

PROCEDURE: HEMOCUE® HEMOGLOBIN 201+ ANALYZER

ISSUE DATE: June 2007

REVISION DATE: July 2010

REVIEWED DATE: May 2018

PRINCIPLE:

The HemoCue® B-Hemoglobin 201+ system consists of disposable microcuvettes with reagent in dry form and a dual wavelength photometer. The microcuvette is used for measuring the sample, as a reaction vessel and as a measuring cuvette. Sodium deoxycholate hemolyzes the erythrocytes and hemoglobin is released. Sodium nitrite converts hemoglobin to methemoglobin, which, together with sodium azide, gives azidemethemoglobin. After conversion of the hemoglobin to azidemethemoglobin the reading takes place in the photometer, which measures the light absorption at two wavelengths (570 and 880 nm) in order to compensate for turbidity in the sample. The photometer follows the reaction and presents the result only when the reaction has stopped. The photometer is calibrated at the factory against the cyanmethemoglobin (ICSH) method, which is the international reference method for the determination of the total hemoglobin concentration in blood, and needs no further calibration.

SPECIMENS:

Patient Preparation: No special instructions

Type: Capillary, venous or arterial blood may be used. Use EDTA, heparin or heparin/fluoride as anticoagulants preferably in solid form to avoid dilutional effect.

Handling: Blood samples not analyzed immediately must be mixed thoroughly at least 2 minutes by inverting the tube 8-10 times. Samples of blood collected with the recommended anticoagulants must be used within 24 hours. Refrigerated samples must come to room temperature and be mixed before sampling.

EQUIPMENT:

1. HemoCue® Blood Hemoglobin 201+ Analyzer
2. Transformer Power Adapter (Part No. 651450)
3. Liquid Controls R&D Systems
4. HemoCue Hgb 201 Microcuvettes
5. "AA" Batteries

REAGENTS:

HemoCue® B-Hemoglobin microcuvettes (Article No. 110108)

- The microcuvettes are to be stored at room temperature (15-30°C). The microcuvettes are stable until the expiration date on the container of microcuvettes in the unopened container. Once opened, the microcuvettes are stable for 90 days. When opening a container always put an open date on the vials. **Always keep the containers closed.**
- The microcuvettes that are packaged individually are to be stored at room temperature (15-30). They are stable until the expiration date printed on the package. Discard after this date.

QUALITY CONTROL:

Two levels of CBC-7[®] HemoCue[®] controls (R&D Systems Cat. No. HC729; 14 x 2.0 mL Dual Pack –7 vials low, 7 vials high) are used. Both levels are run at the beginning of each shift on every day of patient testing. Control limits are $\pm 2SD$'s of the mean and are posted near the analyzer. Values exceeding these limits are to be treated in accordance with the guidelines set in the Quality Assurance Manual. Repeat the Quality Control first and if this fails, use a new vial of Quality Control. Record results on the Quality Control Log for the Healthy Kids Express. Contact the Point of Care Coordinator Pager 360-7930 if Quality Control does not read in the established quality control ranges. DO NOT CONTINUE with patient testing if Quality Control does not read within established quality control ranges.

Run Quality Control daily when patient testing is being performed. Quality Control must be repeated when the testing period has exceeded eight hours in the same day. Quality Control is good for 30 days once opened, when stored at 15-30 °C (59-86°F) or at 2-8°C (35-46°F). Date the vial when opening.

When stored refrigerated remove and allow to warm to room temperature for 15 minutes before mixing and using.

Quality Control is reviewed monthly by the Point of Care Coordinator and the Medical Director signed and faxed back to the Healthy Kids Express to keep on file. This copy is also kept in Point of Care testing area.

Follow the instructions as described in the manufacturers package insert for control preparation. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

CALIBRATION:

The photometer is delivered calibrated against the ICSH (Cyanmethemoglobin) method that is the international reference method for the determination of the total hemoglobin concentration in blood.

Start Up Procedure

1. Pull the cuvette holder out to the loading position. Press and hold the left button until the display is activated (all symbols appear on the display).
2. The display shows the version number of the program, after which it will show the Hour Glass symbol and "Hb". During this time the analyzer will automatically verify the performance of the optronic unit by performing an automatic SELFTEST.
3. After 10 seconds the display will show 3 flashing dashes and the Hemocue symbol. This indicates that the HemoCue Hb 201+ analyzer has passes the SELFTEST and is ready for use. If the SELFTEST fails, an error code will be displayed.
4. The cuvette holder, which is used to move the cuvette in and out of the photometer, has three positions:
 - a. Completely pushed in – measuring position.
 - b. Pulled out – loading position
 - c. Completely withdrawn – for cleaning
5. Underneath the photometer there is a lid covering the battery compartment, which holds five type AA

batteries. Place five type "AA" batteries in the battery compartment observing the indication of polarity in the battery holder.

5. Replace the lid. New batteries can operate continuously for approximately 100-150 hours.

Note: When going from battery power to main power supply, turn off the photometer "POWER OFF" before connecting.

