**LOURDES HOSPITAL**

**169 Riverside Drive**

**Binghamton, New York 13905**

**LAB MANUAL**

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**SUBJECT: HemoCue Hb 201+ ORIGIN DATE: 3/5/12**

**REVIEWED:6/11/2021 REVISED: 6/6/2017**

**REGULATORY REFERENCES: CROSS REFERENCES:Lab-025-046**

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**Principle:** The HemoCue Hb 201+ System provides a quantitative measurement of hemoglobin and is used in the screening of blood samples for hemoglobin concentration. The quantitative determination of hemoglobin is indicated as a general fundamental test in acute as well as elective general care.

The hemoglobin concentration in blood is determined as azidemethemoglobin utilizing a micro cuvette with dry reagent system and a dual wavelength photometer. The microcuvette serves as a pipette, reaction vessel and as a measuring microcuvette.The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from the ferrous to the ferric state to form methmyoglobin, which then combines with sodium azide to form azidemethemoglobin. Measurements are taken at 570nm and 880nm; the latter to correct for turbidity.

SPECIMEN TYPE

 Free flowing capillary blood or thoroughly mixed, anticoagulated, venous blood (EDTA).

COLLECTION- No special patient preparation is required. The purpose of the test and the steps of the procedure should be explained to the patient prior to performing the test. The operator must be wearing gloves during the procedure and immediately after removing the gloves, wash their hands. UNIVERSAL PRECAUTIONS shall be observed for all blood specimens.

EQUIPEMENT AND REAGENTS

HemoCue Hb 201+ analyzer

HemoCue Hb 201 Microcuvettes cuvettes Ref # 111715 (store at room temperature 59°F-86°F)

R&D Systems CBC-7 HemoCue Kit Control (4 vials each low, normal, and high) Ref # HC723 (store refrigerated 2°C-8°C).

IDENTIFICATION and LABELING the patient will be identified using 2 identifiers, patient full name and date of birth. The sample cuvette is placed in the analyzer at the time of collection in the presence of the patient.

QUALITY CONTROL

INTERNAL ELECTRONIC

The HemoCue HB201+ analyzer has an internal electronic “SELFTEST”. Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer. This is automatically performed every second hour that the analyzer is left on.

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 a number of symbols. 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 three flashing dashes and the HemoCue symbol. This indicates that the HemoCue Hb201+ has passed the SELFTEST and is ready for use.
4. If the SELFTEST fails, an error code will be displayed. (refer to HemoCue HB201+ Operating Manual for Error Code Trouble Shooting Guide).

Liquid Quality Control

 Three levels of CBC-7 controls are run every day the HemoCue is used for testing. Unopened controls are stable until the expiration date if stored refrigerated at 2 - 8 C. Once opened, controls are stable for 30 days if stored refrigerated at 2 - 8 C when not in use. Open date and 30 day expiration dates must be written on each vial when opened. Controls are not used beyond either expiration date.

1. Verify that the lot # , expiration date and assay ranges of the QC being used matches that on the Control Assay Sheet and is the same as the Lot # written on the log sheet. Remove one vial of each level from the refrigerator.
2. Bring to room temperature by rolling the vials between the palms of the hands and gently inverting until the erythrocyte sediment is completely suspended.
3. Gently invert the vials 8-10 times immediately before sampling. Do not shake. It is important to mix the vials completely prior to use.
4. Remove the cap, tilt the vial slightly and touch the tip of the cuvette to the control solution and watch it fill completely in one smooth continuous process. Make sure no air bubbles are observed. Another method is to pipette a drop of the control on a piece of hydrophobic paper (parafilm, saran wrap etc.) and touch the tip of the cuvette to the drop and let it fill completely.
5. After sampling the control, carefully wipe the vial rim and cap. Replace the cap immediately. Place the control vials back in the refrigerator within 30 minutes of use.
6. Place the filled microcuvette in the cuvette holder and gently slide the cuvette holder in to the measuring position.
7. Record the control result, date and time of testing and your initials on the HemoCue log sheet. Verify that the results are within the acceptable assay range for the lot # of controls being used.

\*\*If control results are outside of the Assay Range:

 a. Check that the original vial was properly mixed; retest the vial by following the steps above.

 b. Review directions for storage and verify that CBC - 7 was properly stored.

 c. Check that microcuvettes:

 1. Have been stored at room temperature in a dry place

 2. Are not in use past the expiration date

 3. Are being stored in the original unsealed package with the desiccant

 4. Have not been opened longer than 3 months

 e. Test a previously unopened vial of CBC – 7following above steps

 f. If problem cannot be resolved, call Technical Services at 1-800 - 328 - 2400.

