DESCRIPTION/OVERVIEW

1. PURPOSE
   1.1. The HemoCue Hb 201 DM System is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer and specially designed microcuvettes.
   1.2. 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. The assay of hemoglobin is also used as part of a general health screen e.g., in the assessment of women’s and children’s health.

2. PRINCIPLE
   2.1. The hemoglobin concentration in blood is determined as azidemethemoglobin utilizing a microcuvette with a dry reagent system and a dual wavelength photometer. 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 methemoglobin, which then combines with sodium azide to form azidemethemoglobin.
   2.2. Measurements are taken at 570nm and 880nm; the later to correct for turbidity.

REFERENCES
2. HemoCue Hb 201 Microcuvettes Package Insert
3. Eurotrol HemoTrol Quality Control Solution Package Insert

AREAS OF REPONSIBILITY
1. POCT HemoCue hemoglobin testing can be done on any inpatient or outpatient at the University Hospital and University Clinics on the receipt of an order from a physician or nursing staff designate.
2. Staff who have satisfied initial and ongoing competency requirements may perform the testing.

PROCEDURE
1. EQUIPMENT
   1.1. HemoCue Hb 201 DM Analyzer
   1.2. AC Adapter
   1.3. Docking Station
2. REAGENTS
   2.1. HemoCue Hb 201 Microcuvettes
2.2. Eurotrol HemoTrol Liquid Quality Controls

3. ORDERING INFORMATION
3.1. Eurotrol HemoTrol Liquid Quality Controls are ordered through purchasing from HemoCue.
3.2. HemoCue Hb 201 Microcuvettes are purchased from CDU.

4. STORAGE
4.1. The analyzer, docking station, and microcuvettes should be stored at room temperature, 15-30°C.
4.2. Microcuvettes are good for 3 months once opened, or the manufacturer’s expiration date, whichever comes first.
4.2.1. Microcuvettes are sensitive to moisture; therefore, the vial cap should be replaced immediately after removing the microcuvette.
4.3. The unopened liquid quality control should be stored in the refrigerator at 2-8°C.
4.3.1. It is stable for 30 days once opened (in the refrigerator or at room temperature 15-30°C) or the manufacturer’s expiration, whichever comes first.

5. CALIBRATION AND CALIBRATION VERIFICATION
5.1. HemoCue instruments may not be calibrated. Calibration is confirmed daily via the SELFTEST.
5.2. Calibration Verification is performed semi-annually by the Point-of-Care Testing Department.

6. MAINTENANCE
6.1. Correlation Data
6.1.1. The Point-of-Care Testing Department performs all correlation testing.
6.1.2. The HemoCue Instruments are verified to each other and to the laboratory hematology instrument every six months by performing the same sample on each instrument.
6.2. New Instrumentation
6.2.1. The Point of Care Testing Department performs all testing on new instrumentation.
6.2.2. New instruments are tested with quality control solution and a calibration verification is performed with patient sample against the laboratory hematology instrument.
6.3. Instrument Cleaning
6.3.1. The cuvette holder should be cleaned after each day of use.
6.3.1.1. Check that the analyzer is turned off. The display should be blank.
6.3.1.2. Pull the cuvette holder out to its loading position. Carefully press the small catch positioned in the upper right corner of the cuvette holder.
6.3.1.3. 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.
6.3.1.4. Clean the cuvette holder with alcohol or mild detergent. It is important that the cuvette holder is completely dry before being replaced.
6.3.2. The optronic unit should be cleaned when directed to do so on the Trouble Shooting Guide or as desired.
6.3.2.1. You may purchase a HemoCue Cleaner or make your own cleaning swab to clean the optronics.
6.3.2.1.1. Obtain a standard 6” tongue depressor. Roll a piece of gauze around the tongue depressor and moisten with warm water.

6.3.2.2. Push the cleaning swab or HemoCue Cleaner into the opening of the cuvette holder.

6.3.2.3. Move from side to side 5 – 10 times. If the gauze is stained, repeat with a new swab or Cleaner until it comes out clean.

6.3.2.4. Once the swab or Cleaner comes out clean, repeat using a dry swab to remove any moisture from the cleaning process.

6.3.2.5. Wait 15 minutes before replacing the cuvette holder and using the analyzer.

7. SELFTEST

7.1. 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 optronic unit of the analyzer.

7.2. SELFTEST PROCEDURE

7.2.1. Turn on the Analyzer by pressing the On/Off button.

7.2.2. The Start Image, beginning with the HemaCue logo, will be displayed.

7.2.3. Pull the cuvette holder out to the loading position.

7.2.4. The analyzer will display, “Please Wait Selftesting…”

7.2.5. The analyzer will display the Main Menu if the Self Test passes.

7.2.6. If the SELFTEST fails, an error code will be displayed. Clean the optronic unit and try the SELFTEST again. If it fails the second time contact the POCT office at 272-0980.

