1 Purpose: Point-of Care measurement of Hemoglobin by means of a photometer.

2 Principle:
   A. Technique:
      The HemoCue technique is based on an optical measuring microcuvette of a small volume and a short light path. The microcuvette cavity contains reagents deposited on its inner walls. The blood sample is drawn into the cavity by capillary action and is mixed spontaneously with the reagents. The microcuvette is then placed in the HemoCue Hb 201 analyzer in which the transmittance is measured and the hemoglobin level calculated. Thus the technique makes it possible to sample the blood, mix and chemically react it with the reagents in the same microcuvette as is used for measurement.
   
   B. Microcuvette:
      The microcuvette is made of polystyrene plastic and comprises a body having a cavity with a volume of about 10µL. The distance between the walls of the optical window is 0.130 mm, which permits photometric determination of hemoglobin in undiluted blood.
   
   C. Chemistry:
      The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrate converts the hemoglobin iron from ferrous to the ferric state to form methemoglobin, which then combines with azide to form azidemeth-hemoglobin.

3 Policy:
   A. Test will be performed by certified employees using correct policies and procedure designated for LifeBridge Health including the POC Safety and Infection Control Plans.
   B. QC will be performed once a day using a low and high control on each day that patient tests are performed.
   C. Only capillary, venous or arterial blood may be used for testing.
   D. Patient, operator ID will be entered into instrument each time test is performed.
   E. A Physician/PA’s order is required.
4. Specimen:

**Specimen Type:** Capillary, venous or arterial blood may be used. Appropriate anticoagulants in solid form (e.g. EDTA, heparin or heparin fluoride) may be used. Mix all samples thoroughly by inverting tubes 8-10 times.

5. Patient Preparation: N/A

6. Handling Conditions: N/A

7. **Storage Requirements:** The microcuvettes are stored at room temperature (15-30°C, 59-86°F). Do not refrigerate. The microcuvettes that are individually wrapped are stable until the expiration date written on each microcuvette package. Microcuvettes should be used immediately after opened. The microcuvettes in the cylinder vials are good until the expiration on the vials. The vials do need to be immediately recapped.

8. **Rejection Criteria:**

9. **Equipment and Materials:**

   **Equipment:**
   HemoCue 201 DM Analyzer and HemoCue DM Docking Station. The Analyzer and the Docking Station can be stored at 0-50°C, (32-122°F). Operating temperature is at 10-30°C, (64-86°F). Allow the Analyzer and the Docking Station to reach ambient temperature before use. The Analyzer and the Docking Station should not be operated at high (i.e. >90%) non-condensing humidity.

   **Materials/Supplies:**
   1. Alcohol swab
   2. 2x2 Sterile gauze
   3. Lancelet (only use single use lancets provided by the hospitals)
   4. Microcuvette for HemoCue 201 DM
   5. Gloves

10. **Preparation:** Universal precautions need to be followed during testing. Gloves need to be worn during collection and testing of patient samples. LifeBridge Health hand hygiene procedures need to be followed. Hand hygiene is performed before and after the procedure.

11. **Performance Parameters:**
   Initials validation studies will be kept two years after instrument is discontinued.
12. Calibration:

**Standard Preparation:** The photometer is delivered calibrated against the hemoglobincyanide (HiCN) method which is international reference method for the determination of the total hemoglobin concentration in blood. The factory calibration is carried out at 14g/dL, a maximum deviation of + or - 0.3 g/dL is tolerated.

**Calibration Procedure:** Will be performed prior to instrument place in use for patient testing.

13. Quality Control:

**Materials Used:**

a. The HemoCue HB 201 DM Analyzer has an internal electronic “Selftest”. Every time the Analyzer is turned on, it will automatically verify the performance of the otronic unit of the analyzer. This test is performed every eight hours if the analyzer is left turned on. The result of the selftest is stored as an EQC (Electronic Quality Control).

b. Liquid controls: Check the total system of the photometer and microcuvettes is desired liquid control using two levels will be performed on a daily basis when patient tests are performed.

14. Preparation and Handling:

A. Performing Liquid QC:

1. In the Main Menu, press the QC Test button. In the next display, choose Low Level.
2. Fill a Cuvette with the appropriate level of Liquid Control. Wipe off sides and bottom of cuvette but do not wipe of area were control was added.
3. Place the Cuvette in the Cuvette holder and gently insert it into the measuring position.
4. Enter the Lot Number of the control, via the Text mode and Numeric mode buttons.

   If a Liquid Control Lot Number had not previously been stored in the Analyzer and/or has expired, the following text will be displayed: Invalid Control Lot. The result will be displayed when all required information had been entered and the measurement has been completed.

