POC HEMOCUE Hb 201 DM (BLOOD HEMOGLOBIN) PROCEDURE

DATE PREPARED: 11/05

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DATE ACCEPTED: 11/05

ACCEPTED BY: ____________________________
DR. JAMES COTELINGAM
CLINICAL LABORATORY DIRECTOR

REPLACES: POC HEMOCUE (BLOOD HEMOGLOBIN) PROCEDURE

<table>
<thead>
<tr>
<th>REVIEWED BY:</th>
<th>DATE</th>
<th>MANAGER</th>
<th>COMMENTS</th>
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I. **TITLE:** POC HEMOCUE (BLOOD HEMOGLOBIN) PROCEDURE

II. **PURPOSE:**

The HemoCue Hb 201 DM System is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, HemoCue Hb 201 DM and specially designed HemoCue Hb 201 DM Micro-cuvettes.

The quantitative hemoglobin determination is indicated as a general fundamental test in acute as well as elective care. The test is used in assessing the status of a patient in such clinical situations as hemorrhage, hemolysis, dehydration and other shifts in plasma volume – and for verifying the results of transfusion or treatment of other deficiency states such as malnutrition.

Note: The HemoCue Hb 201 Analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

III. **PRINCIPLE:**

*Of the method:* The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocytes are hemolyzed to release the hemoglobin. Hemoglobin is converted to methemoglobin and then combined with azide to form azidemethemoglobin. The measurement takes place in the analyzer in which the transmittance is measured and the absorbance and hemoglobin level is calculated. The absorbance is directly proportional to the hemoglobin concentration.

*Of the procedure:* The system consists of an analyzer together with microcuvettes. The microcuvette serves both as a pipette and as a measuring cuvette and is for single-use only. A blood sample of approximately 10 uL is drawn in to the cavity by capillary action. The analyzer measures at two wavelengths in order to compensate for turbidity, and the hemoglobin level is calculated and presented. The HemoCue Hb 201 system is calibrated against the international reference method for hemoglobin determination, ICSH and needs no further calibration.

IV. **SPECIMEN REQUIREMENTS:**

A. **Conditions for Patient Preparation.**

- The purpose of the test and the steps of the procedure will be explained to the patient prior to performing the test.
- The operator’s hands must be washed before and after testing.
- Standard precautions must be observed, and disposable gloves must be worn when the operator is handling blood products.
- If the patient is able, the patient should wash his/her hands prior to testing with capillary samples taken from the fingertip.
B. **Type of Specimen.**
- Fresh capillary whole blood samples (specimen of choice are obtained from the fingertip or heelstick). Wipe away first drop of blood. If necessary, apply light pressure until another drop of blood appears. Avoid “milking”.
- Venous or arterial blood samples may also be used.
- Appropriate anticoagulants (e.g. EDTA or heparin) may be used, preferably in solid form to avoid dilutional effects.

C. **Handling Conditions.**
- The capillary sample must be tested immediately after collection.
- Venous or arterial blood collected in EDTA must be used within 24 hours stored at room temperature. Mix samples thoroughly prior to testing on mechanical mixer for at least 2 minutes or by inverting tube 8 – 10 times by hand. Avoid mixing for an extended time may give false results due to increased oxygen pressure and viscosity.

V. **REAGENTS AND SUPPLIES:**

1. **Blood collection supplies**
2. **HemoCue 201 DM Hemoglobin Cuvettes** - microcuvettes are stored at room temperature 15-30°C (59-86°F) in a dry place. Do not refrigerate. Use the microcuvettes prior to the expiration date that is printed on each package. Once the seal of the vial is broken, the microcuvettes are stable for three months. The vial should be initialed and dated upon opening; the open vial will expire in three months or printed expiration date whichever is earliest. Keep the vial properly closed. All unused microcuvettes should remain in the original container. Always recap container immediately after removing microcuvette(s) for use.
3. **HemoCue 201 DM Analyzer** - runs on rechargeable lithium ion battery or AC Adapter. Operating temperature is 15-30°C (59-86°F).
4. **Liquid Controls** – store according to manufacturer’s specifications. Currently, the Hema-Trol Whole Blood HGB for Hemocue Hb 201 is approved for use. It is stored 2-8°C and must be allowed to come to room temperature 15-30°C for 20 minutes before testing is performed.
5. **Parafilm®** or other hydrophobic material

