Title: HemoCue Hb201 Hemoglobin procedure
Cross References: Hemocue Competency Record
Hemocue Operator Training Checklist
MGH POCT QC Storage Ordering and Documentation Guide
Hemocue Docking and QC Guidelines

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Written By: Kim Gregory MT(ASCP), NCA, CLS  Date: 7/9/2008

Title (with LTR): HemoCue Hb201 Hemoglobin procedure (LTR19555)
Last Approved: Gregory, Kimberly (8/1/2016 11:41:01 AM)
Purpose

This document outlines policies and procedures that deal with hemoglobin testing by the HemoCue Hb201DM. In an effort to be concise, some information may be excluded from the manufacturer’s recommended procedure. It is recommended that operators familiarize themselves with the manufacturer’s product information that accompanies each package and their manual if one exists.

Scope

Level of Personnel: All RN’s, medical assistants, Cath lab techs, Respiratory Therapists, and MD’s who have successfully completed initial training and maintained annual competency.

Testing Site: Sites approved and on file with the Department of Pathology’s POCT Division.

Policy and Procedure Statement

The waived HemoCue™ Hb 201DM system is used for quantitative diagnostic determination of hemoglobin in blood using a specially designed photometer, HemoCue Hemoglobin analyzer and specially designed HemoCue Hemoglobin Microcuvettes.

Theory

The HemoCue™ Hb 201DM is a system used for the determination of the total amount of hemoglobin in whole blood. The system consists of a specially designed analyzer with specially designed Microcuvettes containing dried reagents. The microcuvette serves as pipette, reaction vessel and as a measuring microcuvette.

The reaction in the microcuvettes is a modified azidemethemoglobin reaction. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from ferrous to the ferric state to form methemoglobin, which then combines with azide to form azidemethemoglobin.

\[
\text{Erythrocytes} \rightarrow \text{Hemolyzed Erythrocytes} \rightarrow \text{O} \rightarrow \text{Hemoglobin} + \text{N02} \rightarrow \text{Methemoglobin} + \text{N3} \rightarrow \text{Azidemethemoglobin}
\]

The HemoCue technique is based on an optical measuring cuvette of small volume and short light path. The cuvette cavity contains the reagents deposited on its inner walls and the blood sample is drawn into the cavity by capillary action and is spontaneously mixed with the reagents. The cuvette is then placed in the HemoCue Hb 201 DM analyzer where the absorbance is measured and the hemoglobin level is calculated. Since two wavelengths are used in measuring 570 nm and 880 nm, the turbidity in a sample will automatically be compensated for correct readings. Carboxyhemoglobin, leukocytosis and turbidity do not interfere with the HemoCue Microcuvette hemoglobin test.

The cuvette is made of polystyrene plastics and comprises a body having a cavity, which takes about 10μl of blood. The distance between the parallel walls of the optical window is 0.130 mm, which permits photometric determination of hemoglobin in undiluted blood.

Regulatory Requirements

1. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.

2. All test results must be maintained in patient records with all required information for four years

Required information:

1. Patient’s name
2. Medical Record Number
3. Patient’s gender
4. Patient’s age or date of birth
5. Date & time test collected, performed and reported
6. Ordering Physician
7. Responsible physician (if not 6)
8. Reference or Target Range
9. Test Performed
10. Test units
11. Lab name

3. Additional information that must be retained for four years:
   1. Testing personnel records
   2. Quality control results
   3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on quality control and any remedial action
   4. QC charts, maintenance sheets, reference and critical ranges

4. Other
   1. Universal precautions must be observed when handling any patient specimen.
   2. A physician’s order or standing order is required prior to performing test.
   3. The Hospital Hand Hygiene policy must be adhered to at all times.

**Competency Assessment**

All operators must read the procedure manual and complete the “Hemocue Operator Training Checklist” during initial training. Competency is assessed at orientation and annually using at least two of the following methods:

1. Performing a test on a blind specimen.
2. Supervisor observes performance of routine work.
3. Each user’s quality control performance is monitored.
4. Written testing specific to the method.

**Expired Operators:**

Operators that fail to meet competency requirements within 365 days will be locked out of the system. They will be required to undergo retraining and competency assessment according to above.

**Limitations/Interferences**

HemoCue™ Hb 201 Microcuvettes are for In Vitro Diagnostic use only.