**\*\*Patient results are not reported unless the quality control is acceptable.**

PROCEDURE:

Patient Testing:

1. The HemoCue cuvette holder should be open to its loading position with the display showing three flashing dashes. Open one microcuvette.
2. Identify the patient per policy and seat comfortably in close proximity to the HemoCue Hb201+. Make sure the patients hand is warm and relaxed. Use only the middle or ring finger. Avoid fingers with rings on.
3. Clean the side of the finger thoroughly with alcohol and allow to air dry completely or wipe off with a dry lint free wipe.
4. Using your thumb, lightly press the finger from the top of the knuckle towards the fingertip. This stimulates the blood flow towards the sampling point.
5. While applying light pressure towards the fingertip, puncture the fingertip with lancet. Discard the lancet in the sharps container. Wipe away the first 2 or 3 drops of blood while applying light pressure. This stimulates blood flow and lessens the likelihood of a dilutional effect by interstitial fluid. Do not milk the finger.
6. Re-apply light pressure towards the fingertip until another drop of blood forms.
7. When the drop is large enough to fill the cuvette completely, touch the tip of the microcuvette to the drop and watch it fill completely in one continuous process. DO NOT REFILL. Visually inspect the cuvette for air bubbles. If bubbles are discovered discard the cuvette in the sharps container and repeat the process.
8. Wipe off excess blood from the outside of the cuvette with a clean, lint free wipe being careful not to touch the open end of the microcuvette, which could result in blood being drawn out of the microcuvette.
9. Place the filled microcuvette in the cuvette holder and gently slide the cuvette holder in to the measuring position. This must be performed within ten minutes after filling the cuvette.
10. During the measurement an hourglass and three fixed dashes will be shown on the display.
11. The hemoglobin value will be displayed within 15-60 seconds and remain on the display as long as the cuvette holder is in the measuring position or the meter is turned off. If operating on battery power the meter will automatically shut off after 5 minutes.
12. Record the patient name, date of birth, patient result, date and time tested and name of person performing test on the log sheet and the Lab Order Result Form.
13. Pull the cuvette holder out to its loading position. Remove the cuvette and discard in the biohazard sharps container.
14. When the display shows three flashing dashes and the HemoCue symbol, the analyzer is ready for the next measurement.

RESULT REPORTING Patient results are not reported unless the quality control is acceptable.

The patient’s results must be recorded in the patients chart using the Lab/Order Form as well as the accession log with patient’s name, date of birth, the date and time of the test, and signature of the person performing the test. The accession log must also include the cuvette lot# and expiration date and the control lot#, expiration date and the acceptable ranges for each level. FOLLOW UP RECOMMENDATIONS

Results 7.0g/dL and less or 18.0 g/dL or greater are considered critical and must be confirmed with a Lab Draw.

 Results out of normal reference range, a blood sample can be submitted to Lourdes Laboratory for confirmation

An abnormal screening result may be used diagnostically for treatment purposes by the practitioner.

**Reference Range:**

Adult males: 14 - 18 g/dL

Adult females 12 - 16 g/dL

Infants, after neonatal period 9 – 14.7 g/dL

Children, 2 yrs. to teenager: gradual increase to adult values

Reportable Range:

 The HemoCue201+ is factory calibrated against the hemoglobincyanide international reference method to a reportable range 0-25.6 g/dL.

LIMITATIONS

1. Air bubbles in the microcuvettes will result in erroneously low values. The microcuvettes should be inspected for bubbles before testing
2. The microcuvette should be filled in a continuous process. It should never be topped off after the initial filling.
3. If the HemoCue displays an error code, refer to the Troubleshooting Guide in the Operating Manual.
4. Excessive squeezing of the finger can dilute the sample with tissue fluid/interstitial fluid and may give lower results.
5. Individuals with compromised capillary circulation and finger temperature can affect results.
6. The measurement should be performed as soon as possible after the blood is drawn into the microcuvettes but no longer than 10 minutes after collection.

INSTRUMENT MAINTENANCE AND FUNCTION TESTS

Analyzer

The analyzer has no serviceable parts. The exterior of the analyzer should be wiped down daily or whenever visibly soiled with alcohol or mild detergent

Cuvette Holder

The cuvette holder should be cleaned after each day of use or whenever visibly soiled.

1. Check that the analyzer is turned off. To turn off; press and hold the left button until the display reads OFF and then goes blank
2. Pull the cuvette holder out to the loading position. Using a pointed object or your fingertip, carefully press the small catch positioned in the upper right hand corner of the cuvette holder
3. While pressing the catch, carefully rotate the cuvette holder towards the left as far as possible. Carefully pull the cuvette holder away from the analyzer.
4. Clean the cuvette holder with alcohol or mild soap solution. It is important that the cuvette holder is completely dry before being replaced.

Optronic Unit

The Optronic unit should be cleaned when directed to do so in the Trouble Shooting Guide of the HemoCue HB 201+ Operating Manual which is available at each primary care site using the analyzer. A dirty Optronic unit may cause an error code or QC to be out of range. To clean the Optronic Unit

1. Push the HemoCue Cleaner Swab or a cotton swab moistened with water or alcohol with no additives into the opening of the cuvette holder. Move the swab from side to side 5-10 times. If the swab is stained, repeat with a new swab. No further cleaning is required if the swab remains clean.
2. Wait 15 minutes before replacing the cuvette holder and using the analyzer

EQUIPMENT PERFORMANCE EVALUATION

If after checking the Troubleshooting Guide in Operators Manual, you feel service is necessary, contact: HemoCue Incorporated, Technical Service 800 - 426 - 7256.

REFERENCES

HemoCue HB 201+ Operating Manual

HemoCue Hb 201Microcuvette package Insert

**Electronic Authorizations:**

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