8. LIQUID QUALITY CONTROL (LQC)

8.1. Each HemoCue must be tested with 2 levels of external liquid quality control every 50 tests.

8.2. Each vial of HemoCue cuvettes must be tested with 2 levels of external liquid quality control before using for patient testing.

8.2.1. Document on the vial of HemoCue cuvettes that QC was performed, the date, and initials of tester.

8.3. LQC procedure

8.3.1. Turn on meter.

8.3.2. Pull out the cuvette holder into the loading position so that it can complete the Selftest.

8.3.2.1. If the meter does not pass the Selftest refer to section 7 of this procedure.

8.3.3. Enter Operator ID by scanning operator’s barcode. Press and hold the scan icon until Operator ID appears on screen.

8.3.4. Select, “QC” on the main menu. Select the “Low” QC Test.

8.3.5. Gently mix the Low QC vial 8 – 10 times immediately before sampling.

8.3.5.1. If using refrigerated QC, remove vials from the refrigerator and allow to warm at room temperature for 15 minutes before mixing.

8.3.6. Do not fill the cuvette from the QC vial. Dispense a drop of low control material onto a hydrophobic surface, e.g., a plastic film or glass slide.

8.3.7. Fill a microcuvette with the low control in one continuous process. Hold the cuvette opposite the filling end and introduce the cuvette tip into the middle of the drop. Do not refill a partially filled cuvette.
8.3.8. Wipe off excess blood from the outside of the microcuvette with a clean, lint-free wipe, being careful not to touch the open end of the microcuvette.

8.3.9. Visually inspect the filled cuvette for air bubbles. Small air bubbles around the edge do not influence the result.

8.3.10. **Wait one minute before placing cuvette in holder.** Push cuvette holder in to start test.

8.3.11. Enter the Cuvette Batch number.

8.3.11.1. Scan the Cuvette vial barcode.

8.3.12. Enter the Control Lot number.

8.3.12.1. Scan the Low Control box barcode or

8.3.12.2. Select the numerical option and type in the number from the control vial and push “OK”.

8.3.13. PASS or FAIL will appear on the screen.

8.3.14. If results pass, repeat above procedure with the High QC level.

8.3.15. If results fail, do not use the analyzer for patient testing.

8.3.15.1. Troubleshoot issue.

8.3.15.2. Select the comments icon and select the action to be taken to troubleshoot issue i.e. “Repeat Test” “Clean Optronics” “Wrong Control” etc…

8.3.15.3. Repeat test.

8.3.15.4. If results fail for a second time, contact the POCT Department at 272-0980.

8.3.15.5. If results fail, repeat procedure with the High QC level.

8.3.16. Once both levels of QC are tested and have passed, patient testing can be performed.

9. **PATIENT IDENTIFICATION**

9.1. Refer to the Hospital Procedure.

10. **SPECIMEN COLLECTION AND HANDLING**

10.1. Standard precautions apply to all Point-of-Care tests.

10.2. Testing personnel should handle all patient samples as per the Bloodborne Pathogen Exposure Plan.

10.3. Capillary, venous or arterial blood may be used.

10.4. Capillary sampling:

10.4.1. Perform the capillary puncture. Refer to the University Hospital Phlebotomy Self-Study Module for details.

10.4.2. Wipe away 2-3 drops of blood. Avoid milking the finger.

10.4.3. Hold the cuvette opposite the filling end and introduce the cuvette tip into the middle of the drop of blood.

10.4.4. Fill the microcuvette in one continuous process. Do not refill a partially filled cuvette.

10.5. Venous or arterial blood from vacuum tubes

10.5.1. EDTA, heparin and heparin/fluoride are acceptable anticoagulants.

10.5.2. Collect specimen in tube. Refer to the University Hospital Phlebotomy Self-Study Module for details.

10.5.3. Mix sample thoroughly by inverting 8-10 times by hand. Tip the filled tube and place the microcuvette tip into the surface of the blood so that the microcuvette fills in one continuous motion.

10.6. Venous or arterial blood from syringes
10.6.1. Sample immediately to avoid clotting
10.6.2. Do not fill the cuvette from the syringe. Place a drop of blood onto a hydrophobic surface.
10.6.3. Introduce the microcuvette tip onto the middle of the drop so that the microcuvette fills in one continuous motion.
10.7. Wipe off any excess blood from the outside of the cuvette using a clean, lint-free tissue, taking care not to touch the open end of the cuvette.
10.8. Visually inspect the filled cuvette for air bubbles. Small air bubbles around the edge do not influence the result.

11. SPECIMEN LABELING
11.1. Samples are analyzed immediately after collection at the patient’s bedside and then discarded. Specimen labeling is not required.
11.2. If testing is to be delayed, the specimen must be labeled with two unique identifiers.