1. The HemoCue Hb 201DM analyzer is only to be used together with HemoCue™ Hb 201 Microcuvette.
2. Measurement of hemoglobin should be made as soon as possible after the blood has been drawn into the cuvette. If the readings in the photometer are made later than 10 minutes after the blood has entered the cuvette, false results may be obtained. It should be noted that oxygenated blood, which has been agitated over a long period, produces oxygen pressure and viscosity at higher than normal levels. The achievement of accurate results for blood in this condition requires analysis to be undertaken immediately after the cuvette has been filled.
3. 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.
4. Precaution should be taken not to hold the cuvette by the filling end. This can contaminate the optical eye. Care should be taken not to contaminate the outer surface of the optical eye with blood.
5. Sulfhemoglobin is not measured with this method.

**Test Kit/Supplies/Equipment**

<table>
<thead>
<tr>
<th>Products</th>
<th>Manufacturer #</th>
<th>People soft #</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcuvettes</td>
<td>HemoCue #111715(100 ind. wrapped) #111716 (50/bottle)</td>
<td>162142</td>
<td>15° to 30 °C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>161654</td>
<td>15° to 30 °C (90 days once opened)</td>
</tr>
<tr>
<td>QC Level 1</td>
<td>RNA Medical # QC HGB-1 (Low)</td>
<td>118479</td>
<td>2 - 8°C (once opened, 30 days RT or 60 days refrigerated)</td>
</tr>
<tr>
<td>QC Level 3</td>
<td>RNA Medical # QC HGB-3 (High)</td>
<td>118507</td>
<td>2 - 8°C (once opened, 30 days RT or 60 days refrigerated)</td>
</tr>
<tr>
<td>(Linearity/Cal Ver.)</td>
<td></td>
<td>n/a</td>
<td>2-8°C (once opened, 30 days)</td>
</tr>
<tr>
<td>CBC-LINE Kit</td>
<td>R&amp;D Systems # HCL001</td>
<td>8653</td>
<td>Room temperature</td>
</tr>
<tr>
<td>Syringes 1 ml</td>
<td>BD #309602</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Reagent Storage Requirements

A. HemoCue™ Hb 201 Microcuvettes:
   - Use the HemoCue Hb 201 Microcuvettes prior to the expiration date. The expiration date is printed on each package.

B. Storage of Microcuvettes kept in a vial:
   - The Microcuvettes are to be stored in room temperature (15-30 ºC, 59-86ºF). Do not refrigerate.
   - The Microcuvettes are stable until the date of manufacturer on the box.
   - Once the seal is broken, the Microcuvettes are stable for three months. Always keep the container properly sealed.

C. HemoCue™ Hb 201 DM Analyzer and HemoCue™ DM Docking station:
   - The Analyzer and Docking Station can be stored at 0-50 ºC (32-122 ºF).
   - The Operating temperature is 18-30 ºC (64-86 ºF).
   - The analyzer and Docking station must be used at ambient temperature.
   - The analyzer and the Docking Station should not be operated at high (i.e. > 90 % non-condensing) humidity.

Calibration

Calibration is not required. The HemoCue Hb 201 DM analyzer has been factory calibrated against the international reference method for hemoglobin determination, ICSH. After the factory calibration, a maximum deviation of ± 0.3 g/dl is tolerated.

Calibration verification

Calibration verification is the process of assaying reference standards or calibration materials in the same manner as patient samples to confirm that the calibration of the analyzer has remained stable throughout the laboratory's reportable range for patient test results. Calibration verification is performed on each new analyzer received. A linearity/calibration verification kit from R&D is utilized. All samples will be run in duplicate and the average plotted to determine linearity. Samples should come within 0.5 g/dL of the target value. Values that fall outside of the acceptable range may be repeated. If they remain out of range, then the reportable range of the analyzer may be limited or the analyzer returned to the vendor for replacement.

Quality Control: Electronic

The HemoCue Hb 201DM analyzer has an internal electronic “selftest” (EQC). Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer. This test is performed every eighth hour if the Analyzer is left turned on. The result of the selftest is stored as an EQC. If the analyzer doesn’t match reference standards, it will display an error code. Cleaning may be required and the test repeated.

Quality Control: Liquid QC

The HemoCue system must be checked daily with RNA Medical controls Level 1 (Low) and Level 3 (High).

1. Follow hand hygiene protocol and put on gloves.
2. In the Main Menu, press the QC test button.
3. The display shows 6 QC Test options:
   - Low
   - Normal
   - High
   - Other level
   - Linearity
   - Proficiency
4. Select the Low Level.
5. Enter the Cuvette Batch Number.
6. Enter the Lot Number for the Liquid Control used.
7. Mix the control solution well and fill the cuvette.

