and hold ⏻ for 4 seconds to enter the setup mode. Press ◀ or ▶ to display the 'No. SEt', 'CHE', 'SEt', 'PC', 'dEL', and 'Elt' screens. Press ⏻ to enter the SEt mode.



C Setting up System

From the SEt screen, press  to enter system setup.
Press  or  to switch between the 12 and 24 hour mode.
Press  to save and advance to the next setup. Repeat this step to set the Date, Time, Test No. Reset, Unit, and Sound.



Note: Please see the User's Manual for other meter setup options.

D Exiting Setup

Press  to save and return to the setup screen. Press  or  until "Elt" is displayed and press  to exit setup.



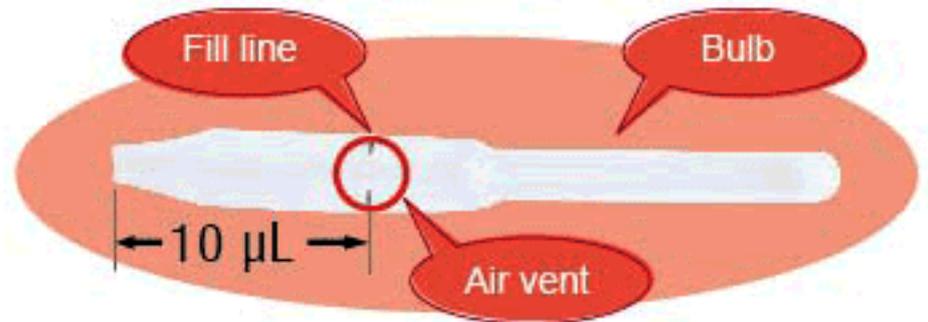
2

Plastic Capillary Tube

Plastic Capillary Tube

A Introduction

An air vent is strategically positioned on the sidewall of the tube to provide automatic air venting and specimen volume control.



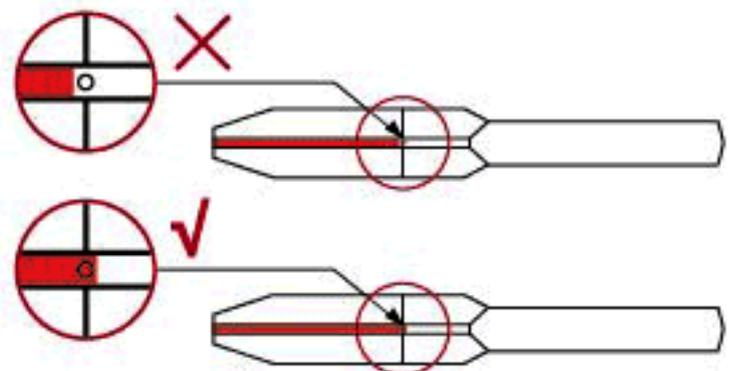
B Collecting Specimen



Without squeezing the tube, hold the tube slightly downward and bring the tip of the capillary tube to touch the blood drop. The blood will be automatically drawn to the black fill line.

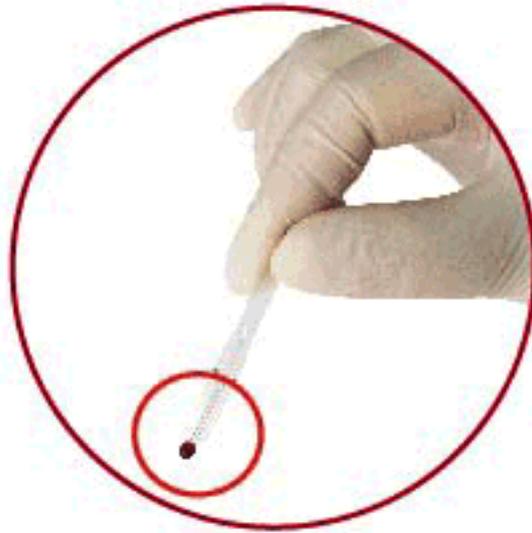
Note: Never squeeze the bulb during specimen collection.

Make sure the blood covers the air vent of the tube or it will be hard to squeeze blood out.



C Forming Blood Drop

Squeeze the plunger until a **full drop** of blood forms at the end.



Note: If the specimen does not come out completely, touch the tip of the capillary tube to the specimen again to allow it to fill up.

D Applying Specimen

Apply the full blood drop in the middle of the specimen application area on the cartridge. Do not touch the specimen application area.



