Purpose:

The waived HemoCue Hb 201 System is to be used for the quantitative determination of hemoglobin in capillary, venous and arterial blood, using a specifically designed analyzer, the HemoCue Hb 201 Analyzer, and specially designed microcuvettes, the HemoCue Hb 201 Microcuvettes. HemoCue Hb 201 Microcuvettes are for In Vitro Diagnostic use only. The HemoCue Hb 201 Analyzer is only to be used with the HemoCue Hb 201 Microcuvettes.

Principles:

The reaction in the microcuvettes is a modified azidemethemoglobin reaction. The erythrocytes are hemolysed 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.

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 into 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 on the analyzer screen. The HemoCue Hb 201 System is calibrated against the international reference method for hemoglobin determination, ICSH, and needs no further calibration.

Required Materials:

- Gloves
- HemoCue Hb 201 Analyzer
- HemoCue Hb 201 Microcuvettes
- Lancet (for capillary sample)
- Pipette or other transfer device (for venous, arterial or control material samples)
- Hydrophobic plastic or glass slide (for venous, arterial or control material samples)
- Lint-free wipe (non-fraying)
St. Peter’s University Hospital
Department of Laboratory Medicine and Pathology
Point of Care
HemoCue Hb201 Hemoglobin Procedure

- HemoCue Primary Docking Station

**Storage and Handling of the HemoCue Hb 201 Microcuvettes:**

The microcuvettes are to be stored at 15 – 30°C (59 – 86°F) in a dry place. Use the microcuvettes prior to the expiration date printed on each vial. Once the seal of the vial is broken, the microcuvettes are stable for three months. Keep the vial properly closed. All unused microcuvettes should remain in the original package.

**Infectious Disease Control Warnings and Precautions:**

The microcuvettes are for In Vitro Diagnostic use only. Always handle blood specimens with care as they may be infectious. Use gloves while performing all aspects of testing. Wash hands before and after patient contact. Dispose of used microcuvettes in appropriate biohazard receptacle.

**HemoCue™ Hb 201 DM Analyzer and HemoCue™ DM Docking Station:**

- The Analyzer and Docking Station can be stored at 0-50 °C (32-122 °F).
- The Operating temperature is 18-30 °C (64-86 °F).
- 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.

**Quality Control:**

**Internal / Electric Quality Control:** The HemoCue Hb 201 Analyzer has an internal electronic self-test. Every time the analyzer is turned on, it will automatically verify the measurement performance. The test is performed every eighth hour if the analyzer remains switched on. The result of the self-test is stored as an EQC. If the analyzer self-test does not match reference standards, an error code will be displayed. Cleaning may be required before repeating the test. **If the error code persists, do not use the analyzer for patient testing.** Use an alternate analyzer that is “in control” or send an EDTA sample to the laboratory for testing. Call the Point of Care Coordinator at ext. 8005.

**External / Liquid Quality Control:** Each new lot or new shipment of HemoCue Microcuvettes must be validated at two liquid quality control levels prior to use for patient testing. Two levels of liquid controls should be run each day of patient testing prior to running patient tests. When controls are out of range, cleaning may be required before repeat quality control testing. If control results remain out of range, contact the Point of Care Coordinator at ext. 8005. **If liquid controls are out of expected range, do not perform patient testing.** Use an alternate analyzer that is “in control” or send an EDTA sample to the laboratory for testing.
Storage and Handling of the Liquid Controls:

The controls are to be stored in the refrigerator at 2-8°C (35-46°F). Use the controls prior to the expiration date printed on each vial. Once control is open, the controls are stable for one month when properly recapped and stored at 2-30°C (35-86°F).

Performing a Liquid Control Test:

The HemoCue system must be checked daily with Eurotrol 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 and Preparation:

Capillary, venous or arterial blood may be used. Appropriate anticoagulants (e.g. EDTA or heparin) may be used, preferably in solid form to avoid dilution effects. Mix all specimen tubes thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 8-10 times by hand. Hemoglobin remains unchanged for days provided the blood sample does not become infected. If the specimen has been stored in the refrigerator, it will be viscid and the blood should be allowed to warm to room temperature before mixing.

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:

Follow hand hygiene protocol and put on gloves.

Turning on the Analyzer
- Power the analyzer on by pressing the power button briefly and then waiting ten seconds.
- Enter your 6 digit Operator ID using the numeric buttons.
- In the Main Menu, press the Patient Test button.
Testing Patient Sample
1. If sample is from a tube, mix the blood well before performing the measurement.
2. For venous samples, place a drop of blood onto a hydrophobic surface, e.g. a plastic film, using a pipette. Capillary samples should be collected according to preceding specimen collection procedure and applied directly to the microcuvette.
3. 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.
4. Look for air bubbles in the filled cuvette. If present, take a new sample. Small bubbles around the edge can be ignored.
5. Place the filled cuvette in the cuvette holder. This should be performed within ten minutes after filling the microcuvette! Gently push the cuvette holder to its measuring position.

Entering the Cuvette Batch No.
1. Enter the Cuvette Batch No. via the barcode scanner or manually enter using numeric keys.
2. Enter the Expiration Date for the Cuvette Batch via the Numeric mode buttons.
3. Press the Confirm button.

Entering the Patient ID
1. Enter the Patient ID via the barcode scanner or manual entry.
2. Press OK to continue.
3. 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.

Results
1. The following text will be displayed: Please Wait Measuring …. If the measurement has not been completed.
2. 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.
3. 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.
4. All results are stored in the analyzer.
5. All results are given directly to the ordering physician.

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.8005)
Reference Ranges:

Age
Day 1  13.5-19.5 g/dL
Day 3  14.5-22.5 g/dL
Day 14 13.4-19.8 g/dL
Day 30 10.7-17.1 g/dL
Day 60  9.4-13.0 g/dL
6 months 11.1-14.1 g/dL
2 years 10.5-13.5 g/dL
6 years 11.5-13.5 g/dL
Adult, female  12.0-16.0 g/dL
Adult, male  13.0-17.0 g/dL

Critical range: <6.5 g/dl or >18.0 g/dL
Reportable range: 4.0 – 23.5 g/dL

Results above 23.5 g/dL should be confirmed by sending a venous EDTA whole blood specimen to the lab. Any result that is not consistent with patient’s condition should have a venous EDTA whole blood specimen to the lab.

Limitations/Interferences:

- HemoCueTM Hb 201 Microcuvettes are for In Vitro Diagnostic use only.
- The HemoCue Hb 201DM analyzer is only to be used together with HemoCueTM Hb 201 Microcuvette.
- 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.
- 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.
- 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.
- Sulfhemoglobin is not measured with this method.

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 is utilized. All samples will be run in triplicate 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.

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

Cuvette holder and optronic unit:
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.
9. Record performance of maintenance on maintenance log. If meter is not in use on any day, write “not in use” for that date on the maintenance log.

Analyzer:
Disinfect the exterior of the analyzer between each patient use with Sani Wipe disinfectants. Document at least once daily on the maintenance log for each date that meter is in use.

Errors:
- Refer to Section 6, Troubleshooting of Operator’s guide.
- Document all corrective actions taken on the maintenance log.
- If error persists, call the Point of Care Coordinator at ext. 8005 who will contact HemoCue Hb 201DM Technical Service for instructions.

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