Blood Hemoglobin Determination:

1. Press and hold the button on the upper left side of the Hemocue.
2. The display shows "Hb" and after approximately 15 seconds "READY" with three blinking dashes.
3. Take a cuvette out of its container. **Reseal the container immediately!** Hold the cuvette by the rear-winged end.
4. Fill the microcuvette with enough blood to fill the cuvette completely. This can be accomplished by obtaining blood taken directly from a capillary site, usually finger, or heel OR by using a pipette to deliver blood from a venous blood collection tube.
5. Fill the cuvette in **one continuous process!** It should **never be topped up after the first filling!**
6. Wipe off the excess blood on the outside of the cuvette tip. Make sure that no blood is drawn out of the cuvette in this procedure.
7. After filling the microcuvette, place it in the photometer. (Note: Measure ASAP but not longer than 10 minutes after filling. Discard the microcuvette if the 10-minute time limit is exceeded.)

ATTENTION

- Air bubbles in the optical eye, caused by inadequate filling of the cuvette may cause false results. Discard the cuvette and fill a new one.
 - Precaution should be taken not to hold the cuvette by the filling end. This can contaminate the optical eye.
8. Push the cuvette-holder to its inner position. When the cuvette-holder reaches its inner position fixed dashes and "MEASURING" will appear in the display.
 9. After 30-50 seconds, the photometer will find the steady state of the chemical reaction and the result will appear in the display. The hemoglobin value in g/dL will be displayed in the window within 60 seconds. The display will show the result for 5 minutes provided the cuvette-holder is left in its inner position.
 10. Remove microcuvette by pulling the cuvette-holder to its outer position and wait for the flashing dashes and "READY" to appear. Dispose of the microcuvette in a properly designated biohazard waste container.
 11. The photometer is now ready for a new measurement. Always perform 2 Levels of Quality Control at the

beginning of the shift or patient run. Quality Control must be performed daily when performing patient testing.

12. If the photometer is not to be used for several hours switch it off.

MAINTENANCE:

The cuvette holder should be cleaned daily with alcohol after having been removed from the photometer. It is important that the holder is completely dry before being replaced in the photometer.

Make certain that the analyzer is turned off. (the display should be blank).

- a. Pull the cuvette holder out to the loading position. Using your fingertip carefully press the small Catch in the upper right hand corner of the cuvette holder.
- b. While pressing the catch, carefully rotate the cuvette holder to the left as far as possible.
- c. Clean the cuvette holder with alcohol and allow to dry before replacing in the analyzer.

The exterior of the analyzer may be cleaned with alcohol or a mild soap solution.

No preventative maintenance is needed for the electronic components of the photometer.

The optic unit should be cleaned only as directed in the Troubleshooting guide of the HemoCue Hb201+ Operating manual.

Procedural Notes:

1. Microcuvettes are stored at room temperature, away from any direct heat source. The vial must be kept tightly capped and cuvettes should be removed as needed for testing just prior to use. Unopened cuvettes are good until the expiration on the vial. Once opened they are good for 90 days.

RESULTS:

HKE Hemoglobin results are recorded on HKE worksheets/records. They are not part of the SLCH Medical record.

The linear reportable range is 3.6-22.6 g/dL. Values above 22.6 g/dL must be confirmed using a suitable alternative laboratory method. Results above 25.6 g/dL are displayed as "ERROR 999" or ERROR HHH".

Send to SLCH main Laboratory for Hgb testing. Patient comparisons are done twice a year vs the Sysmex in the Core Lab

The following hemoglobin values are considered normal:

<u>Age Group</u>	<u>Hemoglobin (g/dL)</u>
0-1 wk.	14.5-22.5
1 wk-1 mo.	10.0-18.0
1 mo.- 6 mo.	9.0-14.9

6 mo.- 2 yr.	10.5-13.5
2 yr.- 6 yr.	11.5-13.5
6 yr.- 12 yr.	11.5-15.5
12 yr.- Adult	
MALE	13.8-17.2
FEMALE	12.1-15.1

The following hemoglobin values are considered physician alert results:

<u>Age</u>	<u>Hemoglobin (g/dL)</u>
<12 years	<7.5
>12 years	<6.0

Error codes: If the display shows Error and figures 900-908, an error has occurred. Refer to the Operating Manual. Call the Point of Care Coordinator.

LIMITATIONS OF THE PROCEDURE:

1. Sulfhemoglobin is not measured with this method
2. Carboxyhemoglobin and turbidity due to e.g. leukocytosis or hyperlipemia do not interfere.

REFERENCES:

1. HemoCue® Operating Manual, HemoCue AB, Angelholm Sweden



Department of Laboratories
St. Louis, MO 63110



POC.1.0067.0 version 1.4

Page 6 of 7



Donna Walck Point of Care Coordinator

Written By:

Technical Supervisor

Date

Medical Director

Date

Annual Review: Medical Director/Designee

Date

Location of hard copy location(s): Core Lab Office
See Test Methods / Test Locations (POC.1.0002.0)

Date Archived: _____