**NOTE: WARNING: POTENTIALLY BIOHAZARDOUS MATERIAL**
Controls are made from human sources and should be treated as potentially infectious.
VI. CALIBRATION

The HemoCue Hb 201 system is calibrated against the international reference method for hemoglobin determination, International Council for Standardization in Haematology method (ICSH) and needs no further calibration.

VII. QUALITY CONTROL:

Valid Liquid Controls must be run prior to patient specimens being analyzed. A Low control and a Normal control are performed only on days that testing is performed. Controls are documented as Pass or Fail on HemoCue Accession Log.

SELFTEST
The HemoCue Hb DM 201 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 test is performed at regular intervals if the analyzer is on.

VII. PROCEDURE:

Note: Utilize Standard Precautions; Always wear gloves when collecting samples or operating analyzer.

The cuvette holder has three positions:

b. Pulled out – loading position.
c. Completely withdrawn – for cleaning or troubleshooting purposes only.

A. Maintenance

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

Cuvette holder is cleaned with either an alcohol pad or a mild soap solution after being completely removed from the photometer. The holder must be completely dry before being replaced in the photometer.

B. Liquid Controls

NOTE: Hema-Trol Whole Blood HGB for Hemocue Hb 201 is stored 2-8°C and must be allowed to come to room temperature 15-30°C for 20 minutes prior to beginning assay. Controls should be mixed thoroughly by gently inverting the vials and rolling them between the palms until all cellular components are completely suspended. Do not shake vial. Hold vial vertically and dispense slowly as free-falling drops onto Parafilm® or
other non-absorbent material. Return controls to refrigerator immediately after obtaining valid results on both levels. Controls are required once every 24 hours on day of testing.

1. The Analyzer is started when the On/Off button is pressed. The screen images will be visible on the Display. All navigation and information handling is performed by pressing the appropriate touch buttons directly on the display screen.

2. The buttons appearing on the display activate the specific functions symbolized by the image on the button. The buttons should only be pressed using the fingertip. When a button is pressed, it will appear highlighted as long as it is kept pressed. When the button is released, the function indicated by the button is activated. An audible signal will sound if the audio function has been activated in the settings.

3. Inputs to the Analyzer such as Operator ID, Patient ID, microcuvette lot number, can be made via manual entry or via the barcode scanner in the back panel of the Analyzer. Note: The scanning range of the barcode scanner is approximately 4-12 inches from the scanner. The QC Lockout will be displayed by a “lock” icon display. In the Main Menu, press the QC Test button. In the next display, choose the required QC level. Remove one microcuvette from container and recap immediately. Controls should be mixed thoroughly. Hold all Control vertically and dispense slowly as free-falling drops onto Parafilm® or other non-absorbent material.

4. Fill a Microcuvette with the appropriate level of Low Liquid Control. Fill the Microcuvette in one continuous process. Note: Always avoid touching the optical eye. Do not refill the cavity of the microcuvette! Note: Wipe off excess blood from the outer surface of the Cuvette with lint-free wipe, being careful not to touch the open end. Note: Make sure that no blood is drawn out of the microcuvette during this procedure. Look for air bubbles in the filled microcuvette. If any air bubbles are present in optical eye, fill a new microcuvette. Small bubbles around the edge can be ignored.

5. Place the filled microcuvette in the cuvette holder and push holder to the measuring position. **Note: This should be performed within 2 minutes after filling the microcuvette!**

6. Enter the required information manually or by using barcode scanner.

7. After approximately 15-60 seconds, the result will be displayed. The result will remain on the display until the confirm button has been pressed.