**Note:** After opening, QC material is good for only 30 days at RT or 60 days when refrigerated or until the printed manufacturer’s expiration date (whichever comes first)

8. Place the filled cuvette in the cuvette holder. This should be performed within ten minutes after filling the cuvette! Gently push the cuvette holder to its measuring position.

9. The following text will be displayed: **Please Wait Measuring….** If the measurement has not been completed.

10. After 15 – 60 seconds, the result will display “Pass” or “Fail”. The result will remain on the display as long as the cuvette holder is in the measuring position.

11. Although the reagents are present in the cuvette in extremely low quantities, dispose of it in the sharps container. Always handle blood specimens with care, as they might be infectious. All results are stored in the analyzer and can be viewed in the display using the scroll function.

12. Press the confirm button “OK” and the QC Test Menu will be displayed. If the QC passes, continue to the next level. If the QC fails, repeat the level with a new cuvette and sample.

13. Repeat the steps 1-9 with Level 3 control solution.

14. Leave the QC-test screen scroll using the right button until Main Menu activity is shown on the display.

**Specimen Collection**

Venous and arterial samples should be collected following hospital approved procedures.

**Capillary Sampling**

1. Make sure the patients hand is warm and relaxed. Use only middle or ring fingers for sampling. Avoid fingers with rings.

2. Clean with disinfectant and allow to dry or wipe off with a dry, lint free tissue.

3. Using your thumb, lightly press the finger from the top of the knuckle towards the tip. This stimulates the blood flow towards the sampling point.

4. For best blood flow and least pain, sample at the side of the fingertip, not the center.

5. While applying light pressure toward the fingertip, puncture the finger using the lancet.

6. Wipe away the first 2 or 3 drops of blood with a lint free wipe.

   **Note! Do not use cotton balls!**

7. Re-apply light pressure towards the fingertip until another drop of blood appears.

8. When the blood drop is large enough, fill the cuvette in one continuous process. Hold the cuvette in the center of the drop for 2 seconds (count to 2 slowly)

9. Wipe off excess blood from the outer surface of the cuvette with a lint free wipe, being careful not to touch the open end of the cuvette.

   **Note! Make sure that blood is not drawn out from the cuvette during this procedure!**

10. Look for air bubbles in the filled cuvette. If any air bubbles are present, fill a new cuvette. Small bubbles around the outer edge can be ignored.

   **Note! If a second sample is to be taken from the same finger stick, wipe away the remains of the initial sample and fill a second cuvette from a new drop of blood!**

**Test Procedure**

1. Follow hand hygiene protocol and put on gloves.
2. Turning on the Analyzer
   - Power the analyzer on by pressing the power button briefly (1 in Fig.1) and then waiting ten seconds.
   - Gently press the button on the screen with your finger. The button will turn black. The touch screen display works on lift.
   - Enter your digit Operator ID using the numeric buttons (3 in Fig.2)

3. Main Menu (Fig. 3)
   - In the Main Menu, press the Patient Test button

4. Testing Patient Sample
   A. If sample is from a tube, mix the blood well before performing the measurement.
   B. Place a drop of blood onto a hydrophobic surface, e.g. a plastic film, using a pipette.
   C. Capillary samples should be collected according to specimen collection procedure on page 7.
   D. Fill the cuvette in one continuous process. Do NOT refill! Wipe off excess blood on the outside of the cuvette tip. Make sure that no blood is drawn out of the cuvette during this procedure.
   E. Look for air bubbles in the filled cuvette. If present, take a new sample. Small bubbles around the edge can be ignored.
   F. Place the filled cuvette in the cuvette holder. This should be performed within ten minutes after filling the cuvette! Gently push the cuvette holder to its measuring position.

5. Entering the Cuvette Batch No.
   - Enter the Cuvette Batch No via the barcode Scanner.
   - Enter the Expiration Date for the Cuvette Batch via the Numeric mode buttons.
   - Press the Confirm button.

6. Entering the Patient ID
   - Enter the 9-10 digit CSN via the barcode scanner or manual entry. (Verify correct patient identification with 2 identifiers
   - Press OK to continue.

7. Verify
   - A display will be shown where it is possible to verify all entered information. If some of the entered information is wrong, press the back arrow to go back and re-enter the information, otherwise press OK to continue.

