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Point of Care Testing	Procedure	5/23/2008	POC_2 Revision 8

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Approval*:
Hematology Division Director University Hospitals Laboratory Medical Director

Approval and Acknowledgements
Refer to QPulse system and Document Details report for laboratory directors(s)' electronic signature approval, employee acknowledgment and effective date.

1. PRINCIPLE

1.1. The HemoCue Hb 201 DM is a system used for the determination of the total amount of hemoglobin in whole blood. Used for treatment during an intrauterine transfusion.

1.2. The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocytes are hemolyzed to release the hemoglobin. The 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.

1.3. The microcuvette serves as a pipette, reaction vessel and as a measuring microcuvette. 10µL is drawn into the microcuvette cavity by capillary action. No dilution is required. The hemoglobin measurement takes place in the analyzer, which follows the progress of the reaction until the end point has been reached.

1.4. The analyzer measures at two wavelengths in order to compensate for turbidity.

1.5. Approved testing personnel performs the Hemoglobin testing per physician request.

2. SCOPE OF DOCUMENT:

2.1 This procedure applies to personnel using the HemoCue hemoglobin test during an intrauterine transfusion (IUT).

3. RESPONSIBILITY:

3.1 The POC coordinators and manager are responsible for maintaining the document; the Hematology laboratory division director is responsible for approving all changes, and reviewing biennially. The laboratory medical director is responsible for establishing and approving all changes before activating the document.

4. SPECIMEN COLLECTION:

4.1. All institutional policies and procedures should be followed in the collection of blood samples. Verify patient identification using at least 2 identifiers.

4.1.1. During a surgical procedure patient is identified per OSU timeout.

4.2. Specimen type: Cord Blood, appropriate anticoagulants such as EDTA or heparin may be used, preferably in solid form to avoid dilutional effects.

4.3. Handling conditions: Start measurement as soon as possible but no later than 10 minutes after filling the microcuvette.

4.4. Minimum specimen volume:

4.4.1. Tuberculin syringe: 750 µL-1mL

a. Form the Tuberculin syringe

4.4.1.a.1. HemoCue cuvette: 10 µL (approximately one drop)

4.4.1.a.2. Pediatric EDTA tube: 250-500 µL

4.5. Criteria for unacceptable specimens

4.5.1. Any clotted specimen is unacceptable, and requires recollection of a new specimen.

4.5.2. Sufficient volume is required to complete HemoCue hemoglobin and CBC with platelet count, manual differential and reticulocyte testing ensure at least 750 µL-1mL is collected in the tuberculin syringe).

5. REAGENTS/SUPPLIES:

5.1. Materials

5.1.1. HemoCue Hb 201 system

a. The HemoCue Hb 201must be used at room temperature 15-30°C (59-86°F).

b. There are no humidity requirements for the HemoCue Hb201.

5.1.1.b.1. Documentation of room temp including min and max temps must be recorded in each area of testing and must be available upon request.

5.1.1.b.1.1. If a minimum/maximum thermometer is used to perform continuous monitoring of temperature between daily temperature readings or following a laboratory

downtime (e.g. laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period.

5.1.2. HemoCue Hb 201 microcuvettes (cat #111715)
   a. Store microcuvettes at room temperature 15-30°C (59-86°F) only. Do not refrigerate.
   b. Microcuvettes are moisture-sensitive. The microcuvette should be filled within 3 minutes after the microcuvette has been taken out of its package.

5.1.3. Gauze or lint-free tissue
5.1.4. AC adapter for battery recharging
5.1.5. HemoCue carrying case

5.2. Controls
5.2.1. Multi-level hemoglobin liquid control; QC HGB (cat# *RNA HGB* from RNA Medical).
5.2.2. QC HGB contains a solution of unfixed stabilized human erythrocytes and preservatives.
5.2.3. The expiration date stated on the packaging is for product stored refrigerated 2-8°C. After opening, each bottle of control is stable for sixty (60) days if stored refrigerated or thirty (30) days if stored at room temperature (up to 25°C). Bottles should be tightly closed after each use.
5.2.4. Internal quality control consists of a self-test. Each time the analyzer is turned on, the optics are automatically checked for performance.