8. Analyzer is pre-loaded with the acceptable range specific to that lot number. Verify result is acceptable and record on the HemoCue Accession Log. (If “ERROR” code appears, see the Procedural Notes section or call POC ext. 57951 for assistance with advanced troubleshooting.)
9. When measurement procedure is completed, repeat using the Normal Liquid Control.

10. **All CONTROLS MUST BE ACCEPTABLE** prior to performing patient testing!!! Instrument will not allow a patient test until both controls are acceptable. If problems persist, contact POC Testing Services personnel at extension 57951.

C. **Patient Testing**

**NOTE:** Testing is to be performed ONLY on patients requiring hemoglobin documentation to qualify for government assistance programs. Routine testing of LSUHSC patients is prohibited!!!

1. On the HemoCue Accession Log indicate the appropriate accession number, time test performed and initials of individual performing the test (Initials’ Column).

2. Identify patient by placing an address-a-graph label or writing in the patient’s name and unique patient id number.

3. Information required to be entered in the Analyzer includes Operator ID, Cuvette Lot number, and Patient ID.

4. In the Main Menu, select the PATIENT TEST button.

5. Obtain a blood sample (follow appropriate blood collection procedure).

6. Fill the cuvette completely avoiding bubbles. Fill the cuvette in one continuous process. Do not “top it off” after the first filling.

7. Wipe off the excess blood on the outside of the cuvette tip making sure that no blood is drawn out of the cuvette.

8. Visually inspect the cuvette for air bubbles. Small air bubbles around the edge do not influence the result. (Filled cuvettes should be analyzed immediately and at the latest 10 minutes after being filled. Filled cuvettes are to be kept lying down. Air bubbles can produce erroneously low readings.)

9. Place filled microcuvette into the cuvette holder immediately and push it into the measuring position.

10. Enter the required information as the Analyzer prompts entry. The result will be displayed when all required information has been entered and the measurement has been accepted.

11. Approximately 15-45 seconds later the result is displayed. To add Comments to the result, press the Comment input button. The result will remain on the display even if the cuvette holder is pulled out, allowing for examination of the cuvette before comments are made. Note: A dotted comment book icon indicates that comments have been added to the result.
12. Record the result on the HemoCue Accession Log and in the patient’s chart (if applicable). (If “ERROR” code appears, see the Procedural Notes section or call POC ext. 5700 for assistance with advanced troubleshooting.)

13. Press the Confirm button “OK” to store the information. The Main Menu will be displayed.

D. Proficiency (CAP) Testing
Follow the same instructions as Patient Testing substituting the Proficiency Survey Sample for the specimen.

VIII. CALCULATIONS:
Not Applicable.

IX. REPORTING RESULTS:

Expected Results:
- Children: 11.0 - 14.0 g/dL
- Infants, after neonatal period: 10.0 - 14.0 g/dL

Children, two years to teenage: show gradual increases with age to adult normals.

X. PROCEDURAL NOTES:

1. Deterioration of controls - Following appropriate mixing of controls, if the cellular components appear to be grossly hemolyzed or appear to be visually clumped or aggregated, report the suspected problem to POC personnel at extension 57951.

2. Many whole blood or hemolysate controls that are available commercially contain additives that cause turbidity (cloudiness). As the photometer compensates for turbidity it can give lower hemoglobin values than those given for the control blood/hemolysate.