8. Results
   - The following text will be displayed: Please Wait Measuring .... If the measurement has not been completed.
   - After 15 – 60 seconds, the hemoglobin value of the sample is displayed. The result will remain on the display as long as the cuvette holder is in the measuring position.
   - Although the reagents are present in the cuvette in extremely low quantities, dispose it in sharp container. Always handle blood specimens with care, as they might be infectious. All results are stored in the analyzer and can be viewed in the display using the scroll function.

Reference ranges
<table>
<thead>
<tr>
<th>Age</th>
<th>Female g/dL</th>
<th>Male g/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 years</td>
<td>12.0-16.0</td>
<td>13.5-17.5</td>
</tr>
<tr>
<td>12 years</td>
<td>12.0-16.0</td>
<td>13.0-16.0</td>
</tr>
<tr>
<td>6 years</td>
<td>11.5-15.5</td>
<td>11.5-15.5</td>
</tr>
<tr>
<td>2 years</td>
<td>11.5-13.5</td>
<td>11.5-13.5</td>
</tr>
<tr>
<td>6 months</td>
<td>10.5-13.5</td>
<td>10.5-13.5</td>
</tr>
<tr>
<td>3 months</td>
<td>9.5-13.5</td>
<td>9.5-13.5</td>
</tr>
<tr>
<td>2 months</td>
<td>9.0-14.0</td>
<td>9.0-14.0</td>
</tr>
<tr>
<td>1 month</td>
<td>10.0-18.0</td>
<td>10.0-18.0</td>
</tr>
<tr>
<td>14 days</td>
<td>12.5-20.5</td>
<td>12.5-20.5</td>
</tr>
<tr>
<td>7 days</td>
<td>13.5-21.5</td>
<td>13.5-21.5</td>
</tr>
<tr>
<td>3 days</td>
<td>14.5-22.5</td>
<td>14.5-22.5</td>
</tr>
<tr>
<td>0 days</td>
<td>13.5-19.5</td>
<td>13.5-19.5</td>
</tr>
</tbody>
</table>

Critical range: <7 g/dl

Reportable range: 4.0 – 23.0 g/dL

**Maintenance**

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

**A. Cuvette holder:**

1. Check that the analyzer is turned off. The display should be blank.
2. Pull the cuvette holder out to its loading position. Use a pointed object to carefully depress the small catch positioned in the upper right corner of the cuvette holder.
3. While pressing the catch, carefully rotate the Cuvette holder sideways as far as possible to the left.
4. Remove the Cuvette holder from the Analyzer.
5. Clean the cuvette holder with alcohol or mild detergent.
6. Move the HemoCue Cleaner from the right to the left 5-10 times, and then pull it out.
7. If the HemoCue Cleaner is stained, repeat with a new HemoCue Cleaner.
8. Wait 15 minutes before re-using the analyzer. Replace the cuvette holder. The cover may be disinfected.

**B. Analyzer:**

- Disinfect the analyzer between each patient used with Sani Wipe disinfectants.

**C. Optronic Unit:**

- Call HemoCue Hb 201DM Technical Service for instructions.

**Instrument Replacement Policy of HemoCue Hb 201DM analyzer**

**A. Before putting an analyzer into service:**

- Check the calibration self test
- Perform the Calibration Verification/Linearity
- Run Liquid controls Levels 1 and 3
- Approve results and store in Hemocue Testing manual.

**Connectivity**

**Downloading**
1. 201 DM Software must be open and running on the server.
2. Downloading is automatic.
   - Simply slide the analyzer into the docking station. **Note! Make sure that the analyzer is turned on.**
   - Analyzer screen will flash “Data Exchange”.
   - Data transfer can be confirmed in either the Hemocue software or Telcor
   - Contact the POCT program with any concerns: (ext.6-1462 or 3-5392)

### Down time procedure

1. The HemoCue Hb 201DM analyzer is designed to work for a long period of time without any direct service. No preventative measurements are needed for the electronic components of the analyzer.
2. In the event of connectivity failure, document the results on the patients chart with the units and reference ranges. Results will transmit once connectivity is restored
3. Contact the POCT program for assistance.(ext.6-1462 or 3-5392)

For Technical Service call 1-800-426-7256

### References

2. Package inserts – HemoCue™ Hb 201 Microcuvettes, HemoCue™ US, 40 Empire Drive, Lake Forest, CA 92630.

### Cross - References

- Hemocue Operator Training Checklist
- Hemocue Competency Record