12. PATIENT TESTING
12.1. Turn on meter.
12.2. Pull out the cuvette holder into the loading position so that it can complete the Selftest.
   12.2.1. If the meter does not pass the Selftest refer to section 7 of this procedure.
12.3. Enter Operator ID by scanning operator’s barcode.
   12.3.1. Select the patient test icon (looks like cuvette with a blood drop).
12.4. Enter the Cuvette Batch number.
   12.4.1. Scan the Cuvette vial barcode.
12.5. Enter the Patient ID.
   12.5.1. Scan the patient’s barcode.
12.6. Place the filled microcuvette into the analyzer’s holder and push it into the measuring position within 10 minutes of collecting the blood sample.
   12.6.1. If readings are made more than 10 minutes after the blood has entered the cuvette, false results may be obtained.
12.7. The result will display on the screen.

13. RESULT REPORTING
13.1. Patient results should be immediately recorded in the permanent medical record.
13.2. Results that appear to be inconsistent with patient therapy should be viewed as questionable and the test should be repeated immediately by the lab reference method.
13.3. Results greater than 23.5 g/dL must be recorded as >23.5 g/dL in the patient’s permanent medical record.

14. REFERENCE INTERVAL AND CRITICAL VALUES
14.1. All POC testing done in the hospital has a reference interval (normal reference range) validated with those tests performed on laboratory instruments. The reference interval thus correlates to that of the laboratory. See the table below for reference range values.
14.2. All critical values must be reported to the appropriate provider. Record this in the permanent medical record.
14.3. The treating physician/provider has discretion to choose if critical values should be repeated by the laboratory reference method.
NORMAL RANGE:

<table>
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<tr>
<th></th>
<th>Females g/dL</th>
<th>Males g/dL</th>
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<tbody>
<tr>
<td>&gt;18 Years</td>
<td>12.0 – 16.0</td>
<td>14.5 – 17.7</td>
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<td>12 Years – 17 Years</td>
<td>11.5 – 15.5</td>
<td>13.0 – 16.0</td>
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<tr>
<td>6 Years – 11 years</td>
<td>11.5 – 15.5</td>
<td>11.5 – 15.5</td>
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<td>6 Months – 5 Years</td>
<td>10.5 – 13.5</td>
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<tr>
<td>1 Month – 5 Months</td>
<td>9.0 – 14.0</td>
<td>9.0 – 14.0</td>
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<tr>
<td>14 Days – 1 Month</td>
<td>10.0 – 18.0</td>
<td>10.0 – 18.0</td>
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<tr>
<td>7 Days – 13 Days</td>
<td>12.5 – 20.5</td>
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<td>3 Days – 6 Days</td>
<td>13.5 – 21.5</td>
<td>13.5 – 21.5</td>
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<tr>
<td>Full Term Birth</td>
<td>14.5 – 22.0</td>
<td>14.5 – 22.0</td>
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</table>

CRITICAL RANGE:

< 7.0 g/dL (0 day – 17 years old)  > 23.0 g/dL (0 day – 2 weeks old)
< 5.0 g/dL (>17 years old)  > 20.0 g/dL (2 weeks – adult)

REPORTABLE RANGE: 0.0 g/dL – 23.5 g/dL

15. INTERFERING SUBSTANCES AND LIMITATIONS

15.1. Measurement of hemoglobin should be made as soon as possible after the blood has been drawn into the cuvette. If readings are made more than 10 minutes after the blood has entered the cuvette, false results may be obtained.

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

15.3. If air bubbles are seen in the circular middle of the microcuvette, the microcuvette should be discarded and a new sample taken for analysis. Small air bubbles around the edge do not influence the result.

15.4. Caution should be taken not to hold the microcuvette by the filling end. Care should also be taken in wiping off excess specimen from the outer surface of the optical eye.

15.5. Sulphemoglobin is not measured with this method.

15.6. Carboxyhemoglobin and turbidity due to leukocytosis or hyperlipemia do not interfere.

15.7. As with all diagnostic tests, Hemocue test results should be scrutinized in light of a specific patient’s condition. Any results exhibiting inconsistency with the patient’s clinical status should be repeated or supplemented with additional test data.

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<tr>
<td>Use</td>
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<tr>
<td>If definitive, how will results be used?</td>
<td>Results are used to determine the hemoglobin in patients suspected of being anemic.</td>
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SUMMARY OF CHANGES

Updated to reflect changes in new machines.
RESOURCES/TRAINING

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DOCUMENT APPROVAL & TRACKING

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<td>Nursing Director</td>
<td>Sheena Ferguson, Chief Nursing Officer</td>
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<tr>
<td>Medical Director</td>
<td>Matthew Luke, MD; Rapid Response Laboratory</td>
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<tr>
<td>Official Approver</td>
<td>Erin Doles, Administrator, Professional &amp; Support Services</td>
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ATTACHMENTS

None