3. ALL HEMOCUE ACCESSION LOGS ARE TO BE FORWARDED MONTHLY TO THE POC LABORATORY AREA.

4. Troubleshooting Information:

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Explanation</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>The photometer shows an error code</td>
<td>May be an occasional fault.</td>
<td>Turn off the photometer and switch it on again after 30 seconds. Take a new cuvette and repeat the measurement. If the problem continues, see specific error code below.</td>
</tr>
<tr>
<td>Symptom</td>
<td>Explanation</td>
<td>Action</td>
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| E00     | No stable endpoint found within the time range.  
1. The cuvette is incorrect.  
2. Printed circuit board is out of order. | 1 a. Check expiration date for the cuvettes.  
1 b. Using a new cuvette, repeat the measurement.  
2. The photometer needs service. Contact POC in the laboratory. |
| E01-E05 | Fault in the optics or electronics | 1. Clean the optronic unit. If a problem occurs, contact POC Testing Services. The photometer needs service. Call POC Testing Services. |
| E06     | Unstable blank value. The Analyzer might be cold. | 1. Turn off the Analyzer and allow it to reach room temperature.  
2. The photometer needs service. Call POC Testing Services. |
| E08     | The absorbance is too high. Light blocking item in the Cuvette holder | Check that Analyzer and Cuvettes are used according to Policy. If problem persists, contact POC Testing Services. |
| E11     | Hardware Error | Contact POC Testing Services |
| E17     | Internal Error | Contact POC Testing Services |
| E23     | 1. Data error Real Time Clock  
2. Real Time Clock backup battery has been drained | The backup battery needs to be replaced. Call POC Testing Services |
<p>| E25     | Analyzer not calibrated | Call POC Testing Services |
| E26     | The Patient test memory is full. No more patient test data can be saved | Call POC Testing Services |
| E27     | The QC memory is full. No more QC data can be saved | Call POC Testing Services |
| E28     | The Analyzer log memory is full. No more Error Codes and Log Notes can be saved | Call POC Testing Services |
| E29     | The electronic selftest failed. The communication selftest failed. The Analyzer may not work properly when connected to a docking station. This is stored as a failed Electronic QC (EQC) in the Analyzer. | Call POC Testing Services |
| E30     | The electronic selftest failed. The optical selftest failed. The Analyzer may work properly when measuring. This is stored as a failed Electronic QC Test (EQC) in the Analyzer. | Call POC Testing Services |
| E31     | Communication Error | Call POC Testing Services |</p>
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<tr>
<th>Symptom</th>
<th>Explanations</th>
<th>Actions</th>
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<tbody>
<tr>
<td>Overrange</td>
<td>Measured value exceeds 25.6 g/dL</td>
<td>Repeat; if still Overrange, obtain patient specimen and send to Clinical Lab for analysis.</td>
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<tr>
<td>No characters on display.</td>
<td>1. The Analyzer is not receiving power.</td>
<td>1 a. Check that the AC adapter is connected to the power supply.</td>
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<td>3. If on battery power, the batteries need to be replaced.</td>
<td>1 b. Check that the AC adaptor is securely connected to the Analyzer.</td>
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<td>4. The display is out of order.</td>
<td>1 c. If the Analyzer is docked, check that the green LED on the Docking Station gives a flashing green light.</td>
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<td>1 d. Check that the adapter is not damaged.</td>
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<td>2. Recharge the Battery via an AC adapter or a Docking Station.</td>
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<td>3. Call POC Testing Services</td>
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<tr>
<td>Display gives erroneous characters.</td>
<td>1. The display is out of order.</td>
<td>1. The photometer needs service. Call POC in the laboratory.</td>
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<td>2. The microprocessor is out of order.</td>
<td>2. The photometer needs service. Call POC in the laboratory.</td>
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<tr>
<td>The Scanner is malfunctioning</td>
<td>1. An incorrect barcode is being scanned.</td>
<td>1. Check that you are reading the barcode from the correct product.</td>
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<td>2. The product has expired.</td>
<td>2. Check the expiration date of the product.</td>
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<td>3. The Analyzer is too close or too far from the barcode.</td>
<td>3. Hold the Analyzer within 4-12 inches from the barcode.</td>
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<td>4. The barcode is Indistinct.</td>
<td>4. Enter the information manually.</td>
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<td>5. The scanner glass is dirty.</td>
<td>5. Clean the Scanner glass according to manufacturer’s instructions.</td>
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<td>6. The barcode is not compatible with the Scanner.</td>
<td>6. Call POC Testing Services</td>
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<td>7. The Scanner is broken.</td>
<td>7. Call POC Testing Services</td>
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<tr>
<td>No transfer of data</td>
<td>Call POC Testing Services</td>
<td>Call POC Testing Services</td>
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<tr>
<td>No transfer of data via USB</td>
<td>No USB-communication</td>
<td>Call POC Testing Services</td>
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<tr>
<td>Analyzer not charged</td>
<td>No charging of the battery</td>
<td>1. a. Check to see that the analyzer is properly docked.</td>
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<td>b. Check that the green LED on the Docking Station gives a flashing green light when docking the Analyzer.</td>
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<td>c. Replace the Battery</td>
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<td>Unintentional downloading</td>
<td>Data is sent out unintentionally</td>
<td>Using a Primary Docking Station (Single or within a set), the Analyzer downloads via IrDA. This means that the Analyzer will start downloading as soon as it is close enough to the Docking Station (even if not properly docked).</td>
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<td>Note: To prevent data from being</td>
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**Note:** To prevent data from being unintentionally sent out, ensure the Analyzer is not within close proximity to the Docking Station when it is not properly docked.
unintentionally transmitted, keep the Analyzer away from the Docking Station.