3

Test Cartridge Preparation

A Inserting Code Chip

Insert the code chip into the code chip slot until it clicks.

Note: Change the code chip with each new box of test cartridges.



Make sure the code on the display matches the code number on the test cartridge canister label and on the code chip.

B Taking Cartridge

Take one test cartridge out of the test cartridge canister and immediately close the canister tightly.



C Inserting a Test Cartridge

After the *Test Cartridge Symbol* flashes on the display, insert the test cartridge completely into the cartridge channel of the test cartridge holder. The specimen application area should be aligned with the two arrows on the test cartridge holder.



Note: Insert the cartridge without bending it.



Ensure that the test cartridge is inserted all the way to the end of the cartridge channel.

4

Blood Specimen Collection and

Fingertip Blood

A Pricking Finger

Make sure the hand is warm and relaxed before pricking. Clean the testing site with an alcohol swab. Dry the testing site before pricking. Prick the side of the finger.



B Obtaining Specimen

Wipe away the first blood drop with a cotton swab. Gently squeeze the finger to obtain the second drop.



Note: The first blood drop contains intercellular fluid and interstitial fluid.

C Collecting Specimen

Use a capillary transfer tube to collect the blood specimen.

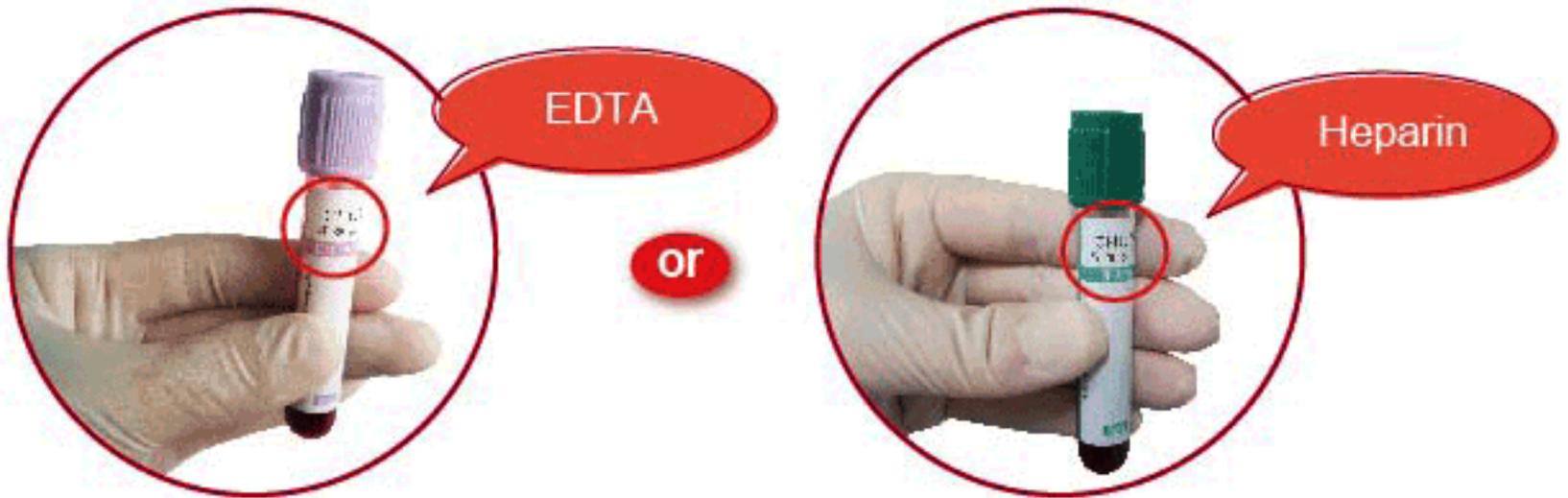


Handling

Venous Blood

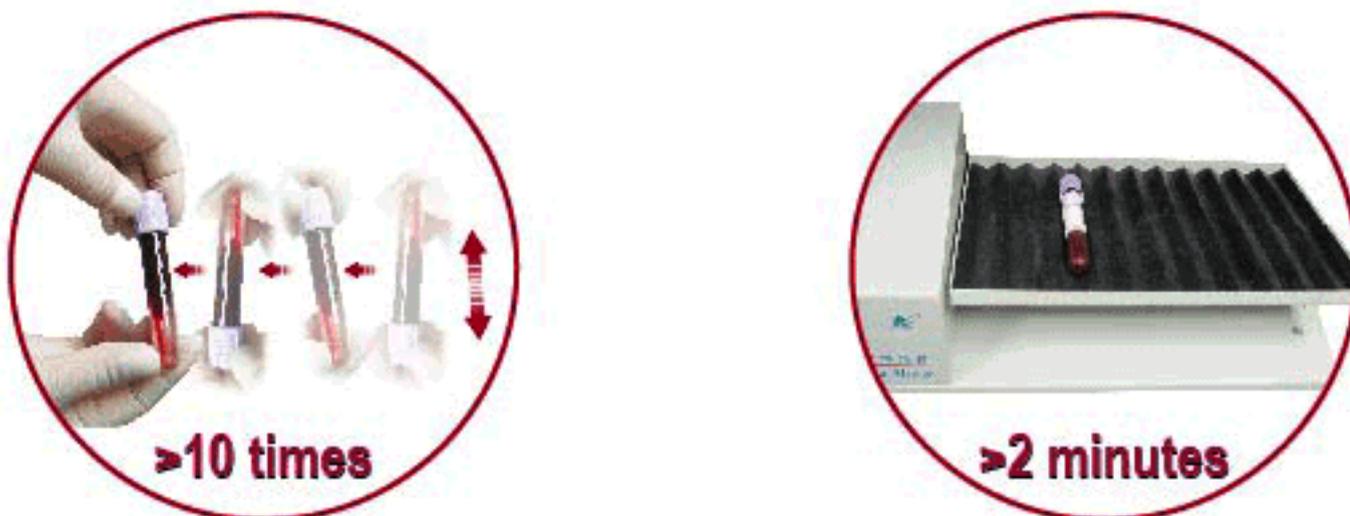
A Treating Specimen

Collect the blood with the tube treated with EDTA or heparin anticoagulants.



B Mixing Specimen Fully

Agitate the specimen at least 10 times by hand, or use a mechanical shaker for 2 minutes before testing.



C Collecting Specimen

Use a pipette to collect a 10 μ L blood sample from the blood collection tube.



Make sure to set the pipette to 10 μ L specimen volume.



< 8 hours



Test only with a fresh blood specimen, within 8 hours of collection. Never test a specimen stored for longer than 8 hours.

5

Specimen Application and Results

A Applying Specimen

Wait until the **Blood Drop Symbol** flashes.

Apply 10 μ L of a blood specimen to the test cartridge.



Never apply a fingertip blood specimen directly onto the test cartridge.



ult Reading



or



