



For validating hemoglobin (Hb) testing.
For *in vitro* diagnostic use only.

Hemoglobin (Hb) Control Solution Package Insert

REF CLIA-Hgb-CON

English

PRINCIPLE AND INTENDED USE

The CLIAwaived, Inc Hemoglobin (Hb) Control Solution is intended to validate hemoglobin testing using the CLIAwaived, Inc Hemoglobin (Hb) Testing System. The control solution is dispensed onto the CLIAwaived, Inc Hemoglobin (Hb) Test Cartridge, inserted in the meter, to confirm that the test cartridges and meter are working together properly and that the test is being performed correctly. CLIAwaived, Inc Hemoglobin (Hb) Control Solution package is sold separately and including all 3 levels: control 0, control 1 and control 2.

REAGENTS

The product is a liquid, stable control prepared from bovine hemoglobin with added chemicals, preservatives (0.06%) and stabilizers (14.5% of sorbitol and sugar). The control does not contain products of human origins.

STORAGE AND STABILITY

- Store the control solution at temperature of 36-46°F (2-8°C).
- Do not freeze.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the expiration date shown on the bottle labels.
- Each bottle of control solution can be used for 30 days after you first open it. The control solution will expire 30 days after the bottle is opened for the first time. Record this opened expiration date on the bottle label.

PRECAUTIONS

- Use only a CLIAwaived, Inc Hemoglobin (Hb) control solution with a CLIAwaived, Inc Hemoglobin (Hb) Meter and Test Cartridges.
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- Shake well and let the controls reach the temperature 59-86°F (15-30°C) prior to test.
- All materials should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used materials should be discarded according to local regulations after testing.
- This product is not intended for use as a standard.
- The use of quality control materials is an important part of good laboratory practices. Quality control materials are an objective method of assessing techniques or practices in use.
- Control solution tests are specified to be accurate only when tested between 59-86°F (15-30°C).
- Check the code chip before performing a test. Make sure to use the right code chip. Insert the code chip into the code chip slot. The code chip slot is located on the right side of the meter.

FREQUENCY OF USE

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

- 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

MATERIALS REQUIRED

- Control Solution 0
- Control Solution 1
- Control Solution 2
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Hb Meter
- Test Cartridges
- Latex gloves

INSTRUCTIONS FOR USE

Allow all test materials to reach the temperature 59-86°F (15-30°C) prior to testing. Refer to the CLIAwaived, Inc Hemoglobin (Hb) Testing System User's Manual for detailed instructions.

1. Prior to testing let the controls reach room temperature, between 59-86°F (15-30°C).
2. Shake the control solution bottle for at least 2 minutes.
3. Turn on the meter.
4. Insert the code chip into the meter and code the meter correctly. Refer to **Coding the Meter** in the User Manual for details. Compare the code number on the code chip with the code number printed on the test cartridge canister label, and ensure the two numbers are identical to avoid inaccurate results.
5. Remove a test cartridge from the closed canister and use it as soon as possible. Immediately close the canister tightly after removing the required number of test cartridges.
6. Wait for the meter to flash the **Test Cartridge Symbol**. Insert the test cartridge into the test cartridge channel in the same direction as the arrows on the test cartridge. Ensure that the test cartridge is inserted all the way to the end of the cartridge channel.
7. While the meter is flashing the **Blood Drop Symbol**, apply one drop of the control solution to the center of the sample well. A line with 3 dashes will appear on the meter to show the test is in progress.
8. Read the results on the screen after 15 seconds. Refer to **Testing** in the User's Manual for detailed testing procedures.

PERFORMANCE CHARACTERISTICS

Precision

A precision study was conducted to examine the precision of the controls tested with the CLIAwaived, Inc Hemoglobin (Hb) Testing System. Three bottles of control solutions from the same lot were tested for each level of controls. Each bottle was tested with 5 meters, 4 replicates on each meter. Within-run CV was calculated for each bottle and total CV was calculated for each level of controls. All within-run CVs and total CVs were less than 3.0%.

EXPECTED RESULTS

The results should fall within the range(s) listed on bottle label and are specific for each lot of control solution. If the results fall within the specified control range, it indicates the Hemoglobin (Hb) Test System is working properly and that the procedures are being performed properly.

- If the results do not fall within the respective range(s):
 - Check the expiration date of the test cartridge and control solution. Make sure that the test cartridge canister has not been opened for more than 3 months. Also make sure the control solution bottle has not been opened for more than 30 days. Discard any expired test cartridges or control solution.
 - Confirm all test materials are between 59-86°F (15 and 30°C).
 - Make sure that the test cartridge canister and the control solution bottle have been tightly capped.
 - Confirm that the brand of control solution is the same brand as the Hemoglobin (Hb) Testing System.
 - Make sure that all test procedures are followed correctly.
 - Make sure the meter is not contaminated.
 - Make sure the code chip number matches the code number printed on the test cartridge canister label and the code that appears on the meter screen.
 - Mix the control solution well prior to testing.

After checking all of the above, repeat the control solution testing with a new test cartridge. If results still fall outside the control range(s), the meter may not be working properly. Contact customer support at 1-888-882-7739 for further assistance.

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