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| Patient samples higher or lower in comparison with those expected. | 1. The cuvettes are too old or damaged, improper storage.  
  2. The optical eye of the cuvette is contaminated.  
  3. Air bubbles in the cuvette.  
  4. The optronic unit is dirty.  
  5. The calibration of the photometer has been changed. | 1. Check the expiration date and storage of the cuvettes.  
  2. Remeasure the sample with a new cuvette.  
  3. Check the cuvette for air bubbles. Remeasure the sample with a new cuvette.  
  4. Clean the optronic unit. Call POC in the laboratory.  
  5. Measure the control cuvette.  
  6. If problem continues, call POC for advanced troubleshooting. |

Call POC ext. 7951 for troubleshooting prior to calling Technical Service Hotline 1-800-426-7256.

XI. LIMITATIONS OF PROCEDURE:
1. Limitations of instrument:
   Lower Limit: 0.0 g/dl  
   Upper Limit: 25.6 g/dl  
   Results above 25.6 g/dl will display an error code: 999.
   Results below 10.0 g/dL should be repeated before being reported to provider.
   Critically Low Result is defined as < 7.0 g/dL and should be confirmed by lab draw per provider’s request. Call to provider and document using the Laboratory’s read-back policy.
   Results above 23.5 must be confirmed by lab draw per manufacturer’s directions.
2. Use of controls other than Hema-Trol may result in “out-of-control” results.
3. Inaccuracies in control results may occur as a result of inappropriate mixing procedures.
4. Linearity of instrument per manufacturer:  
   5.0 - 18.0 g/dl ± 2%  
   18.0 – 25.6 g/dl ± 4%
5. Oxygenated blood, which has been agitated over a long period, produces oxygen pressure and viscosity at higher than normal levels.
6. pH values between 6.3-9.0 do not interfere with this system.
7. Sulfhemoglobin is not measured with this method.
8. Acetaminophen (20 mg/dL), ascorbic acid (3 mg/dL) conjugated bilirubin (40 mg/dL), unconjugated bilirubin (20 mg/dL) creatinine (30 mg/dL), ibuprofen (40mg/dL), leukocytes (600 x 10⁹/L), lipemia (intralipid 4000 mg/dL), triglycerides approximately 1000 mg/dL), salicylic acid (50 mg/dL) tetracycline (20 mg/dL), thrombocytes (2100 x 10⁹/L), urea (500 mg/dL), uric acid (20 mg/dL) have not been found to interfere. The highest concentration or percentages tested is referred to in brackets.
XII. REFERENCES:
3. HemoCue Hb 201 Photometer Operating Manual, HemoCue AB, Angelholm, Sweden
4. HemoCue Hb 201 Microcuvette Package Insert, HemoCue AB, Angelholm, Sweden, HemoCue Distributor USA 40 Empire Drive, Lake Forest, CA 92630

XII1. DISTRIBUTION:
This procedure is on file in the Point-of-Care section of the Clinical Laboratory and in the LSUHSC website at LSUHSC, Shreveport, LA.