Only use a capillary transfer tube to apply the specimen onto the test cartridge.

B

Testing in Progress



C Reading Results

Hb result will display in 4-15 seconds with Hct value displayed at the bottom of the screen. The meter will automatically turn off after 8 minutes of inactivity, or when ⏻ is pressed.



Note: All results below 5.6 g/dL or above 23.5 g/dL must be confirmed by a suitable laboratory method.

The hematocrit value is calculated using the formula $\text{Hct} = \text{F} \times \text{Hgb}$ [g/dL], with $\text{F} = 2.94$. A true hematocrit test is not determined with this System.

Note: The use of this formula is allowed only within the normal hemoglobin range, means from 12.3 g/dL (7.63 mmol/L) - 17.5 g/dL (10.86 mmol/L). If the Hb result is outside this range then the estimated hematocrit result will not be calculated and “–” will appear.

6

Quality Control Test

A Control Solution 0, 1, 2



Note: The Clarity HbCheck Hemoglobin Control Solution is intended to validate hemoglobin testing using the Clarity HbCheck Hemoglobin Testing System. All three levels of control solutions must be tested and all levels have to be within the assigned values.

B Control Solution Testing

Hb Control Solution testing is performed in a very similar manner to blood tests, using the Clarity HbCheck Hemoglobin Control Solutions instead of blood.

Note: Each lab should use its own standards and procedures to perform quality control tests. Test known specimens or controls, at each of the following events, in accordance with local, state, and/or federal regulations or accreditation requirements.

Note: We recommend using only Clarity HbCheck Hemoglobin Control Solutions with your meter.

C When to test

- Each new day of testing
- A new canister of Test Cartridges is opened
- A new operator
- Test results seem inaccurate
- After performing maintenance or service on the meter



If quality control test do not provide expected results, perform the following checks:

- **Ensure the test cartridges used are not past their expiration date.**
- **Ensure the test cartridges are fresh from a new canister.**
- **Ensure the control solutions are not past their expiration date.**
- **Repeat the test to ensure no errors were made during the test.**

Please contact Customer/Technical Support at 1-877-485-7877.