6. SPECIAL SAFETY PRECAUTIONS:

WARNING: BODY FLUID PRECAUTION
Blood is a body fluid capable of transmitting infectious diseases. Universal precautions for the prevention of the transmission of blood borne pathogens must be in effect at all times.

6.1. Do not eat, drink or smoke in the area where the samples are handled.
6.2. Handle all samples as if they are infectious agents.
6.3. Observe established precautions against microbial hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.

7. MAINTENANCE:

7.1. Maintenance procedure
7.1.1. The HemoCue cuvette holder and optics system must be kept clean
   a. The cuvette holder should be cleaned after each day of use.
   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, document on QC log.
   g. To clean the optronic unit, push a cotton swab moistened with 70% alcohol (additive-free) into the opening of the optronic unit.
   h. Move the cleaning swab from the right to the left 5-10 times, and then pull it out.
   i. If the swab is stained, repeat with a new swab until the optronic unit is clean.
   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.

7.1.2. The display screen, meter and outer case may be gently cleaned with additive-free alcohol
7.1.3. Display screen calibration:
   a. Make sure 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 on the upper left corner of the screen.
   c. Gently press the center of the plus sign with a blunt object, being careful not to puncture or scrape the display screen.

d. The first plus signs will disappear and two additional plus signs will appear in sequence.
e. Repeat until the calibration is successful; if the calibration fails, the display calibration procedure will start over again.
f. If the calibration procedure fails more than five times, contact the vendor for service.

7.2. Repaired Instrument

7.2.1. Perform a "re-validation testing process," which includes measuring a combination of linearity material, QC and correlation samples.

a. Measure commercially prepared linearity kit (follow instructions provided).
b. Measure 10 patient samples correlating with instrumentation in CCL.
c. Measure 3 levels of liquid QC.

8. QUALITY CONTROL:

8.1. Electronic control self-checks are performed automatically when the meter is turned on. This verifies the performance of the optics unit of the analyzer.

8.2. Liquid controls:

8.2.1. Three multi-level liquid controls are used: low, normal, high

8.2.2. Frequency of control testing**:**

a. Each time patient testing is performed.
b. Upon arrival of a new lot of microcuvettes.
c. As corrective action when troubleshooting.

8.3. If QC results are out of range:

8.3.1. Check the expiration date of the microcuvettes and controls.

8.3.2. Use caution to run the QC test within 10 minutes of charging the microcuvettes.

8.3.3. Do **NOT** report patient results if quality control results are out of range.

8.4. Preparation instructions:

8.4.1. Remove the control material from the refrigerator and let the material come to room temperature (15-25°C) for 20 minutes prior to use.

8.4.2. Thoroughly mix by gently inverting the bottle and rolling between the palms until all cellular components are completely suspended. Do not shake or use a mechanical mixer. If the cellular components appear to be grossly hemolyzed or visually clumped after proper mixing, the control is unsuitable for use and should be discarded.

8.4.3. Place one drop of control material on plastic-backed gauze.

8.4.4. Fill the microcuvette through capillary action by placing the testing edge of the cuvette on the drop of quality control material.

8.4.5. When completely filled, wipe off the outside of the microcuvette with a clean lint-free tissue, being careful not to touch the open end of the microcuvette. If air bubbles are seen in the optical eye, the microcuvette should be discarded and a new sample be taken for analysis. Small air bubbles around the edge do not influence the result.

8.4.6. Place the microcuvette onto the holding position of the meter.

8.4.7. Close the holding device and allow testing to come to completion, approximately 15-60 seconds.

8.4.8. Document results on the QC sheet each day of patient testing. Ensure lot numbers of controls and microcuvettes are included on the QC log sheet.

8.4.9. The control log is reviewed monthly by the POCT manager and Division Director.

8.5 Acceptance limits and how established (POCT Testing Department)

a. Liquid control ranges are established per shipment of quality control.
b. One vial of QC of each level is run five times to verify new lot of QC compared to manufacturer's ranges.