For results within the Approved area, the Qualitative Test Result will indicate “Pass”.
For a result within the Fail area, or for two consecutive results will indicative “Fail”.
To avoid a QC lockout, the Qualitative Test Result must indicate “Pass”.
To add a comment 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 indicates that comments have been added to the result.
Press the Confirm button to store the information. The Main Menu will be displayed.

5. Open Cuvette holder and remove used cuvette and dispose into bio-hazard container.
6. Repeat number 1 through 4 by selecting Level High and follow procedure.

**Frequency Run:** Liquid controls using a low and high level must be performed once a day when patient testing is performed.

15. **Measuring Range:**

a. Whole Blood:
The measured Hemoglobin value is read directly from the HemoCue Hb 201 analyzer in g/dL. No calculations are necessary. Results above 25.6 g/dL are displayed as “HHH” or “overage”.
The tests are Linear up to 23.5 g/dL.

Critical Value for adult: Hb of 7 g/dL or below.

16. **Limitations:**

a. Measurement of hemoglobin must be made as soon as possible after the blood has been drawn into the microcuvette. If the test is performed after 10 minutes of filling the microcuvette, false results may be obtained.

b. Mixing blood for too long a period can produce increased oxygen pressure and viscosity that may give falsely high results.

c. If air bubbles are seen in the optical eye of the microcuvettes, the microcuvette should be discarded and a new sample taken for analysis. Small air bubbles around the edges do not influence the result.

d. Caution should be taken not to hold the microcuvette by the filling end, which may stain the optical eye. Care should also be taken in wiping off excess specimen for the outer surface of the optical eye.

e. Acetaminophen (20 mg/dL), ibuprofen (40 mg/dL), creatinine (30 mg/dL), salicylic acid (50 mg/dL), tetracycline (20 mg/dL), urea (500 mg/dL), uric acid (20 mg/dL), lipaemia (Intralipid 4000 mg/L, approx Triglycerides 1200 mg/dL) have not been found to interfere. The highest concentration tested is referred to in brackets.

f. Turbidity due to leukocytes does not interfere (tested up to 550 x 10^6/L).

g. Carboxyhemoglobin level up to 10% do not interfere (reference values for
non smokers: 1-2%, smokers 5-6%.

h. pH values between 6.7-8.5 do not interfere with the system.
i. Sulphemoglobin is not measured with this method.
j. Values above 23.5 g/dL must be confirmed using a suitable laboratory method.
k. Inference studies have been performed according to NCCLS document ER-7 Vol 6 No 13\textsuperscript{12}.

17. Procedure:

Performing Patient Sample:

Before obtaining a blood sample, the Analyzer should be in the “Ready” mode. Enter your seven digit operator ID number. Then press the Cuvette button. You will then be instructed to place cuvette containing sample in Cuvette holder.

a. Capillary Blood
   Make sure the patient/s hand is warm and relaxed. Use only the middle or ring finger for sampling. Avoid fingers with rings on.
   1. Apply gloves.
   2. Clean with alcohol and allow to dry or wipe off with dry gauze.
   3. Using your thumb, lightly press 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 gauze. Do not use cotton balls.
   7. Re-apply 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. Note! Do not refill!!
   9. Wipe off excess blood from the outer surface of the Cuvette with paper towel, being careful not to touch the open end of the Cuvette.
      Note: Make sure that no blood is drawn out of 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 edge can be ignored.
      Note! If a second sample is to be taken from the same finger, wipe away the remains of the initial sample and fill a second Cuvette from a new drop of blood.
   11. Place the filled cuvette in the Cuvette holder.
   12. Push the Cuvette holder to the Measuring position. Note! This should be performed within 10 minutes after filing the Cuvette.
13. Enter the patient’s account number by scanning the wrist band or enter manually.
14. After 15 seconds to 60 seconds, the result will be displayed. The result will remain on the display until the Confirm button has been pressed.
15. Open Cuvette holder and removed used Cuvette. Place in biohazard container.
16. Record results on patient’s medical record in Power form.
17. Clean meter after testing at patient’s bedside. Use PDI SaniCloth wipes or bleach wipes. Follow the wet and dry times on the product’s label.

b. Venous and Arterial Blood
   Blood should be well mixed prior to performing the measurement.
   1. Place a drop of blood onto a plastic film (such as scotch tape on paper towel), using a pipette or needle-less syringe.
   2. Fill the Cuvette in one continuous process.
      Note! Do not refill!!
      Note! Wipe off excess blood from the outer surface of the Cuvette with a paper towel, being careful not to touch the open end of the cuvette.
   3. Look for air bubbles in the filled cuvette. If any air bubbles are present, fill a new Cuvette. Small bubbles around the edge can be ignored.
   4. Performed the measurement as described above in capillary testing.

Comments: To add comments to results, 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 indicates that comments have been added to the result.

The Verify button allows the verification of the result by measuring a new sample from the patient.

Press the Confirmed button to store the information. The Main Menu is displayed.

Press the Log button to log out your Operator ID and prevent someone from performing another test using you operator ID.

18. Instrument Ranges:

   MEASUREMENT RANGE: 0 to 25.6 g/dL

19. Cleaning:
**Cuvette holder:**
Should be cleaned daily after each day of use. A dirty optronic unit may cause the Analyzer to display an error code. To clean the Cuvette holder and the optronic unit, proceed as follows:

a. Check that the Analyzer is turned off. The display should be blank.
b. Pull the Cuvette holder out to the Loading position.
c. Carefully press the small catch positioned in the upper right corner of the Cuvette holder.
d. While pressing the catch, carefully rotate the Cuvette holder sideways as far as possible to the left.
e. Remove the Cuvette holder from the Analyzer.
f. Clean the Cuvette holder with alcohol or mild detergent.
g. To clean the optronic unit, push the HemoCue Cleaner into the opening of the optronic unit.
h. Move the HemoCue Cleaner from the right to the left 5-10 times, and then pull it out.
i. If the HemoCue Cleaner is stained, repeat with a new HemoCue Cleaner.
   Note! A cotton tip swab moistened with alcohol (without additives) or water may also be used for cleaning.
j. Wait 15 minutes before putting the Cuvette holder back into the Analyzer. It is important that the Cuvette holder is completely dry before reinserting it into the Analyzer.

**Display Window**
The display can be cleaned with alcohol, with additives.

**Analyzer Outer Case and Docking Station**

a. Make sure that the Analyzer is turned off. The display should be blank.
b. The outer case on the Analyzer and the Docking Station may be cleaned with alcohol or a mild soap solution.
c. The Scanner glass should be cleaned gently with alcohol.

**20. Review Results:**
Note! Access to the Stored Data function is dependent of the operator’s user level and on the predefined setting of Operator ID use. Only a Supervisor can delete data, change an acceptable or rejected result, or add comments.

1. In the Main Menu, press the Stored Data button.
2. Enter Operator ID.
3. Press the Confirmed Button to view the Stored Data.
4. The following options displayed:
   a. Review
      When the Review button is pressed in the Stored Data menu, the following options are displayed:
      1. All Data
      2. PAT
3. QC Test  
4. Analyzer Log  
Select an option by pressing it.  
If required, change the From date via the Digit button. Press Confirmed.  
Repeat the instruction to change the To date.  
The stored data within the date internal will be available for review. The latest record is displayed. If no data within the date internal is found, the following message will be displayed: No Records Found. Press the Previous image button to return to the Data Image.

21. Hemocue Comment Codes:  
When performing quality control or a patient test you may wish to enter a coded statement. Below is the list of codes:

- Specimen sent to Laboratory  
- Repeated test  
- Clean instrument  
- Replace controls  
- Replaced cuvettes  
- Operator error  
- Critical value  
- POC X checks

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 indicates that comments have been added to the result.  
Press the Confirmed button to store the information. The Main Menu will be displayed.

22. Calculating the Display:  
If the function on the display is not activated when pressed, the display needs to be recalibrated.  
a. Make sure that the Analyzer is turned off. The display should be blank.  
b. To recalibrate the display, press the ON/OFF button for at least 10 seconds. A plus sign will appear in the upper left corner of the display.  
c. Gently press the center of the plus sign with a blunt object. Using the fingertip may not work.

23. Reporting Results: In the patient’s medical record.

24. Procedure Notes:
Reference Values:

Adult males: 13 to 17 g/dL
Adult females: 12 to 15 g/dL

Critical Value: Specimen should be obtained and sent to laboratory for Verification. N/A
Critical Value for adult: Hgb of 7 g/dL or below or 18 g/dL and above.

25. Reporting Format:
Patient results should be entered into Power form.
Patient tests and quality control will be stored in the data base and maintained in Pathology.

26. Hazardous Materials:
Used cuvettes should be considered contaminated, potentially infectious and should be placed in Biohazard container.

Protective Equipment Requirements: gloves

27. Limitation Of Procedure:

Linearity:

LINEARITY:
Phometer: 5.0 - 18.0 g/dL + or - 2%
18.1 - 25.6 g/dL + or - 4%

The system (photometer and cuvette) 0 - 25.6 g/dL + or - 0.5 g/dL or 7% whichever is greater.

28. Interfering Substances:
Acetaminophen (20 mg/dL), ibuprofen (40mg/dL), creatinine (30mg/dL), salicylic acid (50mg/dL), tetracycline (20mg/dL/), urea (500mg/dL), uric acid (20mg/dL), lipaemia (Intralipid 4000 mg/L, approx Triglycerides 1200 mg/dL ) have not been found to interfere. The highest concentration tested is referred to in brackets.

29. References:

Jacques Q Wallach, M.D., Interpretation of Diagnostic Tests.

30. **Attachments:** N/A