8.5. Document corrective action, if any, for out of range results on the QC log sheet

8.5.1. If QC is outside the manufacturer's ranges, repeat quality control testing for that level.

8.5.2. If QC is unacceptable, do NOT report any patient results from the device.

9. TEST PROCEDURE:

9.1. Pull the cuvette holder out to its loading position. Press and hold the On/Off button until the display is activated.

9.2. Take the microcuvette out of the package. Always avoid touching the optical eye.
9.3. Hold the microcuvette opposite the filling end and bring into contact with the specimen.
9.4. Allow the cavity of the microcuvette to fill completely by capillary action. **Do not refill the cavity of the microcuvette!**
9.5. When completely filled, wipe off the outside of the microcuvette with a clean lint-free tissue, being careful not to touch the open end of the microcuvette. If air bubbles are seen in the optical eye, the microcuvette should be discarded and a new sample be taken for analysis. Small air bubbles around the edge do not influence the result.
9.6. Place the filled microcuvette in the cuvette holder of the analyzer.
9.7. Push the cuvette holder to its measuring position.
9.8. After 15-60 seconds the result will appear in the display.
9.9. Pull the cuvette holder out to its loading position and discard the used microcuvette.
9.10. Document the result on the HemoCue patient result log.
9.11. To shutdown press and hold the On/Off button until the display is deactivated.

10. CALCULATIONS:

10.1. No calculations are required to obtain results from the HemoCue

11. REPORTING RESULTS:

11.1. The physician documents in the procedure notes that this test was required to be performed in the patients room.
11.2. Results are provided to the physician during the procedure.
11.3. Results are transcribed from the instrument's read-out onto the HemoCue patient log and entered into LIS by POCT staff.
11.3.1. In case of a system downtime the results will be entered following the downtime.
11.4. Requisition the test in IHIS/Beaker using QPulse documents (IHIS-EX3 and IHIS-EX10).
11.5. The test code is "HGCB" for hemoglobin cord blood.
11.6. Refer to Master Test List for reference intervals.
11.7. Refer to Master Test List for Analytical measurement range (technical range).
11.8. Refer to Master Test List for reportable range.
11.9. Refer to Critical Result/Critical value policy for critical values.

12. INTERPRETATION OF RESULTS

12.1. The measured hemoglobin value is read directly from the HemoCue Hb 201 analyzer in g/dL.

13. LIMITATION OF PROCEDURE:

13.1. Measurement of hemoglobin must be made as soon as possible after the blood has been drawn into the microcuvette.
13.2. If the readings are made after 10 minutes of filling the microcuvette, false results may be obtained.
13.3. Mixing blood for too long a period can produce increased oxygen pressure and viscosity that may give falsely high results.
13.4. If air bubbles are seen in the optical eye 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.
13.5. 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 from the outer surface of the optical eye.
13.6. The following chemicals have **NOT** been found to interfere with the testing: Acetaminophen (20 mg/dL), ascorbic acid (3 mg/dL), conjugated bilirubin (40 mg/dL), unconjugated bilirubin (20 mg/dL), ibuprofen (40 mg/dL), creatinine (30 mg/dL), leukocytes (600 x 10^9 /L), salicylic acid (50 mg/dL), thrombocytes (2100 x 10^9 /L), tetracycline (20 mg/dL), urea (500 mg/dL), uric acid (20 mg/dL), lipemia (Intralipid 4000 mg/L approx Triglycerides 1200 mg/dL) . The highest concentration tested is referred to in brackets.
13.7. pH values between 6.3-9.0 do not interfere with the system.
13.8. Sulfhemoglobin is not measured with this method.
13.9. If "HHH" is displayed, the result exceeds the measuring range of the system.
13.10. Values above 23.5 g/dL must be confirmed using a suitable laboratory method.

14. REFERENCES:

14.1. HemoCue™ Hb 201 analyzer operating manual
14.2. HemoCue Hb 201 Microcuvettes package insert
14.3. HemoCue™ Hb 201 package insert
14.4. RNA Medical QCHGB package insert

15. RELATED DOCUMENTS

15.1. Refer to QPulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms.